9th HTAi ANNUAL MEETING

"HTA in Integrated Care for a Patient Centered System"

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POSTERS

20. METHODOLOGICAL ADEQUACY OF ARTICLES PUBLISHED IN TWO OPEN-ACCESS BRAZILIAN CARDIOLOGY PERIODICALS

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Context and objective: The use of rigorous scientific methods has contributed towards developing scientific articles of excellent methodological quality. This has made it possible to promote their citation and increase the impact factor. Brazilian periodicals have had to adapt to certain quality standards demanded by these indexing organizations, such as the content and the number of original articles published in each issue. This study aimed to evaluate the methodological adequacy of two Brazilian periodicals within the field of cardiology that are indexed in several databases and freely accessible through the Scientific Electronic Library Online (SciELO), and which are now indexed by the Web of Science (Institute for Scientific Information, ISI).

Design and setting: Descriptive study at Brazilian Cochrane Center.

Methods: All the published articles were evaluated according to merit assessment (content) and form assessment (performance).

Results: Ninety-six percent of the articles analyzed presented study designs that were adequate for answering the objectives.

Conclusions: These two Brazilian periodicals within the field of cardiology published methodologically adequate articles, since they followed the quality standards. Thus, these periodicals can be considered both for consultation and as vehicles for publishing future articles. For further analyses, it is essential to apply other indicators of scientific activity such as bibliometrics, which evaluates quantitative aspects of the production, dissemination and use of information, and scientometrics, which is also concerned with the development of science policies, within which it is often superimposed on bibliometrics.

100. EVALUATION OF HIV/AIDS PATIENTS' KNOWLEDGE ON ANTIRETROVIRAL DRUGS

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Introduction: Lack of information on antiretroviral drugs or the misunderstanding of available information can facilitate incorrect use of such drugs. This can result in non-adherence to theprescribed regimen, leading to a great possibility of a therapeutic failure.

Objective: To know which information HIV/AIDS patients have on the drugs they use, the source of this information and whether there is a need for additional information.

Methods: A structured questionnaire divided into three parts was used to verify the knowledge a group of HIV positive patients have on the antiretroviral drugs they use, what are their more common questions, the sources of information available, what other information would be of interest for them and the importance or not of receiving information about medicines.

Results: A total of 195 HIV/AIDS patients, who were using either zidovudina + lamivudina 300 + 150 mg (AZT+3TC), efavirenz 600 mg (EFZ) or lopinavir/ritonavir 133.33/33mg (LPV/r), was interviewed. The mean age was 41 years (SD = 9.55) and 70.8% were males. Of the total, 55.4% didn't know the effect of the drug in the organism; 35.9% were unaware of the necessity of taking antiretroviral drugs for the rest of their lives; only 14.4% knew how to proceed when a dosage was missed; 22.1% said they could die and the same amount of individuals believed in aggravation of the disease in case of treatment interruption. The majority, 68.2%, considered it very necessary to receive drug information.

Conclusion: There is an apparent lack of general information among users of antiretroviral drugs and at the same time a need for it. It is necessary that all professionals involved in the health care of the patients agree that an efficient supply of information on prescribed drugs is an ethical component of the treatment that favors and fosters its adherence.

101. EVALUATION OF ORAL AND WRITTEN INFORMATION IN KNOWLEDGE OF PATIENTS WITH HIV/AIDS ON ANTIRETROVIRAL DRUGS

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Introduction: One of the strategies to improve adherence to antiretroviral therapy (ART) is to provide relevant information on the drug used. The quality of this information has the potential to influence the decisions of patients to accept and follow the proposed treatment and make all the right decisions that will favor the success of their treatments.

Objective: To assess the influence of oral and written transmission of information on antiretroviral drugs in knowledge generation in their users and in the retention of information by them.

Method: In the first phase, 18 individuals with HIV/AIDS treated at a referral hospital analyzed three brochures containing information on antiretroviral drugs and chose the best. In the second phase, three groups of 47 individuals with HIV/AIDS who received antiretroviral drugs in the same hospital were formed. The first group, considered the control group (group "C") received their medication at the pharmacy as usual, without any additional information; the second group (group "F") received a brochure with information about the drug in use, which should be read at that moment; and the third group (group "O") received orally, the same information detailed in

the brochure. All answered a questionnaire that assessed their knowledge on the referred drug.

Results: The responses of group "O" had a higher level of agreement with the information they received regarding action of the drug in the body (78.7%), duration of treatment (83%), procedure when missing a dose (91.5%) and storage (95.7%).

Conclusion: The transmission of information, whether oral or written, generates knowledge and the instructions and information when orally transmitted, in a detailed manner and in appropriate language, are more easily understood and assimilated. It appears also that, in the studied group, oral information resulted more immediately effective than written one.

137. CLINICAL TRIAL REGISTERS AS A SOURCE OF TRIALS FOR HTAS

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Background: Since July 2005 all member journals of the International Committee of Medical Journal Editors (ICMJE) required that clinical trials be registered in a public trials register before they are considered for publication. Registration ensures that trial details are available to all researchers and patients, irrespective of the results, which may encourage improvements in trial reporting and reduce publication bias. The introduction of the ICMJE requirement is likely to have led to an increasing number of trials being registered and there is interest in the extent to which such registers can now inform health technology assessments (HTAs).

Objectives: To explore the current state of trial registration and to assess whether it is adequate to search for trials, for inclusion in HTAs, using only public trials registers. To assess the number and type of trials which would be excluded if unregistered trials were not identified.

Methods: We identified two recently updated Cochrane Injuries Group reviews with a large number of included trials published since 2005. We examined the proportion of the included trials which had been registered, the trial register in which they appeared and the yield of searches in individual registers compared to searching via the ICTRP search portal. We are investigating further reviews.

Results: Of the 266 included studies in the two reviews assessed so far, only 9 were identified in public trials registers (CT and/or ICTRP).

Discussion: This exploration of Cochrane reviews indicates that current trials registration seems to be sparse and searching trials registries in preference to searching major bibliographic databases would not be comprehensive.

Implications for the health system/professionals/patients/society: Research registers are improving access to trial information for many interested groups of users, but do not yet capture all prospective trials.

175. LESSONS LEARNED FROM NATIONAL AND INTERNATIONAL COOPERATION BETWEEN HTA-AGENCIES – TWO EXAMPLES

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Background: In 2003, the health care research institute GÖG/Austria (former ÖBIG) had not yet established an HTA-process. However, within the institute, cooperation in multi-disciplinary teams was quite common. From 2003 we were commissioned for HTA reports by the German DAHTA@DIMDI. One of our tasks on national level was to support the Ministry of Health in integrating HTA into the Austrian Health Care System. In a bottom up approach of the major stakeholders and advised by a board of national and international HTA-agencies, we set up a National HTA-Strategy. One of the first steps was developing an HTA Methods Manual, which we did in cooperation with the main Austrian HTA/EBM institutions.

Objectives: Experiences from one international and one national cooperation between HTA-Agencies.

Results: Cooperation with DAHTA@DIMDI was very fruitful for different reasons: At DAHTA a proven HTA-process was already established: Literature search as well as report templates were provided, a peer review process was established etc. In return we brought in feedback and new ideas. Assumed that the language problems are limited, we can recommend this kind of international knowledge transfer between more and less experienced HTA institutions. The cooperation on national level with the HTA Methods Manual was successful for the following reasons: Pooling different know how increased the output quality. Furthermore the acceptance on stakeholders' and decision makers' side increased. Besides staff from the different agencies met and learned from another, new ideas were discussed etc.

Discussion: Due to fragmented decision making bodies, split responsibilities and traditionally low transparency, it will take some time to make decision makers, providers and the public being aware of the advantages of formal established HTA structures. Joint efforts on national and international level are an important factor in gaining added value.

205. HEALTH TECHNOLOGY ASSESSMENT THEMATIC MAPPING IN DOCTORAL THESES AT THE SÃO PAULO UNIVERSITY MEDICAL SCHOOL, FROM YEAR 2005 TO 2010

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Introduction: In Brazil, the Health Technology Assessment Network/Health Ministry promotes multi-disciplinary reviews, new studies, and research about safety, efficacy, effectiveness, performance and economic aspects of health technologies, HTA, when there is controversy, little or none scientific evidence. The incorporation of new products and processes within the Unified Health System has increased HTA activities at the national level. Amid available literature, Web-based databases indexing academic theses, monographs and related publications are important sources for further research.

Objectives: To elicit HTA related themes in the doctoral theses submitted to the Faculty of Medicine/São Paulo University, USP, mapping thematically through the descriptors that represent the searched contents.

Methods: USP Theses were analyzed from 2005 to 2010 in full text in the LILACS database and the USP Theses and Dissertations Digital Library.

Results: Of the total 1.307 theses, there were 111 whose subject relates directly or indirectly with HTA. There were 15, 14, 28, 11, 23 and 10 theses distributed for each year, respectively, from 2005 to 2010. Among these, 477 selected descriptors were grouped for the correction of the dispersion of thematic indexing, relevance analysis and correlation with HTA. The most frequently used descriptors were "coronary disease" and "quality of life", each one occurring six times; other 54 descriptors occurred between six to two times frequencies. Amid the latter, 10 related to Heart Disease, 4 about Surgical Techniques and 4 related to costs and quality of health care. The remaining 423 descriptors were used only once, indicating that various main subjects and medical specialties are related with the HTA theme.

Conclusions: These results support the broad HTA definition and scope, referred in the frequent clinical, observational and economic studies observed at the USP Theses, and indicates requirements for further Health Technology Assessment standardized indexation in Brazil.

207. HTA DATABASE: AN EFFICIENT WAY TO FIND ASSESSMENTS OF HEALTH TECHNOLOGIES

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The HTA database contains over 10,000 bibliographic records of completed and ongoing health technology assessments from HTA organisations around the world. The scope for inclusion is broad, encompassing any study designated as a health technology assessment by the contributing organisation. The HTA database is a valuable source for identifying grey literature as much of the information it contains is not readily available from other sources. For example the reports included are generally not published as journal articles and therefore not listed in other databases but are only available as full reports from the commissioning organisation. Records are submitted by the member organisations of the International Network of Agencies for Health Technology Assessment (INAHTA) as well as around 20 other HTA organisations worldwide. CRD database administration staff also identify new projects by searching HTA websites and new organisations by searching the world wide web. As well as demonstrating the value of the HTA database, this poster will illustrate and explain the record types, the information they contain and the links to external information provided.

249. METHODOLOGICAL SEARCH FILTERS PERFORMANCE PROJECT: WHAT TO MEASURE AND HOW TO PRESENT THESE MEASURES?

Carol Lefebvre[a], Julie Glanville[b], Cynthia Fraser[c], Sophie Beale[d], Charles Boachie[c], Steven Duffy[b], Jenny Harbour[e], Rachael McCool[b], Lynne Smith[e] and Danielle Varley[b]

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Background: Methodological search filters can improve efficiency of retrieval from databases such as MEDLINE/PubMed. Few, however, are validated. Multiple filters exist for some study designs but their comparative performance in real-world settings is unknown. The UK Medical Research Council funded this study to inform decision-making by the National Institute for Health and Clinical Excellence (NICE).

Objectives: to understand how information specialists choose search filters and what information/formats could inform choices.

Methods: 5 reviews were conducted: presentation of performance measures in search filter studies and (analogous) diagnostic test accuracy (DTA) studies; methods for comparing the performance of different filters; how searchers choose filters and clinicians choose diagnostic tests. Twelve interviews, with information specialists associated with NICE, and a wider web-based questionnaire were conducted.

Results: Detailed results will be presented at HTAi. Filter studies/comparison studies tended to report sensitivity/specificity/precision, mostly presented as tables. In DTA studies, similar performance measurements were reported but with greater use of graphical presentation. No studies had explored how searchers select filters but there was some evidence regarding how clinicians choose diagnostic tests. The interviews provided detailed information on the use/choice of filters among information specialists within NICE/Evidence Review Groups. Respondents tended not to use filters routinely but reported adapting/combining the best parts of filters, expressed caution about the reported sensitivity/precision measures and reported a range of approaches for choosing and testing filters. 85/90 questionnaire respondents (94.4%) had used methodological search filters. The most common uses were extensive searches to inform guidelines or systematic reviews/HTAs, rapid searches and scoping searches. Many methods were reported for choosing between filters.

Discussion: This study will inform guidance on how best to *conduct* performance assessments of search filters and how best to *report* performance data. A pilot website will be launched to evaluate different presentations of performance data.

300. EFFECTIVENESS OF A NURSING CONSULTATION AT EMERGENCY DEPARTMENT

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Background: The demand for urgent health care is approaching the system saturation showing progressive and continuous growth. To reduce health care pressure, we propose mild or not urgent diseases care by nursing professionals. In UK it is a skilled practice (Advanced Nurses Practitioners).

Objectives: Compare: waiting time for patients with mild pathologies assisted in Groups 1 and 2; readmissions in the first week; satisfaction degree; average overall stay length.

Methods: Multicenter prospective experimental study. Recruit patients attending emergency service, following inclusion criteria, at Galdakao-Usansolo and Txagorrtitxu, both public hospitals of the Basque health service – Osakidetza. G1 intervention (140 cases): health problems whose protocol allows nursing to be responsible for intervention. G2 control (140 cases): Usual procedure. Doctor is the responsible.

Results: 24 Patients recruited in the pilot study. Two excluded for failing inclusion criteria, therefore n = 22 (11 in each Group). The average person was 37.27 years, with 27.10 DS (76.16% women, 23.81% men). In G1 time assignment was 15.00 minutes (8.99) and in G2 5.1 minutes (7.24). In G1 resolution time was 22.82 minutes (8.35) and in G2 53.64 minutes (53.16). In G1, according to satisfaction, 20% stated that they had been attended as expected while 80% did in G2. However, 87.50% of the patients in G1 expressed that they had been attended much better than expected. Readmissions were not performed for the same cause in any group.

Discussion: Nursing consultation at Emergency Department to assist mild pathologies is effective. It improves resolution times more than double and also patients claim to have been treated much better than expected, thereby increasing satisfaction degree.

Implications for health system: The implementation of the nursing consultation to take care of mild or not urgent pathologies would reduce doctors´ care burden. Besides, interventions costs would be cheaper reducing the number of professionals performing.

368. WEB 2.0 UTILIZATION IN HEALTH TECHNOLOGY ASSESSMENT AGENCIES IN SPAIN

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Introduction: The impact that the information generated by the HTA organizations can have depends largely on the methods and

resources devoted to its dissemination. The use of Web 2.0 in HTA will produce changes in the diffusion processes.

Objective: To map the utilization of the Web 2.0 and its tools in Spanish HTA units (SHTAu).

Methods: A questionnaire was distributed among the information specialists of the SHTAu (n = 8). The aim was to assess their knowledge of Web 2.0, the utilization of its tools and their relevance in the HTA field. They also had to define the tools they used, their behaviour on the net and the possible impact of its use in HTA. Finally they had to assess the importance of Web 2.0 and its implementation in the HTA field.

Results: The response rate was 100%. The knowledge of Web 2.0 was widespread among information specialists. Regarding its use, most of them used Web 2.0 for the purpose of data consultation (63%), although it was increasingly used in daily work and products diffusion (38% in both cases). In terms of net behaviour, 29% acts as viewers and 24% as creators or commentators. Information specialists considered these applications increasingly important in HTA context, and their impact mainly related to dissemination of products, job sharing and to contact interest groups. They highlighted the role of Web 2.0 for better communication with professionals and patients associations. The most used tools were alerts (14%) and social networks (14%), mainly Facebook and Twitter, wikis (11%) and RSS (11%).

Conclusions: The utilization of Web 2.0 tools is a process to implement in SHTAu diffusion. Its use could increase the visibility of HTA and reach a wider range of users. The use of these applications is not a standard of practice; and its possible impact needs assessment.

403. APPLICATION OF A HTA SEARCH FILTER IN PUBMED

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Background: The literature search of primary sources reporting on single studies, is widely used, especially for emerging technologies which generally have not yet been assessed and/or reported by HTA agencies. In these cases the search in PubMed can be helpful on two fronts: the initial bibliographic search and its continuous updating. One of the difficulties when doing a bibliographic search is represented by the identification of pertinent citations, especially if there are many.

Objectives: Utilize a system to update the primary literature (i.e. articles that describe single studies) with PubMed citations and obtain pertinent results when formulating a HTA research question.

Methods: In order to identify, quickly and without any special skills, the most relevant citations in the field of HTA, the Health Technology Assessment Unit has built, through My NCBI PubMed options, a filter that has two effects: The transmission of updated citations on personal e-mail box; The identification of relevant articles pertinent to the research question, immediately identifiable among all the citations. My NCBI offers other economic assessment filters downloadable from the web pages of the National Library of Medicine which we have made available to our employees along with the HTA filter.

Results: The HTA filter was activated about a year ago. Some university hospital health professionals and the clinical documentalist are using the bibliographical updating by email. The HTA filter was given to 40 students who have attended the 2011 HTA training courses and it has been successful in shortening the search time while giving appropriate results.

Discussion: The ease and immediacy in updating the primary literature bibliographic citations, combined with the specificity of the overall results, contributed to a positive feedback regarding the quality of literature searches.

Implications for the health system/professionals/patients/society: The ability to show real-time citations in PubMed on a particular HTA topic allows a first rapid assessment of the available material.

414. DEVELOPING THE HEALTH TECHNOLOGY SECTOR IN THE BASQUE COUNTRY

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Background: The Basque industry is seeking for diversification and has a clear interest in the HWB (Health & Well-being) sector. It's capacities, skills, experience and knowhow can be transferred to the HWB sector. The Ministry of Health is implementing a chronicity strategy that is already a reference point internationally. With the Ministry of Industry is transforming the Basque Country on a health care Living Lab where local and international companies can prove the quality and cost-effectiveness of their product/solutions and implement them globally. There is an excellent relationship and communication between the Ministry of Health and the Basque industry interested in the HWB industry. These and other aspects suggest us that it is the ideal moment to involve economical and social agents in penetrating the Health Technology market.

Objectives and methodology: To develop a strong Medical (or Health) Technology sector by lining it up with the BioRegion's proposals in the field of life sciences, and promoting the creation of new businesses and the diversification of traditional industry towards this sector. Generating awareness of the opportunities, identifying opportunities and key agents and involving them. Focus points: -Map of Agents. Identify and characterise the agents working in the health sector. -Map of Technologies and skills. Identifying existing technologies and skills and matching them with the needed ones to qualify the opportunities. -Setting up "*Connecting Sessions*" (knowledge, connection, trust and co-creation), both cross-sectional throughout the value chain (university-hospitals-technological centres-industry-administration) and vertical (between technological centres, between hospitals, within the industry, ...). -Elaborating Success Cases of industry diversification and collaboration among competitors, and applying them to the emerging sector of medical/health technologies.

Creating National and International network Hubs.

Results/Implications: Tackling the sector as a competitive opportunity for the country/region. Generating the appropriate environment for cooperation and taking on specific short-term business opportunities. Setting the country's commitment to this sector in the long term.

461. CONSIDERATIONS ABOUT THE AGING OF WORKERS IN THE WORK PROCESS - THE IMPORTANCE OF PREVENTIVE MEASURES IN THE WORKPLACE CONSIDERING AN ELDERLY POPULATION - REPORTS ON ASPECTS OF A COMPANY WITH WORKERS OF THE ENVIRONMENT

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In world today we observe a large increase in population over 60 years.The improvement in life expectancy, with specific consequences in recent decades has pointed to projections that

impact on various social issues. In several countries, we are observing that much of this population remains in frank labor activity, conducting their activities. Some people work activities are performed similar to those that started as a young man, having been the work environment designed for young people, often not considering the aging of this population. This paper discusses the issues of a company with environmental activities, with nearly 35 years of existence in the richest state in Brazil, where about 30% of employees have over 20 years of activities in this company and many of them retire conducting similar activities. It is a technology company without many specifics in order activity, where typically 45% develop activities/operational manual work and discussion of the characteristics of working age points to the need for adjustments to the job, tools and work equipment must be considered in order to put an adaptation of considering the factors of aging, chronic diseases and disorders that are characteristic of a different age. It analyzes the main characteristics of the population of about 16,000 workers, mean age 46 years, where 20% have more than 60 years of age. As a company with great external operating activities, analyzes and discusses important ergonomic measures impacting on adaptations of the work. This company has implemented programs in ergonomics and health promotion that consider its implementation and monitoring in the real participation of workers and discussions point to the importance of practical measures aimed at quality of life in relation to age, such as gymnastics, analysis and tracking of chronic diseases and other activities.

Conclusions: It is important to implement measures in companies that pose contribute to the quality of life in retirement, given the necessary medical care for this age group.

523. THE USE OF ELECTRONIC TOOLS TO DISSEMINATE RECOMMENDATIONS FOR THE USE OF HEPARIN IN DVT PROPHYLAXIS- THE SUCCESSFUL EXPERIENCE OF A BRAZILIAN HOSPITAL

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Background: A meta-analysis was published in 2011, addressing the controversy regarding the dose regimen (BID or TID) for thromboprophylaxis with low-dose unfractionated heparin (UFH). The paper indicated equivalence of both regimen in terms of thromboprophylaxis and in occurence of adverse events, favouring the use BID. The 'Comission of Medicines' of the HCPA (a Brazilian university hospital), used different electronic tools to disseminate these findings: a warning inserted within the prescribing system; a newsletter emailed to the prescribers; and, recommendations written whenever UFH was prescribed. Three months after these interventions, an evaluation was performed to compare the proportion of inpatients using UFH before and after them.

Objectives: Evaluate the efficacy of electronic tools to disseminate technical recommendations at a hospital.

Methods: A transversal study was performed. Data was collected in two different periods: before and after the interventions. All inpatients using UFH for thromboprophylaxis were included.

Results: Before, the proportions of patients using UFH in thromboprophylaxis BID and TID were 52.3% and 47.7%. After, the numbers were 71.3% (2×/day) and 28.7% (3×/day); difference significant.

Discussion: The electronic tools were highly efficient in disseminating the recommendations regarding the heparin, it was demonstrated by the substantial adherence of the doctors to them. The use of the heparin BID is more comfortable for the patients. The less number of injections reduces the workload involved. Finally, costs can be reduced. In our case the difference of 20% of inpatients using UFH TID caused a reduction in the expenditures with heparin by 7%, which is not negligeable considering that the hospital expends $53,000 annually with UFH.

Implications for health system/professionals/patients/society: Informational tools can be highly efficient to disseminate the knowledge between the professionals, but they can also actively contribute to the rational use of medicines and to improve the sustainability of the health system itself.

546. HAPPY TO MEET YOU! MY NAME IS HEALTH TECHNOLOGY ASSESSMENT ENGINE

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Background: The literature search in the field of HTA often requires a different methodology than that used to respond to clinical questions. In fact, to obtain information on the available scientific literature particularly related to the evidence based, the publishers offer many organized resources. The utilization of tools, organized in virtual aggregators, which assess health technologies, however, is less frequent.

Objectives: Obtain, in a short time through Google, with a simple and easy approach, the best information produced by reliable sources in the field of HTA.

Methods: The Health Technology Assessment Unit has built a search engine that allows one to obtain in a short time the available information found in reports of international agencies and qualified organizations thus avoiding searching each individual site. The engine, called Health Technology Assessment Engine (HTAE), was built thanks to Google technology and it is an "aggregator" of 100 URLs international and national agencies whose objective is disseminating reports/evaluations and documents related to HTA. In the HTAE were included mainly the sites mentioned in the manuals IHE Report and HTA on the Net HTA 101: Introduction to HTA and the most accredited Italian sites.

Results: The search engine is distributed to participants in HTA training courses. It is currently used by 51 people, from different professional backgrounds who have given positive feedback.

Discussion: HTAE is a useful support that produces quality results by providing an overview of the available documents on the web.

Implications for the health system/professionals/patients/society: The main benefit of using the search engine is to offer in a few seconds, a valid overview, from reliable sources, of the documents available online, both on technologies in use and on those emerging. HTAE can be placed on a registered users iGoogle page. All is needed is a gmail address.

577. TRANSLATING HEALTH TECHNOLOGY ASSESSMENT INTO PRACTICE: IF IT WORKS FOR MEDICINES, WILL IT WORK FOR MEDICAL TESTS?

Karen Kaye and Lynn Weekes

NPS - Better Choices. Better Health. Australia.

Australia has a well established regulatory system for health technology assessment (HTA) for new medicines and new medical

procedures, involving assessment for marketing by the Therapeutic Goods Administration, and assessment for public funding by the Pharmaceutical Benefits Advisory Committee and/or the Medical Services Advisory Committee. NPS has added value to this framework by providing programs and services to connect people with relevant information and help them build knowledge, skills and confidence to use information to enable the best decisions about new and existing medicines. Evidence-based publications are distributed to more than 60,000 health professionals annually, including Australian Prescriber, NPS RADAR and NPS News. Educational interventions, including prescribing feedback, clinical audit tools and educational visiting programs, are delivered to approximately 20,000 health professionals each year. Decision support tools and innovative consumer communications are implemented to support these programs. In 2009, NPS received government funding for a new four-year program to improve referrals for imaging and pathology tests. The program focuses on areas where there is a gap between best evidence and current practice and uses similar interventions. Areas of focus have included imaging for low back pain, vitamin D testing and imaging in respiratory tract infection. A number of opportunities and challenges have been identified to date, including: Potential to deliver synergistic programs, addressing both medicines and test issues; Potential to deliver future interventions to enhance use of co-dependent medicines and technologies; Limited availability of high quality evidence for assessment of medical tests; Limited evidence for effective interventions to influence test use in primary care; Need for different appraisal skills for assessment of test-related evidence; Limited data to inform program priorities and program evaluation; Implementation will continue to be evaluated and adapted to continue to add value to the broader HTA framework in Australia.

578. ROLE OF A LIBRARIAN IN THE PROCESS OF HEALTH TECHNOLOGY ASSESSMENT

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Background: Librarians can assist health professionals to retrieve information that will subsidize the process of health technology assessment (HTA). The number of published articles has increased greatly in recent years and there is a need to search for scientific studies of better quality and to recover consistent and relevant information about the benefits and risks of technologies and their impact on health care.

Objective: To report the role of the librarian in the process of HTA in a Health Maintenance Organization in Brazil (HMO, Unimed-BH).

Method: HTA studies carried out by the HMO HTA Group from 2009 to 2011 were analyzed to assess the participation of the librarian in search strategies and information retrieval.

Results: Librarian participation in the form of health database searches and information retrieval was recorded on 485 (90%) out of 539 HTA studies performed by the group. Most searched areas (50% of searches) were related to oncology drugs, health products and devices. The number of searches has increased progressively from 2009 to 2011. In 2011, for instance, 946 articles were retrieved, 67.8% from Medline database, 21.1% from electronic journals, 4.2% from Cochrane Library and 6.7% from other sources.

Conclusion: The joint work of the librarian with health professionals is of paramount importance in the process of HTA. It requires extensive knowledge of databases, language structure and other essential elements of information management and retrieval.

579. BRAZILIAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT (REBRATS): JOINT WORKING LINES AMONG MEMBERS

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Background: Organizational networks are a strategy employed to optimize the exchange of HTA knowledge and share resources in the development of various products and services. Implemented just over three years ago, the Brazilian Network for Health Technology Assessment (REBRATS) aims to promote the HTA in Brazil. The Network is currently composed of 45 members, including universities, hospitals, government agencies and policy makers.

Objective: To describe joint working lines among members of REBRATS´.

Methods: Analysis of the scientific output of member institutions of REBRATS approved in parallel panel sessions, oral sessions and workshops at the 8th Annual Meeting of Health Technology Assessment International – 2011, Rio de Janeiro, Brazil. Joint working lines were defined as those involving two or more member institutions of REBRATS.

Results: Of the 828 scientific abstracts approved, 178 were submitted by authors affiliated to member institutions of REBRATS. The sessions involved 29 member institutions, 66% of the total. Joint working lines were identified in 31 sessions. REBRATS achieved considerable representativeness with the 17% of all panels and 18% of all scientific abstracts.

Recommendations: Creating a sustainable system of HTA knowledge sharing and promoting good practice in HTA methods and processes are permanent challenges for REBRATS. The network is of considerable importance for the dissemination of information in Portuguese and the development of studies in the Latin American context.

588. COLLABORATION NETWORK IN BRAZILIAN SCIENCE IN BIOTECHNOLOGY

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This work analyses the inter-institutional collaboration network in Brazilian science in biotechnology applied to human health and this network's temporal evolution. The population was selected from the ISI Web of Knowledge based on descriptors which incorporate a series of works that use genomic, proteomic and recombinant DNA techniques. Networks were generated from the selected data for two distinct periods: 2000-2004 and 2005-2009, while another network covered the entire ten years. The results demonstrate that there are a few strongly connected institutions (hubs) and a large number with few connections. In comparing the two periods there is a clear trend for leading institutions to concentrate on connections with new actors. This particularly occurs with the University of São Paulo (Universidade de São Paulo: USP), a pioneer in the Brazilian

biotechnology field. It also reflects relatively little collaboration between institutions from the South-east and those from other regions of the country, as well as few links between national institutions and the production sector. This work aims to increase understanding of the innovation dynamic in biotechnology in Brazil, in that it supplies empirical evidence regarding the configuration of Brazilian research networks and, more specifically, of trends over time.

657. BRINGING HTA TO THE WORKPLACE: RESULTS OF AN EU-FUNDED PROJECT ON OCCUPATIONAL HEALTH AND SAFETY ECONOMICS

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Introduction: Occupational Health and Safety Economics (OHSE) is a relatively new field of science. Interventions is this field may be health-related (vaccination programs, hearing protection, hygiene measures) but other types of interventions are also possible. As such, there is partial overlap with Health Technology Assessment, both in topics and in methods. To stimulate the development of OHSE, the EU funded a project aimed at the establishment of an online repository for OHSE, called the ROWER project.

Methods: Representatives from universities and institutions from five European countries participated in the project: Greece (Alexander Technological Education Institute of Thessaloniki, Center for Research and Technology Hellas), Turkey (EGE University, Izmir), Bulgaria (Southwest University 'Neofit Rilski'), Romania (University of Bucharest) and The Netherlands (University Medical Center Groningen). Expertise included Economics, Microbiology, HTA, Education and Hygiene. *Activities*: The project consisted of a 'state of the art', four meetings and the repository. The meetings were devoted to specific topics (OHS Economics, OHS Macroeconomics, OHS Microeconomics) and were attended by scientists from the participating countries as well as from other countries, such as Canada, UK, USA, Austria, Spain and Poland.

Results: The meetings revealed several key issues relevant for evaluations of OHSE. First of all, reliable registries are required regarding parameters relevant for OHSE, such as workplace accidents, sick leave, etc. Secondly, differences exist in the way that enterprises and government handle responsibilities for workplace health and safety. Some measures require legislation which needs to be enforced. The social security systems are also different. Some countries have a State (or central bipartite/tripartite) institution for insurance for OHS, whereas others have free private insurance (e.g. UK, Cyprus). These differences mean that costs shift to enterprises, individuals (victims) or society in different ways for different countries, making it difficult to compare OHSE across countries. In general, differences in the way that costs related to OHSE have to be paid provides different incentives and different efforts on the part of responsible parties for reducing accidents. For example, in some countries enterprises with many accidents may pay higher insurance premiums or companies may bear partial costs of sick leave and work disability. The observed differences also have consequences for the methodology in OHSE. The full repository can be accessed at www.rower-eu.eu.

670. HEALTH RESEARCH METHODOLOGY E-LEARNING FOR NURSES

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Background: Online modules for teaching research methods and critical appraisal to nursing students have been developed and evaluated at Laval University. The development of a self-directed learning program for nursing education in order to highlight and strengthen the relationship between research and clinical practice has been considered a priority.

Objectives: To evaluate the effect of an online training program concerning critical appraisal and research methods (InfoCritique) on knowledge, satisfaction and self-directed learning readiness in registered nurses.

Methods: Initially, the training program was adapted by translating the web platform from French into Spanish and selecting scientific literature to develop the practical examples, evaluation test and references adapted to a Spanish context. Secondly, teaching strategies were designed and the measuring instruments to be used to evaluate the results of the pilot study developed. Finally, a sample of nursing professionals was selected. The scales used to measure the three main endpoints were passed to each participant before and after the educational programme.

Results: The course will finish the 31st of January. A private blog for project have been developed. As of 26 January 201, 77% of participants had undertaken three of the four modules on offer. Upon being asked whether the degree of interactivity promotes learning, 59.57% of respondents were completely or mainly in agreement with this statement for the clinical trials module, 71.73% for the systematic reviews module, 83.78% for the diagnostic tests module, and 74.19% for the qualitative studies module.

Discussion: The comments provided by students regarding the tool mention the need to increase the theoretical content of the modules, to create a forum or to provide more examples of well-conducted studies.

Implications for the health system/professionals/patients/society: It may provide tools for research methodology; It may promote a research culture in nursing professionals and critical thinking for scientific-evidence-based decision-making.

751. SISREBRATS PROJECT – A BRAZILIAN HEALTH TECHNOLOGY ASSESSMENT NETWORK DATABASE

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Background: The Brazilian Network for Health Technology Assessment (REBRATS) is a network of institutions committed to

promoting and disseminating health technology assessment (HTA) in Brazil. In order to provide HTA information to decision-makers, health professionals and the public, a database of Brazilian studies has been created.

Objectives: a) to develop a database in Portuguese composed by HTA studies conducted in Brazil. b) to offer a peer review process to evaluate the quality of the available publications in HTA in Brazil c) to provide a critical and rational support to decision making process.

Methods: HTA studies conducted by different Brazilian research institutions from 2004 are being registered in the database.

Results: An open access digital database is available in www.saude.gov.br/rebrats. Currently, the database is composed by 235 HTA studies of different methodologies: 11.06% technical reports, 45.96% systematic reviews, 16.60% economic evaluation, 15.32% studies in management of health care technology and 11.06% mixed methodologies. Areas such as oncology and pediatrics present the higher frequency of studies while areas such as ophthalmology, otorhinolaryngology and surgery are scarcer.

Discussion: To achieve the proposed objectives, it is essential that REBRATS provides the scientific material to the final consumer public, ie, the decision-makers. Besides, initiatives to expand HTA studies in Brazil are essential to increment the database, once much of the information in the country comes from developed regions.

Implications: The literature in HTA has increased exponentially in recent years. Identification and analysis of these studies is difficult and time consuming. REBRATS database might help decision makers to identify studies related to HTA in an affordable manner. Moreover, this network is likely to facilitate the development and dissemination of HTA studies in Brazil, to implement a strategic tool to standardize the methodology and to monitor the quality of national studies.

821. THE KNOWLEDGE OF PROFESSORS AND RESEARCHERS FROM A BRAZILIAN MEDICAL SCHOOL ON HEALTH TECHNOLOGY ASSESSMENT

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Background: With the new technologies available to health services, health managers and professionals need more reliable information on their implementation risks, benefits and costs. From 2010 the Health Technology Assessment Centers have been created in some medical schools in Brazil. The objective was to introduce and disseminate the HTA culture by using the available evidence to support decision making towards adopting or discarding new technologies and their rational usage.

Objectives: This work aims to describe university professors' knowledge on HTA.

Methods: A descriptive study which consisted of an electronic questionnaire on HTA handed to the professors of a public university's Medical School.

Results: Among the 23 subjects who answered the questionnaire, 50% claimed they didn't know about the subject. From this group, 43% and 39% didn't regard surgical and clinical procedures as health technologies respectively. 78% of the professors relied on meetings as their main source for the propagation and usage of new technologies. 61% of the total are or were in chief positions, but only 17% consulted with HTA centers to learn about any new technologies. Around 96% of the professors described safety and clinical benefits as the most important factors for using new technologies.

Discussion: There's a need to make professors and researchers more aware of the importance of broadening their knowledge on HTA. The fact that a significant amount of professors in leading positions has taken part in this study showed HTA centers as the best institutions capable of promoting HTA in the academic field.

Implications for the health system/professionals/patients/society: Investigating the health technology evaluation habits of professors in health care and education institutions may be useful to respond to the Brazilian Health System's demands.

878. BRAZILIAN HEALTH TECHNOLOGY ASSESSMENT NETWORK (SISREBRATS) INFORMATION SYSTEM: ADHESION AND QUALITY OF INFORMATION

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Background: The Brazilian Network for Health Technology Assessment - REBRATS developed a database in 2009 called SISREBRATS, unique in Portuguese language, to disseminate the studies in Health Technology Assessment (HTA). Also, this initiative intended to avoid studies duplication, subsidize policymakers in the decision-making process and assist the general society in the process of acquiring knowledge in this area. SISREBRATS includes HTA studies divided into the following categories: systematic reviews, economic evaluation, management of healthcare technology, rapid reviews and others.

Objective: To evaluate the REBRATS members' performance in completing the appropriated forms for studies' inclusion and the quality of information provided.

Method: Identification of the professional who registered the information into the system and the completeness rate of the 11 topics requested to include the study in the database. The SISREBRATS management report was used to provide the necessary information.

Results: Eighty six per cent of the studies were included by staff members of The Ministry of Health and not by their authors. From the 11 selected fields, only 7 were 100% completed.

Discussion: The SISREBRATS has the potential to bring timely information to support decision makers and to disseminate HTA knowledge. The database still faces some obstacles and strategies to increase members' participation as well as improvements to the forms of data entry are necessary.

Implications: In order to shorten the time between the study execution and registration into the database and to improve data quality it is necessary to adapt the platform according to its users needs. These needs should be identified in a survey on the population of HTA researchers in Brazil.

932. ACCESS TO INFORMATION SOURCES OF EVIDENCE. IMPACT OF THE IMPLEMENTATION OF A VIRTUAL LIBRARY. A SWOT ANALYSIS

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Background: Access to evidence has a crucial importance in decision making processes. In an era of information cloud, it is

extremely important to ensure that health professionals have granted access to all the resources their organizations subscribe. Thus, virtual libraries could play an outstanding role to facilitate this process. With continued improvements in book handling and presentation technologies such as optical character recognition and ebooks, and development of alternative depositories and business models, digital libraries are rapidly growing in popularity.

Objective: to analyze the barriers, enablers and motives that could influence in the successful implementation of a virtual library from the perspective of information and communication specialist of the Basque Health System.

Methods: 11 information and communication specialists and librarian of the Basque Health Service, the Department of health and Consumer affairs, CEVIME and Osteba participated in a two round SWOT analysis (Strengths, Weaknesses, Opportunities and Threats). The response rate was 100%. The first phase served to identify the items that could relate to each of the domains of the SWOT analysis and the second to score the finally identified items.

Results: 12 strengths, 17 weaknesses, 26 opportunities and 10 threats were identified by the panellists. After the second round, 13 strengths, 10 weaknesses, 9 opportunities and 4 threats were finally included. The highest scored items per domain were as follows: Professionals and Managers involvement (Strengths); virtual platforms and cohesion (Weaknesses); new technologies and unique point of access (Opportunities) and Budget and lack of planning (Threats).

Discussion: SWOT analysis is valid to identify motives, enablers and barriers when implementing new initiatives. Our analysis shows that professionals' involvement and planning is crucial to implement a virtual library. New information and communication technologies offered the possibility to implement integral and health professional centred solutions.

Group of Information and communication specialists Dolores Ramirez, Anabella Dominguez, Rosa Valverde, Mª Mar Ubeda, Arantza Bolinaga, M. Iruretagoiena, M. Rodriguez, B. Fernández, V. Guillen et al. Basque Health System. Librarians. Spain.

142. PERSPECTIVE OF SOCIAL PARTICIPATION IN THE EVALUATION PROCESS OF INCORPORATING TECHNOLOGY IN HEALTHCARE - THE CASE OF BRAZIL

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Background: The Brazilian Public Health System was established in 1988, thereby ensuring that the citizen universal right to health, having as one of its principles to the participation or social control. The performance of the Brazilian Public Health System in the field of evaluation and incorporation of new technologies represents the public interest as defined by universal policies are committed to the equity and based on scientific knowledge consistent. The year of 2011 represented a breakthrough in transparency and social participation in the process of incorporating technology with the publication of Law no. 12,401, of 28/04/2011, which has set up a National Committe for the Incorporation of Technologies in the SUS/CONITEC.

Objectives: Discuss about the innovations introduced by Law no. 12.401 about the role of society in the decision-making process on the incorporation of new technologies.

Methods: This work was developed from analysis of the information regarding the theoretical legal framework and the description of the procedures of CONITEC.

Results: Inclusion of representative of the population in the processes of analysis for the incorporation of technologies of CONITEC; Increased transparency through the public consultations preceding the decision-making and Holding public hearings to subsidize the decision-making process when it comes to topics relevant to the society.

Discussion: The Ministry of Health, the body responsible for enforcement of the law no. 12.401, since its creation has been used systematically in their processes of work the consultations, and public hearings as the instrument to gather contributions from segments of society aiming to support decision-making processes, and improve public policies on relevant topics, emphasizing the transparency of the process, to the participation and social control. In This new perspective, these efficient instruments will also be used in the evaluation procedures for incorporation of new technologies.

Implications for the health system: The patients and society can strengthen the drafting of the definitions to the incorporation of new technologies in health services.

199. CAREGIVERS FOR PEOPLE WITH SEVERE DISABILITIES

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In recent years, our community is undergoing a series of changes similar to other industrialized countries that have a direct impact on their overall health, their needs and their pattern of use of health services. There is an aging population, with a consequent increase of people needing care by increasing chronic diseases, disability and dependence. Therefore, the Andalusian Public Health System (SSPA) sets off a series of measures to adapt its operation to the new social context in response to the demands and expectations of users. The SSPA includes the objective to promote home care, so the patient can remain at home with his family longer and in the best possible conditions. The key issue is the contribution of caregivers, and the health system should recognize their dedication. This IT application is designed to improve the care given to users of the SSPA implementing a series of positive measures directed to caregivers of severely handicapped, reducing waiting times for consultations, promoting the single query, and general issues related to access to professional and management procedures. The nurse case managers make the registry of caregivers for severely handicapped including them in the application, so that in any hospital or primary care, part of SSPA, can be identified, providing access to these people and those they care for. The persons included in this plan can be identified by a personally card which receives when they are registered at the application.

206. POLICY REGARDING STAKEHOLDER INVOLVEMENT WITH EMPHASIS ON PATIENTS ASSOCIATIONS. HTA ORGANIZATIONS PERSPECTIVE (STUDY PERFORMED UNDER EUNETHTA JA 2010-2012 PROJECT)

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Background: Representatives of the end-users of health care services, patient associations, constitute a key health technology assessment (HTA) stakeholder group. Therefore organizations that produce HTA should implement adequate policies to involve patient associations.

Objective: The objective of the study was to investigate the approach concerning stakeholders involvement with special emphasis put on patient associations from HTA organizations perspective.

Methods: Survey among HTA organizations in Europe was carried out focusing on organizations characteristics and barriers they faced during establishment and obstacles in performing present HTA activities. In the present study issues regarding 'agreement with stakeholders' with special emphasis on relations between patients associations and HTA organizations were investigated. The MS Office Excel program was used to perform numerical analysis of data obtained from the survey.

Results: Surveys from 21 countries were received. Results indicated that certain groups of stakeholders still do not contribute directly to HTA programs. HTA organizations report difficulties in committing patient and citizens representatives. 32% of organizations experienced in performing HTA activities already involve patients in the process of conducting HTA. 29% of those organizations also plan to involve patients in the future. Additionally 60% of organizations not yet performing HTA plan to involve patients in the process.

Discussion: Obstacles to patient associations involvement may result from regulatory issues, shortage of resources, inefficient communication as well as from limited availability and willingness to participate. Overcoming these barriers requires structured and formalized policy for patients and public involvement in HTA.

Implications for the health system: The study has identified main difficulties concerning reaching agreement with patients associations which are one of key stakeholders for HTA organizations. Disclosing HTA organizations policy facilitates mutual collaboration. Presented result can serve as a basis for further discussion.

274. SOCIAL PARTICIPATION IN HEALTH AND IN THE TECHNOLOGY INCORPORATION PROCESS IN BRAZIL

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The current situation points to a greater participation of civil society in world affairs. The involvement of patients and of the public in general in the health arena aims to democratize research conducted on health and social assistance in order to ensure maximum health and social benefit. According to a 2005 study with members of the INAHTA (International Network of Agencies for Health Technology Assessment), 57% of the agencies that responded to the survey indicated consumer participation pertaining to some aspects of HTA within their programs. Of these, 95% involved consumer or patient organizations and 48% involved individuals. In Brazil, community participation is one of the guidelines of the Brazilian Public Health System (SUS) present in the Federal Constitution (1988), together with decentralization and integration. It's also one of the principles outlined in Law 8,080/1990, which establishes the conditions for the promotion, protection and restoration of health, and the organization and operation of corresponding services. Law 8,142/1990 also provides for community participation in the SUS. The participation of the population, through representative organizations, in policy formulation and control of government actions at all levels came into effect through Law 8,742/1993. In 2011, Law 12,401 was enacted, officializing civil society participation in the technology incorporation process into the health system through: the participation of a representative of the National Health Committee (CNS) on the Commission on Health Technology Incorporation of the Brazilian Ministry of Health (CITEC); the execution of a public consultation that includes the disclosure of CITEC opinions; and through a public hearing prior to final decision-making, if the relevance of the matter should justify such a hearing. Based on the above, the need exists to introduce patient perspectives and to include the participation of civil society in the technology incorporation process in Brazil, with the necessary adjustments to the national context and legislation. What are the challenges for social participation in this process?

340. DISRUPTED PREGNANCIES: HOW HEALTH PROFESSIONALS AND PREGNANT COUPLES NEGOTIATE HIGH RISK FOR DOWN'S SYNDROME

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In Denmark, ultrasound screening for Down's syndrome is widely perceived as an – often enjoyable – routine pregnancy examination. For some pregnant couples, this routine takes a disruptive turn when they receive a test result in the 'high-risk' end. Being categorized as high-risk calls into question the expected normal pregnancy and the imagined future parenthood. It generates anxiety, uncertainty and sadness. Based on 4 months of fieldwork at an obstetric ultrasound clinic and in-depth interviews with health-care professionals and 'high-risk' couples, this presentation will show how professionals and couples negotiate and make sense of this disruption. Preliminary analyses indicate how doctors and sonographers work to frame the high-risk category and the CVS as a serious and uncertain situation, but also one of hope. Through their interaction with high-risk couples, doctors and sonographers negotiate, explain, tone down and elaborate on information in order to make the situation manageable for the couples. Couples use medical information and personal experience to negotiate and make sense of a process characterised by waiting and hoping. Couples are subsequently offered invasive diagnostic testing (CVS) which involves a miscarriage risk of 0.5-1%. Achieving certainty (of normal chromosomes) therefore involves a risk (of miscarriage). The majority decides to take the CVS and in most cases, the CVS will show normal chromosomes. However, obtaining medical certainty -normal chromosomes- does not necessarily re-establish the couples' trust in normal pregnancy and future parenthood. This presentation will reflect on how the 'high-risk' category generates uncertainties to which there are no medical answers.

352. THE MEDITATION AND YOGA EXERCISE ON ANXIETY

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Introduction: Humans describe 21 th century as for mentality and meditation. However the big progress in technique and technology it causes the change in nature and quality of plants, as well as human body and mind which are needed to be relaxid and improved human capability. If consider only Americans the anxiety disorders affect about 40 million adults age 18 and older.

Objectives: Find out the positive effect of meditation on anxiety. 1. To detemine the level anxiety among meditation participants. 2. To find out the influence of the meditation on anxiety.

Methods: In the survey involved 46 people, age from 19-60. We'll determine the anxiety level by the test Spieberger Hanin which is

consists of 40 items. The fist 20 items of the test such as" My mind is now relaxed, Im nervous, I'm worried about something" determine current anxiety level, and second 20 questions "I get tired easily, I cry easily, I want to be successful as others" determine the general anxiety level of the person. During the meditation class people will practiced by breathing techniques, yoga and meditation and after whole course, it will be taken the same test again.

Results: Among survey involved 46 people, youngest person was 19 years old, oldest one was 60 years old, an average 49.8. By the test Spieberger Hanin it is counted that up to 31 degrees it is low level anxiety, from 31-44 medium level of anxiety, and 45 and up-high level of anxiety.23.2% of survey involved were with high level of anxiety, 61.4% were with medium level anxiety, rest 15.6% were with low level of anxiety. After completing the course by filling the same test, the result shows the 42.3%were with medium level anxiety, 57.7% of participants were with low level of anxiety and there was nobody with high level anxiety. Meditation has direct reducing effect on anxiety ($r = 0{,}595$: $p < 0.001$) by attending meditation course anxiety reduced by 35.2 percent.

Conclusions: 1. 23.2% survey involved people were with high level of anxiety, 61.4% were with medium level, 11.6% were with low level anxiety. 2. Meditation and yoga exercise has direct reducing effect on anxiety ($r = 0.595$: $p < 0.001$).

369. WHY AND WHEN TO INCLUDE PATIENT ASPECTS IN AN HTA?

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Objectives: The objective of this presentation is to discuss patient aspects in HTA from an academic perspective. Patient aspects need to be explored when a technology, the organization and/or economical aspects of a technology affect and influence patients in one way or another. This means nearly always.

Methods: The patients are the ones experiencing the full path of disease and treatment. They have personal, bodily, social and cultural experiences, understandings and practices in relation to coping with illnesses and the use of technology. They act as patients, consumers, members of families, communities, and as citizens in the society. The analysis is based on theories from anthropology focusing on two modes of knowledge; object-knowledge and relational-knowledge. Both modes can be understood as ways of organizing information. We used examples from the literature about rare diseases as our empirical field.

Results: We found articles that produced object-knowledge, meaning that the knowledge produced becomes an object – something that we can observe, possess, accumulate and recycle. It is knowledge that is "fact" oriented and detached from the influence of social relations, time and space. We found articles that produced relational-knowledge, meaning that the knowledge produced attaches itself to relations between people or between people and objects emerging within a dialogical field. Relational-knowledge is more a social phenomenon than simply an object.

Conclusions: The knowledge that patients' produce about day-to-day reality of living with a specific condition is not so much object-knowledge as it is relational-knowledge. It becomes produced in dialogical fields of living in families, being a child going to school, being an adult going to work, coping with illness and its treatment. It is extremely important that researchers bear in mind that their understanding of knowledge always has implications in relation to the validity and scope of the research results.

380. WHAT DO CARE USERS THINK ABOUT ALTERNATIVES MEASURES TO RESTRAINT AND SECLUSION? AN EXPERIENCE OF THEIR INVOLVEMENT IN HTA

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Background: The implementation of alternatives measures to seclusion and restraint represents a challenge for the health network in Quebec. An assessment of these measures is conducted by the HTA Unit of the Quebec University Hospital Centre (QUHC). Care users involvement activities are also implemented and evaluated in this project.

Objectives: To explore care users' perceptions about alternative measures to restraint and seclusion.

Methods: We conducted focus groups with care users from four regions of the Province of Quebec. We explored their perceptions about relevant alternative measures to seclusion and restraint, and factors that can enhance or prevent the use of these measures. Focus groups lasted 1h30 on average and were audio-recorded. Content was analysed by members of the research team.

Results: Four focus groups were held with mental health services users. They considered defusing crisis and therapeutic approaches as acceptable alternative measures to restraint and seclusion. The complexity of caring for patients in crisis and the lack of training of some healthcare team members were stressed as barriers to use alternative measures to restraint and seclusion. Humanism, openness and communication when providing care were underlined as facilitators.

Discussion: Participants showed enthusiasm to participate in data collection and expressed their desire to receive the study report. The results highlight the point that the ways of using alternative measures to restraint and seclusion shape care users' perceptions. This study brings an input based on care users' real-life experience and confirms the feasibility of data collection from care users to inform HTA.

Implications for the health system/professionals/patients/societies: These results will be compared with data obtained from healthcare professionals and managers to explore the value added by considering the care users' perspective in this specific HTA. This study will inform the possibility of sustaining data collection with care users in future HTA projects.

400. IMPACT OF PATIENT INVOLVEMENT IN A HTA-BASED SPANISH BREAST CANCER PATIENT DECISION AID

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Background: Patient and public involvement (PPI) has become an important activity within health technology assessment (HTA), helping to enhance the quality of research. Increasing international interest has also developed in understanding the impact of patient and public involvement in HTA. In this context, there are also

initiatives in the area of shared decision-making to provide assistance in patient decision-making, establishing support efforts amongst patients and the clinical team.

Objectives: To identify the key areas where PPI has made a difference in a HTA–based process to develop a Spanish breast cancer patient decision aid (PDA)

Methods: Semi-structured interviews with PDA developers were conducted to explore the key areas where PPI was crucial for the tool itself. Previously, in order to develop the PDA a systematic review (SR) of Decision Aids in breast cancer was performed and a qualitative research (QR) techniques were conducted (in-depth interviews and a focus group with stakeholders (patients, family members and health professionals)).

Results: PPI was crucial to reflect preferences of patients diagnosed with breast cancer, main key areas are related to mastectomy, chemotherapy and breast reconstruction. Patients' subjective experience of the illness was also a key area. Experiences of other people who have lived similar situations have been included in the PDA. These were important decisions to face with decisional conflict detected.

Conclusions: Key areas are related to treatment and personal illness experience.PPI in the context of a HTA–based development process of a Spanish breast cancer PDA has been significant in terms of the final content of the PDA. It allows to get real shared decisions regarding treatment. It also provides the opportunity to acquire additional knowledge and experiences reflecting patients' perspectives.

406. KRONET, TO BE A PATIENT MY WAY

Carolina Rubio and Lola Elejalde

Innobasque. Spain.

Background: It takes more than a good health care system to have a healthy population. Ppersonal will is key but not enough to successfully achieve lifetime changes; we need to create the right environments and this is a shared responsibility among, health care systems, social, economical and technological agents, community services and individuals. Kronet is the first online network of chronic patients based on the emotional pulse that adapts its contents to its members' moods. Main principle: The important thing is the person who has the illness, not the illness the person has.

Objectives: To improve chronic patients' quality of life: By learning from other patients. Contributing to patient empowerment. Motivationally. Connecting behaviour to the patient's situation. It is not a question of living better than… it's a question of living as well as possible. *But what's more…* We sought a simple, brilliant idea; In which interaction would be based on common axes of affinity and relationship; That considered the patient's emotional state; In which patients would perceive that the content gives them value; Which would ensure that participation were simple and fast. *We designed the community aimed at:* The chronically sick; People at risk of suffering a chronic illness; Relatives and friends; Non-professional carers *…with a diaphanous, simple and powerful leitmotiv.*

Implications: Health System: Better self-management of patient's diseases, preventing complications and thus, the congestion of health systems. Acquire knowledge of the needs and expectations of patients and incorporate them into policy definition, and to adapt products and services. Professionals: Information to develop skills that improve patients' care, towards a holistic, bio-psycho-social vision of the patient and practice. Patients: Support, information and experiences that contribute to their empowerment and self-management of their disease optimally. Society: Creating environments for a healthy population and a sustainable health care system for the XXI century.

486. A PATIENT PERSPECTIVE ON SERVICE USE IN MULTIPLE SCLEROSIS

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Background: Several multiple sclerosis (MS) patient support programs exist; however, little is known about patient utilization of these programs or remaining unmet need.

Objectives: To understand patient needs and identify gaps in MS services throughout the continuum of care, focusing on diagnosis, treatment, and disease/lifestyle management.

Methods: 1,198 US-based relapsing-remitting MS patients age 18-65 were invited to participate in the survey via PatientsLikeMe, an online health data-sharing platform, in January 2011. The survey was available for 10 days; electronic reminders were sent on day 3.

Results: 234 (20%) patients completed the survey; 82% were female, and mean age of respondents was 45.7±9.8. Patients rated the overall quality of available services (5-point rating, excellent to poor) during diagnosis (47% good or excellent), treatment (78%), and disease/lifestyle management (42%). During treatment, most utilized services included at-home treatment delivery (90% of patients reporting access to service) and treatment starter kits (87%). Few patients utilized self-monitoring devices (28%) or social/legal counseling (28%). For disease/lifestyle management, patients reported highest uptake of internet-based cognitive training tools (69%) and scheduling tools (66%). Less used were financial support for home adaptations (22%) and concierge-type services (27%). During awareness/diagnosis phase, respondents placed high importance on improved communication between health care actors and access to information, yet reported low satisfaction with available solutions. During disease course, respondents also reported high importance and low satisfaction with minimizing pain and symptoms, as well as accessing physiotherapist/physical care.

Discussion: Patients indicate highest unmet need during diagnosis and disease management as compared to treatment. Several available services appear to have low uptake, while others may be inadequate to meet patient needs.

Implications: Patient input into design and evaluation of MS patient support services is critical, and may result in the development of more effective and efficient service offer.

493. PROFILE ANALYSIS OF THE DEMANDS OF THE PUBLIC PROSECUTION OFFICE FOR INFORMATION REGARDING TO THE INCORPORATION OF TECHNOLOGIES BY THE BRAZILIAN PUBLIC HEALTH SYSTEM (SUS)

Eliete Maia Gonçalves Simabuku, Clarice Alegre Petramale, Vania Cristina Canuto Santos, Helaine Carneiro Capucho, Livia Costa da Silveira, Joe Milton Cordova Bocanegra, Marise Santos de Oliveira e Silva, Juliana Reis Vidal and Ávila Teixeira Vidal

Ministry of Health. Brazil.

Background: The Federal Constitution of Brazil in 1988 described the Public Prosecution Office as an independent body that does not belong to Executive, Legislative or Judiciary. Among others, the role of this body is to supervise the execution of the laws that defend the social and individual interests. With independence of action, the prosecutors may send notifications, request information from administrative processes and should be heard in lawsuits involving significant public interest.

Objectives: Evaluate requests for information from the prosecutors in administrative incorporation of health technology, focusing on identifying key issues demanded by that body.

Methods: We performed a descriptive analysis of information requests from the Public Prosecutors Office received by the Committee for Incorporation of Technologies of the Ministry of Health (CITEC) filed in the period 2008 to 2011.

Results: It was found that most of the demands for the incorporation of new technologies originated in the regions with the highest GDP of the country and, in the case of Paraná State, almost all originating from a single city. The drugs for which there was a greater amount of information demands were Trastuzumab and Rituximab.

Discussion: The large quantity of demands for information from the prosecutors may indicate the need for greater transparency of the reports, studies and decisions of the Commission.

Implications for the health system/professionals/patients/society: The analysis of the principal themes defendants and systematization of the control of such information will be used to structure and streamline the answers of future demands, establishing mechanisms of action prior and proactively of CONITEC, new National Committee for Incorporation of Technologies in Public Health System (SUS) that replaced the CITEC. It is hoped that with the establishment of communication channels with the Public Prosecutors Office, giving advertising and transparency to the operations, the quantity of demands will be minimized.

501. PILOT AUDIT TESTING PATIENT REPORTED OUTCOMES (PROS) FROM RADIOFREQUENCY ABLATION OF CARDIAC ARRHYTHMIAS

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Background: Patient Reported Outcomes Measures (PROMs) assess the effectiveness of procedures at improving patient quality of life (QoL). The primary aim of ablative techniques for cardiac arrhythmias is to relieve symptoms (including palpitations and shortness of breath). Currently, there are no UK population validated arrhythmia-specific PROMs tools, and the evidence base for these procedures could be improved if such tools were developed.

Objective: To assess the clinical utility, and feasibility of three PROMs collection tools; the EQ5D, the US-developed but UK-adapted Patient Perception of Arrhythmia Questionnaire (PPAQ) and a new UK-developed short arrhythmia-specific questionnaire (SASQ).

Methods: 791 patients (from three UK clinical centres) who had undergone radiofrequency ablation of arrhythmias (RFA) between October 2009 and November 2010 were retrospectively sent pre- and post-RFA versions of the three PROMs tools by an independent academic centre. The tools assessed 7 domains: expectations met, symptom severity, days missed from social activity and work/school, physician visits, impact on daily activities, and quality of life. Responses were entered onto a confidential national audit database for analysis.

Results: There were 586/791 (74%) responses. Because of the strong response rate, we had enough power to examine the results from these procedures by type of arrhythmia. For example, for atrial fibrillation, all 7 domains showed significant improvement after RFA and these translated into significant reductions in the number of days lost from social activities (PPAQ no. days/month lost 11.4 pre and 4.5 post, $p < 0.001$), an improvement in quality of life (EQ-5D VAS score 55.8 pre and 76.4 post, $p < 0.001$) and 72% reported that their expectations had been met (SASQ).

Discussion: This audit has demonstrated that collection of PROs (even using a long questionnaire) in this patient group is feasible. Further testing of the tools should include analyses of their appropriateness, reliability, validity and responsiveness.

524. INCORPORATION OF HEALTH TECHNOLOGIES IN BRAZIL THROUGH THE COURTS: RECENT ADVANCES, CHALLENGES AND PROSPECTS FOR MITIGATION

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Ministry of Health. Brazil.

Background: The 1988 Federal Constitution of Brazil established that "*health is everyone's right and* duty *of the State*". This legal provision has caused the increase in lawsuits for the supply of high-cost medicines, not provided by the Public Health System (SUS) protocols. In many cases the judges determine to the State to supply the medicines, damaging the budget management.

Objectives: To analyze the recent initiatives of the Judiciary, Legislative and Executive branches to minimize the amount of lawsuits, preserving the constitutional rights.

Methods: We performed a descriptive analysis of federal initiatives related to health technologies: the jurisprudence and initiatives of the Supreme Court (STF), the amendment of legislation by Congress and the regulation of the law by the Executive branch.

Results: In 2009, the Supreme Court held a Public Hearing on Health, which heard 50 experts from various areas aiming to obtain information to their judgments. In 2011, the Congress approved a new law creating the National Committee for the Incorporation of Technologies in SUS (CONITEC), increasing social participation and setting deadline for analysis. The Executive regulated that law and established that after the decision, provision occur within 180 days.

Discussion: There are concerns whether judicial decisions optimization would compromise the State compliance to the health rights. Healthcare system managers would have to balance social and judicial demands to achieve budget transparency. Technological innovation is a continuous and fast process that challenges this balance as well as favours lawsuits proliferation. Therefore coordinated actions are paramount to mitigate discrepancies on budget limitations and social needs.

Implications for the health system/professionals/patients/society: The legal changes expanding the participation of society and the willingness of the Judiciary in more technical inputs before his decisions on public health open the prospect for minimizing the need for lawsuits to the supply of high-cost medicines.

625. MEDICINES INFORMATION FOR PATIENTS SUPPLIED BY PHARMACY DIRECTORATE IN THE BASQUE COUNTRY

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Background: Firstly, nowadays patients use the Internet to find out about their health condition; frequently, their research is focused on pharmacologic treatments. However, the information that the patient can find on the Internet can be written in an incomprehensible way or be biased by the promotional support of the pharmaceutical industry. Secondly, Pharmacy Directorate of the Basque Government provides

information to healthcare professionals by means of a strong network of expert committees, which publish New Drugs Assessment Reports and a Pharmacotherapeutic Bulletin. Based on this, the Directorate considers necessary to supply information about medicines and prescribing-related issues addressed to patients.

Objectives: To provide patients, and citizens in general, objective, evidence-based, independent and comparative medicines information from the Pharmacy Directorate, Health and Consumer Affairs Department of Basque Government.

Methods: 1. To constitute a multidisciplinary Working Group, involving pharmacists, general practitioners, a technician of Health Promotion, a journalist and a patient. 2. To develop a standard operating procedure to regulate the Working Group tasks. 3. To elaborate the Patient Information Sheet. 4. To create a site on the web of the Basque Health Service with objective and independent information addressed to patients and citizens done and guaranteed by the Pharmacy Directorate or by other reliable sources.

Results: The Medicine Information Working Group has been created and its standard operating procedure has been established. Additionally, links of interest with useful medicine and prescribing-related issues for patients and citizens have been included on our website.

Discussion: Patients, citizens and even healthcare professionals need objective, independent and clear health information. Therefore, we believe that this initiative of the regulatory authorities could empower patients to make better informed choices about their health and, finally, contribute to future sustainability of the Basque Health Service.

632. TECHNOLOGY ASSESSMENT FOR HUMAN INSULIN ANALOGUES FOR PATIENTS WITH DIABETES MELLITUS TYPE I: PUBLIC AUDIENCE TO HEAR DIFFERENT PERSPECTIVES (MANAGERS, CLINICIANS, PATIENTS, POLITICIANS AND JUDICIARY PROFESSIONALS) FOR DECISIONS IN SUBREGIONAL LEVEL

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MoH. Brazil.

The Department of Science and Technology (DECIT) of the Brazilian Ministry of Health (MoH) thru its Health Technology Assessment Unit conducted two studies regarding long-acting insulin analogues (LAIA): a Technical-Scientific Note in 2009; a systematic review in 2010. The studies concluded the occurrence of a slight reduction of night time hypoglycemia and recommended the treatment for patients with diabetes mellitus type 1 (insulin dependents) unstable or with difficult control. In order to find more evidences MoH ordered a study of LAIA's cost effectiveness. The MoH was invited by the Public Prosecutor's Office at Santa Catarina State to a public audience due to the fact that LAIA is the major cause of litigation in that state. The following organizations also participated: two diabetes patients organizations; two medical societies (endocrinology and diabetes); two federal universities and political representatives. There is a strong tendency that the State of Santa Catarina state will follow its neighbour state, Paraná, that since 2001 started the free distribution process of medications and supplies to diabetics residents by two state laws: nº 13.380 of 02/12/2001 and nº 13.438 of 01/11/2002. In 2006 a Clinical Protocol for the Distribution of LAIA's was draw in order to complete the hall of insulins already available through MoH. Santa Catarina tends to be the next state to distribute insulin analogues to 1,184 patients that actually receive through judicial actions. So, the judicialisation was the driving force in LAIA incorporation by the States.

661. PYDESALUD: A WEB PLATFORM TO PROMOTE PATIENTS' PARTICIPATION IN THE DECISION-MAKING PROCESS

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The National Health System in Spain is starting to promote shared decision-making between patients and healthcare professionals. For this reason, the Evaluation Unit of the Canary Islands Health Service (SESCS), The Canary Island Foundation for Research and Health (FUNCIS), the CIBER of Epidemiology and Public Health (CIBERESP), and La Laguna University (ULL) are all working together to develop initiatives to promote patients' participation in the decision-making process in relation to their health, thereby facilitating the creation of a new digital public platform (PyDEsalud) of value to Spain and Latin America. PyDEsalud is an integrated platform of health related informational services on common chronic diseases to empower interested Spanish speaker people, that aims to identify the issues and problems that concern to people with different health conditions; this brings relevant information to patients and their families, which is culturally appropriate and complete on those aspects most important to them. PyDEsalud is split into three different modules: 1. Patient experiences: From qualitative research methods (in-depth interviews filmed in a large number of patients with chronic diseases distributed throughout all regions of Spain). 2. Decision aids to promote shared decision-making: Using a mixed research methodological approach (qualitative and quantitative), patients receive information about the most important aspects related to their health problem, the treatment options and the most likely expected outcomes. 3. Research needs and priorities from the patient point of view: Patient consultations (Delphi technique), distributed by e-mail, to identify the most relevant information needs for patients. With information based on the best scientific evidence, PyDEsalud has major potential as a valid source of information for patients and their families, in addition to lifelong education for professionals (in primary and specialised care), as this can provide patient-centred information, aimed at professionals, researchers, managers and anyone who works in health departments.

684. PRIMARY CARE BARRIERS TO TYPE 2 DIABETES MELLITUS MANAGEMENT IN CANARY ISLANDS. INDICA STUDY

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Background: In Spain, the prevalence of diabetes mellitus is 6% while in the Canary Islands is 9.4%. These figures exceed the values for the majority of European countries (2-5%). Type 2 diabetes (T2DM) is 90% of all cases of DM. In recent years, many resources have been allocated to control it, without achieving desired results. The aim of INDICA study is to assess two interventions, one on patients/families and another on physician/nurse to promote behavior change in T2DM.

Objectives: To identify challenges/barriers to primary care professionals (physicians and nurses) and patients about the adherence to recommendations in T2DM. To obtain reliable information for the design and implementation of INDICA interventions.

Methods: Qualitative research. 24 participants distributed in nineteen semi-structured interviews with physicians (n = 9), nurses (n = 5) and patients (n = 5) and one focus group of patients (n = 5). Fieldwork was conducted in four of the Canary Islands. Data analysis: Grounded theory with Atlas.ti 6.1.

Results: Professionals and patients reported the low awareness of the disease and the misconceptions as the main barriers to treatment adherence (diet, exercise and medication) in T2DM patients. The treatment adherence is influenced by sociocultural/economic structure in which patients and their families are inserted, and the available resources. These difficulties grow by the overburden with work of health professionals and the lack of information materials.

Discussion: Mutual understanding between patients and health professionals facilitates focusing on personal needs of patients, however, the problems with time and resources in Health System difficult to establish this trust. To improve the approach of T2DM in primary care some actions should be taken to create, promote and improve the sociosanitary context, helping to prevent, delay or reduce the occurrence of complications, improving the patients' quality of life.

Implications: Our results contribute to design and implementate INDICA's interventions, which claim to improve tertiary prevention of T2DM.

696. PATIENT DECISION AIDS ON TYPE 2 DIABETES: A SYSTEMATIC REVIEW

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Background: The shared decision making (SDM) and the patient decision aids (PtDAs) facilitate patients and health care professionals to make decisions about treatments or diagnostic tests on which there is uncertainty. Type 2 diabetes is a chronic disease, and many patients have to decide between various treatment options and make life style changes to decrease the risk of complications.

Objectives: To carry out a systematic review to identify PtDAs for type 2 diabetes, and to identify studies that analyze patients' preferences for treatment or participation in SDM.

Methods: Medline, CINAHL, Embase, PsycINFO, Cochrane Library, and CRD databases were consulted from 1996 to 2011. References of relevant articles were examined for further eligible studies. We included primary studies and previous systematic reviews which contains PtDAs for type 2 diabetes or relevant variables related to SDM. Two investigators independently extracted the data.

Results: A total of 3032 references were considered after the elimination of duplicates. We selected 43 studies, and 12 of them met the inclusion criteria: 5 randomized trials related to a PtDA (4 about the "Statin Choice" and one about the "Diabetes Mellitus Medication Choice"), 4 studies related to perceptions and preferences of participation in SDM, and 3 studies about treatment preferences on type 2 diabetes. The use of PtDAs increases the knowledge of patients about diabetes, decrease their decisional conflict, and in some cases improve the glycemic control.

Discussion: The use of PtDAs has proved useful for type 2 diabetes, but more research is needed to evaluate its role to enhance patient-clinician communication, and to promote better lifestyle habits.

Implications for the health system/professionals/patients/society: The PtDAs improve communication between patients and health care providers, improve the knowledge of users about diabetes, and increase their participation in decision making.

731. A SYSTEMATIC REVIEW OF PATIENT CENTERED OUTCOMES TO GUIDE UPCOMING HTA

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Background: "Patient Centered Outcomes" (PCO) are the results that patients are concerned with, from the patient's point of view. The knowledge of these patient relevant outcomes aims at obtaining efficient HTAs where patients' preferences and their needs are as important as the clinical effectiveness described for the technology assessment.

Objectives: To retrieve important endpoints for patients (PCO) in the context of studies assessing drugs and to describe these PCO in order to take into account patients' focus in all HTA.

Methods: A systematic review of the evidence related to drugs assessments studies and patient's preferences, views, concerns, experience and satisfaction, was performed. Data-bases included were MEDLINE, EMBASE, Cinahl, PsycInfo, LILACS, SCIELO, Cochrane Database and IBECS. Websites of NICE, AHRQ, National Guideline Clearinghouse (NGC) and ISPOR were also consulted.

Results: 65 articles were finally reviewed. PCO identified were classified in categories and subcategories. "Patient satisfaction" (first category) included: therapy satisfaction, efficacy satisfaction, physician confidence, treatment expectative, drug confidence, adverse events and ease of dosing. Second category "patient physician relationship" included communication skills, attitudes skills, lack of information and oral and written information. Third category, "adherence and compliance", included treatment expectation and tolerability. Fourth category, "patient needs", included drug use information, disease information and patient threats on adverse events. Last category, "specific patient's subgroups", included elderly, cancer, AIDS and third world.

Conclusions: HTA related to drug assessment should include as relevant outcomes patient satisfaction, patient physician relationship and patient adherence and compliance. Some specific conditions (elderly, cancer, AIDS and third world) may require taking into account particular relevant outcomes for patients. PCO may guide future HTAs to facilitate selecting endpoints relevant from the patients view and to get higher impact.

827. EVALUATION OF MANUSCRIPT AND COMPUTERIZED SYSTEMS FOR VOLUNTARY NOTIFICATION OF INCIDENTS IN HEALTH: PATIENT SAFETY

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Background: The use of technology in health can result in adverse events and other incidents on health. The communication (voluntary reporting) of these incidents is essential for the safety of the user of technologies and, therefore, the more rapid and safe for this procedure, the more interventions can be performed in order to minimizes risks and damage.

Objectives: Evaluate the voluntary reporting of incidents in health carried out in manuscript (MS) and computerized systems (CS) used in a teaching hospital in São Paulo, Brazil.

Methods: Exploratory descriptive study. We analyzed whether voluntary reports on incidents MS and CS, in two quarters of 2010 (April-June and September-November, respectively), after educational campaigns to encourage the notifications. The systems were compared in terms of the number of reporting, time of sending these until the sector responsible for analyzing them, types of incidents reported and the quality of the information.

Results: The 1089 notifications evaluated, 668 (61.2%) were performed by CS and 421 (8.6%) by MS. The average time of dispatch was 3 days when it was used the MS while with the CS immediately. The type of reported incidents was on medications (MS: 37.2% and CS: 33.8%). In general, the notifications of CS had more quality than those in the MS, on the classification and detailing the incident. Notifications of CS were all legible and without erasures and 155 (36.8%) of those performed by MS unreadable and 94 (22.3%) had no erasures.

Discussion: The health technology as the systems by which it carries out voluntary reporting in hospitals must be evaluated, in order to use this that is more efficient to minimize damage to the patients. The CS seems to be better than the manuscript in case evaluated, because it was faster and got more quality information.

Implications for the health system/professionals/patients/society: The computerization of the notifications reduces the time of the professional to the report, by encouraging the development of more effective actions and quick to reduce incidents of risks and damage to the patients, bringing safety to the users of the health system.

829. DIPEX PROJECT: DATABASE OF INDIVIDUAL PATIENT EXPERIENCES. AN INTERNATIONAL COLLABORATION TO UNDERSTAND HEALTH EXPERIENCES

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Background: DIPEx in Spain is a result of the International Collaboration between DIPEx United Kingdom. DIPEx UK was established in 2001 by GP Dr. McPherson and Dr. Herxheimer (www.healthtalkonline.org). Since other countries have joint this group to produce DIPEx in Australia, Canada, Germany, Israel, Japan, Korea, Netherlands and Palestine.

Objectives: The main goal of DIPEx is to promote the spread of accessible, well researched illness and health related experiences and information throughout the world for the benefit of patients, professionals, health services, health care providers and carers.

Methods: A maximum variation sample of approximately 30-50 respondents is recruited for each module, to identify the widest practical range of patient/carer experiences within the project. Recruitment continues until 'data saturation' is achieved. Qualitative semi-structured audio or video recorded interviews using a narrative approach are collected and transcribed verbatim. Through the constant comparative method the interviews are analysed and summaries representing the full range of the data in the interviews, not just the most frequent experiences, are included. Illustrative clips are chosen to represent the main points included in the summary and to ensure that the best sections from each interview are used. Lincoln and Guba's credibility criteria and techniques to enhance rigour are used.

Results: In this presentation we will show the palliative care module developed in DIPEx Spain as a sample of this project (www.dipex.es). Patient and carers experience with health care services and beliefs about health care information and difficulties in decision making process are presented.

Discussion/Implications: By providing highly reliable data on patient experiences, we believe that these perspectives help people to make better informed decisions backed by solid evidence and to cope with the impact of the illness.

876. IMPLEMENTING COMMUNITY BASED SUPPORT FOR PEOPLE WITH SEVERE MENTAL ILLNESS – EXPERIENCES FROM DENMARK

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Background: Community based mental health care is diverse and does increasingly also encompasses activities by volunteers. One example of such a service is the so-called 'community families', who offer people with severe mental health problems regular contact with private individuals/families. The initiative originated from the US in the 1960s, but has since spread to other countries including Denmark.

Objectives: The present paper analyses experiences with a country-wide pilot project (2006-2011) in Denmark, which introduced 'community families' in seven local authorities. The analysis draws on a research project which investigates the qualitative/quantitative effects of the pilot project and which encompasses several sub-projects. The present paper focuses on issues related to patients participating in the project especially motivation for and experiences with participation in the project.

Methods: The analysis draws on qualitative interviews with patients participating in as well as patients who previous had participated in the pilot project. Data was collected during the entire project period.

Results: Predominantly the motivation was a desire of establishing a relationship to adults outside the psychiatric system and of acquiring an oasis from the system. However "the longing" for was typical mixed with anxiety about and concern for that the relationship would go wrong. The motivations were mirrored in the experiences. Positive input with someone who did care about you without discussing "plans for treatment" and "mental illness" was the leading experience. Added to this many patients faced challenges which often were overcome due to the desire of keeping the relationship. Worry of being odd and of missing the "family" were also central issues.

Discussion: Central in the discussion is the issue of the involvement of professional staff in a service like this "outside the system".

Implications: To facilitate a successful 'community families'-relationship it seems crucial that the professional staff is involved when the match patient-family is done and is accessible when needed to resolve a challenge or to assist in finalizing a relationship.

907. ANALYSIS OF MEDICARE'S STAKEHOLDER COMMITTEE AND ITS INPUT INTO EVIDENCE REVIEW AND DECISION MAKING

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Background: The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) has the charge to give guidance to the Centers for Medicare &Medicaid Services (CMS) on the clinical benefit of medical items and services and evidence that support their use with Medicare beneficiaries.

Objective & Methods: We collected MEDCAC rosters from June 2008 to January 2011. We aggregated information to create a database to perform basic analyses on the composition of the MEDCAC, member expertise, and MEDCAC meetings. We then performed an

analysis to identify which individuals were called to serve for each MEDCAC meeting and their perspective/expertise.

Results: CMS assembles MEDCAC panels to include a range of stakeholder perspectives. Each panel includes practicing clinicians, health economists, private industry, and patient advocates. Our analysis revealed that of the 128 licensed physicians available to be called by the MEDCAC, about one third have been called as panelists; and 84 licensed physicians were not called at all. A similar percentage exists for members affiliated with health plans. Nearly half of the patient/consumer and industry representatives were called. Between April 2008 and May 2011, only 67 of the available 179 members of the MEDCAC were called to sit on a panel. Thirty of the 67 panels were called more than once, excluding the Chair and Vice-chair, 10 individuals were called three or more times.

Discussion and implications: The analysis yielded notable findings in the composition of meeting panels, frequency of member participation, and expertise of those participating in any given meeting. It yields a broad look at the composition of the MEDCAC, with a specific focus on the relevance of panelists' background. The information provided in the database has the potential to a valuable tool as stakeholders assess the composition of future MEDCAC meetings and the role of stakeholder involvement.

915. ENGAGING PATIENTS INTO THE GOVERNANCE OF A HEALTH CARE PROGRAM THROUGH AN INTERACTIVE APPROACH

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Background: Patient-centered care, which involves the collaboration between patients and health care teams to achieve quality healthcare, as emerged as a health services and policy research priority in Canada, over the recent years. Congruent with this theme, a need for better evidence to develop efficient patient-centered care policies and practices, has also arisen.

Objectives: The objectives of this research were to appreciate patients, health care professionals and decision makers' preferences and opinions towards the collaboration with patients into the governance of a health care program in general, as well as an interactive approach to consult patients, more specifically. This study was conducted at the University of Montreal Health Center, within its Patient Health Education Program.

Methods: A qualitative research design was developed to appreciate stakeholder preferences and opinions. Eleven individual interviews were conducted with healthcare professionals and decision makers. One focus group, which gathered 6 patients, was organized. A genera interview guide, which built on the interactive approach conceptual framework, was developed.

Results: Participants to the study showed much openness towards the collaboration with patients into the Program governance. This collaboration should foster consultation, instead of direct participation to decision-making. Opinions related to the interactive consultation approach were generally favorable. However, it should be associated to other consultation means.

Discussion: The successfulness of this interactive collaboration approach, and its effectiveness, as perceived by stakeholders, may be closely related to the presence of facilitators such as a strong organizational will and leadership, support being provided to stakeholders during its implementation, and effective patient recruitment.

Implications: Evaluative research shall help assess the effectiveness of this interactive patient collaboration approach in an implementation context.

939. HEALTH VALUATION AND THE PATIENT PERSPECTIVE

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The use of health technology assessment (HTA) to control the uptake of new technologies has become standard in most European countries. HTA must balance the interests of society and individual patients, ensuring that technologies with a tangible benefit to patients are approved and that these technologies deliver effective care at a reasonable cost, while harmonising decisions with additional societal preferences such as increased willingness to pay for orphan disease treatments and end-of-life care. The question of how "effectiveness" is defined and how patient preferences are included in this measure remains unclear, with the dominant cost/QALY paradigm being based on a generic tool for preference elicitation and index values derived from the general population rather than patients. This paper highlights the limitations of the EQ-5D questionnaire from a patient perspective, demonstrating a lack of responsiveness to health status changes in several patient groups, and explores a range of disease dimensions that are not captured by the generic measure.

584. SYSTEMATIC REVIEW OF THE UTILIZATION OF PARTICIPATORY ACTION RESEARCH IN PUBLIC HEALTH AND HEALTH SERVICES

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Background: Participatory Action Research (PAR) is a methodology which aims to obtain feasible and useful information to improve issues which have a collective implication, based on the active participation of communities under research, which become active subjects of the intervention. PAR evolves from the confluence of a series of critical research traditions and social pedagogy. In 2004 a systematic review explored the literature on PAR. Since then, and although in the last years an increase could be observed in the number of publications that claim to be based on PAR, no other systematic review has addressed the actual applications of this approach in public health and health services research. There are also some doubts regarding the theoretical and practice approaches used in those interventions, as well as regarding the benefit that it could provide.

Objectives: This abstract aims to address that gap, describing and evaluating published interventions conducted in public health and health services research which are based on PAR principles or methods, and to describe and assess its main characteristics, results and possible effects.

Methods: An electronic search was conducted on Medline in February 2011 using a search strategy including the terms "Participatory Action Research", "Action Research" and "Community based participatory research", from 2004 (year of publication of a systematic review of CBPR studies) to 2010. A manual search completed the electronic search.

Results: Initially, 1588 publications were identified, of which 1163 were excluded after reading the title and abstract. Of the remaining 425 papers pre-selected, 175 were considered for inclusion after full lecture of the manuscript. These studies are being analyzed in order to characterize type of intervention, characteristics of the population participating, health problem addressed, setting in which the intervention takes place and degree of the intervention in the community.

608. INCREASING VISIBILITY OF PATIENT, CARER AND CITIZEN INVOLVEMENT IN HTAS – AN EVALUATION OF THE 'LAY LEADS' PILOT PROJECT AT NICE

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Background: Health technology assessments (HTA) should focus on patients, carers and citizens to ensure that patients are at the centre of health systems. To increase visibility of patient, carer and citizen views, opinions and evidence, NICE initiated the 'lay leads' pilot project. This mandates the lay members of the four Technology Appraisal Committees to include these views, opinions and evidence in committee presentations and proactively raise them during discussions. This paper: presents a two-phase evaluation project assessing the 'lay leads' process; discusses how this evaluation helps to identify the impact of patient/carer involvement initiatives; identifies topics where committee chairs and members believe that patient/carer contributions influenced decision making.

Methods: We: undertook nine semi-structured interviews with committee chairs and lay members, with subsequent thematic analysis (evaluation phase-1); used the findings from phase-1 to inform two questionnaires (phase-2): an in-depth questionnaire, sent to all lay members and chairs (N = 15), an overview questionnaire, sent to all other committee members (N = 116).

Results: Phase-1: Although completely supportive of the 'lay leads' process, proving its viability, chairs and lay members identified challenges, areas for development and inconsistent implementation across committees. Thematic analysis produced five themes, and numerous sub-themes, to be further investigated by phase-2. Phase-2: quantitative results and qualitative quotes demonstrated broad support of the process. Challenges, highlights and impact will be compared with phase-1 and presented.

Conclusions: Patient/carer contributions can influence committee decision making. The 'lay leads' process is a viable method of strengthening? Lay members' roles and improving visibility of patient input. This, in turn, should help patient, carer and citizen support and involvement in HTA processes, leading to patient-centred systems and care. This project is a rare example of evaluation of patient involvement in HTAs, and of the impact it has.

108. USE OF GUIDELINES FOR THE IMPLEMENTATION OF THE HTA

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Background: The HTA may be seen as being a comprehensive process through which are evaluated the clinical, social and economic impacts of health technologies, taking into account aspects such as efficiency, effectiveness, cost, security, cost-effectiveness, among others. The implementation of guidelines is increasing in several regions, and be a useful instrument managers in healthcare and other actors involved, such as the pharmaceutical industries, health plans and the judiciary when this is called to intervene.

Objective: The objective of the article is to compare the use of national guidelines from various countries for the implementation of the evaluation of health technologies (ATS). The paper will try to answer the following questions: : why are there guidelines on technology assessment in health? Which countries have adopted? Why do they differ from one country to another? What are your purposes in each country? What is the trend of adoption with respect to the same? How they can be classified?

Methods: Data is from *International Society for Pharmaecoeconomics and Outcome Reseach* (ISPOR), and is created a taxonomy to compare each relevant topic.

Discussion and conclusions: Formal guidelines have been developed primarily to inform managers and decision makers within the regulatory authority, if the pharmaceutical product adds extra value to be repaid. Already the methodological guidelines were established to develop the State of the art based in modern economic theory. It can also be influenced by several factors that would affect the dissemination of technologies in health, such as: (i) the health care needs of the population (disease prevalence and different needs); (ii) of the economic conditions of countries (rich countries tend to spend and invest more in technology); (iii) cultural and organizational characteristics (such as the reimbursement system, the incentives provided to health care providers to modernize and reduce costs; (iv) the degree of competition between the providers and hospitals; (v) the size of the hospitals, the ownership of the same (public or private); (vi) the affiliation of hospitals (College or University not), as well as the underlying legal framework, such as constitutional precepts and all legislation underlying infra.

172. "DAM-BUSTING": A CHECKLIST OF TESTS FOR IDENTIFYING ERRORS IN DECISION ANALYTIC MODELS OF HEALTH TECHNOLOGIES

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Background: Given that cost-effectiveness models are central to decisions of whether health technologies are publicly funded, they should be as free from errors as possible. A key aspect of model reliability is internal validity: the correctness of the technical implementation with reference to the specification. In the UK, NICE has instructed that every effort is made to ensure that models are free from errors, and an ISPOR-SMDM working group has recently recommended that models should be subjected to rigorous verification in a transparent manner. Whilst there are several established checklists of modelling best practice, there are currently no published checklists for error identification.

Methods: We present a practical checklist of tests designed to identify errors in cost-effectiveness models. Tests apply either to Markov models, decision trees, or to discrete event simulations, or to all types of model. Most tests consider the impact of changes to input parameters on model outputs, such as the ICER and total mean costs per patient. In each case, the actual model output is compared to the output expected if the model is free from errors. We present an example of how our checklist has identified errors in a cost-effectiveness model submitted to NICE.

Discussion: Given that errors are rather common in economic models, and that our checklist can be applied quickly, we recommend that it is used to test all economic models of health technologies.

Implications for the health system/professionals/patients/society: Routine application of the checklist will reduce the frequency of errors in economic models, and thus improve the accuracy of recommendations from NICE and similar bodies concerning whether health technologies should be publicly funded.

328. PATIENT INVOLVEMENT IN CLINICAL GUIDELINES IN SPAIN: A NATIONWIDE PERSPECTIVE

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Background: GuíaSalud is an organization belonging to the Spanish National Health System (NHS) within the NHS Quality Plan and in which the 17 autonomous communities participate. On its website,

users have access to a catalogue of clinical guidelines (CG) included in it after fulfilment of six quality criteria. The NHS CG Programme proposes patient participation in the development of CG.

Objectives: To quantify patient participation in the development of CG according to the development organization, patient material inclusion, type of participation and whether the methodology was described.

Methods: All the CPG included in the catalogue up to December 2011 were selected. The following variables were searched: type of participation, description of patient involvement, patient affiliation, and patient materials.

Results: Patients participate in 31% (23/75) of the CG included in the catalogue mainly as external reviewers 39% (9/23). Only one CG describe the methodology process of participation. No patient participation was identified in any of the CG previous to the NHS Programme (9/75). There is 61% (14/23) patient participation and 87% (20/23) patient material inclusion in the CG belonging to the NHS Programme, and only 21% (9/43) and 42% (18/43) in the CG outside the Programme. Patient participation and patient material inclusion is more frequent in CG developed by Health Technology Assessment (HTA) Units (60% and 85%) than in those developed by other entities (20% and 40%).

Discussion: From within the NHS Quality Plan, efforts are being made to increase patient involvement in the NHS CG, and therefore in their quality itself. The HTA units along with GuíaSalud, have shown their commitment and capacity to involve patients in the development of CG. Nonetheless, is still necessary to continue making efforts in this area.

Implications for the health system/professionals/patients/society: To involve more patients in CG and to develop experiences that allow patient participation in HTA reports in order to increase their quality.

329. CLINICAL PRACTICE GUIDELINE ON PREVENTION AND TREATMENT OF SUICIDAL BEHAVIOUR: SUICIDAL IDEATION AND BEHAVIOUR DECISION ALGORITHMS IN PRIMARY CARE AND EMERGENCY SERVICES

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Background: Primary Care and Emergency Services play an important role in the evaluation and management of patients with ideation or suicidal behaviour and often are the first place of contact with the healthcare system.

Objectives: To make recommendations and decision algorithms about the management of the suicidal ideation and suicidal behaviour in Primary Care and Emergency Departments settings.

Methods: A systematic review of the literature was made with further selection, evaluation and summary of the results. Recommendations were based on "considered judgment" of Scottish Intercollegiate Guidelines Network (SIGN). In absence of evidence, recommendations were formulated by consensus of the guideline working group.

Results: Key actions were established to face an ideation or suicidal behaviour in Primary Care setting, including criteria to refer these patients to a mental health specialist with priority or urgency. In the Emergency Department, information about content and how to perform the psychopathological assessment to all patients treated for suicidal behaviour was made. A medical record has been also developed to facilitate the gathering of all aspects to be assessed. Finally, we have been established when it is necessary a psychiatrist assessment and the hospitalization criteria. All this is summarized in clinical decision algorithms.

Discussion: Management of both suicidal ideation and behaviour is a challenge for GPs and emergency staff. Despite the quality of included studies and the lack of evidence in some aspects (in Primary Care and Emergency Services is greater amount of recommendations by consensus of the group), this CPG is intended to provide criteria and tools to address these difficult clinical situations.

Implications for the health system/professionals/patients/society: The CPG makes recommendations about different aspects of the management of patients with ideation or suicidal behaviour to help the decision-making of patients and healthcare professionals.

331. DEVELOPMENT PROCESS AND STRENGTH OF RECOMMENDATIONS OF THE CPG ON PREVENTION AND TREATMENT OF SUICIDAL BEHAVIOUR

María del Carmen Maceira[a], Yolanda Triñanes[a], Gerardo Atienza[a], María Álvarez-Ariza[b] and Ernesto Ferrer-Gómez[b] on behalf of the Working Group of the Clinical Practice Guideline on Prevention and Treatment of Suicidal Behaviour

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Background: Suicide is a major public health problem. This Clinical Practice Guideline (CPG) attempts to provide answers to the most important questions about the assessment, treatment and prevention in the form of recommendations which have been prepared systematically and according to the best available evidence.

Objectives: To provide evidence-based recommendations to health professionals about treatment and prevention of suicidal behaviour. The CPG also includes a section with specific information for patients and relatives.

Methods: Guideline Working Group was composed of a multidisciplinary team. The group used the proposed methodology for the drafting of CPGs in the Spanish Health System. Recommendations were formulated based on "formal assessment" or "considered judgement" of Scottish Intercollegiate Guidelines Network (SIGN). Due to the broad scope of the guide, it was structured in two parts: Evaluation and Treatment, and Preventive aspects.

Results: We have developed the Clinical Practice Guideline (CPG) on Prevention and Treatment of Suicidal Behavior that consisted of 41 clinical questions. The first part of the guide addressed 14 clinical questions. There were 64 recommendations, 22% of them were of high quality of evidence (grade of recommendation A and B), 42% of intermediate levels (C and D) and 34% developed by consensus of the group. The second part addressed 27 clinical questions with 60 recommendations, 12% of them were of high quality of evidence (grade of recommendation A and B), 73% of intermediate levels (C and D) and 15% developed by consensus of the group.

Discussion: The best quality of evidence was found in the questions on treatment, risk factors and evaluation. In Primary and Emergency Care the majority of recommendations were developed by consensus of the group. With regard to preventive aspects, the evidence was moderate-low. There is a lack of conclusive evidence about some preventive interventions.

Implications for the health system/professionals/patients/society: This CPG is intended to be a useful tool to assist in decision-making in the care of suicidal behavior and help patients make informed decisions. Suicide can be prevented by setting the appropriate measures.

335. INFORMATION FOR PATIENTS AND RELATIVES IN THE CPG ON PREVENTION AND TREATMENT OF SUICIDAL BEHAVIOUR: DEVELOPMENT AND EVALUATION

Yolanda Triñanes[a], Amparo González-García[b], Gerardo Atienza[a], María del Carmen Maceira[a], María Álvarez-Ariza[b], Ernesto Ferrer-Gomez del Valle[b] and Marisa López-García[a] on behalf on the Working Group of the CPG on Prevention and Treatment of Suicidal Behaviour

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Background: The importance of producing patient information and adapting reports of Health Technology Assessment (HTA) and Clinical Practice Guidelines (CPG) is widely recognized.

Objectives: To offer evidence-based information for patients with suicidal behavior and their relatives and to design an evaluation of their perception on this material.

Methods: Guidance of national and international HTA agencies on writing information for patients were adopted in relation to development, content, format and style. This information was elaborated by the working group of the CPG on Prevention and Treatment of Suicidal Behaviour, a multidisciplinary team with experience in the management of suicidal patients. To assess patient perception on this material, a Likert type scale with open questions was designed to measure the following areas: content, format and readability, utility and general satisfaction.

Results: Information adapted to the patients was drawn up as part of the CPG and covers general aspects of interest about the suicidal behaviour, preventive interventions and postvention. The final version of this material was divided into: General Information, Information for Patients and Information for Family Members and Carers. The evaluation of patients perception proposed allows for assessing the impact and utility of these publications for patients.

Discussion: Assessing the impact and patient perception of this type of material requires an effort from HTA agencies, although this feedback is necessary. The evaluation should be planned during the preparation of the document.

Implications for the health system/professionals/patients/society: The elaboration of patient and relatives information material seems to be crucial. It is necessary to take into account their views and concerns in both development and in the subsequent assessment.

567. MONTELUKAST AS MONOTHERAPY IN CHILDREN WITH MILD PERSISTENT ASTHMA: IS ITS USE RECOMMENDED?

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Background: The Clinical Practice Guideline (CPG) of the Basque Health Service regarding asthma management (2005) recommends the use of inhaled glucocorticoids (IGCs) rather than antileukotrienes as monotherapy in children with asthma. In contrast, the prescription of montelukast has increased in the Basque Country since 2005.

Objectives: To assess the evidence published since 2005 regarding the use of montelukast in paediatric asthma following the GRADE method; to determine whether the previous guideline recommendation needs to be modified.

Methods: A search for CPGs and systematic reviews published since 2005 was performed. Primary studies published since the last selected review were identified. The definition and weighting of the outcomes was made by 12 professionals (paediatricians, pneumologists, GPs, pharmacists, nurses and methodologists) and by the parents of children with asthma surveyed at primary and specialized care. Meta-analysed data for selected outcomes was searched. RevMan program was used to meta-analyse data of the outcomes not contemplated in the reviews. Evidence assessment and the elaboration of recommendations were made following the GRADE method.

Results: Neither of the identified guidelines recommends the use of antileukotrienes as monotherapy for children with asthma. One systematic review published in 2010 provided meta-analysed data for 6 of the 14 selected outcomes, showing that IGCs are associated with a significant decrease in asthma exacerbations (RR = 0.83; CI95% = 0.72;0.96), better lung function and clinical results compared with montelukast. Data for the other eigth outcomes were extracted from primary studies and meta-analysed. The results showed that IGCs decrease the growth rate by 0.56 cm/year (CI95% = 0.32;0.79). Whether and how it affects final height remains unclear.

Discussion: The evidence still does not support the use of montelukast as monotherapy in paediatric asthma. In consequence, a strategy to promote the adherence of clinicians to recommendations regarding montelukast should be designed to provide better healthcare for children with asthma.

603. EVIDENCE-BASED GUIDELINE IMPLEMENTATION WITHIN PRIMARY CARE PRACTICES ON HYPERTENSION AND DIABETES

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Background: The implementation of evidence-based guidelines (EBG) into the clinical practice of primary care teams is essential to achieve quality assurance in this setting. There is a need to define the framework for deciding the effectiveness to develop and introduce clinical guidelines, as patients with diabetes and hypertension typically obtain most of their care from primary care providers (PCPs).

Objectives: To undertake a literature review on the effectiveness of guideline implementation on hypertension and diabetes in a primary health care setting.

Methods: The MESh terms used in this review were: implementation, guideline, hypertension, diabetes and primary health care. MEDLINE, Cochrane Controlled Trial Register, EMBASE, and the specialized register of the Cochrane Effective Practice and Organization of Care (EPOC) group were used as data sources. Separate analyses were undertaken for comparisons of different types of intervention.

Results: There are four types of strategies for implementing an evidence-based guideline in hypertension and diabetes: (1) educational training, including face-to-face training individual or grouped sections, manuals for self-directed learning, patient management flow-charts, practice based education and newsletters; (2) internal or external audit, including feedback reports on performance and peer review; (3) Information Communication Technology devices, such as computer-based reminders, phone-call reminders and SMS reminders; (4) combination among the different kind of interventions. These approaches have been reviewed and have shown that there is a need to integrate more than one strategy to control hypertension and diabetes in a primary care setting.

Discussion: The implementation of EBG instruments is likely to improve the process of care in diabetes and hypertension, rather than patient outcomes.

Implications for the health system/professionals/patients/society: Decision-makers need to integrate several approaches on the management of hypertension and diabetes in order to achieve clinical effectiveness activities to maximize population benefits. Multifaceted approach is essential to implement evidence-based care guidelines within primary care setting.

614. A SYSTEMATIC REVIEW OF CLINICAL PRACTICE GUIDELINES ON THE DIAGNOSIS OF ALZHEIMER'S DISEASE

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Background: The early diagnosis of Alzheimer's disease (AD) has health, economic and social benefits. As a result, a great number of trials evaluating different diagnostic techniques have been published in the last years. We have also seen a rapid increase in the number of CPGs published in different countries that provide recommendations for diagnosis. To our knowledge, however, there are currently no systematic reviews of CPGs comparing the recommendations for the diagnosis of AD.

Objectives: This review seeks to identify the highest quality CPGs available addressing the issue of diagnosis in order to provide a summary of the recommendations on which there is broad agreement.

Methods: A systematic search was conducted using PubMED, the National Guideline Clearinghouse, TripDatabase, NICE UK and GuíaSalud to identify CPGs for the diagnosis of AD published between 2006 and 2011. All publications aimed at health professionals that used a system for grading recommendations were retrieved to be assessed using the Appraisal of Guidelines Research and Evaluation instrument (AGREE II). This evaluation was performed by three independent reviewers. Recommendations were identified and compared between them weighting their level of evidence.

Results: Forty-one out of the 46 documents identified were excluded for not meeting the eligibility criteria. Five guidelines were evaluated using the AGREE II instrument, and the three of them assessed as being of high quality were included in the review. An important inter-guideline consensus was found regarding diagnostic criteria, cognitive and neuropsychological testing and the use of imaging.

Discussion: Although a lengthy and methodologically challenging process, these findings are very encouraging as the agreement found boosts the power of each individual guideline. However, this is a fairly novel exercise that requires further improvement.

Implications for the health system and professionals: The consistent picture emerged from this SR ensures that professionals are provided with the best evidence-based recommendations.

671. BRAZILIAN CLINICAL PRACTICE GUIDELINES IMPLEMENTATION: AN EFFECTIVE TOOL FOR INTEGRATED PATIENT-CENTERED CARE

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The Brazilian Clinical Practice Guidelines Project (BCPGP) was developed in the context in of the Brazilian Medicine's National Policy in order to promote the rational drugs' use and the reorganization of pharmaceutical assistance since 2000. Each BCPG is designed to establish diagnostic and treatment criteria for each disease, also recommending follow-up and patient orientation. The Hospital Alemão Oswaldo Cruz (HAOC) through the Program of Support for Institutional development of the SUS provides funds and management to this project since 2009. Each guideline may require the development of evidence-based reports for the inclusion/exclusion of new or old technologies. The scientific documents are prepared by expert consultants in the area and reviewed by a technical team of pharmacists and doctors. Subsequently they are discussed in a technical group defined by Brazilian Ministry of Health (BMH) and published for public consulting (PC). After the incorporation of the relevant suggestions at PC it becomes a rule. In the period from 2009 to 2011 fifty-four BCPGs were published and six were published in PC. Currently are under development forty-four BCPGs. During this period sixty-nine reports were prepared regarding technologies related to the development of these BCPGs. The continuous need for assessments of new technologies, as well as constant updates on the diseases' diagnosis and treatments justifies the continuation and expansion of our project. The effective implementation of BCPG at a national level should be done through the establishment of several Clinical Effectiveness Centers of Integrated Care, to ensure integral assistance of patients, costs reduction and measurement of clinical outcomes. This Brazilian project lasts now for 12 years, with much yet to come but also with many accomplished issues related to HTA, quality improvement and policy making at public health system. Sharing such an experience might be useful for other countries.

813. UNDERSTANDING THE NEED TO TEACH HEALTH TECHNOLOGY ASSESSMENT IN HEALTH COURSES: THE PERCEPTIONS OF TEACHERS FROM A BRAZILIAN MEDICAL SCHOOL

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The concerns about Health Technology Evaluations (HTE) from an academic and scientific perspective are recent in Brazil. When investigating the professors' knowledge of HTA in a Brazilian Medical School, a difference between what professionals claim to know and what they actually know about the subject could be identified. Disseminate HTA during the formation of health professional would be a way to reverse this situation? This work aims to know faculty's perceptions about the importance of HTA for the formation of health professionals in Brazil. An electronic questionnaire was handed to the health education professionals from a Brazilian public medical school as part of a descriptive study. Among the inquired professionals, 78% said it was important to have an HTA approach during undergraduate studies, and 61% said it was also important for post-graduation as well. Even though the sample was formed by 86% of medical doctors, an HTA approach to professional formation would comprise all health-related courses. The study showed that academic interest was considered by 87% of the professionals as a criterion for decision-making regarding the acquisition of new technologies. In the justifications, the subjects pointed out that a single thorough evaluation is able to provide evidence to adopt or discard a specific technology and therefore this fact would be enough to justify approaching the theme during graduation and post-graduation. The educational process during graduation could be an alternative to avoid misconceptions and mistakes regarding HTA. The fact that a significant number of subjects pointed academic interest as an important criterion for adopting new technologies also highlights the

possibility of elaborating educational strategies from an HTA perspective. The academic institutions, especially those which are composed of university hospitals in Brazil, could be built upon neutral discussion, which could in its turn minimize the strong influence of commercial purposes.

818. HTA TRAINING FOR THE STRATEGIC PERSONNEL IN THE BRAZILIAN HEALTH SYSTEM (SUS)

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Background: The health systems of different countries have gaps in the processes of incorporating and utilization of technologies. The Department of Science and Technology (DECIT) of the Brazilian Ministry of Health has been promoting, since 2005, many courses in order to incentive the training of health professionals, managers and researchers in the field of HTA. In 2011 a total of 16 courses were held and more than 450 professional were trained.

Objectives: To identify the participants and to verify the quality of the courses offered by DECIT: a distance education in HTA; a Rapid Review workshop and a MBA in economics and HTA.

Methods: A documental research was used to identify the participants and a semi-structured questionnaire was used to verify the perception of the participants of the quality of the courses.

Results: The majority of the participants came from teaching and research institutions, state health departments and federal organizations. Most of them were from the field of pharmaceuticals. As to the geographical distribution, most were from the southeast (48) and central areas (43) of Brazil, followed by northeast (26), north (20) and south (11). All the participants that answered the survey (122/148) indicated that the course was satisfactory and the subjects presented were of high relevance and also of high applicability on the professional practice.

Discussion: It is necessary to have good articulation mechanisms between personnel departments of SUS, financing organizations and teaching institutions in order to train a large number of professionals.

Implications: More Health Professional properly trained will enable the creation of HTA units which will disseminate HTA culture in Brazil.

841. BRAZILIAN EXPERIENCE IN TRAINING DECISION MAKERS AND MANAGERS IN THE ELABORATION OF RAPID-HTA: TOOL AGAINST HEALTH JUDICIALIZATION

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The workshops for the elaboration of rapid HTA were coordinated by the General Coordination of Health Technology Assessment, Department of Science and Technology of the Ministry of Health of Brazil, from the demands of the technical areas of the Ministry, State and Municipalities Secretaries of Health The main objective of this training is to prepare managers about the use of methods the quality of scientific evidence to answer primarily to the judicialization. Other objectives are to promote the "Methodological Guidelines for the elaboration of rapid HTA," to encourage the use of these guidelines and promote the concepts of search, analysis and synthesis of scientific literature, with guidelines for searching, principles of Evidence-Based Medicine and Epidemiology. In 2008, were promoted seven workshops for the elaboration of rapid HTA, two in Brasilia, one in João Pessoa, Belem, Rio de Janeiro, Belo Horizonte, and São Paulo. In all, 104 people participated in the workshops, including pharmaceuticals (42), clinicians (28), nurses (5), lawyers (4), librarians (3), among others (22). The participants were representatives of the technical areas of the Ministry of Health, Secretarats of Health, hospitals, and universities. At the end of the workshops, we applied an evaluation questionnaire. 73% of respondents to the questionnaire, 96% of these workshops considered excellent or good in the relevant items of content, presentation of the themes and debates quality of the material offered. A positive point was the training workshop participants began to use critically the scientific literature of quality in their daily practice in the management and health care in relation to the assessment, development and, especially, legalization of health technologies. As a challenge, there is still incipient institutionalization of HTA in government structures, with no guarantee of continued development of quality advice, even the workshops being held at the request of managers today.

675. STUDY ON THE USE OF CLINICAL PRACTICE GUIDELINES IN SPECIALIZED CARE: EXAMINATION OF BARRIERS AND FACILITATORS FOR THEIR IMPLEMENTATION

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Background: There is little knowledge of adherence to the recommendations of the guidelines and the barriers to their implementation that have been detected.

Objectives: Explore the knowledge and attitudes of Specialized Care professionals in terms of the use of CPGs. Identify the most relevant barriers and facilitators to their proper dissemination and implementation. Identify the strategies and actions for improvement that contribute to minimizing the impact of the barriers that have been detected.

Methods: In order to fulfil the study's objectives, it is essential to discover the opinion of the actors taking active part in the creation, dissemination and use of the CPGs. As a result, the decision was made to issue a questionnaire in order to discover the level of knowledge and attitudes of healthcare professionals working in Specialized Care towards the Clinical Practice Guidelines.

Results: The questionnaire was completed by 209 Specialized Care doctors. The application of the recommendations in the CPGs is considered to be easy by 61.2% of participants, while 28.2% considered this procedure to be difficult. Among the reasons behind the difficulty were: the complicated nature of practical application, the lack of organizational, financial and infrastructure-related resources, the variable nature of the patients, the lack of time, little evidence with low-quality recommendations, disagreement, a lack of interest and motivation and the lack of knowledge of the CPGs due to unsatisfactory dissemination.

Discussion: The dissemination/implementation strategy for the guidelines is insufficient. As such, different actions aimed at acting on both the barriers relating to local resources and the health organisation itself as well as those relating to the healthcare professionals and those associated with the implementation process must be established.

708. ON BEHALF OF THE PATIENTS: INCORPORATION OF PATIENTS IN THE MAKING OF A CLINICAL PRACTICE GUIDELINE

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Background: Patient participation in Clinical Practice Guidelines (CPG) is at a developing stage in Argentina but it´s taking up speed. Experiences and expectations of target population should be part of the development process of guidelines for healthcare. There are various methods for ensuring that these key perspectives shape the different stages of guideline development including formal consultations with patients and public to determine priority topics, participation of patient representatives in the guideline development group, or external review by stakeholders. Alternatively, information could be obtained from patient interviews and focus groups or from literature reviews of patient/public values, preferences or experiences. In order to fulfill AGREE II quality standards the CPG should contain sound evidence of such process and that patients' views have been included and respected.

Objectives: The purpose of this presentation will be to discuss Argentine National Guideline for Tobacco Cessation experience in including patients' participation and discuss achievements and ways to cope with potential barriers.

Methods: Patient participation was sought in a variety of ways during the development process including: -Inclusion of former smokers now involved in group therapy for smoking cessation in the consensus panel. -Inclusion of high quality guidelines in which patient participation had been considered, as resources for our guideline. -Inference of patient acceptability of interventions by the members of the consensus panel applying the rating of interventions by the GRADE consensus. Most of the members were involved in smoking cessation therapy and provided their views from everyday experience. In order to comply with GRADE statements, interventions should be considered acceptable for the patients. -Access for the general population to the preliminary version through open websites. -Survey of patient opinions using a Likert-scale instrument which was applied in COPD, cardiovascular and healthy smokers.

Discussion and implications for the health system: We will discuss the barriers and methods used to deal with them and present the results of an ongoing survey of patient opinions. Lack of consideration to patient opinions and values are potential barriers to guideline implementation. Taking into account their views and opinions can facilitate GPC dissemination and acceptation.

712. FORMAL CONSENSUS IN THE DEVELOPMENT OF A CLINICAL PRACTICE GUIDELINE: THE FORCE OF THE SILENT MAJORITY

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Background: Controversial topics arise during the development of Clinical Practice Guidelines. Members of a consensus panel may bias their opinions due to previous experience, non- acknowledged conflicts of interests, emotional involvement, etc. Formal consensus methods as the RAND and Delphi techniques are useful to allow free expression of all members involved and to minimize the "bandwagon effect". Formal consensus methods are not widely used in Argentina, and discussion are often solved through non-formal controversy, allowing the strongest opinion leaders and expansive personalities in the panel to prevail over the quieter ones.

Objective: The purpose of this presentation is to discuss our experience while developing a National Guideline for Tobacco Cessation.

Method: We used the Delphi method to help consensus from the expert panel emerge. The technique allowed the members to express their opinions and to give a structured feedback to the opinions of others. Consensus on the strength of a recommendation was obtained with 75% of positive answers. Members were divided randomly in groups with a facilitator per group. If no consensus was achieved, objections of each member were read anonymously. A second ballot followed and if no consensus was achieved opinions were again asked from the members. After two rounds of analysis if no consensus emerged, the issue was discussed in a plenary session.

Results: In most recommendations of the guideline, consensus was easily obtained (93 to 100% of concordance). As a consequence of the formal consensus method applied, the voice of the strongest opinion leaders and experts was balanced by the views of the majority of the experts who ended relying on evidence more than in individual opinions.

Discussion and implications for the health system: Formal consensus methods allow that all opinions are equally respected and rated and improves transparency in the decision-making process. We will discuss the approach we used to include this methodology in a Latin American setting.

716. KEEPING A SYSTEMATIC SEARCH OPEN WHILE DEVELOPING A CLINICAL PRACTICE GUIDELINE CAN BUY TIME FOR PATIENT SAFETY

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Background: Evidence evolves rapidly and current information may not be valid tomorrow.

Objective: We present our experience while developing the Argentine National Guideline for Tobacco Cessation. We undertook a systematic search of Clinical Practice Guidelines in English and Spanish using the keywords "smoking cessation" AND "guidelines", "tabaquismo", "cesación", "guías" from 2005 onwards using several search engines. Relevant results were identified by two independent reviewers. Our initial search yielded 1.040.000 results from google scholar®. After excluding duplications and non relevant documents, we identified 250 potentially relevant documents. After focusing our search in systematic reviews, clinical practice guidelines and meta-analysis we obtained 35 CPG that were evaluated through the AGREE instrument, and 76 Meta-analysis (MA) that were evaluated using the SIGN quality instrument. We also added 7 MA previous to 2005 that gave answers to some clinical questions. The search was repeated in several occasions while the guideline was under development. In spite of this exhaustive revision process, two MA related to drug safety issues were published after the first version of the CPG had been completed. This evidence had not been included in the CPGs and other documents used as the basis of our CPG. This generated a huge debate among panel members because the drug discussed was one of the main points in the GPC and its role in the treatment of smokers was strongly questioned when the GPC was about to be published. The issue was of such importance that a plenary panel session was

summoned out of schedule to rediscuss several recommendations of the GPC which ended up in the change of the strength of several recommendations. The ongoing literature search helped us to change evidence-based recommendations and we believe in this case was directly related to protect and assure the safety of patients. This could not have taken place if the evidence search process had not been ongoing until publication date.

723. UNDERSTANDING A WEAK RECOMMENDATION. POTENTIAL BARRIERS IN GUIDELINE IMPLEMENTATION

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The GRADE instrument advices that guideline recommendations are classified by strength. Strong recommendations apply to most patients in most circumstances without reservation. For weak recommendations, best action may differ depending on circumstances or patients or societal values. Instruments used for guideline development are applied across diverse language and cultural settings. English words are often understood by guideline developers in Latin America but this cannot always be the case for users. Assuring the correct transference of wording of international quality assurance instruments (such as GRADE) from one language to another and even from different countries using the same language is a key element for the acceptability of a final recommendation. In the case of the National Guideline for Tobacco Cessation for Argentina we used this classification scheme, but when translated to Spanish the word weak ("débil") sounded or was interpreted as feeble (in a deprecative way) by guideline users. We found an unexpected barrier when practitioners and members of the panel who read the guideline interpreted that a weak recommendation meant a recommendation against doing or had a scornful or pejorative sense, in spite of having explained the meaning to them. In order to keep the message clear we finally changed the words "strong" and "weak" and opted for "recommendations type I" and "type II" (which were also provided by GRADE as an option) explaining the implications for practice. Language barriers have the potential to impede guideline implementation and should be taken into account whenever the GRADE consensus recommendations are used in guideline development in non-English speaking countries.

729. UTILISING A MODEL OF PATIENT AND PUBLIC INVOLVEMENT IN DEVELOPING NICE PATIENT EXPERIENCES GUIDANCE

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Background: Patients are increasingly involved in developing guidelines and quality standards, although relatively few good practice models describe the context and process required to achieve good patient-centred guidance. This paper will consider these issues by presenting the model utilised in the development of NICE Patient Experiences Guidance.

Objectives: a. To describe a model of patient involvement which can be utilised internationally to ensure the relevance, appropriateness and acceptability of guidelines development. b. To describe the context and process of successful patient involvement. c. To identify the impacts of patient involvement in the guideline development process.

Methods: Six patients (guideline group included 26 individuals) were involved throughout the guideline development process including scoping the focus, synthesising data, critiquing research results, writing recommendations, dissemination and implementation. The context of involvement included utilisation of good ways of working. The process was designed to enable collaborative involvement and to maximise the impact of patient involvement.

Results: The development of the NICE Patient Experiences Guidance was characterised by collaborative patient involvement, with patients involved as equal partners who were involved throughout the process by contributing to the scoping, evidence synthesis, writing and reviewing of recommendations and the dissemination and implementation of the guidance. Specific examples of the impact of patient involvement on guideline development will be presented.

Discussion: The model of patient involvement ensured active patient collaboration in guideline development. The context and process were vital in maximising the potential for patient involvement to have an impact on guideline development.

Implications for health systems, professionals, patients and society: This model of patient involvement in guideline development could be utilised internationally to ensure the relevance, acceptability and appropriateness of guidelines that aim to enhance the quality and effectiveness of health care.

871. IMPACT OF PROFESSIONAL KNOWLEDGE ABOUT THE INJECTABLE DRUGS PREPARATION AND ADMINISTRATION IN A CLINICAL UNIT CARE OF THE CEARÁ STATE

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Background: Medications are considered the technology most commonly used health worldwide. However, medication errors cause potential risk to patients and may occur due to characteristics of patients, health professionals knowledge, gaps in health care systems, inadequate graduate and continuing education of various professional.

Objective: To evaluate of professional knowledge about the preparation and administration of injectable drugs.

Methods: A descriptive survey type and the study was conducted at the Public Emergency Unit of a hospital in Ceará, Brazil.

Results: Were 28 respondents (38.3%) of nurses and 70 (44%) of nursing assistants and technicians, making a total of 98 (42.4%) of the nursing staff crowded sector of emergency. We can see absolute predominance of females in the sample with 79.60% of the participants. Concerning the time of technical training or higher was found interesting contrast in our data. We have a mix of experienced professionals with over ten years of training (39.79%) and early career professionals in under five years of training (35.72%).

Discussion: The nurse points more frequently needs major concerns, but more specific for better security practices to dilution and administration of injections. Such reporting is visible when 64.28% of the sample of nurses indicate that training on labeling, product monograph, awareness of the need of the drug as a point of interest to improve performance. The majority of nurses (89.28%) with sensitivity training on stability and preservation of solutions and incompatibilities and drug interactions is referred to by 85.71%.

Implications for the health system/professionals/patients/society: The development of protocols specifying what should be

done in certain situations would help significantly the safe use of health technology by nurses. However, the actual data point in the sense that not all situations fit protocols listed, but some could be implemented, facilitating and improving patient care and decreasing the time of admission.

921. A BRIEF ANALYSIS FOR THE CLINICAL PATHWAY IN CHINA

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Background: Clinical pathway (CP) is an application of rational process and time management for specific disease and surgery in practice, which is known for improvement of patient healthcare quality, cost control, hospital management, patient satisfaction and a sustainable healthcare system. The CP was firstly introduced into China in 1990s.

Objective: To find the current status of clinical pathway in China.

Methods: We used word clinical pathway in title by searching the web of clinical pathway (www.ch-cp.org.cn), CNKI, etc. and collected the CP information on title, date, specialities of CP and main contents, etc. Search date till December 30, 2011.

Results: 1. 112 clinical pathways were developed by Ministry of health in China and issued in 2009. These CP were pilot implemented in 110 selected hospitals. Few CP described the sources of funding, composition of group that authored the CP and financial disclosures. 2. The CP related to 22 specialities and the top ten were: General surgery 10, Cardiovascular 7, Orthopedics 7, Digestion system 6, Neurology 6, Neurosurgery 6, Respiratory 6, Stomatology 6, Cardiac surgery 5, Dermatology 5, etc. 3.The contents of CP mainly include: disease and target population, diagnosis, treatment option, standard length of stay in hospital, criteria for CP entrance, preoperative evaluation, time and choice for use of prophylactic antibiotics, operation day, postoperative hospital stay recovery, discharge standard, variance and reason analysis, etc. 4. The major barriers of CP implementation include: poor of doctor's participation, communication and education, lack of explanation of the variance process and poor of the document for patient, etc.

Conclusions: Clinical pathway is a tool for guide evidence-based healthcare. However, CP is unable to meet the needs of complex diseases and individual care. More communication with relevant doctors and patients would be better for CP implementation.

931. THE UTILITY OF CLINICAL PRACTICE GUIDELINES IN THE DISINVESTMENT DECISION-MAKING PROCESS

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Background: The disinvestment of obsolete health technologies can be an important step towards improving efficiency in health systems by allowing technologies that provide no added value to these systems to be selected. Clinical practice guidelines (CPGs) may be a good means of identifying such obsolete technologies, which would then become candidates for disinvestment.

Objectives: To recognize the possible impact of a CPG concerning the "Management of type 1 diabetes" on the disinvestment decision-making process in a Spanish health context.

Methods: This CPG consisted of 57 clinical questions and 179 recommendations concerning the "Management of type 1 diabetes mellitus". Recommendations were classify in three options: "Do not do", "Do under specific conditions" and "Do it" recommendations.

Results: Only two of the 179 recommendations included in this CPG concerned health technologies that were not to be used in any case ("Do not do" recommendations).Both were related to the same clinical question (Methods to dispense insulin). Most of the recommendations (82) indicated the use of these technologies in a specific population or under specific conditions, and a further 75 recommendations proposed their use in all patients with type 1 diabetes.

Discussion: This guideline has provided interesting information to support investment and disinvestment decisions in a Spanish health context. In most cases, the identification of obsolete health technologies is related to a restriction of their use to specific conditions, although in a few cases these technologies can be disinvested.

383. ORGANIZATIONAL MODEL OF HOSPITAL BASED HTA AT THE LOCAL HEALTHCARE LEVEL IN ABSENCE OF ADEQUATE RESOURCES

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Although HTA is recognized as a priority by the Italian National Health Plan and many Regions included it in their strategic business plans, the facts are that the current serious historical situation and scarcity of financial resources has created a paradox: the bigger the crisis is, the higher the need of an HTA approach. The bigger the crisis, the lower the amount of resources for HTA. Therefore we propose to develop a Hospital Based HTA low cost model at the Local Healthcare level, tailored for a Public health care system such as the Italian one. With this model, there is no need to establish an HTA Unit, and the distribution of the workload is based on a bottom up system. The model proposes the establishment of a Local Healthcare commission (including at least one expert in HTA) and the appointment of Referents, with some basic training, in each Department and Care Unit for each Hospital center. The model relies as much as possible to a system of "automated" data collection useful for assessment, using appropriate data collection forms. The commission pinpoints complexity/impact levels and prioritization criteria for the evaluation. On the basis of the bottom up process the petitioners together with the representatives fill out the forms and submit them to the Medical Direction. Low complexity/impact requests are analyzed directly by the Medical Direction. Medium and high complexity/impact requests are analyzed by the corporate commission. Very High complexity/impact requests will be submitted to an Agency of experts. The objective of this model is to distribute the workload to multiple levels, giving the task of collecting information primarily to the applicants, relieving the corporate commission of the task of data collection and of low impact/complexity requests evaluations that will be done by the Medical Direction.

27. HEALTH TECHNOLOGY ASSESSMENT EVIDENCE CRITERIA: WHAT TYPES OF EVIDENCE SHOULD BE PRESENTED FOR PRODUCTS USED TO SCREEN FOR DISEASE IN THE UNITED STATES?

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New technologies can be tools of innovative change in healthcare. They can be associated with improved treatment options, quality of

care for patients, and cost savings. Distinguishing valuable technologies from those that offer added costs with no improvements in outcomes is the art of technology assessment. A key function of that art involves selecting those patients, conditions, providers and settings in which a technology may offer improvements over current care. With recent scientific discoveries such as the mapping of the human genome, development of genetic marker tests, and the growing interest in stem cell technologies, innovation is far ahead of any type of assessment that is currently used to establish which technologies should be made accessible to patients. Screening technologies are on the forefront of innovation and may have a dramatic impact on the care of patients in terms of identifying disease and appropriate treatment options at an early stage. As a result, screening technologies are of key interest to health technology assessment (HTA) agencies in the United States and abroad. Similarly, because screening technologies are developing quickly and are believed to have the potential to make a significant change in patient care, it is important to develop a robust level of HTA criteria to evaluate these new technologies and determine which technologies should be integrated into the practice of medicine and made accessible to patients. Findings from this study indicate that while technology assessment organizations do have standard sets of criteria to evaluate products that are therapeutic, the assessment and level of evidence used to evaluate screening technologies are less clear. The objective of this research study is to evaluate existing technology assessment standards for screening technologies in order to establish a best practice that may be implemented by US technology assessment organizations to broaden the criteria used in assessments for screening products. The results of this study indicate that the best practices should include criteria to: support screening reliability, sensitivity and specificity; evaluate data to identify appropriate patient populations; reference to the natural course of the disease; consider ethical implications; and the impact of cost.

55. THE ROLE OF HTA IN HEALTHCARE MANAGERS IN THE REPUBLIC OF KAZAKHSTAN

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Relevance: The growth of new health technology makes it difficult to control the flow information and choosing the right healthcare decision-making managers. On this basis, there is an urgently need systematic and critical assessment, which will weigh the various options for intervention and identify the best alternative reliable evidence for decision-making through the introduction of HTA.

Objective: To study the level of knowledge of healthcare managers in the HTA.

Methods: Questionnaire was conducted 89 health managers.

Results: The best experience in expert activity and have a degree PhD, MD found managers in Almaty ($p < 0.05$). There is experience in public health (management, administration) of the respondents of both cities ($P < 0.05$). 73% of managers in Almaty know English (elementary). Among respondents Almaty ($p < 0.05$) there is no view on the impact of HTA on price of medical services organization, but respondents in Astana ($p < 0.05$) firmly believe that HTA affects price of medical services organization and is able to improve the quality and effectiveness of medical services ($p < 0.05$). Respondents in both groups believe that HTA improves income clinics, only the managers of Astana ($p < 0.05$) suggest that HTA reduce the burden of disease in the patient. Almaty respondents 68.4% state that didn't apply new medical technologies, which further improved the quality of healthcare, but all respondents are use in their work EBM.

Conclusions: An integrated approach to assessing the appropriateness of health technologies involves an interrelated assessment of clinical and cost effectiveness. There is a positive trend among managers with a basic knowledge of English, and applying Internet resources in work, their understanding of the need for the introduction of new medical technologies in the clinic, which creates the possibility of introduction and development of HTA through capacity building and strengthening of basic knowledge in the field of EBM.

81. COAUTORSHIP AND INSTITUTIONAL COLLABORATIONS ON COST-EFFECTIVENESS ANALYSES: A SYSTEMATIC NETWORK ANALYSIS

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Objective: Cost-effectiveness analysis (CEA) is an important research design for determining the efficiency of healthcare interventions and guiding medical decision-making. Our aim was to characterize collaborative patterns on CEA conducted over the past two decades in Spain.

Methods: A bibliometric analysis was carried out with the information obtained through a comprehensive literature review and from reports of health technology assessment agencies. We identified CEA with outcomes expressed as a time-based summary measure of population health (e.g., disability- and/or quality-adjusted life-years), conducted in Spain and published between 1989 and 2011. For each paper, we particularly recorded the year of publication, the journal title, the name and number of authors and their institutions. Networks of coauthorship and institutional collaborations were established.

Results: One-hundred and thirty-one papers were analyzed, in which 526 authors and 230 institutions participated. The overall collaboration index was 5.4. Six major groups (one with 14 members, three with 7 members and two with 6 members) were identified. The most prolific authors were generally affiliated with the private for-profit sector (e.g., consulting firms and pharmaceutical industry). Private for-profit sector consolidated collaborative networks including public hospitals and academia. Collaborations within the public not-for-profit sector (e.g., healthcare administration and primary care) were weak and fragmented.

Conclusions: Our analysis reflects current practices among collaborative networks that contributed substantially to the production of CEA at a country level. This empiric evaluation raises challenges for redesigning future health technology assessment policies and provides a framework for similar analysis in other regions.

86. LAWSUITS RECEIVED BY THE BRAZILIAN MINISTRY OF HEALTH FOR THE TREATMENT OF HYPERTENSION IN 2010

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Background: With the enactment of the Federal Constitution of 1988 (CF/88), Brazilian citizens gained the recognition that health is a

fundamental right. The citizens awareness is frequently questioned before the Judiciary considering that health must be guaranteed by the Government. However, recognition of the right to health has led to an excess of lawsuits to guarantee citizens access to new technologies that often has no scientific evidence of safety, efficacy, cost and effectiveness.

Objectives: Describe the characteristics of lawsuits received in the Ministry of Health for Hypertension (HAS) in 2010.

Methods: Analysis of database of lawsuits petitions in 2010 in the Secretariat of Science, Technology and Strategic Inputs of the Brazilian Ministry of Health. In total 339 requests or hypertension drugs were carried out. It was analyzed only the requests of drugs with two combined active substances total of 45. Drugs with a single active principle were excluded from the sample.

Results: There were 45 drugs with two combined active substances requested in lawsuits 40% (n = 18) was for Valsartan + sinvastatin a drug that has not been incorporated to the Brazilian Public Health System (SUS), but sivastatin alone is at the population disposal for free. Losartan + hidroclorotiazid were responsible for 20% (n = 9) also not incorporated to SUS, however both drugs isolated are offered for free by SUS. Amilorid + hidroclorotiazid had 9% of the solicitation (n = 4) and is not at SUS. It was found also that 31% of the prescriptions came from SUS Physicians.

Conclusion: Lawsuits against SUS are in many ways not related to the patients benefit; it can be also related to the pressure to incorporate new technologies. Expends with lawsuits against SUS can weaken one of the most democratic idea of "health for all", threatening the sustainability of the system.

116. DESCRIPTIVE PROFILE ANALYSIS OF TARIFFS AND DELIBERATION OF TECHNOLOGY OF CITEC DURING THE YEAR 2010

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Background: The Committee for Incorporation of Technologies (CITEC) is an advisory body of the Ministry of Health in Brazil, which has the function evaluating requests for incorporation, inclusion or exclusion of technologies in the context of the Brazilian Public Health System (SUS), according to the guidelines of the National Policy for the Management of Technologies in Health in Brazil.

Objectives: Show the profile of analysis of tariffs and deliberation of CITEC during the year 2010.

Methods: If you look at all the technologies based on official meetings of CITEC during the year 2010. The following variables were considered: time between each meeting, technologies evaluated by meeting and final position of technology based.

Results: There were 15 meetings of CITEC during the year 2010, an average of one meeting every 24 days. Were conducted a total of 86 technologies, an average of 6 technologies for meeting. Of these, 54 had deliberations completed (34 incorporations, 15 had not incorporated, 4 excluded and one with request for exclusion, not excluded) and 32 technologies based on deliberations are not completed, in its majority by evidence studies incomplete.

Discussion: The mean time of meeting of CITEC (every 24 days) and considered acceptable, taking into account that for each resolution is necessary to the participation of 5 representatives of different institutions, but taking into account the number of technologies based on meeting, shows a limitation to the notes of decisions mainly by studies of scientific evidence incomplete. The implementation of the law n° 12,401 and the decree 7,646 will help to solve these limitations**.**

128. HTA IN HOSPITALS: A PANORAMA OF HEALTH TECHNOLOGY ASSESSMENT CENTERS (NATS) IN BRAZIL

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Background: In 2009, twenty-four NATS, located at teaching hospitals, were included in the Brazilian Network for Health Technology Assessment (REBRATS) as a segment of specialized health services.

Objective: To describe the organizational and technical situation of the 24 NATS installed at the teaching hospitals, after two years of implementation.

Methods: A survey with self-completion questionnaires was sent to all NATS during September and October of 2011 in order to evaluate the following dimensions: managerial (infrastructure, organizational flow, human resources, capacity-building), technical (production of HTA studies and dissemination), economic (budget and sustainability). Opinions regarding difficulties were analyzed.

Results: Twenty responses were obtained (83%). The NATS were legally established in 70% of the hospitals, most of them subordinated to the Director-General. The majority of the NATS possess between four and six professionals dedicated to conducting HTA, 27% of them are doctors, 14% are engineers, 12% are pharmacists and 11% are nurses. Training is conducted at 80% of the NATS. In 50% of the cases, the topic selection comes from units at the hospital itself. Drugs are the main types of technology analyzed, with efficacy and effectiveness being the aspects that are evaluated most. Half of the NATS have their own budget and 85% do not receive external financing. Only 30% possess a formalized flow to attend to internal demands and 10% to attend to external demands. The main difficulties, cited by 80% of the NATS, referred to financial resources and trained personnel.

Conclusion: Strategies to strengthen HTA in hospitals are fundamental to improving the quality of health care. The implementation of NATS at hospitals is recent in Brazil and requires continuity in financing, monitoring strategies and training that aims to consolidate REBRATS.

141. CHALLENGES AND BARRIERS TO INTRODUCING HEATH TECHNOLOGY ASSESSMENT IN CHINA

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Background: Health technology assessment (HTA) using pharmacoeconomic techniques is one widely used measure to ensure efficiency in healthcare decision making, specifically in pharmaceutical pricing and reimbursement. In 2011, the Chinese Pharmaceutical Society Pharmacoeconomics Committee released a draft set of guidelines based on undertaking economic evaluations.

Objective: The purpose of this study was to identify potential challenges and barriers to introducing and implementing a pharmacoeconomic-based HTA system in China.

Methods: Secondary research was carried out looking at barriers encountered in countries when introducing an HTA policy and determining if similar hurdles exist in China.

Results: Four main obstacles were identified when undertaking analyses. First, the pricing and reimbursement mechanisms used in China spread over a number of administrative divisions (MoHRSS, NDRC, MoH, and hospitals), and vary across numerous provincial bodies, so integrating a number of single entities with a clear process and responsibilities will be challenging. Second, there is a lack of administrative and practical expertise to facilitate the use of HTA in decision making; this is one of the often cited causes of reimbursement

listing lag in the Korean HTA experience. Third, there is a foreseeable issue of availability and quality of local cost and disease prevalence data. Finally, the issue of introducing a common cost-effectiveness threshold or decision making criteria will be contentious due to regional variation in needs and inequity between urban and rural areas.

Conclusions: The future of HTA in China is still unclear as no explicit decision has been made on whether and how to implement the guidelines. It is clear however, that moving forward the government will need to address the dual challenges of achieving wider access to medicines by more Chinese people and the issue of the ever-increasing healthcare burden.

157. GOVERNMENTAL PERFORMANCE REQUIREMENTS CONCERNING EVALUATION OF GENETIC SCREENING PROGRAMS

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Background: Newborn screening is a well established prevention program in Swiss health policy. Since 2007, the new federal law on Human Genetic Testing stipulates the conditions under which human genetic testing may be performed. As far as genetic screening programs are concerned, they are subject to governmental authorisation. The adding of a genetic test regarding cystic fibrosis to the established newborn screening was introduced in January 2011 within a pilot study subject to governmental authorisation. Following an advisory opinion of the Expert Commission for Human Genetic Testing, the Federal Office of Public Health granted the authorisation for the pilot study under the requirement of a detailed application concept including an evaluation concept. Data collection has to aim among other things, at providing evidence of efficiency and benefits for cystic fibrosis-patients including genetic counselling. Question: How is an evaluation concept in the authorisation procedure of a genetic screening program to be appraised, taking into account medical, ethical outcomes and policy impact criterias?

Results: On one hand the screening program has to achieve political goals, where specifically ethical issues have to be taken into account, whereas on the other hand it has to provide health outcomes. Swiss government released an HTA Handbook for full HTA reports providing evidence of clinical effectiveness, appropriateness and cost-effectiveness, but there is no instrument yet for assessing the performance of political and ethical requirements.

Conclusions: The triangulation of HTA and policy evaluation methods with specific indicators may fulfil all needs in the evaluation of a screening program. A handbook to facilitate the appraisal of an evaluation concept of a genetic screening program with political impact for patients and public health benefits has to be developed.

181. FUTURE CHALLENGES FOR HEALTH TECHNOLOGY ASSESSMENT IN KOREA

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Background and objective: The health technology assessment (HTA) was implemented by the requirements of the National Health Insurance program in Korea since 2007. The main purpose of our study is to provide an overview of the HTA in Korea. Primarily, we review the entire process of reimbursement decision making for new health technology. We suggest the developed framework of better processing HTA for making sound resource allocation decisions in Korea.

Methods: We systematically collected and reviewed relevant information to describe the HTA process and reimbursement systems.

Results and discussion: HTA in Korea has been driven by the requirements of the NHI. To be listed on the NHI fee schedule, medical procedures must be reviewed by the HTA committee for the safety and effectiveness issues. The review for NHI reimbursement decision making was focused on the cost-effectiveness and benefit appropriateness, and the review process was conducted by the Expert Assessment Committee in Health Insurance Review and Assessment service (HIRA). From 2007 to 2010, a total of 691 applications was submitted and 304(44.0%) were eligible to be assessed for HTA. Among 105 cases in 2011, 20 cases were accepted for a reimbursement, 62 cases were rejected and others are still pending. In this study, firstly, we considered keeping up the continuity between the clinical assessments and the reimbursement decisions for the transparency of the HTA. Secondly, we suggested to improve the decision making process with introducing the involvement of stakeholders. Thirdly, we reviewed to develop the explicit cost effectiveness evaluation guideline for coverage decisions. Lastly, we considered to set the disinvestment system from potentially obsolete technologies.

Conclusions: The HTA in Korea faces accumulated experiences as the future challenges for the long term plans. The focused areas would be the continuity of the assessment process, engagement of stakeholders, development of economic evaluation guidelines, and setting the disinvestment system.

217. DIFFERENCES IN THE INFLUENCE OF PRESCRIBING RESTRICTIONS. IMPLICATIONS FOR FUTURE EFFICIENCY SAVINGS

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Background: Prescribing restrictions have successfully switched prescribing to generics leading to disinvestment in premium priced patent protected products. However their nature and follow-up varies, e.g. in Norway, prescribing restrictions for atorvastatin based on trust followed by delisting of low strength atorvastatin to enhance generic statins. In Austria, patented statins only reimbursed if patients not achieving target lipid levels with generic statins. In Croatia, physicians from the Institute from Health Insurance visit GPs suspected of abuse with possibly fines.

Objectives: Assessing influence of different prescribing restrictions on utilisation patterns of statins, PPIs and ACEIs/ARBs to guide future efficiency/disinvestment decisions.

Methods: Principally observational study of the influence of prescribing restrictions on utilisation of different statins (C10AA), PPIs (A02BC) and ACEIs/ARBs (C09) based on DDDs (2010 DDDs) before and after their introduction using only administrative databases. Comparison with published findings where pertinent.

Results: Appreciable differences in subsequent utilisation of patented statins between 3 countries: 66% reduction in atorvastatin utilisation in Austria in 2007 vs. 2003 (year before restrictions), 59% reduction (atorvastatin and rosuvastatin) in Finland 1.2 years after restrictions, and 44% reduction in Norway in 2008 vs. 2004 (full year before restrictions). Utilisation of esomeprazole also fell in Norway

after restrictions but to a lesser extent than statins, and rose in 2009 vs. 2008 (restrictions introduced in February 2007). Prescribing restrictions limited ARB prescribing in Austria and Croatia but greater influence in Croatia with more aggressive follow-up including potential fines.

Conclusions: Prescribing restrictions have enhanced generic utilisation leading to savings. However, care needed when planning as their nature and follow-up can appreciably influence subsequent utilisation patterns and efficiency savings.

227. NEW HEALTH TECHNOLOGY ASSESSMENT OF SURGICAL INTERVENTION IN KOREA

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Objectives: The new health technology assessment (nHTA) of Korea was adopted in April 2007 and has been implemented for more than 4 years. The results of nHTA are being utilized as evidence for verification of safety and effectiveness at the time of adoptation for the new health technology by Ministry of Health & Welfare. This study aims to analyze results of nHTA for surgical treatments from 2007 to 2011 in South Korea, and present some suggestions for the future of the nHTA.

Methods: Of the 768 cases of new health technology that were assessed in accordance with the Article 53 of the Medical Law since the adoption of the New Health Technology Assessment System. The 63 cases of surgical treatment by excluding 86 cases of test were analyzed. This Study analyzed the cases of technologies acknowledge as new health technology and technologies at research stage that need further researches due to lack of evidences on their effectiveness.

Results: 63 HTA results among the 287 cases of surgeries were completed through systematic review and analyzed. Majority of the technology that were acknowledged as new health technology had no safety issues when compared to the existing technology or were similar to existing technology. Effectiveness was accepted only if it is similar or superior to the existing technology. Health technologies were rejected because there was no research in comparison to the existing technology, corresponding comparator was not appropriate.

Conclusions: Analysis of the results of assessment over the last 4 years illustrate that the new technology must have similar or superior safety and effectiveness when compared with the existing technology in order for surgical treatment to be recognized as new health technology in Korea. Exceptionally, there were cases that were acknowledged even without comparative results if there is no substitute technology or comparative research is difficult for ethical reasons. Therefore, efforts must be put in generating evidences by activating researches that can prove the safety and effectiveness of the corresponding technology by comparing them with the existing technology.

232. COMPARING AND CONTRASTING REFORMS TO IMPROVE PRESCRIBING EFFICIENCY FOR DOPAMINERGIC DRUGS IN CROATIA VERSUS OTHER DRUG CLASSES

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Background: Parkinson disease (PD) is the second most common neurological disease affecting the elderly. Consequently, should be a focus of 'payer' scrutiny with growing drug utilisation and ageing populations. In addition, increasing use of newer premium priced patent protected add-on therapies to stabilise or even improve motor function over time is likely to increase costs. However, potential for moderating drug expenditure through reforms including reference pricing for the class and encouraging generics.

Methods: Observational retrospective study of the Croatian Institute for Health Insurance (HZZO) database of drugs used to treat patients with PD in Croatia (N04BA to BX) from 2000 to 2010 in DDDs (2010 DDDs). Review of recent reforms in Croatia to increase prescribing efficiency and their impact.

Results: Recent reforms including reference pricing (class and molecule), education (formularies), price: volume agreements, financial incentives and prescribing restrictions, decreased health insurance expenditure by 13% in Croatia in 2010 versus a similar period in 2009, reducing Fund's arrears to pharmacies. Reforms also stabilised expenditure on renin-angiotensin drugs 2001 to 2007 despite near doubling of utilisation. Utilisation of drugs to treat PD increased by 218% during the study period. There was a greater increase in reimbursed expenditure (360%), which was driven principally by increasing use of patent protected add-on therapies. However, lower expenditure/DDD for multiple sourced and other drugs following recent reforms helped stabilise reimbursed expenditure since 2005.

Conclusions: PD is a complex treatment area with expenditure driven by newer add-on therapies, which are needed to improve care. Consequently, may require different philosophies to enhance prescribing efficiency than PPIs, statins and ACEIs/ARBs. Reimbursed expenditure has though recently stabilised through reforms, and should start falling, despite increasing volumes, as newer add-on therapies lose their patents. However, this remains to be seen.

255. APPRAISALS AND VALUE JUDGMENTS IN HEALTH TECHNOLOGY ASSESSMENT PROCESS IN BRAZIL

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Background: Treating the shortage of health resources with bioethics and rationality seems to be the only alternative to face the usual dilemmas of health technology assessment. This paper wants to evaluate the current tendencies of Brazilian health manager's decisions during this process.

Objective: To appraise the value judgments in critical decisions involving resource allocation and use of technologies in Brazilian health system through the view of health managers and professionals.

Methods: The research was conducted through a decision making questionnaire to incorporate health technologies. It was completely answered by 193 managers and professionals from various health sectors. There was presented five scenarios that mimic real world dilemmas regarding the choice of resource allocation in an environment of severe budget constraint. The scenarios discussed different factors that could differentiate the decision to incorporate technology: patient age, diseases prevalence, financial cut-off, and prevention versus treatment. Two scenarios (2 and 3) addressed the financing of technological incorporation, involving diseases with different prevalence, by reducing existing programs and creating new taxes. The fifth scenario dealt with the choice between prevention and treatment.

Results: The results show a conservative trend. The majority of respondents chose not to incorporate the technology in scenarios 2 and 3, regardless of disease prevalence: 48.7% in the situation of reduction of other programs and 58% in the situation of creating a new tax. In scenario 5 is noted a preference for allocation of resources

in prevention. It is observed that 64.8% of respondents chose to allocate more resources on prevention rather than treatment. *Conclusion:* The Brazilian health managers and professionals are significantly influenced by economic and budgetary issues when deciding about resource allocation. In search of a paradigm for decision making, most of health managers and professionals opted for caution and prevention.

Implications: This research demonstrates how the absolute scarcity of resources limits the development of health policies in Brazil. Against this background, the cost-effectiveness analyses and the establishment of priorities become essential tools for resource allocation, in order to avoid a technological gap in the country.

280. PROPOSALS ON RISKS OF IATROGENIC PRION DISEASES

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The awareness of the transmissible nature of "prion diseases" starts from studies by Cuillé and Chelle in the 1930's, but the appearance of a variant of Creutzfedlt-Jakob's Disease (vCJD) in 1996 triggered the intensification of scientific production and led to the reconsideration of their infectious nature. Consecutive findings such as the plurality of conformations prion proteins may adopt, together with the series of neuropathological mechanisms common to other neurodegenerative diseases (ie Alzheimer's Disease) would help explain the controversy that study results frequently generate. As a consequence, a new process for public health risk prevention has arisen, which must adapt itself to the development of knowledge in this area. Since 1974, many CJD cases related to surgical procedures such as cornea transplant, stereotaxic electroencephalography, dura mater graft or, in the pharmaceutical field, administration of growth hormone from a human pituitary gland, have been reported and led to the introduction of safer clinical practices (ie. specific procedures for decontamination of surgical material or progressive substitution of materials of human origin by others obtained through synthetic or biotechnological procedures). Nowadays, in the pharmaceutical field, the critical elements that have generated most debate are drugs derived from human blood and urine, which have caused some regulatory measures to be adopted in application of the precautionary principle. The latest findings regarding the potential infectivity risk of drugs derived from human urine are outlined. The risks are discussed and the preventive measures adopted in different countries for the drugs derived both from blood or plasma as well as from urine are listed. In our opinion these measures can serve as a model for a broader generalization according to new pathophysiological approaches that must be taken into account when studying this complex group of degenerative diseases.

292. ROLE OF HAS IN THE EVALUATION OF PUBLIC HEALTH INTERVENTIONS: INVENTORY AND PERSPECTIVES

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Background: As part of its mission to assess the quality of healthcare delivered to the population, the French National Authority for Health (HAS) is responsible for assessing the quality, effectiveness and efficiency of different prevention programs.

Objective: to describe the characteristics of public health interventions' evaluations conducted by the HAS and to specify the role of HAS, among other French and abroad advisory bodies involved in the evaluation of public health interventions in 2011, particularly in the area of prevention.

Methods: This work was based on: 1) review of 52 public health interventions' assessments performed by HAS since 1997 2) analysis of the public health themes and evaluation methods of several advisory bodies from US, UK, Belgium, Quebec, and Germany.

Results: Most public health interventions assessed by HAS dealt with screening. The relevance of screening strategies, prior to their implementation or the introduction of major changes in existing programs was evaluating according to criteria derived from Wilson and Jungner. Cancer, sexually transmitted infections and perinatal conditions were the most frequent diseases under study. Out of 15 assessments on the relevance of screening strategies, the recommendations were in favour in 7 cases and against in 8 cases. Evaluation of public health interventions is shared among several agencies in France where there is no agency dedicated to the assessment of preventive interventions, unlike in some other countries.

Discussion and implication for the health system: The overlap of the productions between HAS and other French advisory bodies should be clarified. HAS has acquired a solid expertise in the evaluation of screening strategies. Assessment of these complex interventions requires a multidisciplinary approach to document epidemiological, medical, economic, organizational, legal and ethical aspects depending on the issues identified and to ensure the development of evidence-based public health. This expertise could be used in the field of health promotion.

293. APPROPRIATENESS IN UTILIZATION OF CT AND MRI FOR INPATIENT CARE IN CHINA

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Background: CT and MRI are two of the most widely used high-tech medical equipment in China. This study aims to examine appropriateness in CT and MRI use for inpatient care in China.

Objectives: To assess the appropriateness of utilization of CT and MRI in inpatient care, and to identify the influencing factors of appropriate use of CT and MRI.

Methods: Four provincial-level regions were selected, including Shanghai, Zhejiang, Hunan and Shaanxi in the east, middle and west part of China. Four hospitals, including two tertiary and two secondary hospitals in each province were conventionally selected. Medical records for inpatient care were randomly sampled, regardless of use of CT or MRI. The sample consisted of 1,583 clinical records. Clinical experts reviewed all medical records, evaluated the appropriate use of CT and MRI, and identified reasons for inappropriateness.

Results: We found 45.5% and 46.2% of the sample with CT and MRI scans, respectively. Experts review showed 89.1% and 93.4% of records with appropriate CT and MRI used or without used, respectively. The overuse rate of CT was 2.0% while the underuse rate was 8.9%. The overuse rate of MRI was 0.3% while the underuse rate was 6.3%. The result of logistic regression showed that clinic departments of internal medicine and gynaecology, better insurance coverage and having surgical operation were more likelihood of appropriate CT use, and teaching hospital and tertiary hospital were more likelihood of appropriate MRI use. There are several causes of the inappropriateness of CT and MRI, among which providers' mis-recommendation was the major reason.

Discussion: In general, the utilization of CT and MRI was appropriate while overuse and underuse of CT and MRI coexisted; the underuse rate was higher than the overuse rate for either CT or MRI.

Implications for the health system: This study could potentially be used to inform policymaking on CT and MRI management in China.

297. WHEN IS NON-INVASIVE PRENATAL DIAGNOSIS COST-EFFECTIVE?

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Background: Scientific advances have made non-invasive prenatal diagnosis (NIPD) based on cell-free fetal DNA in maternal plasma possible. The next stage is to consider implementation in a healthcare setting. One application which has been widely promoted is the use of NIPD to target anti-D prophylaxis on "at risk" pregnancies where the fetus is RhD positive.

Methods: We have undertaken the first detailed cost-effectiveness analysis of large scale introduction of NIPD testing for fetal RhD status. Two scenarios were considered. Scenario 1 assumed that NIPD is used to target antenatal prophylaxis but that postnatal tests continue to direct post-delivery prophylaxis. In Scenario 2, NIPD also displaced postnatal testing if an RhD negative fetus had been identified. Costs of high throughput NIPD testing; savings for prophylaxis; and estimated clinical impact (e.g. on maternal sensitisations) have been modelled. The two NIPD scenarios are compared with universal anti-D prophylaxis to estimate cost-effectiveness.

Results: The basic cost of an NIPD in-house test is £16.25 per sample (excluding royalty fee). The threshold royalty fee is £2.18 and £8.83 for Scenarios 1 and 2 respectively. At a £2.00 royalty fee, mass NIPD testing would produce no saving for Scenario 1 and £507,154 per annum for Scenario 2. Incremental cost- effectiveness analysis indicates that, at a test sensitivity of 99.7% and this royalty fee, NIPD testing in Scenario 2 will generate one additional sensitisation for every £9,190 saved. If a single-dose prophylaxis policy were implemented nationally, as recently recommended by NICE, Scenario 2 savings would fall.

Conclusions: Findings for both scenarios indicate that NIPD-targeted prophylaxis is unlikely to be cost-effective in England and Wales. However, first trimester testing and other emerging technologies will influence cost-effectiveness, as will different national contexts. The threshold royalty fee per test will also influence this conclusion. These and other factors will be considered.

298. WHAT IS THE BEST STRATEGY TO IMPROVE THE CANCER SCREENING RATE?

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Objective: Although cancer screening programs have been conducted nationwide in Japan, screening rates have been below 20%. Since local municipalities are responsible for implementing cancer screening, strategies to improve cancer screening rates have varied. Mass surveys have been the major programs for cancer screening, and the opportunity for screening in a clinical setting has been limited. The best available strategy to improve cancer screening rates in Japan was investigated.

Methods: The target screening programs, which have been conducted nationwide, are for gastric, colorectal, lung, breast, and cervical cancers. Based on the national data in 2009, the partial correlation coefficients between the screening rates and strategies for improving screening rates were calculated. Strategies to improve the screening rate were as follows: personal invitation by mail; personal visit by community health workers; total number of persons who had been screened in the clinical setting, which is a surrogate indicator for screening access in clinical settings; and no charge for screening.

Results: Of the five strategies to improve screening rates, the correlations were the highest for invitation letters, and they were statistically significant for all cancer screening programs (0.283 for gastric cancer screening; 0.321 for lung cancer screening; 0.298 for colorectal cancer screening; 0.256 for cervical cancer screening; 0.132 for breast cancer screening). The correlations between the screening rate and no charge for screening were limited (0.029 for gastric cancer screening; 0.133 for lung cancer screening; 0.060 for colorectal cancer screening; 0.084 for cervical cancer screening; 0.007 for breast cancer screening). The correlations between screening rates and personal visits by community health workers and the number of persons who had been screened in the clinical setting varied.

Conclusions: Since sending personal invitation letters is the most effective strategy to improve the screening rate, a call-recall system is required at the national level.

338. THE PRODUCTION OF KNOWLEDGE IN HTA WITH A FOCUS ON PATIENT ASPECTS

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Objectives: The objective of this presentation is to discuss how knowledge is produced in HTA reports with a specific focus on patient aspects. The aim is to contribute to discussions about what kind of knowledge is considered relevant in the reports, and how to be more explicit about knowledge production in HTA.

Methods: We reviewed one Danish HTA report titled, *Patient Education* from 2009. We critically examined the range of decisions made throughout the HTA process, demonstrating how the decisions were affected by the stance of the researchers and contributors. The analysis was theory driven based on anthropological literature about knowledge and knowledge production. Three questions guided the analysis 1) whose knowledge is being addressed? 2) what counts as knowledge? and 3) how knowledge is constituted and produced?

Results: We found that contrary to research dissemination in general, the names of the researchers in this multidisciplinary project group faded into the background. It was not readily detectable, whose knowledge the report represented. Furthermore we found that the argumentation for using secondary data instead of primary data was not discussed explicitly. We also found that the report, compared with scholarly research in general, did not explicate the premises for its knowledge production. For instance terms as *patient* and *expert patient* seemed to be taken for granted. But, who and what is the patient?

Conclusions: We acknowledge the valuable contribution of both this and other HTA reports. However, we suggest that HTA organizations, researchers, and others (including patients) involved in producing HTA reports, reflect on and discuss more explicitly and critically the process of knowledge production and the implications for the choices they made.

361. THE ROLE OF THE NORWEGIAN PRIORITY COUNCIL AND HTA IN CHALLENGING PATIENT PATHWAYS

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Lack of coordination between providers at different levels of care has been considered a main health policy challenge in Norway. This is particularly a problem with regard to chronically ill patients, such as

those in need of Long Term Mechanical Ventilation (LTMV). Currently there are about 1300 patients in Norway who receive LTMV, and the demand is increasing. The treatment is initiated by the hospitals whereas the primary health care undertakes both practical and economic responsibility for daily care. Register data have shown that the use of LTMV differs substantially between geographical areas. The Norwegian priority council (NC) is an advisory body responsible for providing recommendations on quality improvement and priority setting issues to the Norwegian health care system. The members of the council represent central, regional and local health authorities, health care providers, institutions of higher education, and NGOs. The NC has discussed different challenges regarding LTMV, and this presentation will review both the discussions and the measures that have been undertaken. The discussions in the NC were based on a draft of National Guidelines issued by a group of experts. The NC identified a need for HTA reports (including health economic analyses) on the topic. The NC called for the finalizing of the national clinical guidelines to ensure more equal services and better coordination between the hospitals, the primary health care and the patients and their families. The lessons learned are that the broad composition of the NC makes it a suitable arena for discussing i) how to establish integrated care, ii) the need for comprehensive guidelines, and iii) the usefulness of HTA to support both better integrated care and national clinical guidelines.

420. PREPARING DIAGNOSTIC AND THERAPEUTIC GUIDELINES IN ONCOLOGY – DDT-ONCO: THE EXPERIENCE OF THE BRAZILIAN MINISTRY OF HEALTH

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Introduction: Although well established in developed countries, experiences of preparing guidelines in oncology are new in developing countries. In Brazil, these guidelines – that should be updated every four years - are focused on the most prevalent malignant neoplasms in the country and are used as a guide to hospitals enabled as high complexity units in oncology. The selection of oncology diseases to be covered by the guidelines is made from demands of the Brazilian MoH and society, such as patients organizations, medical specialty societies, academic groups or pharmaceutical companies. The working group (WG) responsible to develop the guidelines in oncology has been working since 2010. This team, comprising representatives of the Ministry of Health (MoH), research institutes and teaching hospitals, defined the following structure for the guidelines: Literature search methodology; Introduction; International Classification of Diseases (ICD-10); Diagnosis; Inclusion/exclusion criteria; Therapeutic options; Treatment monitoring; Regulation/control/evaluation by the public health system; and References. The Health Technology Assessment (HTA) Unit of the MoH conducts critical analysis of the literature search methodology used in each guideline.

Objective: to present the results of the WG in the period of 2010-2011 and discuss the main difficulties to implement the guidelines in the Brazilian context.

Results: Between 2010 and 2011, the WG was requested to prepare 23 guidelines in oncology. Of this total, 12 had their first version concluded – 8 were already submitted to public hearing - and 11 are still being prepared.

Discussion/conclusion: DDT-ONCO aims to contribute to the establishment of parameters, the improvement of technical regulations and management of oncology care in Brazil. However, some difficulties still need to be overcome: (i) the use of off-label drugs in oncology practice; (ii) the inadequacy of procedures and instruments of control and evaluation adopted by the public health care system; and (iii) the low level of scientific evidence usage by health care providers. *Recommendations:* it is necessary to define strategies to evaluate adherence of users and health professionals to the guidelines in oncology.

484. BURDEN OF DISEASE AND FISCAL IMPACT DUE TO CARDIOVASCULAR DISEASE IN ARGENTINA

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Background: Chronic diseases cause around 18 million deaths per year worldwide and are responsible for more than 50% of the disease burden in Argentina. This problem has financial consequences, leading to an increase in healthcare spending and a decrease in tax revenues.

Objectives: To estimate the burden of cardiovascular disease (CVD), hypertension (HTN) and diabetes (DM) in terms of disability adjusted life years (DALYs), costs associated with loss of social productivity, and its fiscal impact in Argentina.

Methods: We estimated the number of deaths due to CVD, HTN, and DM and then associated to: a) the estimation of the Value of a Statistical Life (VSL) in order to obtain the loss of social productivity and b) the Projected Tax revenue Lost (PTL), an equation we designed from the VSL which aims to estimate the projected tax loss associated with these pathologies.

Results: CVD caused between 605,607 and 2,164,798 DALYs in 2008. The cost of lost productivity associated with premature death due to CVD, HTN, and DM was estimated to be $ 570.1; $ 109.8 and $ 223.5 million dollars. We estimated a direct medical cost equivalent of $ 1058.4 total, $ 147.9 and $ 323 million dollars, respectively. The PTL for 2011 reached $ 73; $ 14 and $ 29 million dollars.

Discussion: These financial results should be considered as the floor of the potential economic impact. In this sense, future studies should investigate the complex issue of sequelae associated with CVD and also consider the epidemiological variables as an intertemporal input in order to include the part of the past that still has impact on present.

Implications for the health system/society: In Argentina, most of the burden of CVD disease is related to modifiable risk factors leading to hypertension and diabetes. These innovative analyses, particularly the design of the PTL equation, provide financial arguments that increase the cost-effectiveness of prevention policies.

505. COVERAGE DENIALS BY HEALTH CARE INSURANCE PLANS: A REVIEW OF BENEFICIARIES' COMPLAINTS SENT TO NATIONAL REGULATORY AGENCY FOR PRIVATE HEALTH INSURANCE AND PLANS (ANS)

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Introduction: Since 1999 private health plans sector has been regulated by a federal agency created specifically for this purpose (National Regulatory Agency for Private Health Insurance and Plans - Agência Nacional de Saúde Suplementar - ANS). Despite the advances brought by the regulation, many beneficiaries currently suffer negative of authorization for procedures required by their doctors or other health professionals.

Objectives: This study investigates the aspects of the beneficiaries' access to health care coverage in the supplementary health care sector in Brazil. The objective of this research is to analyze the coverage denials carried by health care insurance plans, as well as the reasons for these denials.

Methods: This is an exploratory data research, based on quantitative aspects, in which was used existing and available information from ANS. The universe surveyed in this study corresponded to the complaints due to coverage denials reported to ANS, in 2008, from beneficiaries of private health care plans located on the State of Rio de Janeiro, Brazil.

Results: It was observed that there were several reasons given by the private health care plans to justify coverage denials, namely, the absence of network of healthcare provider (17%), the fact that the procedure is not included on the Minimum Mandatory Coverage List (16%), divergence between the auditor of the health insurance company and the physician (9%), procedure without contractual coverage (7%), among others. The procedures for diagnostic purposes topped the list of the most denied ones, followed by surgical and clinical procedures.

Discussion: This study shows evidences of the practice of part of the private health care plans market with respect to not allowing procedures and confirms the findings of other studies that point out the use of micro regulatory mechanisms as a way of curtailing the beneficiaries' access to health care services.

527. USING EVIDENCE FOR TECHNOLOGY INCORPORATION: NEW RULES IN THE MEXICAN GOVERNMENT

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Health technologies covered by Mexican health care public institutions are listed in the Basic Chart and Catalogue of Health Supplies (BCCHS). Created and actualized by the government General Council of Health (GCH) and dating from 1975, the BCCHS is nowadays conformed by more than 2,500 health technologies that include drugs, vaccines, implants, medical equipment, medical devices and in vitro diagnostic tests. Until recently, decision for the incorporation or technologies in the BCCHS were made through the vote of representatives of the major public health care providers, upon revision of submissions made by manufacturers. Aiming mainly at incorporating evidence with transparent and explicit rules, the GCH devised and implemented a group of legal reforms that are now allowing for a clear path towards de incorporation of technologies that will improve efficiency in the public health care system. With the new legislation, clinical effectiveness and safety issues are dealt with by the regulatory body (COFEPRIS) and the GCH focuses on economic assessment and context analysis. Submissions (made now by public health care providers, non government organizations, manufactures and even academic bodies) must now include an economic assessment developed by the solicitor according to the, 2008 'Guidelines for the preparation of economic assessments' that is now mandatory. The committees, within the GCH, make decisions using economic assessment findings as an input, and taking into consideration contextual elements. There is an explicit cost-effectiveness threshold, and committees can incorporate any technology below it, but are obliged to explain incorporations above the threshold according to established exceptions, such as the needs of special groups of patients (i.e. orphan drugs), programs targeted to needy population, organizational impact of new technology, and potential long term benefits of technology incorporation.

563. EVALUATION OF SERTRALINE AS AN ANTIDEPRESSANT FOR THE BRAZILIAN PUBLIC HEALTH SYSTEM

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Background: Major depression is associated to morbidity and loss of productivity and its prevalence in Brazil is high. Brazilian Public Health System provides four antidepressants for depression´s treatment (fluoxetine, amitriptyline, clomipramine and nortriptyline). These drugs are incorporated to Brazilian´s list of essential medicines which is periodically revised to access its adequacy. Ministry of Health has recently evaluated the suitability of the listed antidepressants as a group and the possibility of incorporating sertraline to the aforementioned list.

Objectives: Evaluate the efficacy and safety of sertraline to support its incorporation to the Brazilian list of essential medicines.

Methods: An oriented literature review was performed to identify meta-analysis, systematic reviews of randomized clinical trials and treatment guidelines. Scientific databases were accessed together with information available on health technologies agencies.

Results: Seven studies met established criteria and were selected for analysis. Direct comparison between fluoxetine and sertraline did not depict significant differences when efficacy and safety outcomes were evaluated. Sertraline comparison to tricyclic antidepressant showed marked differences when adverse effects related outcomes were analyzed. Guidelines advocated the use of sertraline in specific medical situations.

Discussion: Sertraline was not considered an essential medicine and should not be incorporated to the government official list. Methodological limitations of the selected studies, such as the short follow-up times, played an important role in supporting the hypothesis of sertraline´s non-superiority in relation fluoxetine and tricyclic. Sertraline is more expensive than fluoxetine and its incorporation would cause a heavier budget impact to the government.

Implications for the health system: The Health Technology Assessment conducted in this work contributes to the rational use of medicines, as it shows that the use of sertraline brings no extra benefit to the population than the already incorporated antidepressants.

566. APPROPRIATENESS OF SERUM URIC ACID AND ANTI-STREPTOLYSIN O DETERMINATION IN A HEALTH MAINTENANCE ORGANIZATION – UNIMED BH

Silvana Bruschi Kelles, Daniela Azevedo, Carlos Amaral, Christiane Bretas, Lelia Carvalho, Sandra Avelar, Maria da Glória Horta, Jose Luiz Nogueira, Antonio Luiz Ribeiro, Mariana Ribeiro and Mônica Castro

UFMG/Unimed BH. Brazil.

Background: Inappropriate use of laboratory tests, even inexpensive ones, increases health care system costs without clear benefits for patients. Two such tests were studied: uric acid and anti-streptolysin O (ASO). The routine determination of uric acid is not justified, unless there is a clinical suspicion of gout, since drug therapy for the majority of individuals with asymptomatic hyperuricemia is not justifiable by risk/benefit analysis. Gout is far more common in men aged between 30 and 60 years (approximately 95% of cases) and women usually present gout after menopause. Anti-streptolysin O test is only indicated to detect the presence of a prior streptococcal infection in patients aged from 5 to 15 years, with a clinical suspicion of rheumatic fever or post-streptococcal glomerulonephritis.

Objectives: To evaluate the appropriateness of serum uric acid and ASO determinations, the overall expenditures with these tests in a Brazilian HMO and the potential savings if they were performed according to the age and sex prevalence of gout and rheumatic fever.

Methods: All acid uric and ASO serum tests recorded on the HMO database from Dec/2010 to Nov/2011 were analyzed. Uric acid tests were classified as appropriate when performed in men and women above 26 years and 46 years old, respectively. ASO determinations were classified as appropriate when performed in children aged between 3 and 18 years.

Results: There were 156,841 uric acid and 7,820 ASO tests recorded on the database. The total costs of both tests were US$313,709: US$ 292,606 for uric acid and US$ 21,102 for ASO. Overall 37.7% of these tests were classified as inappropriate based on age and sex (uric acid: 19.9%; ASO: 80.6%). Twelve month total expenditures with inappropriate tests were estimated in US$75,465. Conclusions: Adherence to simple epidemiological evidence to order uric acid and ASO tests could result in significant annual savings.

571. REVISION SURGERY AFTER TOTAL HIP ARTHROPLASTY IN A HEALTH MAINTENANCE ORGANIZATION IN BRAZIL

Silvana Bruschi Kelles, Daniela Azevedo, Carlos Amaral, Christiane Bretas, Lelia Carvalho, Sandra Avelar, Maria da Glória Horta, Jose Luiz Nogueira, Antonio Luiz Ribeiro, Mônica Castro and Sergio Bersan

UFMG/Unimed BH. Brazil.

Background: Total hip arthroplasty (THA) aims to relieve pain and improve diseased joint kinetics and function. There are several types of prostheses and their indications depends on factors such as patient age, hip pathology, bone quality and surgeon's experience.

Objective: To assess revision surgery (RS) in patients submitted to THA in a Health Maintenance Organization (HMO) - Unimed BH, in Brazil.

Methods: Data on patients submitted to THA were extracted from the HMO's administrative database, from Jan/2004 to Feb/2011. If more than one code procedure was assigned to the same patient, data were analyzed to classify the new intervention as contralateral or RS. Survival of the prosthesis was calculated as the time elapsed between the first THA and RS. Patients were included in the study if they remained as active clients on HMO. Censure was Feb/28/2011.

Results: There were 2205 THA performed in 1988 patients. Of these, 10.3% had two surgeries and 0.3% had three surgeries. The average age was 66.9 years, (SD 16.2 years) and 61.6% were female. The number of THA increased from 2004 to 2011 and also the number of different surgeons performing the procedures. A total of 131 RS were performed (110 patients), yielding a RS rate of 6.6%. The median of time elapsed between THA and RS was 24.6 months. The average age of patients undergoing RS was 63.0 years (SD 14.3) and 71 (64.5%) were women. Patients over 65 years old presented a significant lower risk of RS (HR = 0.68, CI 95% = 0.48 to 0.95). Gender was not associated with the RS, but the surgeons' experience was.

Conclusions: Follow-up of this THA cohort showed a RS rate of 6.6%. The RS rate of "real world" patients submitted to THA reveal all limitations of care, impact of comorbidities, age and ability of surgeons.

580. EVOLVING HEALTH TECHNOLOGY ASSESSMENT IN ISRAEL

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Background: In the ever-changing health arena, policy-makers face dilemmas of balancing needs with supply, within scare resources. HTA is a sophisticated targeted tool to enhance wise decision-making.

Objectives: To describe and deliberate on the 20 years evolution in HTA in Israel during 1993-2012.

Methods: The evolving methodology of practiced HTA is reviewed, flexibly integrating changes in society, morbidity trends, and technological developments within fiscal appropriations to meet health needs.

Results: For a decade, "Classic" HTA based on epidemiological data, population needs and economic evaluations synergized with social, ethical, legal and economic aspects was used for comprehensive technology assessment. This era was followed by 1) fragmentation to three parallel pathways that ensued: national, hospital-related, individual-targeted-community-oriented HTA and 2) three time-spans assessment processes: annual, long-term and immediate, respectively. A shift in HTA reporting trends from extensive comprehensive time-consuming reports to rapid assessment forms was entrenched. Bonding between recommendations for adoption and funding appropriation was enforced. Quality-of-life considerations become more significant in HTA. Dynamics of morbidity, technology innovation (such as personalized medicine, nanotechnologies, information and communication technologies) and social awareness became key factors. Changes in clinical evaluation and economic analysis were employed, enhanced by weighing social values and public involvement incorporated in final recommendations.

Conclusions: As health technologies evolved rapidly, constantly increasing the national economic burden, policy-makers aspire to wisely allocate resources for beneficial health-services to improve health-outcomes. HTA supplies data, priority parameters and recommended choices when comparing alternatives for implementing new health services. However, while maintaining its advantageous structure, HTA must be flexible and reflect changing environments, to maximize benefits.

599. EVALUATION OF THE DIAGNOSTIC YIELD OF THE DETERMINATION OF THE PROTEINS ABETA-42, TOTAL TAU AND PHOSPHORYLATED TAU IN CEREBROSPINAL FLUID AS BIOMARKERS OF ALZHEIMER DISEASE

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Background: The search for biomarkers as a diagnostic aid to the identification of patients in pre-dementia stages is a fast growing research area. Cerebrospinal fluid (CSF) biomarkers may be of value for early diagnosis of the AD.

Objectives: Report on the current state of scientific knowledge on the efficacy and cost-effectiveness of the determination of the proteins in CSF as biomarkers of AD.

Methods: A bibliographic search of systematic reviews and meta-analyses, economic evaluations, clinical practice guidelines (CPG) and consensus of experts was performed in the electronic databases (Medline, Embase, Cochrane, CRD). Studies were sought on the diagnostic yield of the Aβ-42 and/or T-tau and/or P-tau proteins in CSF; these included measurements of results related to the diagnostic capacity of these proteins as biomarkers of AD (sensitivity, specificity and diagnostic certainty).

Results: The literature review enabled identifying six meta-analyses (MA) and three scientific literature reviews. The methodological quality of the MA varied with scores from 7-9 points, on a scale of 10, and 5-7 points for reviews. We also identified other

relevant publications from different groups of experts which reviewed the diagnostic criteria of AD to incorporate the latest scientific progress and some recent cases of CPG.

Discussion: The diagnosis of AD dementia rests mainly on clinical criteria. The biomarkers in CSF are highly promising diagnostic technologies which could favour early diagnosis of AD and which have proven their diagnostic validity (sensitivity and specificity) for AD dementia. However, their clinical utility (evaluation of clinical stage, preclinical phase or clinical course of AD) is still to be determined.

Implications for the health system/professionals/patients/society: We do not yet have a biomarker for diagnosis and clinical course of AD that can be easily and generally applied to clinical practice. The favourable results found with these biomarkers are still limited to the research setting.

600. THE IMPORTANCE OF PROCESS FOR PATIENTS IN THE HTA SYSTEM: A SPOTLIGHT ON AUSTRALIA

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Background: It is considered fundamental that HTA agencies are able to describe the methods underpinning their assessment of new technologies. However it would seem that very few agencies are able to describe with the same detail *how* patients' views are to be incorporated within HTA. This is despite evidence of improved patient outcomes being core in the assessment and decision making regarding new technology. It raises the question as to whether the needs of patients are being neglected because of a lack of good process in HTA.

Methods: In 2009 the final report of the Australia Health Technology Assessment Review was published. This report recommended that the Australian HTA system (which includes the Medical Services Advisory Committee [MSAC]) provide improved opportunities for stakeholder input and ensure that information on how technologies are assessed and decisions are made be more accessible. Two years later MSAC has introduced some new processes and evaluation approaches as a product of this review. A form of consultation has been included; early on in the evaluation stage, yet documentation as to the specifics of the consultation process are lacking. As a result responses are few and patients find themselves then advocating in the media because of the limited avenues within the HTA system.

Implications for health care system: Without a formalised process, it is difficult for patients to be engaged about decisions in HTA. As such the *process* needs to be viewed as being just as important as the methodology. Additionally there needs to be recognition that good and fair process involves consultation, mechanisms for reviews and appeals and public deliberation on when prioritising or establishing new services.How best to undertake these processes is the question for HTA.

607. SOCIOECONOMIC DIFFERENCES IN ACCESS TO IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD) IN PIEDMONT, ITALY

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Background: ICDs are generators of electrical impulses, implanted in patients at risk of sudden death due to ventricular fibrillation. Their use has increased continuously ever since they were first introduced. Implantation rates have risen most significantly since 2000. In several countries, significant geographical differences have been found for small areas, as well as social, sex and ethnic differences with regard to the use of ICDs. However, it is not clear whether these differences are due to inequity of access or differences in need. Piedmont (North West of Italy) is one of the regions with the highest implantation rates in Europe. Socioeconomic position is widely considered as a proxy of need of health care.

Objectives: To evaluate socioeconomic differences in access to ICD in a population based cohort of subjects affected by congestive heart failure (CHF).

Methods: From 2001-2007 Hospital Discharge Database (HDD) of Piedmont Region, 54.147 incident cases of CHF of residents aged 35 or more were selected. All discharges occurred during 5 years preceding the index admission, hospital discharges occurred outside Piedmont (n = 2.295), in-hospital deaths (n = 4.815) and patients whose information on educational level was missing (n = 3.227) were excluded. The outcome of the study was having had an ICD implanted within one year from the date of admission (n = 1093). Educational level was considered as indicator of socioeconomic status. Age, gender, period of observation, comorbidities measured by Charlson comorbidities index (CCI) and admitting hospital were considered as potential confounders. All variables were collected from HDD. Cox proportional hazards models were fitted.

Results: A crude direct relationship was observed between access to ICD and educational level. The association was confirmed after adjustment for all the covariates. Compared to less educated, subjects with medium (HR: 1.29; 95%CI: 1.11-1.49) and high (HR: 1.35; 95%CI: 1.13-1.61) educational level had higher probability to receive an ICD. All the covariates showed statistically significant effects.

Discussion: The study shows inequalities in access to ICD in an Italian population with CHF suggesting a not direct link to the need of health care. Policy interventions should be activated in order to improve equity in access of health care.

636. HTA AND INNOVATION POLICY IN THE ENGLISH NHS

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Previous reviews of health innovation policy in the UK have focussed on the development and exploitation of new technologies, e.g. Cooksey (2006). The recent Department of Health policy document 'Innovation Health and Wealth' focusses on the faster adoption of proven technologies to achieve health and economic benefits. In the current macroeconomic climate real increases in health budgets are not expected and the NHS has been set a target of increasing productivity by around 20% over 5 years, to meet the increasing demands on the service from an ageing population with rising expectations of service quality. Innovation in procedures, devices, drugs and service delivery is now seen as key to achieving this target, and promotion of the UK's life sciences industry is seen as a key economic objective. Identifying the most appropriate technologies is important and indicates an increasing role for HTA in policy and decision-making. The most successful use of HTA in the NHS has been the NICE Technology Assessment programme but although NICE is expanding its activities into devices and diagnostics, the scope of its appraisals is limited. although NICE guidance is often mandatory, its adoption by the NHS is not consistent. The NHS needs more help in interpreting the guidance and other NHS bodies such as the NHS Institute for Innovation and the NHS Technology Adoption Centre are seeking to expand their role in technology adoption. Industry, faced with changes to the drug pricing system,is also keen to see faster adoption and argues for a wider interpretation of the

benefits of technology within an HTA. The innovation debate is being conducted during a major reorganisation of the NHS. How HTA should be adapted to meet the future needs of decision-makers in the UK will be discussed against this uncertain policy background.

665. RANKING HEALTH TECHNOLOGY INNOVATIONS AND THEIR IMPACT ON HEALTH THROUGH BEST-WORST SCALING: FUCHS AND SOX REVISITED

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Background: In 2001, Fuchs and Sox published a study about the relative importance of thirty medical innovations and concluded that the most important innovations were related to *cardiovascular disease* (ACE inhibitors) and *diagnostics* (MRI and CT scanning). Ten years on, the added value of these innovations in terms of health impact remains an issue.

Objectives: To identify medical innovations, categorize these according to their added value in healthcare and their impact on resources, and rank them according to their health impact.

Methods: Medical innovations were identified through a systematic literature search in MEDLINE. Explicit criteria were used to filter. Remaining innovations were used in two online best-worst scaling (BWS) case 1 experiments with balanced incomplete block designs. One experiment included technological innovations (devices and procedures), the other pharmaceutical innovations. Experts were asked to select innovations with the most, and the least impact on life expectancy and quality of life of the patient.

Results: The search yielded 1970 journal articles. After filtering, forty-one innovations remained and were categorized as devices (16), procedures (9) and pharmaceuticals (16). Innovations were also categorized as big- (9), medium- (17), and small-ticket (15). Most innovations are outpatient (26) e.g. genetically engineered vaccines; therapeutic (26) e.g. ranibizumab for age-related macular degeneration; and add-on technologies (24) e.g. bone densitometry. Results from the ranking study are due February 2012.

Discussion: Compared to the study of Fuchs and Sox, identified medical innovations in this study also related most to cardiovascular disease, however identification was done transparent and systematic. Pharmaceuticals were separated from technologies, and ranking was done through BWS instead of standard ranking.

Implications: Insight in health impact of medical innovations and how they relate to existing innovations is relevant for health policy and practice. Study findings could result in recommendations for more appropriate use of existing and new medical innovations.

694. CONFORMITY OF DEMANDS FOR INCORPORATION OF TECHNOLOGY IN THE BRAZILIAN HEALTH SYSTEM: A PRELIMINARY ANALYSIS

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Background: In Brazil, the National Commission for the Incorporation of Technology in the Brazilian Health System (CONITEC) has the responsibility to advise the Ministry of Health in the incorporation, amendment or exclusion of new technologies in health. The CONITEC is regulated by presidential decree, which introduced changes in brazilian process of technological incorporation, among which, the establishment of more rigid technical-scientific criteria for the submission of requests for incorporation of technology.

Objectives: Analyze the compliance of requests for the incorporation of technology in health in the Public Health System (SUS) in regards to requirements defined by the Decree 7646/11.

Methods: It was a cross-sectional descriptive study. We analyzed the reports of conformity analysis of the demand for incorporation of technology in health care received by CONITEC after the publication of the Decree which regulated the Commission (22/12/2011 to 21/01/2012).

Results: CONITEC received 31 requests for incorporation of technologies, of which 14 (45%) were not in accordance with the requirements of the Decree for submission of demands. Among the non-compliant, 13 (93%) were from the pharmaceutical industry and 1 (7%) of the association of patients. The main breached requirements were: analysis of the budgetary impact in the SUS (absent in 93% of the requests do not comply); indication of gold standard (71%) and study of economic assessment comparing the technology based on health care technologies available in SUS (71%).

Discussion: In spite of the recent introduction of new rules for the incorporation of technologies and investments from the public sector in professional training, it is possible to perceive the fragility of the institutions in health technology assessment area, especially in studies adapted to the Brazilian reality, which need to be carried out under the perspective of SUS.

Implications for the health system/professionals/patients/society: The strengthening of health technology assessment and a consequent rational selection of appropriate interventions to the citizens and users of the system are necessary for the improvement of brazilian public policies, increasing the efficiency and effectiveness of the services and the quality of health care provided.

703. INCORPORATION OF NEW ONCOLOGICAL MEDICINES IN THE UNIFIED HEALTH SYSTEM IN BRAZIL

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The Unified Health System (SUS) faces a huge pressure for the incorporation of oncological medicines. In the past, the lack of a specific regulation increased the number of lawsuits. The introduction of technology assessment in the incorporation process of new medicines has slightly changed the scenario. This study aimed at describing the criteria and sources of information adopted by three main stakeholders of this process in Brazil: Brazilian Committee for Incorporation of Health Technologies (CONITEC), responsible for the decision related to the National Relation of Essential Medicines (RENAME); National Cancer Institute (INCA), the reference provider for setting the national policies for cancer care; and the Prosecutor´s Office of Rio de Janeiro State. Interviews were carried out with representatives of each stakeholder. The CONITEC reported to follow a specific regulation for incorporation, which requires the presence of evidence on benefits, safety, cost and budget impact of the new medicine. The INCA´s decisions are handled by two advisory boards that should prioritize the adoption of new medicines based on the impact of delaying adoption, clinical and societal relevance and operational viability of use. The judges rely on a medical advice board that evaluated the claims considering the medical prescription, the market registration and the National Policy of Pharmaceutical Assistance. The main source of information used is the medical literature. Despite the existing regulation at the national level, the incorporation process at the provider's level is not clearly defined and depends very much on the board member's expertise, who do not always have access to the same evidence and are subjected to bias. This scenario seems to perpetuate the presence of the justice as one

of the main stakeholders, unless a more proactive and integrated incorporation process replaces the existing ones.

727. ARE THERE CONFLICTING INCENTIVES BETWEEN HTA AND PROCUREMENT IN THE MEDICAL DEVICE MARKET?

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As healthcare providers seek to ensure appropriate provision and coverage, there is growth in the use of Health Technology Assessment (HTA) beyond pharmaceuticals, to all medical technologies. This abstract reviews potential incentives and market dynamics introduced into the medical device market when HTA is applied, and provides comparisons with pharmaceuticals. The current regulatory process for medical devices encourages rapid competition. This rapid competition then provides value to the end user though price competition driven by established procurement mechanisms. The application of existing HTA methods has the potential to disrupt this dynamic and reduce the rewards to innovators of medical devices - through: 1) placing higher evidence requirements on initial entrants and 2) allowing market dynamics to subsequently drive a reduction in prices. A cycle of price reductions results because the comparator price ('old' technology) is reduced as a consequence of 'disinvestment' following the first recommendation in favour of the product concerned ('new' technology) and because subsequent entrants' prices are reduced through procurement competition as well as the fact that they do not necessarily need to cover the same R&D investment. Using a case study on drug-eluting stents (DES), we examine whether the economic characteristics of medical devices introduce particular challenges to the application of HTA and whether the experience of DESs suggests directions for policy formulation. The study finds that HTA decisions on medical devices can have a material impact on the market dynamics (and therefore on prices) following a recommendation, because of the manner in which medical devices are procured. It also identifies an apparent disconnect between the application of traditional HTA methodology and procurement processes, raising a number of policy issues for consideration. These include the interplay between different drivers of value in HTA and procurement, and the implicit 'genericisation' of evidence through the procurement process.

741. THE SCIENTIFIC EVIDENCE AS A GUIDE TO THE LINES OF CARE: THE CLINICAL PROTOCOLS AND THERAPEUTIC GUIDELINES WITHIN THE BRAZILIAN PUBLIC HEALTH SYSTEM

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Background: In Brazil, the management of many diseases has been guided by its Clinical Protocol and Therapeutic Guidelines (CPTG), which address crucial issues to achieve concrete results in better patient's quality of life.

Objectives: To describe and discuss the current state of the CPTG development and its application within the Brazilian public health system.

Methods: Centered on the CPTG development fundamentals, we reviewed the amount of documents elaborated and the state of its implementation, including the medicines access.

Results: The CPTG are elaborated by experts in each clinical condition and evidence-based medicine. Their development is oriented by the Ministry of Health (MoH) norms, published in 2009, which define the document structure and other issues, as the need of declaring potential conflicts of interest and the authors' confidentiality until the CPTG publication. Besides, the text is submitted to public consultation before publishing its final version. So far, the MoH published CPTG for a total of 62 clinical conditions, including the indications to more than 360 outpatient medicines, which represents almost 45% of the outpatient medicines available in the public health system.

Discussion: The CPTG are established with the best available scientific evidence and to deal with diagnosis, treatment and monitoring, in order to get the best patient-centered care and the rational technologies use. Whenever possible, the treatment is defined in lines of care, where health technologies are described in algorithms, which simplify the services vision. Nevertheless, unlike most global guidelines, where prevails extensive discussions on the various alternatives for diagnosis and treatment, the CPTG regulates the health technologies that will be guaranteed by the public health system.

Implications: In a public health system that ensures universal, equitable and comprehensive access to health technologies, a health policy based on impartial recommendations is an essential step to achieve the best patient-centered care.

750. THE ROLE OF SOCIO-ECONOMIC FACTORS IN THE UPTAKE OF BREAST SCREENING

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Despite the adoption of breast cancer screening as an integral part of cancer control strategies in many developed economies, the merits of it remain the subject of intense debate. In this paper we model uptake of screening in Britain, controlling for individual heterogeneity, using a panel approach. The paper uses data collected as part of the British Household Panel Survey over an 18-year period for 2,175 women. The structure of this dataset allows us to employ a random effects probit model, which controls for state dependence, while the inclusion of Mundlak terms controls for unobserved heterogeneity (consistent with Wooldridge (2005)). This allows us to examine the effect of the universal screening programme over its lifetime on attendance and examine variations related to age, socio-economic group and martial status. Results show that women who fall within the age range adopted by the screening programme are more likely to go for screening than those who are not. An individual with a child under the age of 16 is less likely to avail of screening though this result is conditioned on marital status. Occupation does not appear to influence uptake, nor does self-reported health status. Individuals with upper secondary education are more likely to attend for screening than others. Contrary to previous studies a significant relationship between screening uptake and income was found. Also, significantly, differences were found between constituent part of Britain, with those in Scotland being less likely to avail of screening than those from other parts of Britain. From both an equity and efficiency perspective these findings have potentially important policy implications in terms of timely access to subsequent diagnosis and treatment.

781. MEDICAL TECHNOLOGY EVALUATION I: AN INNOVATIVE APPROACH TO IDENTIFYING PROMISING TECHNOLOGIES

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Background: There is a growing interest in the health technology assessment (HTA) of medical technologies, and in particular those

with the potential to improve the efficiency of health services while offering the same or better patient benefits. However, there are a number of barriers to simply extending existing HTA methods. These include the large number of new devices and diagnostics, an evidence base which is often sparse, and the need for timely guidance on products which may have a short market life.

Objective and method: In the UK, the National Institute for Health and Clinical Excellence (NICE) has, as part of its Medical Technologies Evaluation Programme (MTEP), developed, a novel methodology for topic selection. The overall aim of the programme is to promote the adoption of technologies which offer demonstrable advantages over standard care. Individual products are notified to NICE, usually by a commercial sponsor, with details of their claimed patient and health system benefits. If the product is novel and suitable for evaluation, a summary is presented, with expert patient and clinical advice, to NICE's independent Medical Technologies Advisory Committee (MTAC) which is comprised of clinicians, academics, scientists and lay people. The Committee decides whether there is sufficient 'plausible promise' for the development of guidance and, if so, decides which NICE guidance programme is most appropriate. If the technology is not selected, the sponsor receives a written explanation.

Results: In a review of the programme's activity to date, 89 device and diagnostic technologies have been notified to the Medical Technologies Evaluation Programme and we will present summary on those selected for guidance development. This approach to identifying and selecting innovative technologies enables guidance to be developed only for those products where early assessment of the sponsor's value proposition is favourable, and ensures that published guidance is relevant and valuable to the health system.

817. ANALOGUE INSULINS – DIABETES AS A PRIORITY OF HEALTH RESEARCH IN MINISTRY OF HEALTH OF BRAZIL

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In 2007, the Department of Science and Technology of Ministry of Health, which objectives to promote and sponsor strategic health researches, determined research priorities in Health Technology Assessment with technical areas from the Ministry. From this partnership, it was gotten as result a public call for research issues in priority areas in Brazil, like diabetes. This issue was considered relevant mainly because insulins are the technologies more frequently asked by judiciary actions referring to diabetes, moreover its huge prevalence and important impact on quality of life. On Brazilian Public Health System, the available treatment to T1DM is NPH insulin, which allowed reducing the severe complications' prevalence. In this scenario, it had been promoted a project about the cost-effectiveness analysis of recombinant analogue insulins for type 1 diabetes (T1DM). After the judgment of proposals, two projects were selected about cost-effectiveness and quality of life, based on secondary data. Quality of life is an important variable, in being the mainly treatment's aim and in increasing patient's adherence. Both selected projects have used short time models (decision analysis) and long-time models (Markov model). These models make the projects robust relating to outcomes and costs measurement – chronic complications and life time events. The importance of cost-effectiveness analysis in developing countries must have been shown, aiming the health system's sustainability and the guarantee of patients' access to the best available treatment. With the results of the sponsored researches, we wish to support the Council of Technology Incorporation's decisions.

857. IMPLEMENTATION OF THE CENTER OF HEALTH TECHNOLOGY ASSESSMENT IN A PEDIATRIC HOSPITAL IN CEARÁ, BRAZIL

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Secretaria da Saúde do Estado do Ceará. Hospital Infantil Albert Sabin. Brazil.

Background: The Comittion for Health Technology Acessessment (CATS) of the Department of Health in the State of Ceará, Brazil, has been developing activities of Health Technology Acessessment (HTA). One objective of CATS is to expand the Hospital Network of Centers for Health Technology Assessment (NATS). In the year to 2011, The NATS was implemented at the Hospital Infantil Albert Sabin (HIAS) with to intend to institutionalize the policy of HTA.

Objectives: To describe the process of implementation of the NATS of the HIAS, Ceará, Brazil.

Methods: Report of experience of implementing a NATS in a Hospital specializing in pediatrics. The project was formatted based on the Model of Goodman and the methodology recommended by the Ministry of Health, then the marketing strategy TEASER was used.

Results: The implementation began with the completion of the First Exhibition of HTA, focusing on the interfaces of the sectors related to NATS. The members of these sectors had their participation in the HTA an also an opportunity to presente the hospital workers their specifics proposes of HTA for technology incorporation, dissemination and deletion of materials, medicines and care protocols. The NATS of HIAS has effectively participated in meetings of the service, keeping na eye on opportunities for intervention as HTA, in order to drive the decisions of management, based on methodological qualified of studies.

Discussion: The implementation of the NATS of HIAS is a major challenge, due to its complexity and size as a pediatric teaching hospital. This was an experiment which made possible to access all workers, as well as students about the relevance of the HTA.

Implications for the health system/professionals/society: However, we can see the maximization of health benefits to be obtained from the available resources, ensuring users' access to effective and safe technologies in terms of equity.

864. EFFECTIVENESS OF HTA AGENCIES IN 10 COUNTRIES ACROSS FOUR CONTINENTS

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Background: Health technology assessment (HTA) agencies assist with the efficient allocation of limited health care resources. It is hypothesized that the output of each country's HTA agency is a function of the country's capacity and organizational power, and capacity.

Objectives: To ascertain the relationship between the output of HTA agencies and the organizational and functional capacity of the countries from which the HTA agencies originate using a part of a

previously developed HTA life cycle framework across 12 HTA agencies.

Methods: Twelve HTA agencies (AHRQ, BIQG/GOEG, CADTH, DAHTA@DIMDI, DECIT-CGATS, HAS, HITAP, IQWiG, LBI-HTA, NICE, MSAC, SBU) from 10 countries in four continents were selected for our analysis. Economic and organizational information relevant to each HTA agency and its country of origin was retrieved by survey and internet search. The information was categorized by level: a) country's capacity (1st level), b) organization's power (2nd level), c) organization's capacity (3rd level) and d) HTA agency's output (4th level). The position of each agency was ranked within each level. Agreement of ranks was compared across all levels.

Results: NICE in the UK had the least rank variation across all levels. Agencies providing low(est) capacity of country and organization (DECIT (Brazil); HITAP (Thailand)), scored relatively better in power and output. In general, greater variation across levels started at organization' capacity.

Discussion: Based on the assumption of a top-down determination of an agency's output, results indicate that agency's effectiveness is mostly defined at the organization itself. Implications for the health system/professionals/patients/society. Insight into a possible determination of HTA agencies' capacity constraints could be of value to support the capability of HTA for countering health care capacity constraints.

877. EUPRIMECARE PROJECT: HOW TO IDENTIFY AND PRIORITIZE QUALITY INDICATORS IN PRIMARY CARE

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Background: The objective of the EUprimecare project is to use research methods to describe different primary care models in Europe, assess their quality in different dimensions and determine their cost. The purpose is to analyze variations of both quality and cost as they apply to specific organizational models in Europe, and to study the possible trade-offs between quality and costs in each model. The following dimensions of quality were to be considered: access, equity, appropriateness, patient- and professional satisfaction. Continuity and comprehensiveness were also reviewed as components of appropriateness.

Objectives: To present the -non-clinical, organizational quality indicators, capable to measure structure, process and outcomes of PC in each identified model.

Methods: Focus group discussions were organized both with patients and primary health care professionals in order to understand the views that both groups have about quality in the different countries participating in the project (Estonia, Finland, Germany, Hungary, Italy, Lithuania and Spain) in order to identify a list of quality criteria. Non-clinical indicators for each criteria were identified from a literature review and prioritized by scoring according to importance and measurability. The process resulted in a set of 20-20 indicators that could be measured at the population survey and reviewing medical records, as well as on a professional survey. Other 16 indicators are considered to be ready to be measured with the help of national databases. In parallel, a literature review was performed to identify clinical indicators specific for primary care activities. The range of services provided in the different countries is quite different, so the common list was established by agreement of the partners.

Conclusions: A list of indicators to be measured both at the population and clinical level was produced.

896. HTA BASED ON HEALTH CARE SYSTEM IN BRAZIL

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Private healthcare plans are responsible for about 45% of all health assistance in Brazil. This sector has been regulated by a federal agency created specifically for this purpose (Agência Nacional de Saúde Suplementar - ANS). This work presents an overview of the Brazilian private health plan policy over the period 2001-2012. The elaboration of a list of medical procedures constitute the minimum obligatory coverage for all plans. Due to medical technology advance this list has to be updated periodically, with the incorporation of efficient new procedures. This dynamic process of revision must be conducted based on a rigorous assessment of both the cost-effectiveness of the procedures and its countrywide availability, as the newest technologies tend to be concentrated in the most developed and populated urban regions. Data were collected from the Technical group established with members from society. The work was available in our website for public consultation with more than 8000 suggestions with the user ID, Hmos, providers or patient. Finally, the result describes the tools used by ANS for identifying useful and accessible new technologies that can provide, based on clinical evidences, real health improvement for the population assisted by healthcare plans, with the rejection of high cost procedures that increase expenditure without providing clear benefits for patients. We conclude that the HTA based on health care system in Brazil is still growing with regard to the quality of health services offered to the beneficiaries.

115. REGIONAL COST-EFFECTIVENESS ANALYSIS OF UNIVERSAL CHILDHOOD HEPATITIS A VACCINATION IN BRAZIL

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Objective: To conduct a cost-effectiveness analysis of a universal childhood hepatitis A vaccination program in Brazilian regions with different hepatitis A endemicity.

Methods: An age and time-dependent dynamic model was developed to estimate the incidence of hepatitis A for 24 years. The analysis was run separately, according to the pattern of regional endemicity, one for Southern + Southeast (low endemicity) and one for the North + Northeast + Midwest (intermediate endemicity). The decision analysis model compared universal childhood vaccination with current program of vaccinating high risk individuals. Epidemiologic and cost estimates were based on data retrieved from a nationwide seroepidemiological survey for viral hepatitis, primary data collection, National Health Information Systems and literature. The analysis was conducted from the healthcare system and societal perspectives. Costs are expressed in 2008 Brazilian reals.

Results: In this model a universal national immunization program would have a significant impact on disease epidemiology in all regions, resulting in 64% reduction in the number of cases of icteric hepatitis, 59% reduction in deaths due to disease and a 62% decrease of life years lost, in a national perspective. With a vaccine price per

dose of R$16.89 (US$7.23), vaccination against hepatitis A was a cost-saving strategy in the low and intermediate endemicity regions and in Brazil as a whole from healthcare and society perspective. Results were most sensitive to icteric hepatitis incidence, ambulatory cases and vaccine costs.

Conclusions: Universal childhood vaccination program against hepatitis A could be a cost-saving strategy in all regions of Brazil. These results may be useful for the Brazilian government for vaccine related decisions and for monitoring population impact if the vaccine is included in the National Immunization Program.

119. PAY-FOR-PERFORMANCE IN PRIMARY HEALTHCARE IN DEVELOPING COUNTRIES: THE CASE OF PIRIPIRI, BRAZIL

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Pay-for-performance (P4P) is increasingly implemented worldwide to improve the quality, efficiency and the effectiveness of healthcare services and systems. Despite rarely implemented and evaluated in Brazil, the Ministry of Health launched in 2011 a national P4P scheme for primary care settings. Piripiri, a municipality located in Brazil's poorest region, pioneered in 2008 with the implementation of an evidence-informed P4P scheme, the Program of Incentive to Improve Performance in Family Health (PIMESF). We present PIMESF's fundaments, implementation, financing and main impacts on access to, and quality of family healthcare teams as well as on teams capacity for self-assessment. PIMESF features optional enrollment and additional team-based remuneration according to improvements on negotiated of health indicators. Results are monthly audited by cross-checks of available databases minimizing 'gaming'. The program is locally funded and represents 15% of remuneration on health personnel. PIMESF seems to have improved access and quality of primary healthcare through decreased clinical practice variation on monitored indicators including achievement of 90% of pregnant women with at least seven pre-natal consultations with clinician adherence to clinical guidelines, 98% of suitability of samples for cervical cancer screening with 70% of coverage of target population, 100% of under one-year infant tetravalent vaccination, and 30% of target population with dental treatment started. PIMESF seems to also have improved process of care and work flow through increases in team cohesion, self-assessment capacity and satisfaction among providers. Moreover, since PIMESF inception, there has been a 69% reduction in infant mortality between 2009-2011. Lessons learned from this small-scale local P4P program can inform the design, implementation, and evaluation of similar programs or its scale-up to bigger jurisdictions.

122. THE DEVELOPMENT OF DATA TOOLS AND HTA BASED PROCESSES AND INSTRUMENTS FOR EFFECTIVE AND EFFICIENT MANAGEMENT OF MEDICAL EQUIPMENT: THE EXPERIENCE OF NEUQUÉN (ARGENTINA)

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Background: Neuquén health system is based on the strategy of Primary Health Care. Consequently, health services are organized as a network of different levels of care. Enhancing of health technology management is vital at all levels because of its impacts on quality, equity and sustainability of health services.

Objective: The aim of the study was to develop data tools for information use and HTA based processes and instruments to enhance medical equipment management.

Methods: A team of researchers of Lanús University, managers and professionals of Neuquén Health Secretary was established. Literature review was conducted to determine the state of the art of health technology management conceptual frameworks and to identify standardized tools and processes oriented to ensure that healthcare technology is selected appropriately, used correctly and to maximum capacity and lasts as long as adequate. Based on this review, a survey was implemented to provide updated information on number, diversity, location, condition, functionality, requirements, etc. about medium and highly complex medical equipment in public health sector facilities. Main indicators were developed to analyze baseline situation. Systematization of experiences provided a comprehensive range of instruments and implementation alternatives for critical adoption of health technologies. Tools and processes were adapted and applied in a pilot. Information provided by the survey fed the pilot.

Results: The database created will become an integral part of the Provincial Health Information System and will provide the basis for functional inventories development. Process and instruments for critical incorporation of medical equipment were officially adopted. Indicators identified allow monitoring and reporting although further development is still required. Evaluation capacity entails additional strengthening interventions.

Discussion: Clear policy, technical guidance, and practical tools are needed for effective and efficient management of healthcare technology to impact on health system's capacity to adequately respond to health needs and expectations on sustainable basis.

149. PRIORITY SETTING FOR HTA: LITHUANIAN EXPERIENCE USING THE DELPHI METHOD

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Introduction: Compared with other countries Lithuania is long overdue in implementing health technologies assessments as decision making support. However decision makers face priority setting challenges in the health care system. This study aimed to assess the feasibility of the developed priority setting framework for HTA.

Methods: The Delphi study consisted of three rounds: rating the key topics; identifying health problems and health technologies for their solving; assigning weights to the criteria and evaluating health technologies according to them. The study was conducted in 2011 using electronic survey among the national panel of eleven experts. The participants represented a broad section of the health care sector: policy makers, health services professionals and academics with diverse professional roles.

Results: In the first round key policy relevant topics according to their level of importance were rated whereas the candidate health technologies in order to solve priority health problems in the health care system were identified by experts in the second round. The list was created of 22 health technologies including pharmaceuticals, vaccines, medical devices, diagnostic methods, public health interventions, organizational systems and others. Based on this list, experts were asked to evaluate them using the qualitative criteria including budget impact, health benefit, relevance to health policy makers, alternatives, timeliness, evidence, ethical, legal and social implications.

Conclusions: The priority setting framework for HTA is the first developed tool based on the Delphi consensus procedure in Lithuania.

Although this framework may have potential limitations and more in-depth evaluation is required, it could be applicable for priority setting in the national health care system.

176. IDENTIFYING USEFUL BENCHMARKS FOR FUTURE HTA EVOLUTION IN CHINA

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Background and objective: In 2011 the Chinese Pharmaceutical Society Pharmacoeconomics Committee released a draft set of academic guidelines for the application of economic evaluation. No formal announcement has yet been made regarding how health technology assessment (HTA) would be integrated into the healthcare decision-making process. However, the publication of academic guidelines suggest that HTA may be introduced into the pricing & reimbursement system in the foreseeable future, with significant impact on the world's fastest-growing pharmaceuticals market. The objective of this paper is to identify among other emerging HTA systems, the most appropriate analogue for the future introduction, and therefore likely future evolution, of HTA in China.

Conclusions: While a number of HTA policies were considered, including those of South Korea, Thailand, the United Kingdom, and Australia, Taiwan was viewed as the most appropriate analogue for imitation. There are several reasons to consider Taiwan the most analogous HTA system, based on cultural, economic and structural grounds. There has recently been a political convergence in pharmaceutical research and development, as well the drug approval process, in China and Taiwan. This occurs under the "Cross-Strait Medical and Healthcare Cooperation Agreement" signed in 2010, which stipulates that both countries will assist on pharmaceutical R&D and cooperate on their systems and regulations relating to clinical trials. Finally, the Chinese guidelines share the most in common with those in Taiwan compared with other nascent or intermediate HTA systems. For example, both countries stipulate in their respective guidelines that submission of pharmacoeconomic data are voluntary and budget impact analysis is recommended. These important factors contribute to the conclusion that it is likely that China will initiate an HTA policy similar to that utilized in Taiwan.

234. THE MIXED BRAZILIAN HEALTH SYSTEM AND THE NEED TO IMPROVE THE USE OF HEALTH TECHNOLOGY ASSESSMENT

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Health in Brazil is a constitutional citizenship right, despite being provided by a mixed public-private system. In 1988 the Unified Health System (SUS) was created with predicting full universal access for health with equality for all funded by fiscal budgets of national and subnational governments. On the other hand, a supplementary health system and free enterprise in health was also guaranteed. This paper analyzed the model of financing and provision of services in the Brazilian health system and discussed how the Health Technology Assessment (HTA) could improve its efficiency and inform the decision making process to better results. The public system is financed by the Brazilian society through percentages of fiscal budgets of governments and special taxes for social security. The federative unities are required to apply percentages of their income on health actions. States and municipalities must spend at least 12% and 15% of revenue on health care, and the Federal Government makes an application linked to the annual growth of Gross Domestic Product. In the private sector, the financing includes pocket payments, the supplementary system of private insurance pre-paid, health insurance coverage variables for collective funds and initiatives of self-management of workers and companies resources. The provision of health services in the public sector takes place through its own services but also include contractors private providers. In this context, private demands to incorporate new health technologies in the SUS, specially claiming the constitutional right for health, is growing, pressing and affecting the public funding, requiring the development of national capacity in HTA to support decision making process. Therefore, mixed systems of health as the Brazilian should enhance the use of HTA to ensure the management of health technologies informed by best evidence, producing greater effectiveness at lower costs.

349. EVALUATION OF ETHICAL CURRICULUM

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Introduction: Our research aimed to evaluate medical ethical curriculum at the undergraduate and postgraduate institutions in order to promote the level of the student's ethical awareness and enable them to make ethical decisions.

Objective: To analyze undergraduate and postgraduate ethical curriculum.

Methods: The curriculum was evaluated using a questionnaire by the means of which students and medical professionals opinions were asked regarding the current program, the educational methods, and its success in achieving its goals. The evaluation of curriculum covered by 9 medical institutions and 13 postgraduate training hospitals included 673 students and 114 medical professionals.

Results: Total of 691 completed questionnaires were retuned (response rate-82.5%). In the evaluating in the process of the course a 39.2% of students and 24.2% of medical professionals agreed that the program reached to the goal. A 36.6% of students and a 29.3% of medical professionals agreed that they had obtained new knowledge. According to the student's options, the current program was enough in terms of exposing them to ethical issues (more than 36.9%) followed by giving them understanding and acceptance of their professional obligations and human and moral aspects of medical ethics (40.4%). A 40.2% of students and 27.3% of medical professionals obtained ethical decision making skill. 33.3% of students and 33.8% medical professionals agreed that the program had practical contents and amount of information was enough. In regards with evaluating the educational methods 31.8% and 22.2% of participants agreed that teaching methods were good in terms of quality. A 30.9% and 15.6% of participants mentioned that training environment is good to learn ethical course. In regards of assessment of students 41.2% of students and 22.2% of medical professionals agreed formative and summative approaches were useful.

Conclusion: As a result the current ethical curriculum is different in medical educational institutions, because of their trend of the training and capacity of teachers. Also rate of satisfaction in postgraduate training institutions lower then undergraduate schools, therefore we need to develop ethical core curriculum which provide international training requirements of medical ethics.

371. RISK FACTORS ASSOCIATED TO ICU ADMISSION AND DEATH IN SEVERE ACUTE RESPIRATORY INFECTIONS (SARI) IN PARAGUAY

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Background: Severe acute respiratory infections (SARI) are the most common causes of morbidity and mortality in the world, particularly in developing countries.

Objective: To determine risk conditions associated to intensive care unit (ICU) admission and death in patients with SARI in Paraguay, from January to October, 2011 (Epidemiological Week 1 to 43).

Methods: Data were obtained from the national surveillance system for SARI; bivariate and multivariate analyses (logistic regression) were performed.

Results: In the study period, 3420 cases of SARI were reported, 15.6% (532) of them were admitted to ICU and death was recorded in 5.7% (196). In 31.1% (1064) of the cases, at least one risk condition was found, distributed as follow: chronic heart disease 13.1% (449), chronic pulmonary disease 10,6% (361), diabetes 5,3% (181), obesity 3.5% (121), asthma 2.5% (87), chronic kidney disease 1.8% (62), immunodeficiency due to disease or treatment 3.2% (111), Down syndrome 0.7% (25) and pregnancy 1,3% (46). Factors significantly associated with mortality were: presence of any risk condition (RR = 3.8, $p < 0.0001$): chronic heart disease (RR: 3.9, $p < 0.0001$), chronic lung disease (RR = 1.7, $p < 0.001$), chronic kidney disease (RR = 5.0, $p < 0.001$), immunodeficiency (RR = 2.7, $p < 0.01$), diabetes mellitus (RR = 4.0, $p < 0.0001$) and chronic neurological disease (RR = 2.5; p = 0,01). Asthma, chronic hepatic disease, Down syndrome, obesity and pregnancy were not associated to mortality. Presence of any risk condition (RR = 1.5, $p < 0.0001$) was also associated to ICU admission such as: chronic heart disease (RR = 1.5, p = 0, 005), chronic lung disease (RR = 1.4, $p < 0.01$), chronic kidney disease (RR = 3.1, $p < 0.001$), immunodeficiency (RR = 1.7, p = 0.024); Down syndrome (RR = 4.3; $p < 0.001$); obesity (RR = 1.6; p = 0,041).

Conclusion: The presence of risk conditions increases mortality and need for ICU. Diabetes mellitus was associated with mortality but not to ICU admission. Unlike during the pandemic 2009, pregnancy and obesity were not associated with mortality.

378. EPIDEMIOLOGICAL AND CLINICAL CHARACTERISTICS OF SEVERE ACUTE RESPIRATORY INFECTIONS (SARI) IN PARAGUAY

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Objective: To determine the epidemiological and clinical characteristics of cases of SARI.

Material and methods: All SARI cases reported by sentinel sites from January to August 2011 (EW1-35) were included in the analysis. The variables analyzed were age, sex, and admission to ICU, mortality, co-morbidity and/or risk factors, swab sampling and etiological agent.

Results: Up to the epidemiological week (EW) 35, 2594 cases of SARI were notified. Age distribution showed that 35% (889/2594) of the cases were younger than 2 years old and 14% (372/2594) 60 years or older. Admission to ICU was observed in 16% (417/2594) of the cases and the mortality rate was 6%. Comorbidity and/or risk factor was present in 27% (692/2594) of cases. Swab samples were taken in 77% of cases (1993/2594), and in 14% (294/1993) the results were positive. Respiratory Syncytial Virus (RSV) was the most common viral agent identified 63% (186/294), followed by influenza A H3N2 26% (76/294) and Adenovirus 5% (14/294). The autumn-winter period (SE 9 to 22) showed the highest circulation of RSV (168/186).

Conclusions: The main respiratory virus involved in the etiology of SARI in the autumn-winter period was the RSV and not influenza virus as expected, affecting not only children but also older adults.

394. SPENDING ON MEDICINES AND INPUTS TO CONTROL DIABETES IN THE STATE OF MINAS GERAIS, BRAZIL

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Background: Diabetes mellitus is a syndrome characterized by chronic hyperglycemia with absolute or relative deficiencies of insulin and/or in its action. The National Health System (SUS), through the pharmaceutical assistance must ensure medications and supplies needed for the monitoring of capillary blood glucose of diabetic patients, defined by ministerial decree.

Objectives: The aim of this study is to evaluate the financial impact of inputs for monitoring capillary blood glucose in relation to medicinal products for treatment of diabetes mellitus in the state of Minas Gerais in 2011.

Methods: Survey distribution and financial cost through the computerized management of pharmaceutical assistance (SIGAF) in thez State of Minas Gerais in 2011 of oral antidiabetics (glibenclamide 5 mg and metformin hydrochloride 850 mg), human insulin NPH and regular human insulin and indicator strip that measures the glucose.

Results: The costs for regular and NPH Insulin in 2011 were U$ 8,320,793.31, with oral antidiabetic agents was U$ 2,032,284.77, as with reagent strips for monitoring blood glucose level was U$ 6,978,321.99. The total spending on drugs for the treatment of diabetes mellitus was U$ 10,353,078.08. It is observed that the cost of test strips correspond to approximately 67.5% of this value.

Conclusions: These results demonstrate that the costs of inputs for monitoring of blood glucose have a significant financial impact on the State diabetes program. Moreover, they suggest the need for research regarding the reasonableness of the use of these inputs by patients. Education strategies, such as the pharmaceutical guidance for patients who perform self-monitoring blood glucose levels, aid in the proper use of these inputs and can avoid any waste.

468. HEALTH TECHNOLOGY ASSESSMENT POLICY IN BRAZIL

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Background: In 2003, the Ministry of Health (MoH) of Brazil created a work group to organize the HTA activities. In 2005, a HTA Unit as formed on Department of Science and Technology (DECIT) to lead HTA policy-making in Brazilian Health System (called SUS). In 2009, a policy was consolidated with strategies to maximize the health benefits obtained from health technologies.

Objectives: To describe the HTA Unit activities developed in 2005 to 2011.

Methods: Based on author's experience and annual reports, we describe the most important activities that were headed by MoH.

Results: The request for HTA reports was organized to support SUS reimbursement decisions. Four methods guidance for undertaking HTA reports were organized: rapid reviews, economic evaluations, budget impact analysis and horizon scanning. 400 rapid reviews were produced by internal team and 276 HTA reports by research institutions. Throughout the country, educational initiatives formed 170 masters in HTA and trained 1,000 professionals in workshops. Headed by DECIT, a Brazilian Network for HTA were structured, with 45 institutions (Universities, hospitals, regulatory agencies and policymakers). Several national and international collaborations were linked, like: Brazilian Cochrane Centre, Brazilian regulatory agencies, HTAi, INAHTA and Mercosur (Southern Common Market). Around US$20 million (uncorrected) were applied in HTA activities between 2005 and 2011. These efforts were crowned with the 8th HTAi Meeting in Rio de Janeiro, attended by over 1,000 subscribers, 60% of them Brazilians.

Discussion: The developed activities were essential to organize the MoH and to disseminate a HTA culture/policy in Brazil. Most activities were made due straightness with government stakeholders (judiciary and legislative). However, financial and human resources are needed to improve HTA in local level.

Implications: The continuity of an HTA policy is essential to sustainability of Brazilian Health Systems.

512. SOCIAL RELEVANCE OF EVIDENCE-BASED MEDICINE AND THE BRAZILIAN PHARMACEUTICAL MARKET

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Background: The Brazilian pharmaceutical market is the ninth largest in the world, the third in the Americas and the first in Latin America. It is expected to grow between 8% and 11% by 2013, according to data from IMS Health. A relevant share of this market is related to phytotherapics and self-medication, which occurs especially among the poorest families.

Objectives: Determine the use of medical supplies according to social class and relate it to the market as a whole. Identify the expenditures made by the social classes C, D and E and relate them to classes A and B. Relate Evidence-based medicine to social justice and the right to health.

Methods: We researched the online databases of the Ministry of Health, the National Agency of Sanitary Surveillance (Anvisa) and the Pharmaceutical Industry Association in Brazil (Interfarma), seeking for all the information about social class variation in medicine's use in the country.

Results: In 2009, the Brazilian families spent about 23.8 billion reais (15.86 billion dollars) on pharmaceutical supplies. Social classes A and B (with the highest income in the country) consumed, respectively, 2.2 and 3.1 billion reais (9.3% and 13% of total). Social class C consumed 5.5 billion reais (23.2%), class D consumed 8.1 billion dollars (34%) and class E consumed 4.9 billion reais (20.5%). Together, classes C, D and E spent 18.5 billion reais (77,7%).

Conclusions: Classes C, D and E are responsible for a relevant share of Brazilian pharmaceutical market. They have no access to evidence, but to mass media. Therefore, lack of evidence, beyond the potential damage to health, can affect the income of the poorest families in Brazil. A comprehensive access to medical evidence can reduce unnecessary use of medicines and self-medication in social classes C, D and E in Brazil, protecting the right to health and increasing social justice.

517. TECHNO-SURVEILLANCE, RE-STERILIZATION OF MEDICAL PRODUCTS IN URUGUAY

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Background: Re-sterilization of medical products is a widespread practice, unregulated through current legislation. There is no background of surveys regarding re processing of medical products in Uruguay.

Objectives: To assess the situation of the re-sterilization of medical products in Montevideo`s Sanitary system, in state and private sectors. Specific objectives; To survey the management of the re-sterilized therapeutic devices at institutional level; To evaluate the existence of procedures regarding detection, investigation and communication of the adverse events related to re-sterilization of therapeutic devices at institutional level; To diagnose the companies outsourcing the sterilization in order to assess the service's quality; To establish a recommendation guide for re-sterilization and report of sentinel events.

Methods: The following activities were performed. -Bibliographic research of technical aspects of re-sterilization and of normative in reference countries. -Interviews to area leaders of the National Sanitary authority. -Quantitative convenience based survey to health institutions in Uruguay (Private and State-owned) which covered aspects of personnel, security and methodology of sterilization. -Survey of all the companies that sterilize through ethylene oxide for health services.

Results: All the institutions reprocess single-use Medical devices (MD). MD reprocessing has deficiencies in criticality studies, documentation, process validation and adverse effects monitoring. Personnel safety conditions are adequate.

Discussion: Similar accomplishment characteristics were found in state and private sector. Because it is outsourced, the control of the sterilization services is considered a critical control point. State techno surveillance is being developed. The guide in the present work allows aligning efforts in the compliance with good reprocessing practices of MD.

Implications for the health system/professionals/patients/society: The sterilization of MD affects patient security during healthcare; the regulation of this process allows establishing safety mechanisms for professionals using medical products and guarantying the reporting system of adverse effects.

521. HEALTHCARE IMPROVEMENT GROUP: A TEAM WORKING AT THE HOSPITAL

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The University City Hospital of "São Bernardo do Campo", a city of 900 thousand inhabitants of the Saint Paul State - Brazil, perform hospital assistance to adults, women and newborns, possessing a neonatal intensive care unit of 19 beds and adult intensive care of 8 beds. A new form of work is being performed, from 2011, with the management to the improvement of health care. The management includes creating a rapid response team at the hospital after two cases of death in given birth women: one by sepsis and another by

pulmonary embolism. This attitude has mobilised the institution in the creation of this time involving medical staff, nursing, laboratory, image and articled clerks, a multiprofessional team with goals for package installation of sepsis in 6 hours - protecting 5 million lives from harm. Another action taken was the drafting of the protocol for the prevention of aspiration and aspiration pneumonia for reduction of complications, particularly in adult intensive care unit. In conjunction with the risk management the healthcare improvement group improves healthcare is detecting potential risks to the patient and working on assistive protocols. The nursing team performs monthly indicators of fall, pressure ulcer, noncompliance of medication, phlebitis and accidental extubation. Works with the protocol of secure surgery and prevention of central catheter-related infection and pneumonia associated with mechanical ventilation with the orientation of international recommendation bundles. Detection of sentinel event is analyzed by the health improvement group and corrective actions are taken. This is a new way of managing the patient care that is reverting to a greater interrelationship multiprofessional and better quality of work.

587. EVALUATION OF RAPID TESTS FOR HEPATITIS C VIRUS DIAGNOSIS AS AN ALTERNATIVE FOR CONVENTIONAL DIAGNOSIS: IMPLICATIONS TO INCREASE ACCESS TO DIAGNOSIS IN MIDDLE INCOME COUNTRIES

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Background: Hepatitis C virus (HCV) diagnosis is commonly made by EIAs and molecular tests, however these methods are expensive and time consuming.

Objectives: The aim of this study is to evaluate 3 rapid test for anti-HCV detection among serum (S), whole blood (WB) and oral fluid (OF) samples in order to assess its feasibility for use by populations at high risk for HCV in Rio de Janeiro, Brazil.

Methods: Paired samples were obtained from 157 individuals referred to Virals Hepatitis Centers in Rio de Janeiro. HCV Rapid Test (Bioeasy) and Imuno-Rápido HCV (*Wama*) were employed for (S) and (OF) samples collected with Salivette (Sarstedt) and the first were also used among (WB) samples. The volume was increased two fold for (OF) samples. For OraQuick HCV Rapid Antibody Test (OraSure Technologies) as for Bioeasy and Wama assays using (S) and (WB) samples, manufacturer´s instructions were followed. Sera samples were tested by anti-HCV and HCV-RNA using commercial EIA and PCR respectively.

Results: Highest concordance was obtained among Bioeasy test for (WB) 83.54% and sera 82.1% followed by Oraquick 77.8%, Wama test for (S) 73.77%, Wama test among (OF) 70.13% and lastly Bioeasy (OF) 66.15%.

Discussion: All 3 rapid tests presented good concordance compared to conventional EIAs. Because performance was similar for all tests and specimen types, other characteristics, such as convenience, time to result and cost will likely be determining factors for selection of a rapid HCV screening test for a specific application.

Implications for the health system/patients/professionals/society: Viral Hepatitis Centers could benefit from increased testing capacity, and clients might benefit from more rapid access to education, counseling, and referrals when using rapid HCV tests, especially among middle income countries that have less access to the diagnosis.

611. HTA METHODOLOGICAL GUIDELINES AS A TOOL TO IMPROVE QUALITY IN HEALTH EVIDENCE: THE BRAZILIAN EXPERIENCE

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Background: A host of health systems have adopted HTA as part of the decision-making process for incorporating and disinvesting heath technologies. To analyze the short- and long-term consequences of the application of technologies, a number of methods, including systematic reviews, economic evaluations, and others are necessary.

Objective: To describe the Ministry of Health of Brazil's strategy for improving good practices in HTA studies by reporting its experiences in developing methodological guidelines for the HTA field.

Method: Descriptive analysis based on Ministry of Health data from 2005 to 2012.

Results: Following establishment of the General-Coordination for HTA in 2005, the need for methodological guidelines to guide internal reports and external studies demanded by the Ministry of Health was identified. The first action involved developing methodological recommendations for rapid review and economic evaluation, the two most pressing issues at the time. To this end, expert researchers in the field were contracted to prepare draft versions, which were submitted for analysis by a broad range of actors – health managers, decision-makers, researchers, health professionals –, for the purpose of validation of the final versions. In 2007, the first edition of *Methodological Guidelines for Elaborating Rapid Review* was published, followed in 2009, by the release of *Methodological Guidelines for Economic Evaluation Studies*. The first guide was revised and expanded in 2009 and 2011, while the latter underwent review in 2010. Today there are four additional methodological guidelines under development: horizon scanning, budget impact analysis, systematic review, and medical device analyses. Each is scheduled for publication in 2012.

Conclusion: The Brazilian experience in the development of guidelines has proved to be positive in a number of ways, serving, among other factors, to define the most important recommendations based on the specific type of study; promote methodological standardization among studies; and provide Portuguese-language material on the issue, as the majority of publications in the field are in English. Based on this, we believe that our strategy could be considered by other countries currently in the process of implementing HTA processes, in particular those without previous experience in this area.

711. HEALTH ECONOMIC AND OUTCOMES RESEARCH (HEOR) EVIDENCE IN HEALTH TECHNOLOGY ASSESSMENT (HTA) FOR DRUG FORMULARY AND REIMBURSEMENT DECISIONS ACROSS GLOBAL REGIONS

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Background: Worldwide, HEOR information in HTA is used to varying degrees by decision-making agencies.

Objectives: To analyze how decision makers in USA, Asia, and Latin America currently use HEOR information as part of HTA in the decision-making process and what their future expectations are.

Methods: Decision makers in the United States, Asia, and Latin America were surveyed.

Results: More respondents in Asia than in Latin America (LatAm) claimed that decisions are always, or often, based on HTA (38 vs.

19%). In Asia, only 13% said HTA was used rarely, whereas in LatAm they use HEOR data rarely (30%) or not at all (23%). In both regions, approximately 10% of responders (9% and 11%) said that HEOR information was mandatory in HTA. Another 24% (LatAm) and 44% (Asia) indicated non-mandatory use. In the USA, 73% of respondents claimed regular usage of HEOR; 77% expect increased use in the future. The use of HEOR data was reported as "no" by the USA (14%), LatAm (15%), and Asia (0%), respectively. In Asia and LatAm 53% and 44% did not use outcomes-based contracting, whereas 12% and 11% in each region stated that OR is used for contracting. In the USA 67% reported current use in contracting and 72% expected an increase.

Discussion: Distinct regional differences are evident in the use of HTA and the integrated use of HEOR. Despite greater incorporation of HEOR in HTA in Asia, both, Asia and LatAm, use data comparably for contracting. In the USA using outcomes in contracting is reported more frequently.

Implications: Different healthcare policy priorities reported by the respondents, which ranged from cost containment via more patient centric policies to universal access, may reflect the difference of utilization of HEOR in decision-making across different healthcare systems and can be expected to change over time.

736. BRAZILIAN EXPERIENCE ABOUT DECISION ON INCORPORATION OF BEVACIZUMABE AND RANIBIZUMAB FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION AT PUBLIC HEALTH SYSTEM

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Age-related macular degeneration (AMD) is an eye disease that attacks the macula of the eye and leads to a progressive loss of central vision. This condition occurs in two forms, dry and wet. Wet (neovascular) AMD is characterized by the development of choroidal neovascularization (CNV), which is responsible for almost 90% of severe visual loss due to AMD. The vascular endothelial growth factor (VEGF) has been implicated in the development and progression of CNV, since it induces angiogenesis, vascular permeability and inflammation. More recently, drugs that inhibit VEGF action have been used for the treatment of wet AMD. Ranibizumab and bevacizumab are two monoclonal antibodies that inhibit VEGF, preventing the proliferation of endothelial cells and formation of new blood vessels. Ranibizumab is indicated for neovascular AMD treatment; however bevacizumab has no approval from national and international regulatory agencies for this indication. In 2011, the National Committee for Technologies Incorporation in Public Health System (CONITEC) of the Brazilian Ministry of Health received a request for the adoption of ranibizumab for wet AMD. It's known that intravitreal bevacizumab has been used off-label by ophthalmologists worldwide and a scientific literature review showed that these two drugs have the same efficacy and tolerability for neovascular AMD treatment. Moreover, a Brazilian cost-effectiveness study showed that bevacizumab is more cost-effective than ranibizumab and the budget impact with the use of ranibizumab is 30 to 40 times greater than with bevacizumab. Since it's estimated that there are 230.000 to 300.000 elderly with wet AMD in Brazil, the Brazilian Public Health System (PHS) wouldn't be able to fund ranibizumab. So, CONITEC has decided not incorporate ranibizumab and to adopt bevacizumab in the PHS for neovascular AMD treatment, allowing its use only in specialized centers capable to prepare sterile fractions of drug to intravitreal use.

844. EVALUATION OF MOLECULAR METHODS FOR HEPATITIS C VIRUS DIAGNOSIS TO OBTAIN DATA FOR ECONOMIC EVALUATION FOR MIDDLE INCOME COUNTRIES

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Background: Nowadays, several commercial molecular assays are available for hepatitis C virus (HCV) diagnosis in order to identify the cases and monitore antiviral treatment, but these methods are expensive to be implemented in limited resource laboratories.

Objectives: The aim of this study is to evaluate three molecular methods for HCV RNA quantification in order to establish the best option for HCV diagnosis in middle income countries.

Methods: A total of 64 sera samples were obtained from 27 individuals referred to Viral Hepatitis Ambulatory at Rio de Janeiro (IOC/Fiocruz) whose 21 donate one single sample and 6 donate serial samples during the course of HCV infection. Three methods were tested: Cobas Amplicor HCV Monitor v2.0 (Roche Diagnostics, France), VERSANT® HCV RNA 3.0 Assay (Siemens Healthcare Diagnostics, USA) and in house Real Time PCR based on Taqman methodology. For Real Time analysis, RNAs were extracted by two different methods: QIAamp DNA Mini kit (Qiagen, USA) and NucliSENS® easyMAG® (Biomerieux, France). All assays amplify the 5' non coding region of HCV genome.

Results: Mean (± Standard Deviation) of HCV load (copies/mL) were 2,864,666 (± 7,361,411) for Cobas Amplicor HCV; 966,716 (± 2,472,802) for Versant HCV; 222,642 (± 468,572) for Real Time with Biomerieux extraction and 161,024 (± 1,175,545) for Real Time with Qiagen methodology. Discordant results were presented among 6 samples, while 29 were quantified by all the four methods and 29 samples were undetactable by all methods. Among serial samples, Cobas Amplicor HCV and Real time with Biomerieux extraction presented highest sensitivities, since both methods could detect HCV RNA until 72th week after initial of symptoms. DISCUSSION: All methods can be employed for HCV RNA quantification due to comparable efficiency, however real time PCR with Biomerieux extraction presented good efficiency and low cost compared to other methods and it can be used for HCV diagnosis.

Implications for the Health System/Patients/Professionals/Society: This study gives information about the efficiency of molecular methods for HCV diagnosis that will be used for future cost benefit analysis.

872. APPLICABILITY OF HEPATITIS B VIRUS RAPID TESTS TO IMPROVE HEALTH ACCESS IN MIDDLE INCOMING COUNTRY

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Background: Commercial enzyme immunoassays (EIA) have been used for conventional diagnosis of HBV infection using serum samples. However rapid assays can provide advantages over these conventional assays, such as, the time of execution and the cost.

Objectives: The objective of this study was to evaluate the sensitivity and specificity of HBV rapid assays among sera samples as compared to commercial EIA to improve health access in middle incoming countries.

Methods: Sera samples were obtained from 1352 individuals whose 225 were from Viral Hepatitis Centers (high endemicity) and 1127 were from North and South Region of Brazil (low endemicity). Hepatitis B surface antigen (HBsAg) were detected using two rapid tests: (T1) Vikia HBsAg (Biomérieux, France) and (T2) Imuno-Rápido HBsAg (Wama, Brazil) and compared to commercial EIA (ETI-MAK-4, Diasorin, Italy). RESULTS: HBsAg was detected among 74 samples and it was not detected among 1352 samples giving sensitivities of 97.3% and 95.9% for T1 and T2 while specificities were 100% and 98.3% for T1 and T2, respectively. When sensitivities and specificities were evaluated according HBV endemicity, both assays presented values higher than 98% among high endemicity areas. However among low endemicity areas, both assays presented high specificity (100% for T1 and 98.3% for T2) and low sensitivity (33.3% for both assays). DISCUSSION: These results showed that rapid assays can be used with great efficiency among Viral Hepatitis Centers, but these assays did not present good performance among low endemicity areas. Since specialized technicians and equipments are not necessary, rapid assays will be very useful to increase the access of diagnosis in high endemicity areas.

Implications for the Health System/Patients/Professionals/Society: This study gives information about the performance of HBV rapid assays that will be used for future cost benefit analysis to improve health access diagnosis in middle income countries, such as Brazil.

894. EVALUATION OF THE THERAPEUTIC VALUE AND COST OF DRUGS REQUESTED TO THE HEALTH SECRETARIAT OF THE STATE OF CEARÁ/BRAZIL

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Background: Medicines are the intervention with the greatest impact within the health systems both by its financial value as its social value. However, the increase in drug litigation is making it common to purchase new drugs that have not always proven safety and efficacy.

Objective: To evaluate the therapeutic value of drugs requested by judicial lawsuits and administrative demands to the Health Secretariat of the State of Ceará/Brazil between the years 2004 and 2006, and make a link with the expenses in the given period.

Methodology: The requested pharmaceuticals were evaluated for essentiality, participation in drug lists of national reference, number of active ingredients and registry at ANVISA/Brazil. Studies were carried out to assess the therapeutic value for the drugs that were not part of any standard list and presented frequency rate of ≥ 10.

Results: 75.2% of the drugs were classified as non-essential; 63.6% were non-standard; and 89.0% were monodrugs. Ten specialties were not registered at ANVISA. Of the 20 drugs that had the therapeutic value analyzed, 84.2% (17) were considered to be of high value and expected degree of relative use; two resulted in dubious or no value; and one was not classified because there were no evidence found that could frame it in the classification adopted in this study. Over the period of time of this study, R$ 68,235.28 were spent for the purchase of drugs classified as of doubtful therapeutic value.

Implications for the health system/professionals/patients/society: There is a need of greater awareness by health professionals of the therapeutic potential of the standard lists. There is also a need to monitor patients' use of not standardized drugs and regular evaluation of administrative and judicial demands which will contribute to the rational use of drugs and financial resources.

908. ESTIMATING ACCESS TO HEALTH SERVICES IN BRAZIL THROUGH A MARKET FRONTIER ANALYSIS

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Background: The Brazilian public health care system provides health care services free of cost but many factors may prevent individuals from accessing it.

Objective: To evaluate the perspectives of expanding public health care services in Brazil. Method: utilizing the access frontier analysis, a tool to estimate the dimensions of markets, we reviewed empirical data to estimate the potential for growth of the Brazilian public health care system.

Results: The current market for public health services in Brazil is composed by uninsured and privately insured individuals. The current access frontier is composed by individuals who seek to obtain care but are unsuccessful or obtain less than needed (2.5% of the population). The main factors that prevent access are the distance to the health center, time to schedule a doctor's appointment, waiting time to receive care and insufficient quality of services. These factors also play a role in the future access frontier (individuals who need care but do not try to access services, who totalize 17% of the population), alongside with lack of money, difficulties of transportation, incompatible operating hours, long waits and concerns about interrupting work activities. Disabled and dependent individuals, those with the poorest family and social support networks, the homeless, the poorest and those who live in the most remote areas are largely excluded from the market and constitute the supra-market zone, so far poorly quantified.

Discussion: To fulfill its role of promoting redistribution and social inclusion, the Brazilian public health care system must mitigate the barriers that currently prevent more than 20% of the population from accessing services. In the short run, strategies to reduce waiting times, facilitate administrative processes and increase quality of care are needed. In the long run, it must develop programs and policies to enable utilization by the poorest and those with special needs.

49. EFFICACY COMPARISON OF TWO PROGRAMS FOR LIFESTYLE CHANGE PROMOTION DIRECTED TO SCHOOL CHILDREN OBESITY PREVENTION: THE BELO HORIZONTE HEART STUDY

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Objectives: Adoption of healthy lifestyles by school children, through achieve health literacy, increase physical activity, decrease sedentary behaviors, reduce fatty food consumption, increase fruits and vegetables consumption.

Background: Due to rapid lifestyle changes in Brazil, we are now facing a childhood obesity epidemics. There is a need for effective programs to address this problem.

Methods: Cohort multi-component health promotion intervention study, with 9 intervention of interest (TAKE 10!) and 8 comparative intervention control (Shake It Up Kids) Brazilian schools for matched comparison to determine its impact on outcomes assessed longitudinally in a cohort of 2,038 children using pre-intervention and follow-up children survey on transtheoretical stage of behavior changing evaluation.

Results: We found respectively a 54.33 and 25.31; 17.15 and 64.06; 91.97; 29.12 and 50.89; 4.65 and 14.38 percent increase in *TAKE 10! Program children* numbers in preparation and action stages at post-

intervention compared to pre-intervention (P < 0,001), for fatty foods consumption, consumption of fruits & vegetables, physical activity, sedentary habits behavior related to TV/DVD screen time, sedentary habits behavior related to computer/games screen time, respectively. Analyzing only the precontemplation and contemplation stages, we found similar numbers. Children from intervention group had 79%, 78% more risk (RR) to reduce fatty food consumption and increase F&V consumption respectively; and 67%, 75% and 2.0 times likely to increase physical activity, reduce TV/DVD and games/computers screen time respectively. We needed around 3 children (NNT) to archive these benefits these benefits.

Conclusions: The TAKE 10! program stimulated children forward movement through eating and physical behavior stages, providing them with processes that facilitate healthy lifestyle choices, potentially reducing children obesity prevalence.

Implications: It is expected that this results stimulates Brazilian public health institutions to adopt this health technology to promote healthy lifestyle promotion recommendations for Brazil and share this experience with other developing countries.

69. RISK FACTORS FOR LOW BIRTH WEIGHT IN BOTUCATU CITY, SP STATE, BRAZIL: A STUDY CONDUCTED IN THE PUBLIC HEALTH SYSTEM FROM 2004 TO 2008

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Background: Low birth weight (LBW) has a complex etiology and may be a result of premature interruption of pregnancy or intrauterine growth restriction.

Objectives: To provide information on determinants of LBW and contribute to the understanding of the problem in Brazil.

Methods: A case-control study was conducted in Botucatu city, SP state, Brazil. The study population consisted of 2 groups with 860 newborns in each group: low weight newborns (LWNB) and a control group (weight ≥ 2500 g). Secondary data were collected using the Live Birth Certificate and records from medical charts of pregnant women in Basic Health Units and in the Public University Hospital. Variables were as follows: maternal socio-demographic characteristics, pregnancy and birth conditions including quality of prenatal care. They were based on parameters established by the Ministry of Health, one of them, the modified Kessner Index.

Results: The factors associated with LBW were: prematurity (OR = 56.98, 95% CI 29.52-109.95), twin pregnancy (OR = 20.00, 95% CI 6.25–100.00), maternal smoking (OR = 2.12, 95% CI 1.33–3.45), maternal malnourishment (OR = 2.30, 95% CI 1.08-5.00), maternal obesity (OR = 2.30, 95% IC 1.18-4.48), weight gain during pregnancy less than 5 kg (OR = 2.63, 95% CI 1.35–5.00) and weight gain during pregnancy more than 15 kg (OR = 2.26, 95% CI 1.16-4.41). According to the modified Kessner Index, 64.4% of prenatal visits in the LWNB group were adequate.

Discussion and implications for the health system: LWNB are a quite heterogeneous group of infants concerning their determinants and prevention actions against LBW and the follow-up of these infants have also been very complex. Ultimately, the challenge to be faced by health authorities has currently been political, so that the right to health care has to be ensured to all pregnant women and newborns through improved and already well defined actions towards health care.

87. FAILURE ANALYSIS IN PREINSTALLATIONS FOR MEDICAL TECHNOLOGY

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In the hospital environment, a technology failure is defined as any event where a medical device has stopped functioning properly and thus, has an associated probability for patient or user injury. The more complex the medical technology under analysis is, the larger is the number of technical problems that may arise. Preinstallations have become a major concern in the strategic planning for medical technology acquisition since an adequate approach leads to the optimal and safe use of the devices in the clinical facilities. Failures due to the wear of the materials, electrical issues, user skills and facility deficiencies can be avoided if there is a suitable preinstallation procedure that controls these aspects. A failure analysis adapted from the Failure Mode and Effects Analysis (FMEA) was carried out on medical technology preinstallations in order to determine the most prevalent causes of potential future failures on the use of a device. Derived from the analysis of the preinstallation procedures of a CT scanner, a business process management method was applied in order to discover the bottlenecks and establish the cause-effect relationships. Severity indicators are generated from a number related to the seriousness of the incident multiplied by a previously defined failure occurrence probability. The numerical evaluation was based on Saaty's Analytic Hierarchy Process and paired relationships were considered to determine the "cause-failure mode-consequence" chain. The resulting failure mode causes were compared with the expertise of radiological technicians that were experienced in the installation of a CT scanner in two different hospitals. The highest severity scored failures involved shielding calculations, the selection of isolating materials for the installation and the maximum allowable working temperature. All of these parameters are related to the stages that are previous to the acquisition. More research on this field is being conducted at National Laboratory of Research on Medical Instrumentation and Imaging.

641. THE INTEGRATION OF HEALTHCARE PROCESS AS CORNERSTONE OF THE STRATEGY OF CHRONICITY

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Objectives: To develop integration experiences between health services organisations as well as coordination of the clinical processes between professional and assistance levels. To coordinate the contributions of 14 projects of the strategy of chronicity on the integration/coordination axis.

Methods: A normative integration has developed constituting organizations of integrated services (OIS). Projects and activities of coordination and clinical integration have been driven, both from a "top-down perspective, and as facilitating initiatives "from the health professionals". In this sense, the 2012 financing contract incorporates Population Action Plans (PAP), in every health organization, that foster coordinated interventions among the health care organizations at local levels.

Results: Four integrated health-care organizations, that group each one a Regional Hospital and its Subregion of Primary health care, as well as a Network of Mental health, have been constituted. To date there are more than 100 projects/activities running on clinical process

coordination where both, professionals of Primary and Specialized level, are working together. These projects include more prevalent diseases and relevant aspects for the healthcare process as the use of new technologies (ICTs). It has been stated the concrete contributions from the Projects of the Strategy of chronicity to the Integration Process. The most important are: Advanced nursing skills; Non face to face attention (Tele-health). OSAREAN: Multi Channel Centre; Stratification; Electronic history: OSABIDE GLOBAL; E-prescription; Active patient; Financing and contracting; Sub-acute hospital; Prevention and promotion.

Discussion and conclusions: Although it presents a big difficulty matching the development of the 14 projects of the strategy of chronicity and their contributions to the integration of the healthcare process, a synergic effect is being given, that confers great dynamism to the development of the strategy. In 2012, changes in the Financing-Programme have accelerated the process of local integration through the joint work of the health service organizations.

800. EARLY AWARENESS AND ALERT SYSTEM TO SUPPORT THE INCORPORATION OF NEW TECHNOLOGY IN BRAZIL

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In 2011, a proposal for Early Awareness and Alert System (EAAS) for new and emerging technologies was published to the Unified Health System (SUS, in Portuguese) in Brazil. This proposal was defined after discussions with academic experts, public managers and technical areas of the Ministry of Health and regulatory agencies. Simultaneous, new regulation to guide the incorporation process established the National Committee for Incorporation of Technologies (CONITEC, in Portuguese). This study aims to describe a strategic plan to set a EAAS to support the decisions of CONITEC. The proposal plan is based in three main aspects related to: Infrastructure for EAAS: 1. Development of information system to manage the information on new and emerging technologies; 2. Development of a methodology for setting priorities on new and emerging technologies; 3. Training of staff. Process of EAAS: 1. Establishment of a work flow for the EAAS; 2. Recruitment of institutions to develop the scanning process; 3. Establishment of collaboration with national and international institutions and agencies for exchanging experience. Expected Results: 1. Production of reports on new and emerging technologies; 3. Dissemination of informs to others stakeholders in the SUS. The technologies related to oncology and chronic non-communicable diseases were prioritized to start the EAAS. The limited human and financial resources are challenges to overcome, but the establishment of the EAAS is of fundamental importance to turn the existing incorporation process more proactive in the early identification of relevant innovations for the public health system.

96. THE COSTS OF OVERWEIGHT AND OBESITY-RELATED DISEASES IN THE BRAZILIAN PUBLIC HEALTH SYSTEM

Luciana Bahia[a], Evandro Coutinho[b], Laura Barufaldi[a], Gabriela Abreu[a], Thaina Malhão[a], Camila Pepe[a] and Denizar Araujo[a]

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Background: Prevalence of overweight/obesity in Brazil has increased, resulting in higher costs for Health Systems due to related diseases.

Objective: To estimate the costs associated to overweight/obesity diseases in Brazilian Public Health System.

Methods: We searched for meta-analyses and large individual studies presenting Relative Risks (RR) of overweight (OW) and obesity (OB) for several diseases. Population attributable risk was calculated for conditions with significant association (RR ≥ 1.20) and for those considered important problem of public health (RR < 1.10 and ≤ 1.20). Neoplasms, type 2 diabetes, cardiovascular diseases, asthma, and osteoarthritis (knee and hip) were selected. OW/OB prevalence rates were obtained from a national survey, stratified by sex and Brazilian capitals. A national database (DATASUS) was used to estimate the annual cost with the selected diseases in the adult population. Information was stratified by sex, type of service (inpatient or outpatient) and year. Data were collected from 2008 to 2010 and the results reflect the 3-years average. Data are expressed in US 2010 dollars using purchasing power parity.

Results: The annual costs with the selected diseases were US$ 2.14 billion, US$676 million for outpatient care and US$1.47 billion for inpatient care. OW and OB attributable risks varied a lot, from 2% to breast cancer to 48.5 to diabetes. Approximately 11% of inpatient costs (US$162.9 million) and 8.5% of outpatient costs (US$57.9 million) were due to OW/OB. The costs of outpatient care attributable to OW/OB were higher in women than in men (US$33.1 vs $24.7 million), although the inverse was seen in inpatient care costs (US$66.6 vs $96.5 million).

Conclusion: The costs of obesity-related diseases are high, but still underestimated, as DATASUS collects data only for financial purposes. Investments in prevention seem to be a better approach to reduce the burden to the society and the health system.

97. THE COSTS OF ALCOHOL-RELATED DISEASES IN THE BRAZILIAN PUBLIC HEALTH SYSTEM

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Background: Excessive alcohol intake has been related to several diseases, resulting in higher costs for Health Systems.

Objective: To estimate the costs associated with alcohol intake-related diseases in Brazilian Public Health System.

Methods: We searched for meta-analyses and for large individual studies presenting Relative Risks (RR) estimates associated to excessive alcohol intake. Diseases were selected for calculating population attributable risk (PAR) if their associations with alcohol intake have the following parameters: RR ≥ 1.20 or RR < 1.10 and ≤ 1.20, but important problem of public health. Neoplasms, cirrhosis and pancreatitis were included in the analysis. Alcohol influence on traumas and psychiatric illness could not be evaluated. The prevalence rates of excessive alcohol intake were obtained from a large national survey and varied between capitals (4.6 to 12.4%). A national database (DATASUS) was used to estimate the annual cost with selected diseases in the adult population. Information was stratified by sex, type of service (inpatient or outpatient) and year. Data were collected from 2008 to 2010 and the results reflect the 3-years average. Data are expressed in US 2010 dollars using purchasing power parity (PPP).

Results: The annual costs with the selected diseases were US$344 million, US$259.7 million for outpatient care and US$84.3 million for inpatient care. Alcohol intake attributable risks vary a lot, from 0.67% for esophagus cancer in women to 25.9% for cirrhosis in men. In average, approximately 1.7% of inpatient costs (US$4.41 million) and 4.5% of outpatient costs (US$3.85 million) were due to excessive alcohol intake.

Conclusion: The costs of alcohol-related diseases are high, but still underestimated, as DATASUS collects data for financial purposes,

usually well below the real costs of diseases. More investments in population education for preventing excessive alcohol intake seem to be a better approach to reduce the burden to the society and the health system.

103. RARE DISEASES AND ORPHAN DRUGS: DEFINITIONS AND REGULATION

Giacomo Balbinotto Neto[a], Ramon Wiest[b] and Franciele Cipriani[b]

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Background: Rare diseases are a health problem affecting approximately 6% to 8% of the population of Europe and the USA, equivalent to about 55 million people. Due to rarity, the reduced consumer market makes it difficult, expensive and risky research development for the production of medicines for their treatment, making this issue becomes not just a public health problem, but also a social and economic problem.

Objective: The objective of the paper will be to define the concept of rare diseases and orphan drugs around the world and analyze its main implications for research, development ans marketing.

Methods: the epidemiological criteria used for the definition of a rare disease, as well as the legal institutions that resulted in the most varied denominations. The development of products for the treatment of rare diseases, the so-called orphan medicinal products, from epidemiological and economic perspective. was carried out a review of key concepts contained in the literature reviewed in order to contextualize such respects the social and economic order factors.

Results: There is no single definition for the term around the world and not even the World Health Organization was able to establish a single meaning to be adopted by its member countries, however, broadly, is considered rare any abnormal condition, damage or change in health status that is not common, i.e. that does not occur frequently.

Discussion: It was concluded that that rare diseases are a public health problem and its implications require a government intervention. The fact there is no single definition about the rare disease concept in different countries hinders the deployment of cohesive policies can promote early diagnosis and, consequently, an effective treatment. On this fact, patients end up subject the socioeconomic implications of the disease. Set policies for access and health care and establish institutional mechanisms capable of reducing the lack of research and research in this area are among the priority measures to be established. In Brazil there is a specific policy for rare diseases, so that they are treated by the public health system in the same way as the most prevalent diseases.

105. ECONOMICS OF OBESITY: THEORY AND IMPLICATIONS

Giacomo Balbinotto Neto[a] and Patricia Alves[b]

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Background: Obesity is a public health problem which affects millions of people around the world. It is considered an illness with multiple causes and, therefore, it is challenging to public health services because of the increasing health problems caused by overweight within the population, including children.

Objective: The objective of this paper is to present in what ways Economics can contribute to the understanding and solving of this issue. Obesity has always been present within the society, however, in the last three decades, it has grown rapidly. The Economics try to correlate in what ways the economic growth affects the behaviour of the individuals when it comes to choosing food and physical activities practice. The paper will revise the major model that relate economic factor to obesity. Besides that, it present a review of the major evidences of costs and consequences of obesity in cross county-a analysis.

Method: Data about the obesity around the world will be presented, in addition with the most common illnesses related to overweight. Moreover, studies about the cost of illness and in what ways the economic models are applied to the obesity problem will be presented. It will be presented the major disease relationed to obesity, the incidence around the world and a survey of costs of obesity in many countries.

Discussions and implications: From theoretical point of view will be presented an economic model about consumption of food. It will be emphasized the income and price effects of food in weight. One of major contribution of the paper is to show/demonstrate how economics can collaborate to reduce obesity index and measure its economic impact. Besides that economics can contribute to the formulation of health public policies to reduce obesity. With economics we have instruments to avalites public policies that works and not works. The major conclusion of the paper is that economics theory is important to understand human behaviour that is associate with obesity and can contribute to the solution.

155. DIABETES MELLITUS TYPE 2 PATIENT'S PREFERENCES CONCERNING LIFESTYLE INTERVENTIONS: A DISCRETE CHOICE EXPERIMENT

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National Institute for Public Health and the Environment. Netherlands.

Background: Globally, a sub-optimal uptake of lifestyle programs among diabetes mellitus type 2 (DM2) patients is observed, while research shows notable delays in the development of the disease among participants in different lifestyle programs. Among DM2 patients, different studies were conducted that identified an extensive list of barriers and facilitators for participation in lifestyle interventions. However, very little is known about the relative importance of such factors.

Objective: This study investigated the preferences and willingness to pay of diabetes type 2 patients concerning lifestyle interventions by means of a discrete choice experiment (DCE).

Methods: A questionnaire was distributed amongst 2500 participants who were diagnosed with diabetes mellitus type 2 (DM2), 35-65 years of age, and not suffering from any serious complications due to their DM2. The first part of this questionnaire contained questions on participant's demographic and background characteristics, their opinion on lifestyle programs and the EuroQol-5D. Second, a DCE was included, participants were asked to complete 18 choice tasks. Each choice task consisted of the following five attributes (each with three levels): menu plan (flexible, general, elaborate), physical activity plan (flexible, general, elaborate), structure of the consults (individual, in groups of 5 or 10 patients), expected outcomes (no weight loss, 5 or 10 kilograms of weight loss) and out-of-pocket costs (€75, €150, €225). The questionnaires will be distributed in February 2012, data is expected in May 2012.

Results: Not yet available, but will be presented at the conference in June 2012.

Discussion: Not yet available, but will be presented at the conference in June 2012.

Implications: Based on the results of this paper recommendations will be made as to what constitutes a lifestyle program that is most appreciated by DM2 patients.

183. THE COSTS OF PNEUMOCOCCAL DISEASES IN LATIN AMERICA: A SYSTEMATIC REVIEW OF COSTS AND PRODUCTIVITY LOSS STUDIES

Luciana Bahia[a], Maira Takemoto[a], Marisa Santos[b], Cristiana Toscano[c] and Denizar Araujo[a]

[a]State University of Rio de Janeiro. Brazil. [b]National Institute of Cardiology. Brazil. [c]Federal University of Goias. Brazil.

Background: Rotavirus (RV) disease is one of the most important causes of diarrhea-related morbidity and mortality worldwide. In the Region of the Americas, RV causes approximately 75000 hospitalizations and 15000 deaths each year, which generates a significant economic burden for healthcare systems and the society.

Objective: To systematically review rotavirus infection cost and productivity loss studies conducted in Latin America and Caribbean (LAC) region.

Methods: A search of relevant databases (Cochrane Central Register of Controlled Trials, EMBASE, MEDLINE via Pubmed, LILACS and CAPES Thesis Databank) was performed till November 2011. Complementary searches were performed using websites grey literature sources and non-scientific search tools. Medical Subject Headings (MeSH) terms for rotavirus infections, healthcare costs and productivity loss studies, were combined with a variety of free text words to build a broad and sensitive search strategy. Only papers from LAC region were analyzed.

Results: 444 citations were retrieved, 410 were excluded after title and abstracts screened based on inclusion and exclusion criteria, 34 articles were fully extracted,10 were excluded after full text reading, and 24 articles remained for analysis. There were four papers from both Brazil and Mexico, three from Peru, two from Chile, one from each country Bolivia, Costa Rica, Venezuela, Honduras, Panama and Colombia, and four analyzing a group of LAC countries. Only five were cost-of-illness studies, while the others present costs estimates within cost-effectiveness analysis of vaccine implementation. Productivity loss was included in eleven studies.

Conclusion: Most costs estimates in Latin America studies are included in cost-effectiveness vaccine studies with a mix of sources for health resources utilization. For productivity loss the human capital approach method was used in all studies based on self-reported or country specific average/minimum wage (mainly female wage). There are a few studies with primary data collection in small samples.

184. THE COSTS OF ROTAVIRUS INFECTION IN LATIN AMERICA: A SYSTEMATIC REVIEW OF COSTS AND PRODUCTIVITY LOSS STUDIES

Luciana Bahia[a], Maira Takemoto[a], Marisa Santos[b], Cristiana Toscano[c] and Denizar Araujo[a]

[a]State University of Rio de Janeiro. Brazil. [b]National Institute of Cardiology. Brazil. [c]Federal University of Goias. Brazil.

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201. EFFECTIVENESS AND SAFETY OF ARCTIC FRONT® CARDIAC CRYOBALLOON CATHETER FOR THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION

Luis M. Sánchez-Gómez, Setefilla Luengo Matos, M. Mar Polo de Santos, Andrés Fernández Ramos and Antonio Sarría Santamera

AETS. ISCIII. Spain.

Background: Pulmonary venous isolation remains the cornerstone of most atrial fibrillation (AF) ablation procedures. Although a range of different ablation energy sources are available, cryotherapy using the Arctic Front® cryoballoon catheter could reduce complications and improve the effectiveness compared to others procedures.

Objectives: Synthesize current research evidence regarding effectiveness, cost-effectiveness and safety of Arctic Front® cryoballoon catheter for the treatment of paroxysmal atrial fibrillation.

Methods: Rapid HTA. The Arctic Front® cryoballoon catheter technology was identified by the early-warning system, "SINTESIS-new technologies," of AETS. The searched databases were: PubMed, EMBASE, CRD, and Cochrane Library. Clinical studies using Arctic Front® cryoballoon catheter published in any language until December 2011 were reviewed.

Results: We selected 9 case-series studies and 4 comparative studies. Case-series studies show a treatment success, defined as freedom from recurrent AF, ranged from 45% to 89% after a mean follow-up that ranged from 6 to 19.9 months in 2149 patients. Phrenic nerve palsy was the more frequent adverse event reported and varied from 1.6% to 14.3% of patients. Results of comparative studies show that after a mean follow-up that ranged from 6 to 12 months, treatment success varied from 55% to 70% after cryoablation using the Arctic Front® cryoballoon compared to 45% to 80% after radiofrequency ablation. One ongoing Spanish clinical trial, comparing the Arctic Front® cryoballoon versus radiofrequency for the pulmonary venous isolation ablation, was found. The estimated final data collection date for this trial will be March 2012. No cost-effectiveness studies were found.

Discussion/Implications for the health system: At present, cryoablation using the Arctic Front® cryoballoon catheter seems to be an effective procedure, but not more effective nor safer than radiofrequency ablation for the treatment of paroxysmal atrial

fibrillation. Further studies would be advisable to confirm these results.

376. EFFECTIVENESS AND SAFETY OF BAROREFLEX ACTIVATION THERAPY DELIVERY BY THE RHEOS SYSTEM IN PATIENTS WITH DRUG-RESISTANT HYPERTENSION

Mar Polo de Santos, Setefilla Luengo-Matos, Luis M. Sánchez-Gómez, Pilar Díaz-del Valle, Andrés Fernández-Ramos and Antonio Sarría-Santamera

AETS- Institute of Health Carlos III. Spain.

Background: The Rheos System is a new implanted medical device that electrically stimulates the carotid baroreflex and can reduce blood pressure (BP).

Objectives: Synthesize current research evidence regarding effectiveness, safety and cost-effectiveness of Rheos System in reducing BP in drug-resistant hypertension patients.

Methods: Rapid HTA. Baroreflex activation therapy (BAT) by the Rheos System was identified through the early-warning-system, "SINTESIS-new technologies", of AETS-ISCIII. The searched databases were: PubMed, EMBASE, CRD and Cochrane Library. Clinical studies using the Rheos System published in any language until December 2011 were reviewed.

Results: We found two finished multicenter clinical trials and one ongoing RCT. The US Rheos Feasibility Trial recruited 27 patients, 10 in American and 17 in European centres. The US branch showed a mean reduction of 22 mmHg in systolic blood pressure (SBP) and 18 mmHg in diastolic blood pressure (DBP) after a 3 months follow-up. The European branch, found a mean postoperative reduction of 28 ± 22 mmHg in SBP and 16 ± 11 mmHg in DBP. The European Device Based Therapy of Hypertension Trial (DEBuT-HT) (45 patients) found a reduction of 53 ± 9 mmHg in SBP and 30 ± 6 mmHg in DBP in 18 patients who completed a 58 ± 6 months follow-up. The randomized Rheos Pivotal Trial (265 patients) showed a mean SBP reduction of χasi35 mmHg in 81% patients after a 21 ± 8 months follow-up. The implant procedure was successfully completed in all cases. The majority of patients remained free of serious adverse events. Nevertheless, complications varied from 19 to 100% patients, the majority of mild complications were procedure-related. One economic evaluation study showed an incremental cost-effectiveness ratio of 64,400 per additional QALY gained at base case.

Discussion/Implications for the health system: BAT by the Rheos System seems to be an effective and safe treatment in drug-resistant hypertension patients. The procedure could be cost-effective. Further research is advisable.

807. DEADLINES FOR ANALYSIS OF TECHNOLOGIES INCORPORATION IN THE BRAZILIAN PUBLIC HEALTH SYSTEM (SUS)

Juliana Reis Vidal, Ávila Teixeira Vidal, Eliete Maia Gonçalves Simabuku and Clarice Alegre Petramale

Ministry of Health. Brazil.

In 2011 was published the law 12,401 which created the National Committee for Incorporation of Technologies (CONITEC) in the Brazilian Public Health System and defined the deadline of 180 days for the analysis and decision on the incorporation of health technologies. Before this law was not a legal deadline for this decision. The objective of this study was to analyze the period of time between the request of incorporation and the decision of the Brazilian Ministry of Health of previous cases to law 12,401. A survey was carried out on the Ministry of Health database about dates of the request protocols and the deliberations on the incorporation of the year 2011. The survey identified that on average the period of time between the incorporation request and the Ministry of Health decision took 909 days, however this period was highly variable depending on the priority and urgency for the SUS. Processes derived from internal demands usually were analyzed in less time. Regardless of the priority of the Ministry of Health, with the new law, the CONITEC has a specific deadline for the evaluation of the process. It is understood that this will provide greater agility in processes, thus benefiting the Brazilian population's access to safe and effective technologies.

858. SOCIAL TECHNOLOGY: REDUCTION OF INCOME INEQUALITY AND THE EVOLUTION OF THE PRIMARY HEALTH CARE INDICATORS, THE EXPERIENCE OF BRAZIL

Martha Teixeira, Adilson Sacramento, Diralucia Brito, Lucivaldo Alves and Marcelo Carvalho

Secretary of health of the State of Bahia/Brazil. Brazil.

Background: From a concrete social demand, income inequality, the Brazilian government introduced in 2003, the Benefit Family Program, a program with multiple relations (income, health and education), aimed to supporting families in extreme poverty (per capita monthly income up to U$ 40) and poverty (monthly income per capita between U$ 40 and U$80) having in its composition pregnant women, nursing mothers and children from 0 to 17 years, by granting a benefit in value ranging from U$18 to U$134.

Objective: To present a social care strategy and the evolution of the primary health care indicators.

Methods: This is a reporting of an experience of the use of a social technology. The strategy for achieving this goal is to demonstrate the evolution of the Benefit Family Program and two primary health care indicators: children with low weight and number of prenatal consultations, by region of Brazil, from 2005 to 2009.

Results: There is a great inequality between the two largest regions, Northeast with 52.39% of the population with income less than 1/2 minimum wage, while the Southeast region has 19.61%. In 2009, the total of benefited families is 25,533 for 100,000 inhab. The results show that there is, in each region, a small variation in the number of benefited families and in the two poorest regions with high rates of illiteracy there is an improvement of primary health care indicators, but are still much lower than those of the others regions. In the analysis period, the health care indicators showed a huge breakthrough, however, during the first years there were a sub-notification of these indicators, a real improvement occurs from 2008.

Discussion: An important contribution observed in this process lies in strengthening the structure of the health system through the insertion of a Social Technology.

Implications: It is expected that this systemic effort build an improvement in living conditions.

498. PERSONALIZED THERAPY IN ONCOLOGY: A SYSTEMATIC SEARCH FOR RANDOMIZED TRIALS IN PATIENTS WITH ACUTE LEUKAEMIA

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Background: The indication "acute leukaemia" comprises 2 major types of disorders: acute lymphoblastic leukaemia (ALL) and acute myeloid leukaemia (AML). Both ALL and AML are heterogeneous disorders and are divided into several subgroups, for example,

according to cytogenetic categories. The subgroups differ with respect to disease progression and prognosis. Personalized therapies have been implemented in various treatment approaches in order to consider the different molecular tumour characteristics.

Objectives: The aim of our project was to determine the availability of randomized controlled trials (RCTs) on personalized therapy in patients with acute leukaemia.

Methods: A systematic literature search was conducted in the databases MEDLINE, EMBASE and CENTRAL (Nov 2011) to identify published RCTs on personalized leukaemia therapy. The thesaurus terms "Individualized Medicine", "Personalized Medicine", "Pharmacogenetics", "Pharmacogenomics", "Gene Expression Profiling", "Monoclonal Antibodies" (supplemented by specific monoclonal antibodies), some related terms and free text queries were used to represent the interventions of interest. After removing the duplicates the titles and, if available, abstracts of the retrieval results were screened by 2 reviewers independently of each other according to predefined inclusion and exclusion criteria.

Results: Overall the systematic literature search yielded 593 hits. 56 publications on personalized therapy with a randomized study design were identified: 22 on ALL, 30 on AML and 4 covered various haematological diseases. 55% reported antibody-based therapies whereas the remaining ones described conventional therapies with cytostatic drugs. In the latter trials, the drug dose was adapted individually.

Conclusions: Our literature analysis indicates that in patients with acute leukaemia personalized therapy approaches can be developed and their effects investigated in studies of the highest evidence level (RCTs). In the context of acute leukaemia, personalization of treatment refers to subgroups of patients defined by tumour characteristics and/or their prognostic profiles.

593. PHARMACEUTICAL CARE: A NEW TECHNOLOGY TO EVALUATE THE EDUCATION OF ASTHMATIC PATIENTS

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Background: Compliance was a widespread problem with over 2 000 severe asthma adults. Pneumologists and pharmacists team develop an Asthma Education Program´s Performance Scale in Clinics Hospital, São Paulo University Medical School since 2003. The instrument was validated with through field studies with 6 point scores accounting for progressive performance in asthma inhalers use. The correct performance sums score 6.

Objective: Evaluate patients' learning effectiveness from instrumented pharmaceutical care.

Methods: poor asthma control patients were referred to pharmacists' consultations. First Pharmaceutical Consultation: Patient demonstrates the inhaler use. At each step, a score was attributed according to performance. The goal was score 5. Scores denoting wrong steps motivated reinforced correct use explanations. Second Monthly Consultation: Once patient inhalers' use was scored, required re-explanations were reinforced with a video. Third: Again using performance scored, re-explanations and program patient's discharge. Pneumologist semestrial consultations remain and free medicines were available at the pharmacy monthly.

Results: From September 2011 to February 2012, 10 severe asthma adults (average 49.9, range 45-50 years of age) participated. Scores significantly improved from 1st (2,4 ± 1,4) to 2nd consultation (5,0 ± 0,5), (Friedman test, $p < 0,05$) and also 1st compared to 3rd consultation 5,4 ± 0,5) ($p < 0,0001$), but not from 2nd to 3rd. The pharmacists made 43 interventions about the correct inhalers use: 12 regarding deep inspiration and expiration before inhalation; 9 concerning angle < 90º head inclination, 8 on aspiration rhythm and 14 remainders: dose preparation, deep aspiration and 10 seconds total lung capacity maintenance. The 1st consultation length was 59 ± 13 minutes, 2nd 16 ± 10 and 3rd 25 ± 6 minutes. All patients achieved score 5 goal. **Conclusions:** Improved inhalers patients' awareness and use knowledge were reported as empowerment and autonomy successes. The program requires 3 pharmacists consultations: 2 for teaching and 1 for reinforcement, in total 80 minutes, a very cost-effective intervention.

659. BODY MASS INDEX (BMI) IS ASSOCIATED WITH DIASTOLIC BLOOD PRESSURE AND GLYCATED HEMOGLOBIN AMONG PATIENTS WITH HEART FAILURE

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Background: It is well established that obesity indicators are associated with blood pressure and glycated hemoglobin. However, there is no defined association among patients with heart failure.

Objective: To evaluate independent associations among Body Mass Index (BMI, overall obesity), waist-hip ratio (WHR, central obesity), glycated hemoglobin and blood pressure in patients with heart failure.

Methods: A cross-sectional study among subjects aged ≥ 18 years with heart failure was carried out. Waist circumferences (WC, in cm) and hip circumferences (HC, in cm), weight (kg) and height (m) were performed in order to calculate waist-hip ratio (WHR) and Body Mass Index (BMI-kg/m^2). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) blood pressure (mmHg) and glycated hemoglobin (%) were obtained from medical records. Data were expressed as mean ± SD or percentage. Pearson correlation and multiple linear regression were used to assess the objectives.

Results: 34 patients (64.7% NYHA III and IV, 56% men, aged 61.9 ± 13.9 years) were enrolled. Among men and women averages were, respectively: WHR (1.0 ± 0.06 and 0.9 ± 0.07), BMI (25.3 ± 3.3 and 32.0 ± 9.9), glycated hemoglobin (6.4 ± 1.2 and 6.3 ± 1.6), SBP (114.7 ± 18.8 and 122.5 ± 18.0), DBP (69.5 ± 12.3 and 75.3 ± 9.2). There were statistically significant positive correlations with BMI and glycated hemoglobin ($r = 0.5$, $P < 0.05$) and DBP ($r = 0.5$, $P < 0.05$) among women. A multiple linear regression analysis showed a significant direct association between BMI and glycated hemoglobin (Beta = 0.08, SE = 0.04 P = 0.05) and DBP (Beta = 0.5, SE = 0.2 P = 0.05), after adjustment for age. There were no correlations among men.

Discussion: BMI was positively and independently associated with glycated hemoglobin and diastolic blood pressure among women with heart failure. There were no correlations with WHR.

Implications: BMI should be applied for patients with heart failure, whereas WHR is not appropriated for these patients.

757. POINT OF CARE (POC) MICROFLUIDICS-BASED TEST FOR THE DIAGNOSTIC OF DRY EYE

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Background: Diagnosis of dry eye and blepharitis is difficult and sometimes frustrating given the overlapping symptoms and signs, however appropriate therapy depends on proper diagnosis of the diseases. Due to the lack of standardized, efficacious diagnostic tests

for both conditions, there is a need for the development of objective parameters for the correct diagnosis and treatment of the diseases.

Objectives: Identify and validate protein biomarkers for the diagnosis of dry eye and blepharitis assessing the reliability of biomarker panel for discriminating the pathologies from tear samples.

Methods: Tears were collected from patients using a Merocel sponge, and analyzed by 2D-PAGE. Deregulated proteins were analyzed through expression/interaction networks. Validation of candidate biomarkers was performed using ELISA assays. Machine learning statistics were used to determine the accuracy of the biomarkers for the discrimination between study groups.

Results: Comparison of 2D-PAGE tear protein profiles for dry eye, blepharitis, and control individuals indicated changes in the expression levels of fifteen proteins. Network analysis of these proteins showed expression/interaction connections with other proteins revealing additional putative markers. A further validation study demonstrated the high diagnostic power of five biomarkers: S100A6, annexin A1, annexin A11, cystatin-S, and phospholipase A-2-activating protein.

Discussion: A panel of five biomarkers is able to correctly classify dry eye individuals with accuracy (AUC) higher than 97.9% (sensitivity ≥ 94.3%; specificity ≥ 97.6%). The same panel also permits discrimination between dry eye and blepharitis subjects, with a global correct assignment of 73.2%.

Implications for the health system/professionals/patients/society: To provide the society with a more objective, easier and cheaper Immediate Point of Care diagnostic for Dry Eye, and avoid health system congestion caused by pathology related in almost 30% of the visits to the ophthalmologists.

778. NOVEL DIAGNOSTIC SYSTEM OF LIMBAL STEM CELL DEFICIENCY DIAGNOSIS METHODS BASED IN THE DETECTION OF MUC5AC MRNA IN CORNEAL EPITHELIUM: LIMBOKIT

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Background: The method described herein constitutes a robust system for the early detection and for mild cases of Limbal Stem Cell Deficiency (LSCD) and for the corroboration of uncertain clinical cases.

Objectives: To evaluate a LSCD diagnosis method based on the detection of the MUC5AC transcript, by reverse transcription - polymerase chain reaction (RT-PCR).

Methods: Impression cytology was used to gather cells from corneal and conjunctival epithelium from the same eye. The presence of the *MUC5AC* transcript goblet cells in the cornea was determined by RT-PCR using a custom-designed primer pair and agarose gels.

Results: Our study included 59 corneal samples, together with their respective conjunctival samples for RT-PCR assays. The *MUC5AC* amplicon was detected in 56/59 (94.9%) corneal epithelium samples and 3 showed inconclusive results.

Discussion: The detection of the *MUC5AC* transcript in corneal epithelium is a highly specific and objective technique. Overall, these findings indicate that molecular analysis facilitates a precise clinical diagnosis of LSCD, thereby reducing the risk of surgical failure.

Implications for the health system/professionals/patients/society: It is important confirmation of previous LSCD to a cornea transplant to avoid undeliverable recurrence of the pathology after surgery optimizing transplant outcomes and costs. Provide doctors with a treatment monitoring system after cornea transplant. Evaluate the corneal pathological status before a surgical procedure or after prolonged use of contact lenses that could end in LSCD.

792. PROGNOSIS OF GLAUCOMA SURGERY FAILURE BY CUSTOMIZED GENE EXPRESSION PCR-ARRAY

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Background: Glaucoma is associated with increased intraocular pressure (IOP) generated by the impairment of proper drainage of aqueous humor of the eye. Conjunctival and episcleral scarring are the main limiting factor of filtering surgery.

Objectives: To validate a previously customized design PCR-Array for the expression analysis of genes related with the success and failure of glaucoma filtering surgery.

Methods: A total of 21 eyes from 21 patients (12 women and 9 men with a mean age ± standard deviation of 67.16 ± 5.94 years) with uncontrolled primary open glaucoma (POAG), treated with filtering surgery were enrolled. Surgical failure was defined as an IOP higher than 21 mmHg. Conjunctival epithelium samples were obtained from impression cytology after surgery. RT-PCR Arrays including 18 genes related with the prognosis of the surgery were used for analysis of gene expression profiles in patients with failure of glaucoma surgery in comparison with those with successful surgery. Correlation between gene expression pattern and the surgical success/failure was explored with the principal component analysis (PCA).

Results: Eleven patients showed successful filtering surgery (mean IOP 13.83 ± 3.71 mmHg), and ten patients showed surgical failure (mean IOP 23 ± 2.82 mmHg) both with mean follow-up of 18 months. Conjunctival epithelium gene expression analyses by using a customized design PCR-Array clearly discriminated the surgical success group from failure group.

Discussion: Conjunctival epithelium gene expression analysis with a predesigned PCR-Array is a suitable tool to use in the prognosis of success or failure of glaucoma filtration surgery.

Implications for the health system/professionals/patients/society: Knowing a patient´s prognosis may help identify cases with increased risk of failure, and thus adjust the therapeutic options.

874. HORIZON SCANNING OF GENOME-BASED TECHNOLOGIES IN EARLY WARNING AND AWARENESS SYSTEM (EAAS)

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Background: In some countries, such as the US, the development of genome-based tests is monitored by Horizon Scanning activities. Is this a new class of health technologies that warrants specific attention, and are Early Warning and Awareness Systems (EAAS) focusing on this technology? This question is posed in the context of the development of best practice guidance on identifying and assessing genomic technologies for public health.

Objective: To describe current practice on horizon scanning of genome-based technologies (GBT).

Methods: A literature search was carried out in PubMed. An online survey consulted members (n = 20) of the International Network, EuroScan, on horizon scanning for GBTs. Preliminary results (60% response rate): Seventy-five percent of EAAS scan for GBTs, and mainly through their routine scanning activities. Two EAAS also identify GBTs through project-based scanning. For four systems scanning for GBTs is not a priority area. Three-third of the systems is interested in identifying tests to be applied at population and individual level. One system currently only identifies tests that can be applied at the population level. Three-third of systems is most

interested in identifying pharmacogenomics tests, followed by tests for prognosis of diagnosed disease, and for risk assessment for future disorder. Three-third of the systems are interested in identifying tests relating to all types of diseases (common and rare), one system only scans particularly for monogenetic diseases. The systems prioritize genomic tests on the same basis as other health technologies (or diagnostics).

Discussion: Identification of genome-based technologies does currently not differ from that of other new health technologies by members of EuroScan. This is different from the US, where focused scanning practices was developed at the Center for Disease Control. This might be explained by the fact that in the US, there is no longstanding tradition of Horizon Scanning for new health technologies, as there is in the member of EuroScan.

897. MEDICARE'S 2012 NCD LIST: WILL CMS FOCUS ON PATIENT-CENTERED CARE FOR ONCOLOGY?

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Background: Medicare's plans to update its 2008 Potential National Coverage Determination (NCD) List. The Centers for Medicare & Medicaid Services (CMS) intended to issue quarterly updates, yet no updates have been made since 2008. In September 2011, CMS requested that stakeholders weigh in on how to revise the list. CMS plans to post a revised list after its review of public comments, which were due November 2011.

Objective and methods: We conducted an analysis to identify the potential items and services likely to be on Medicare's radar for an NCD in 2012. We reviewed eight prominent sources whose reviews or topic lists correlated with past NCDs and therefore may relate to Medicare's NCD horizon scanning. Derived from publicly available sources, we characterized topics that CMS could open a NCD on in the future.

Results: We compiled a list of the items and services identified by each source, generating a list of over 80 potential topics. Of these 80 topics, about 25% were oncology related. Of the oncology-related items and services, nearly 50% were related to genomics and personalized medicine. The topics that appeared most frequently across all sources were: screenings for prostate and lung cancer; treatments for localized prostate cancer; therapies in the management of non-small-cell lung cancer; and pharmacogenomic testing for breast and colon cancers.

Discussion and implications: The analysis shows that while the 2008 list did not place a heavy emphasis on oncology, recent changes to the oncology healthcare landscape are likely to influence CMS' decision making in 2012. We based this conclusion on the influx of many new and high-cost oncology therapies; the existence of more than a hundred molecular tests to better target oncology care; and the rapid growth of new cancer chemotherapy agents (an estimated 400) in development.

905. PROFILE OF REQUESTS IMIPRAMINE FOR THE TREATMENT OF NEUROGENIC URINARY BLADDER

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Background: The neurogenic urinary bladder (NUB) is the loss of normal bladder function. Anticholinergics are indicated as first-line treatment, however, drugs with low efficacy and safety have been used as adjuvant therapy, for example the anti-depressant drugs, particularly imipramine (IM).

Objectives: To describe the IM requests for treatment of NUB to the Secretary of Health of Ceará - Brazil (SESA-CE) in the period of 2010 to 2011.

Methods: Study of drug utilization. Data were collected from the requesting for the treatment of NUB. The collected variables were: type of procedure, sex, age, clinical diagnosis, cause of injury, method of bladder emptying and prescription drugs.

Results: We evaluated data from 11 cases, 91% administrative. About 63% of patients were male, mean age 39.7 years, the principal diagnosis its neurogenic bladder secondary to paraparesis or sequel of trauma. The first cause of spinal cord injury its myelodysplasia. The bladder catheter was described as a method of emptying the bladder in 72% of cases. The numbers of medications required ranged from one to seven (mean 4.1) and the daily dose of IM ranged to 25 mg a 225 mg. The IM was associated with another drug for the NUB treatment in 82% of cases, the most frequent drug association it´s oxybutynin. Two cases described IM as monotherapy.

Implications for the health system/professionals/patients/society: The findings suggest large variability in the institution of pharmacological treatment for NUB. In this study it wasn't possible to observe a relationship between treatment and type of injury. It is necessary to monitor patients for adverse reactions and identify treatment options more effective and safety.

920. CAN PROGNOSTIC TOOLS BE USED TO ESTIMATE MORTALITY RISKS?

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Balancing rising healthcare costs while considering quality of care and equity is a formidable challenge and this has given rise to the development of new prognostic tools for estimating mortality risk. The question remains where such tools could be considered for use by clinicians and/or funders to assist in decision-making. The tool that is evaluated is ePrognosis online tool which was developed by University of California-San Francisco. It holds a series of published geriatric prognostic indices that can provide evidence-based -information on mortality risks. This newly-developed tool was analyzed and a few sample cases of patients were run through the tool to determine the mortality risk results and the applicability of these results to decision-making. Limitations and strengths of the tool were also determined by these case studies. The tool contains 16 indexes for estimating mortality risks and the choice of use of any of these indexes is dependent on prediction accuracy, model generalizability, usability, clinical efficacy and timeframe. By selecting specific cases of elderly patients, the tool was able to predict the mortality risks (with caveats) and in the process be able to inform the clinician on the next pathway of care (e.g. either the need for additional drug therapy or palliative care or surgery). Though other factors need to be considered alongside (such as ethics, patient's preference, societal values), the tool does provide insight into the need for specific type of care given the patient's mortality risk. Consideration might be given to using this tool for decision-making by clinicians. However, given the limitations of the tool and the wide patient characteristics, it should not be used for funding decisions at this time.

930. AN EDUCATIONAL GUIDE FOR ADULTS AND YOUNG PEOPLE WITH TYPE 1 DIABETES

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Background: The correct education of DM1 patients is vital to ensure appropriate control of the disease. In order for this education to be valid, however, it must be adapted to the characteristics and circumstances of the target patient.

Objectives: To provide adults and young people receiving intensive treatment for type 1 diabetes with a guide to help them take control of their disease in a Spanish cultural and social context.

Methods: On the basis of the wide-ranging clinical experience of the professionals involved and a comparison of their experience with the most up-to-date scientific evidence contained in the clinical practice guideline "Management of diabetes mellitus type 1", which was published in Spain in 2012, a multidisciplinary expert group in diabetes education and the clinical management of patients with diabetes mellitus type 1 has brought together the most important educational aspects for adults and young people in a Spanish context.

Results: This educational guide promotes the understanding of type 1 diabetes from a very basic to a more advanced level, covering the most basic aspects of treatment as well as specific aspects related to pregnancy, leisure activities, oral hygiene, food labelling and current legislation.

Discussion: The education of DM1 patients includes aspects that are common to all contexts (insulin treatment, metabolic goals, etc.) as well as others, such as diet, leisure activities, current legislation, etc., that need special effort in order to be applied to each specific context.

Implications for guideline developers/users: This educational guide will become an important support for daily life and will therefore increase the independence of adults and young people with diabetes mellitus type 1 in a Spanish context.

41. HTA HAND IN HAND WITH PROCESS EVALUATION TO ASSESS IMPACTS AND OUTCOMES OF A SCREENING PROGRAMME

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Introduction: In the Swiss health policy system providers of new medical technologies may apply for reimbursement. The application for coverage they have to hand in requires a full HTA report furnishing evidence of clinical effectiveness, appropriateness and cost-effectiveness. For this reason Swiss government has released an HTA Handbook. The implementation of a screening programme embraces more than an introduction of a medical technology. The providing of a medical technology happens in well-rehearsed clinical settings. A screening programme however proceeds in new organisational structures in multiple political context. Moreover it aims population centered targets for the benefits of patients. *Question:* How to assess outcomes and population centered targets of a screening programme which takes place in new organisational setting?

Results: Methods to assess population centered targets and outcomes from implementation processes are known from the policy evaluation field. In the admission request for health funds coverage the evaluation concept for the implementation of the systematic Colon Carcinoma Screening Programme (CCP) shows how methods triangulation of HTA and policy evaluation can meet the requirements of Swiss health policy.

Conclusions: HTA has to develop further and to open the conventional HTA methodology into policy evaluation criteria when technology includes an implementation process with population centered targets in political contexts and new organisational structures.

98. ELECTRIC VENTILATION: PRELIMINARY RESULTS OF DIAPHRAGMATIC PACING STIMULATION IMPLANTATION

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Background: Most patients with high cervical spinal cord injury (SCI) are dependent on mechanical ventilator support. Associated significant complications, mainly respiratory infections, lead to decreased life expectancy. In the United States, yearly health care expenses of ventilation dependence costs over US$ 170.000. Diaphragm pacing stimulation (DPS), named electric ventilation, stimulates motor nerves of the inspiratory muscles to produce inspiration. This new technique is designed to replace or reduce the need for mechanical ventilation through natural negative-pressure ventilation with the patient's own diaphragm.

Objectives: To evaluate the effectiveness of the NeuRx (Synapse BioMedical, Oberlin/USA) as a substitute for mechanical ventilation in a series of tetraplegic patients with high cervical SCI. To the best of our knowledge those are the first cases of DPS in Latin America.

Methods: Five long-term ventilation dependent patients were assessed by electroneuromyography, ENMG. They had a single laparoscopic implant of the diaphragmatic phrenic nerve pacing in October and November 2011 at the Heart Institute (InCor-HC/FMUSP), Hospital das Clínicas, São Paulo University Medical School. A multidisciplinary team ensure home or hospital care.

Results: Five patients, 2 males, average age 28.8 ± 9.2; level SCI C3(N = 2), C2C3(1), C4(1) and C4C5(1); average time under complete dependence of ventilation from 1 to 14 years; with at least some Phrenic ENMG response, except for one patient with partial dependence. Three months after the implantation three patients are off mechanical ventilation and another can stay off over five hours daily. The fifth patient is still conditioning the diaphragm.

Discussion: Although the long-term follow-up is necessary to get definitive conclusions, the early results have been promising, since some studied patients can stay long periods off mechanical ventilation now.

Implications for the health system: DPS may solve Mechanical Ventilation dependency for well selected patients, where no previous alternative existed.

409. CONDITIONAL COVERAGE WITH EVIDENCE GENERATION FOR SURGICAL TREATMENT OF HIV-ASSOCIATED LIPOATROPHY IN SPAIN. RESULTS AFTER TWO YEARS OF FOLLOW-UP

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Background: On March 2010 the Spanish Ministry of Health decided the public coverage of surgical treatment of facial lipoatrophy for HIV-AIDS patients under a research protocol to evaluate their

long-term safety and effectiveness in order to overcome limitations of available evidence regarding those treatments.

Objectives: Assess safety and effectiveness information of surgical treatment of HIV-associated facial lipoatrophy produced within a monitoring study of conditional coverage with evidence generation in Spain.

Methods: Prospective observational study. The study design and final protocol was elaborated by a Committee of Experts. HIV patients with moderate to severe facial lipoatrophy, asking for treatment and giving informed consent, are considered for inclusion. Surgeons perform the treatment under ambulatory or short hospitalization basis, with follow-up visits scheduled at 1, 12, 18 and 24 months. A web application is available for recording clinical data, surgical intervention and follow-up data (adverse events, lipoatrophy grade, patient subjective assessment, QoL and photographs).

Results: Twenty two hospitals from 11 autonomous regions are participating. Until December 2011, 1,110 patients have been included. 41.9% of those patients showed a degree III (severe) in facial lipoatrophy pre-treatment. A total of 898 patients have been treated with the fillers that were recommended in the protocol: 55% with autologous fat or polyacrylamide gel and 45% with biodegradable fillers. Patient's self-perception of disease impact assessed by a visual analogue scale changed from 7.80 at baseline to 2.28 at one year follow-up ($p < 0.05$). Only adverse events of minor severity have been reported (edema, pain, eritema, injection site bleeding).

Discussion: The conditional coverage with evidence generation is being useful to provide valuable clinical information in Spain. It permits both patients to have access to a new intervention and to produce additional evidence based on real clinical setting prior to adopt definitive decisions on coverage.

495. CRITERIA TO SELECT AND PRIORITIZE HEALTH TECHNOLOGIES REQUIRING ADDITIONAL EVIDENCE GENERATION

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HAS. France.

Background: Evidence gaps identified during health technology assessment are one of the major obstacles to ensuring timely access to new health technologies. "Access with evidence generation" (AEG) mechanisms, allowing temporary access to promising technologies while concurrently requesting the generation of additional evidence, have therefore been developed. However, AEG mechanisms imply setting up resource and time consuming studies. The process for selecting the most valuable technologies for further research is often informal and varies from one health care system to another. Objectives: One aim of the Strand A of the EUnetHTA Joint Action 2010-2012 Work package 7 is to develop a set of selection/prioritization criteria that should: - help select, among several technologies in need of additional evidence generation, those that are really worth performing complementary studies - support transparent decision making - be applicable in different health care systems.

Methods: The development of these criteria was based on a literature review, surveys of WP7A partners and consultation of key people.

Results: The process of selection/prioritization of health technologies requiring additional evidence generation consisting of three steps (determining the importance of the disease and of the technology; identifying critical evidence gaps and determining the relevance and feasibility of additional data collection) has been defined. Nine most relevant elements were identified from this process and a list of 9 criteria based on these information elements has been created. The criteria have been split in two groups: primary ones, exclusive, that determine the eligibility of a technology for ADC, and secondary ones that allow further selection and prioritization. The secondary criteria may be weighed and vary according to national/regional context.

Conclusions: Selection/prioritization criteria for health technologies requiring additional evidence generation are of outmost importance for HTA doers. The developed criteria should enable the best use of limited resources and improve the transparency of decision making.

690. OPPORTUNITIES TO PROMOTE EFFECTIVE AND INNOVATIVE CARE PRACTICES DURING NORMAL CHILDBIRTH CARE IN SPANISH NATIONAL HEALTH SYSTEM (NHS)

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Background: The Clinical Practice Guideline (CPG) for normal childbirth in the Spanish National NHS (developed by 21 multidisciplinary professionals together with three female charity representatives) makes various recommendations as regards to eliminating clinical procedures that are unsafe or of little usefulness and others that promote effective health-care practices.

Objectives: To identify opportunities for promoting effective and innovative health-care practices that are not widespread in Spanish hospitals.

Methods: We developed a survey with 33 questions classified into six areas (hospital admission, first, second and third stage of labour, analgesia and monitoring) related to the main recommendations of the CPGs for normal childbirth in the Spanish NHS. This survey was submitted anonymously to 1,107 professionals in July 2011 via the Spanish Associations of Midwives and Gynaecologists. The cumulative responses were collected in October 2011. Herein we describe the degree of compliance with the effective intrapartum care practices recommended in the CPG -'Do it'-.

Results: 629 (57%) hospital professionals answered the survey, however only 388 (35%) provided information regarding the type of institution (public and private) in which they work. On the basis of all responses ($n = 629$), this study shows a low degree of adherence (< 60%) as to the use of analgesia other than traditional epidural analgesia and the freedom to choose the birthing position. When comparing by hospital type ($n = 388$), statistical significance was reached in the "childbirth professional" profile, the use of non-pharmacological analgesia and non-traditional epidural analgesia.

Implications: This study of the degree of compliance with evidence-based recommendations has effectively identified areas for improvement with regards to patient-oriented-outcomes. In Spanish hospitals, particularly in private institutions, it has identified several opportunities for improving the quality of childbirth by expanding the supply of various innovative analgesic practices and. increasing the choices of options for mothers.

695. THE NECESSITY OF ADHERENCE TO EVIDENCE-BASED RECOMMENDATIONS REGARDING THE USE OF INFLUENZA VACCINES IN ASTHMATIC CHILDREN

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Background: The clinical practice guideline (CPGs) for management of asthma in the Basque Health Service (2005) does not recommend

the administration of influenza vaccines in asthmatic children. In contrast, however, many countries (including Spain and the Autonomous Community of the Basque Country) recommend its administration in at-risk populations such as asthmatic children.

Objectives: To update and evaluate the evidence published since 2005 regarding the prophylactic use of the influenza vaccine in paediatric asthma patients using the GRADE method, and to determine whether the previous guideline recommendation need to be modified.

Methods: In order to update the questions a search for CPGs and systematic reviews (SR) published since 2005 was conducted, and for the primary studies published since the last selected review. A working group consisting of 12 professionals (paediatricians, pneumologists, GPs, pharmacists, nurses and methodologists) and the parents of children with asthma surveyed at primary and specialized care defined and weighted the importance of the outcomes. The synthesis of the evidence and the assessment of the quality of studies were carried out following the GRADE system.

Results: Neither of the guidelines selected establish *asthma* as an indication for influenza vaccination. The SR (2008) selected in the updated search shows that, although the vaccine appears to be safe, there is no evidence of a decreased number of exacerbations in asthmatic children. Indeed, although the quality of life of a small number of children with exacerbations confirmed by influenza infection may improve slightly, its clinical repercussion remains unclear.

Discussion: The evidence available to date does not support prophylactic administration of the influenza vaccine in asthmatic children to reduce exacerbations. In light of this, health strategies that adhere to evidence based recommendations regarding the use of these vaccines in paediatric asthma patients should be implemented.

936. OTHER CAUSE OF HEALTH JUDICIALIZATION IN BRAZIL: AMBULATORY AND HOSPITAL PROCEDURES

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Brazilian Federal Constitution in 1988, the State assumes the responsibility for ensuring the health of its population, making it a fundamental right. Under the constitution, the citizen's access to positions of power was also expanded with the opening of the individual and collective judiciary demands, providing a favorable environment to the judicialization's phenomenon. In 2011, 240,980 health care processes were accounted by the CNJ. There are many studies about drugs' judicializaton, but few of them talk about ambulatory and hospital procedures. These can be, from actions of transport for treatment, to appointments, therapies, surgeries, exams and invasive surgeries of high complexity. The study of these demands can amplify the scope of health care's evaluation, about the difficulties care access and coverage attendance as a set of actions that should comprise the comprehensive care. This study investigates the lawsuits to the execution of ambulatory and hospital procedures about their coverage and accessibility, describing the profile of lawsuits against the Minas Gerais Secretary of State for Health from 1999 to 2009. It is a descriptive quantitative study. The classification of procedures is referenced in Unified Table of Procedures of SUS and CBHPM Table. The statistical analysis includes the distribution of absolute and relative frequencies, amplitude and average. It shall use the Pearson χ^2 test, with a significance level of 5%. Preliminary results indicate that in 6112 suits filed in the period from 1999 to 2009, 982 (16%) are related to ambulatory surgical procedures. It was identified 259 types of procedures, which 158 (61%) are covered by SUS. These are categorized into the following groups: surgical (50%), diagnostic purposes (30%) and clinical procedures (20%). The other 101 (39%) types were not found in the table. It suggests that they are not coveraged by SUS and may be related to the incorporation technology.

53. AWARENESS OF PHYSICIANS TO USE THE HEALTH TECHNOLOGY ASSESSMENT IN THE PRACTICAL ACTIVITIES

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Background: Rational use of health resources to provide quality, timely, equality access and the strengthening and protection of public health remains a priority in the Republic of Kazakhstan. The participation of stakeholders in the evaluation process at all stages can improve the efficiency and applicability of the HTA. An important key to the success of science-based health policy-making process is to exchange experiences and knowledge between those who hold and those who use the results of the HTA.

Objective: To determine the level of preparedness of the physicians to use HTA report in practice.

Methods: Questionnaire was conducted among 240 respondents in Almaty and Astana. Experience in public health among physicians with the highest category in Almaty 36.7% ($p < 0.05$) and no categories in Almaty 8.1%. Consequently, physicians in this category have sufficient experience in the profile of its private activities, which, given the availability of expertise in the management of health care provide a basis for their effective involvement in the evaluation of medical technologies. Respondents the first category Astana 24.4%, believe that the use of new medical technologies will improve the reputation of the clinic, the opposite opinion have the same category in Almaty 50.0%. The physicians of the highest category in Almaty application of new medical technologies will improve the reputation of a physicians.

Conclusions: Physicians don't quite understand, realize the impact of HTA on the competitiveness of the clinic, although there is a tendency of thinking about the fact of the competitiveness of the market for medical services. There is a positive trend among young physicians with good English, and applying Internet resources, their understanding of the need for the introduction of medical technologies in the clinic, which creates the possibility development HTA through capacity building and strengthening of basic knowledge in the field of EBM.

130. STAKEHOLDER ENGAGEMENT IN BRAZILIAN HTA RESEARCH: LESSONS FROM THE MINISTRY OF HEALTH

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Background: Since 2005, the Ministry of Health (MoH) supports HTA research by Brazilian institutions. At the same time and so far, we have developed activities to bring stakeholders with research methods and/or results in order to strengthen the Brazilian Network for HTA (REBRATS).

Objectives: To describe the activities developed in 2011 by the MoH with previous supported projects (2005-2010) to engage stakeholders in Brazilian HTA research.

Methods: For monitoring activities we organized a large meeting of two days and two rooms through the HTAi 2011 in Rio de Janeiro. For dissemination activities we provide a structured abstracts book based in INAHTA Briefs and for ongoing studies.

Results: We performed nine intensive parallels meetings with 111 stakeholders and 44 projects: cardiology (4 projects); drugs (4); health technologies (11, in two meetings); oncology (3); tuberculosis (4); viral hepatitis (4) and women and child´s health (14, in two meetings). The HTA researches structured 71 abstracts, which may be combined by conditions (the most frequent): infectious diseases (14 studies); cardiology (13); oncology (11). By material nature: drugs (22); organizational systems (19); devices (16). By purpose or application: treatment (31); diagnosis (25). By study type: economic evaluations (22); epidemiology designs (17); systematic reviews (14) and descriptive (14). 31 ongoing studies were also summarized.

Discussion: The parallels meeting themes and the Brazilian briefs book reflect the epidemiology burden and the market pressure in the country. On the other hand, the great number of economic evaluations may be a consequence of the legal requirements of health system decision in previous years. Both activities increased the stakeholder's interest in Brazilian HTA Program, but their impact in modifies decision making is difficult to measure.

Implications: More resources to support Brazilian HTA research are needed to strengthen the relationship between stakeholders and REBRATS.

148. HTA IN THE CZECH REPUBLIC: WHO SUPPORTS IT?

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Objectives: With respect to the experience from healthcare reform policies in many developed countries (e.g. Germany, the Netherlands), a tendency to implement the value-for-quality and evidence-based principles in the decision-making process seems to prevail, while introducing and/or restructuring health technologies. Health technology assessment (HTA) that represents a complex advisory tool for such decisions is not broadly used in the Czech Republic. Furthermore, the demand for analyses of this kind does not appear to be large. One of the explanations can be that some powerful actors in the healthcare sector try to block the introduction of HTA. However, in reference to the EU Directive on the application of patients' rights in cross-border healthcare (2011/24/EU), all member states shall establish a HTA agency aiming at creating a health technology assessment network. The aim of the paper is (1) to identify principal actors in the Czech healthcare sector, (2) to reveal their economic interests, and (3) to evaluate their support towards the HTA issue.

Methods: First of all, the authors analyse, how the Czech healthcare system has been dealing with the challenge of incorporating the HTA into the decision-making process. Second, the key health care actors are identified. For doing so, the authors use the reputational method. Finally, in order to specify the level of key actors´ support to the HTA issue, their positions are examined in a series of structured interviews.

Results and conclusions: The paper is based on the belief that any change in the healthcare sector can be successfully implemented only if the key actors support it, and if their interests are, in a long-term perspective, balanced. The results of this paper quantify the support given to the HTA issue by key actors in the Czech healthcare landscape, and thus provide strategic information for Czech healthcare policy makers.

239. HEALTH TECHNOLOGY ASSESSMENT OF THE ANTI HCV STRATEGIES IN ITALY: EVIDENCES FROM THE WEF PROJECT

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Background: Hepatitis C usually takes over a decade to progress. A high percentage of patients with chronic HCV also contract cirrhosis, and around 5% every year will develop liver cancer. These complications, in addition to the highly disabling effects of the disease on patients, mean that hepatitis C has a significant economic impact on the NHS. The prevalence of the disease in the population at risk in Italy is 9-10%, with most cases occurring in the south. Early detection of HCV is the best way to improve patients' quality of life and rationalize health-related investments, given the disease's long preclinical phase, the availability of treatments that can improve prognosis and the high prevalence in the target population.

Objectives: The aim of this study was to provide an HTA of an anti-HCV screening program in the Italian NHS.

Methods: A multi-stakeholder round table was conceived involving clinicians, patients, organization experts, economists, epidemiologists and bioethicists. The discussion basis was a two-arm Markov model which was designed by following the indications of the round table as well as literature information. Results were considered in terms of incremental cost per QALY gained. We performed a univariate and a multivariate sensitivity analysis to explore the effects of variations in the key parameters on the model's results.

Results: The screening strategy ICER is € 4008.97/QALY. This value is acceptable, as it is lower than the threshold underlying NICE's decisions and it is considered consistent with the ethical values of the Italian SSN. According to the Monte Carlo simulation, ICER remains below £40,000/QALY in 99% of scenarios.

Conclusions: The anti-HCV screening program is a valid health-related investment for high risk populations, improving patients' quality of life and survival with an acceptable expenditure increase for the SSN.

271. ESTABLISHING LOCAL PRIORITIES FOR A HEALTH RESEARCH AGENDA

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The Peninsula Collaboration for Leadership in Applied Health Research and Care (PenCLAHRC) has been running for over two years, in which time it has implemented a HTA style question prioritisation process to enable service users and clinicians to become more involved in health services research. The prioritisation process has three aims: (i) to ensure that the questions posed are relevant to health care practice and the service user experience, (ii) to build capacity in NHS staff to be engaged with and understand evidence based practice, and (iii) to facilitate faster implementation of research findings into practice in the local NHS. The aim of this presentation is to describe our experiences of implementing this strategy in a localised setting (including how we engaged with a variety of

stakeholders), and to share examples of projects that have gone through the process to form various pieces of research or implementation. We will also discuss what the future might hold for a localised strategy such as ours in the prevailing economic, and health research climate, highlighting the barriers and resolutions that developed along the way.

321. A SYSTEMATIC REAPPRAISAL OF HEART FAILURE CLINICS (HFC) EVIDENCE USING THE GRADING OF RECOMMENDATIONS, ASSESSMENT, DEVELOPMENT AND EVALUATION (GRADE) SYSTEM

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Background: Chronic heart failure (CHF) is the leading cause of hospitalizations worldwide in the population over 65 years. Annual hospital costs are of USD6'000.000 in the U.S. and €15'000.000 in Europe. Although cornerstone of CHF treatment is pharmacological, it has evolved into preventive management models, such as HFC, which try to reduce hospitalizations in this group of patients.

Objective: To systematically review reported impact of HFC on mortality, hospital admissions, quality of life and costs in order to decide implementation of this strategy in a tertiary level hospital of a middle income country.

Methods: Bibliographic search was conducted on October 2011 in the databases PubMed, Lilacs, Embase, Cochrane and CRD without limits of language. Only meta analysis and randomised controlled trials not included in founded metaanalysis were reappraised using the GRADE approach. 30 relevant results were founded, four of which were meta-analysis, two were RCTs not included on those metaanalysis and one was an economic model derived from a metaanalysis of RCTs. A soft table was created using GRADEpro3.5v. Epidat3.1 was used to pool data.

Results: Pooled Odds Ratios for mortality at 12 months and hospital admissions at 6 months, were 0.75 CI (0.68-0.82) and 0.68 CI (0.55-0.83) respectively. Quality of life according to Minnesota living with heart failure questionnaire improves at least 5 points when compared with conventional follow up. Costs also favor HFC by € 451 for patient by year.

Discussion: According to scientific evidence, and following GRADE approach, results of reappraisal are: global quality of evidence is moderate to high; results are consistent across studies; there is a net benefit on patients health as well on costs. Finally, a strong recommendation to stakeholders was made to adopt HFC model to follow up CHF patients in this population. Local clinical and economic assessments will be made to verify effectiveness in this middle income setting.

348. VALUES IN THE ADOPTION OF HEALTH TECHNOLOGIES: A SURVEY FROM THE 14TH NATIONAL HEALTH CONFERENCE

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Background: Health Plans for Brazilian Public Health System (SUS) are developed in a participatory manner at national conferences held every four years. In 2011 occured The 14th National Health Conference centered on the theme "Quality and access: challenges for the SUS".

Objective: To describe the views of delegates at the 14th National Health Conference about technology assessment criteria for the Brazilian public health system (SUS).

Methods: Survey applied at the Ministry of Health's exhibit booth, December 1-4, 2011. Three variables were studied to the survey: "Delegate Profile," "Time Engaged in Public Oversight," and "Knowledge of Health Technology Assessment for Adoption by the SUS".

Results: The survey encompassed 11.5% (502/4370) of all conference attendants. Of these, 43.6% represented citizens/patients; 33.6% health professionals; 13.1% policymakers; 3.8% service providers and 5.9% others. The majority have been active in oversight of the SUS for more than five years. The values in the adoption of health technologies were ranked by delegates as follows: improved quality of life and patient survival (60%); evidence on the effects of prevention, diagnoses, treatment or rehabilitation (49%); evidence on patient safety (46%); impact on the population's health (43%); relationship between benefits and costs (40%). Health system costs and patient costs were ranked next to last and last, respectively.

Conclusions: Considering the results, the patient-centred system is feasible in Brazil. The Brazilian Health Technology Assessment Network (REBRATS) should value the perspectives of patients and health professionals as an additional contribution to the application of Law No. 12401/2011, through which the National Commission for the Incorporation of Health Technologies is established.

612. TRENDS IN ALZHEIMER-SPECIFIC DRUG CONSUMPTION IN THE BASQUE COUNTRY

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Background: Alzheimer's disease (AD) is a progressive non-reversible brain disorder and the most common form of dementia. Indeed, in 2007 AD caused 2.6% of all deaths in Spain, with this rate being slightly higher in the Basque Country. As a result, AD has become an important health challenge. Although it cannot currently be cured, several palliative treatments are available.

Objectives: This study aims (1) to describe the prevalence of AD-specific drug consumption in real-world practice in the Basque Autonomous Community over the last five years; (2) to analyse the economic impact derived from their use and; (3) to compare this consumption within the Basque Country and with other existing data obtained in Spain and other European countries.

Methods: A retrospective study covering individuals who received at least one prescription of an AD-specific drug, such as Donepezil, Galantamine, Rivastigmine or Memantine (ATC codes: N06DA02, N06DA03, N06DA04 and N06DX01, respectively), between 2006 and 2011 is being conducted in the Basque Autonomous Community. To allow comparisons with previous studies, the statistical measures chosen for drug consumption are the DDD (defined daily dose) and the DHD (DDD per 1000 inhabitants per day). Data are being gathered from the pharmacy directorate of the Basque Health Service.

Results: Results are currently unavailable since study is underway. However, it is hypothesized that (1) there has been a significant increase in the use of AD-specific drugs over the past few years and; (2) the distribution of consumption will reflect differences within the three Basque regions.

Discussion and implications: An increased awareness of drug consumption could contribute to reducing variability within medical practice and minimising inequalities in the delivery of clinical care. Furthermore, knowing the costs derived from these treatments will provide a partial yet important estimate of the economic impact of Alzheimer's on the Basque Health Service.

849. INTERNATIONAL PARTNERSHIPS TO IMPROVE HEALTH TECHNOLOGY ASSESSMENT TRAINING IN BRAZIL: EMPIRICAL EXPERIENCES FROM THE BRAZILIAN NETWORK OF HEALTH TECHNOLOGY ASSESSMENTS (REBRATS)

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Background: The use of evidence-based information by decision markers and health professionals is still limited in Brazil. As a result, in last decade, the Brazilian Ministry of Health (BMH) has developed several actions to improve Health Technologies Assessments (HTA) to support strategic decision-making and planning for public health system. Among several strategies applied so far, there was the establishment of the *Brazilian Network of Health Technology Assessments* (REBRATS), a national network composed by teaching hospitals and other health-related institutions with the main purpose of enhancing both HTA training and use of HTA. As a part of the REBRATS, the private Hospital Alemão Oswaldo Cruz (HAOC) has engaged several activities to promote the dissemination of HTA in Brazil.

Objective: To document our empirical experience with the dissemination of HTA in Brazil.

Methods: Private non-teaching hospital holding a nation-wide training course in HTA for health professionals at several levels of public health system.

Results: Implementation of a training course of HTA for health professionals developed in cooperation with the Institute for Clinical Effectiveness and Health Policy (IECS) from Argentina and BMH. Eighty professionals engaged in the public health system attended to a training course characterized by both distance learning and face-to-face classes. A Master of Business Administration (MBA) focused on Economics and HTA, developed in partnership with the Foundation Institute of Economic Research (*FIPE*) along with BMH. Thirty students attend to this course, which is in its ongoing phase.

Conclusions: Our experiences highlight major issues around the dissemination of HTA in a developing country: lack of basic knowledge of epidemiology and evidence-based medicine and challenge of integrating different perspectives and organizations to perform HTA. The anticipation as well as strategies on how to overcome these problems are likely to be of interest for similar initiatives in other developing countries worldwide.

28. ACCESSING HEALTH CARE IN A FISHING COMMUNITY: AN EXPLORATORY STUDY OF ADA KOFE COMMUNITY IN THE TEMA METROPOLIS, GHANA

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Access to health care for indigent population in Ghana remains a challenge despite introduction of the National Health Insurance Scheme (NHIS) in 2004 to address the problem of financial barriers to health care access. The situation is worse in rural settlements where there are inadequate or lack of health facilities and health care professionals. The Ada Kofe community is a fishing community in the Tema Metropolis with most of the inhabitants fully engaged in fishing as their source of livelihood. The community lacks primary health care facility and as result inhabitants face geographical and financial difficulties when accessing health care. The study aimed to explore access to health care services in Ada Kofe community. Household survey was employed to collect data on health insurance cover, usual source of care, and other barriers to health care access in the community. The results showed NHIS coverage of 44.7%. Although most households had usual place of ongoing care, 56.7% specifically used hospital OPD outside the community for their health care needs. This creates financial and geographical difficulties which in extreme cases may lead to avoidable deaths. About one-third of households faced variety of barriers when accessing health care in the community due to lack of health care facilities and health insurance cover. More than half of the households in the community do not have health insurance cover. Moreover, the community lacks primary health care center and as a result household members travel outside the community to access health care. An establishment of NHIS registration centre in the community will increase enrolment and facilitate access to health care. Provision of community health centre will also help remove some of the financial barriers households faced when accessing care.

42. EVALUATING THE QUALITY OF LIFE OF DIALYSIS PATIENTS IN ANEMIA TREATMENT

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Background: Anemia is the most common abnormality found in chronic kidney disease (CKD). It's more severe in dialysis patients, in which the disease is advanced. It increases the morbidity and the mortality of CKD patients and it's also responsible for their reduced quality of life. Anemia's main cause is the deficiency of erythropoietin. Its treatment is based on the administration of erythropoiesis stimulating agents. Nowadays, there are few and precarious studies about the quality of life of these patients.

Objective: This study sought to evaluate the health care professionals perception about the quality of life of dialysis patients using different erythropoiesis stimulating agents: *Continuous Eythropoietin Receptor Activator*, CERA and Epo-rHu (Recombinant Human Eythropoietin).

Methods: The quality of life was measured by interviews applied to health care professionals. The questions were elaborated and previously submitted and approved by the local ethics committee. The professionals had to answer questions about specifics health conditions in anemia treatment. The erythropoiesis stimulating agents compared were Epo-rHu (Recombinant Human Eythropoietin), and *Continuous Erythropoietin Receptor Activator*, CERA, in different scenarios that considered various frequencies of administration.

Results: According to the health care professionals interviewed, patients treated with CERA once a month must try on higher quality of life then those treated with Epo-rHu three times a week. The average quality of life assigned to the patients treated with Epo-rHu and CERA were respectively 6,3 and 7,8. The sample variance was small and the results confirm what was already reported.

Discussion: In the perception of health care professionals, anemia treatment with CERA is associated with some improvement in quality of life compared to Epo-rHu therapy. However, more studies with the patients must be done to check the preliminary results found with practitioners.

70. OUTLINES OF SEIZURE FREQUENCY IN CHILDREN WITH STRUCTURAL-METABOLIC EPILEPSY: A MALAYSIAN EXPERIENCE

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Background and objectives: Seizure free patients or substantial reduction in seizure frequency are the most important outcome measures in the management of epilepsy. The study aimed to evaluate the patterns of seizure frequency and its relationship with demographics, clinical characteristics, and outcomes.

Methods: A retrospective cohort study was conducted at an outpatient paediatric neurology clinic, included 120 children with structural-metabolic epilepsy. The recruited children were followed-up for one year since the first visit. The required data were extracted from the medical records.

Results: Seizure frequency showed no significant association with demographics, and clinical characteristic. However, significant reduction in seizure frequency from the baseline to the last follow-up visit was only seen in certain subgroups of patients including Malays, females, patients < 4 years of age, patients with global developmental delay/intellectual disability, and patients with focal seizure. There was no significant association between seizure frequency and rate of adverse events. Polytherapy visits were associated with higher seizure frequency than monotherapy visits (27.97 ± 56.66, 10.94 ± 30.96 attack per month, respectively) ($p < 0.001$). There was a clear tendency to get antiepileptic drugs used at doses above the recommended range in polytherapy (8.4%) rather than monotherapy (1.4%) visits ($p < 0.001$). A significant correlation was found between seizure frequency and number of visits per patient per year ($r = 0.450$, $p < 0.001$).

Conclusions: Among children with structural-metabolic epilepsy, Malays, females, patients < 4 years of age, patients with global developmental delay/intellectual disability, and patients manifested with focal seizure are more responsive to antiepileptic drugs therapy than other subgroups of patients.

82. BURDEN OF DISEASE ASSESSMENT WITH SUMMARY MEASURES OF POPULATION HEALTH FOR THE REGION OF VALENCIA: A POPULATION-BASED STUDY

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Objective: An important input to decision-making and health planning is a consistent and comparative description of the population health status. The purpose of this study was to describe the burden of disease in the Region of Valencia (Spain).

Methods: Disability-adjusted life years (DALYs) were calculated and divided into years of life lost (YLLs) and years lived with disability (YLDs). Using death registry data and Valencian population estimates in 2008, we calculated the number of deaths and YLLs. YLDs were based on age- and sex-specific data for countries of the EURO-A subregional level (which includes the Region of Valencia). The results were stratified by age group, sex and underlying cause of death. The DALY values were used to rank the leading conditions of disease burden.

Results: In 2008, the total number of DALYs lost was about 551,417 (293,906 men and 257,511 women). Non-communicable diseases explained 89% of the total DALYs. The main categories of DALYs lost were neuropsychiatric conditions (167.1 thousands of DALYs), malignant tumors (84.9 thousands), cardiovascular diseases (72.4 thousands) and sense organ diseases (46.0 thousands). Depression (46.8 thousands of DALYs), dementias (42.0 thousands), ischaemic heart disease (27.1 thousands), hearing loss (22.2 thousands), stroke (19.9 thousands) and lung cancer (19.4 thousands) were the leading specific causes of disease burden.

Conclusions: We provide for the first time ever information on the burden of disease in the Valencian population. At this local level, the use of DALYs can help to monitor the population health status and guide the debates on rational priority-setting.

169. OUTCOMES OF STROKE REHABILITATION

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Background: The high prevalence of disability after stroke and its high socio-economic cost makes necessary to optimize efficiency in the care of these patients.

Objectives: To analyze the effectiveness and efficiency of the rehabilitation treatment of patients after a stroke and to know which are the most influential variables in their functional recovery and destination on discharge.

Methods: We included all patients admitted in the Rehabilitation Services at two hospitals after a stroke over a period of eight months. The assessment includes the collection of demographic data, social risk (scale of Gijón), comorbidity (Charlson), neurological severity (NIHSS), functional assessment using the Barthel Index (BI), length of stay and destination on discharge. Analyses were performed using linear regression models and logistics.

Results: 241 patients were included. 93.3% of patients are in a situation of total or severe dependence on admission. The average stay was 35 ± 22 days and 81.5% of patients return home after hospitalization. The neurological severity was the variable that most influenced the treatment efficiency. Functional recovery was increased daily with a mean IB effectiveness of 0.9. The variables that most influence this effectiveness were age, degree of paresis of the lower extremity and the IB. The variables most associated with returning home included low social risk, comorbidity, and the IB.

Discussion: There are many variables that interfere with stroke rehabilitation, making it difficult to predict the effectiveness and efficiency of treatment. The identification of variables to predict the potential for recovery is important to stratify patient groups with homogeneous prognosis.

Implications for the health system/professionals/patients/society: A comprehensive assessment allows to identify the patient's prognosis for recovery, treatment goals and organize a plan for hospital discharge. Knowing the efficiency of our Rehabilitation Services is the basis for improvement strategies.

191. QUALITY OF LIFE AND SUBJECTIVE QUALITY OF WORK LIFE IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background: The number of MS patients is increasing worldwide. Most of them are in productive age, but they have limited options concerning active inclusion in the workforce. One can expect that increasing their quality of life (QOL) would reduce the unemployment due to MS.

Objectives: (1) QOL and subjective quality of work life (SQWL) analysis in patients with MS, (2) main aspects affecting the SQWL identification, (3) suggestion of steps to suppress MS patients inhibition and increase their willingness to work.

Methods: The Multiple Sclerosis Quality Of Life – 54 questionnaire and the questionnaire designed by the Institute of Sociology in Prague to detect a SQWL index in general population were used, filled-in by 237 and 199 patients respectively. The reasons for a low employment rate in MS patients were analysed in semi-standard interviews with 5 experts, and in a brainstorming session of a group of 16 MS patients.

Results and discussion: It was proved, that (1) QOL depends on the type of MS (relapsing-remitting MS 68%, primary progressive 57%, secondary progressive 53%, progressive-relapsing 43%). (2) A significant difference in the SQWL index was established between employed with MS (7.2 full-time and 9.5 self-employed) and the general population (5.8 and 8.5, respectively), where the MS patients show a higher index as the only alternative to the employment is the disability retirement. (3) The most important problems reducing QOL and productivity in MS patients were identified to be the character, fatigue, change in health, anxiety and depression, ignorance of the disease by the patient, and uninformed public.

Implications for patients and society: A handbook "Facts and myths about MS" was published that can help patients to cope with the issues related to MS, motivate them to find jobs, and provide arguments for discussions with employers, colleagues and/or family members.

218. AN ASSESSMENT OF THE IMPACT OF ANTI-TNF THERAPIES ON PRODUCTIVITY LOSSES DUE TO RHEUMATOID ARTHRITIS IN ALBERTA, CANADA

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Objectives: To assess the impact of anti-TNF therapies on the self-reported number of unable-to-work days and the change in weekly working hours among paid-work employees with rheumatoid arthritis (RA).

Methods: We analysed data of Alberta Biologics database, a prospective observational cohort of consecutive RA patients receiving anti-TNF therapies since January 2004. Patients reported their employment status during the last six months at baseline, at 3 months of treatment, and every 6 months thereafter. The impact of anti-TNF therapy was assessed by a trend analysis. All paid-work employed patients treated by anti-TNF therapies were followed up to compare the self-reported number of unable-to-work days per patient per year and the number of weekly working hours reduced by RA between before (baseline) and after (1, 2, and 3 years) the treatment using an one-sample t-test (significant level at 5%).

Results: Among 1041 anti-TNF patients in the database, there were 270 paid-work employed patients (34% male, mean age 48 years, and disease duration 12 years) at baseline. From them, 215, 176 and 129 patients were followed up and reported employment data at 1, 2, and 3 years after the first anti-TNF agent was initiated, respectively. On average, the annual number of unable-to-work days per patient reduced from 20 days at baseline to 8, 9, and 4 days at 1, 2, and 3 years, respectively. The corresponding numbers for the reduced weekly working hours were 4.2, 1.3, 0.9, and 0.5 hours. The differences were statistically significant between before and after (any year), but not among the years after the treatment.

Discussion: The number of unable-to-work days and the reduction in weekly working hours of employees with RA are positively impacted by treatment with anti-TNF therapies. The greatest improvements are in the first year of treatment but are sustained through the follow-up period.

219. ANTI-TNF THERAPIES HAVE A SIGNIFICANT LONG-TERM IMPACT ON HEALTH-RELATED QUALITY OF LIFE OF RHEUMATOID ARTHRITIS PATIENTS

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Objectives: To study the long-term impact of anti-TNF therapies on Health-Related Quality of Life (HRQOL) in rheumatoid arthritis (RA) patients. Data on this subject are limited due to the short duration of most studies.

Methods: The Alberta Biologics Pharmacosurveillance Program database includes consecutive RA patients starting anti-TNF therapy in the Province of Alberta from January 2004 to March 2009. Patients complete HRQOL questionnaires at baseline, 3 months, and every 6 months thereafter. The HRQOL is measured using EQ-5D (US value set). We estimated the mean EQ-5D score at baseline and then 1, 2 and 3 years. Statistical significance ($p < 0.05$) was assessed using one-sample t-test. The anti-TNF patients were divided into those who stayed on their first medication and those who switched to another anti-TNF (primary failures, change in agent within 90 days; secondary failures at any time point thereafter).

Results: At baseline, 663 patients had EQ-5D scores and for 432 patients EQ-5D was followed for 3 years. The mean age was 55 years (SD 14.6), 72% were female and the mean disease duration was 14 years (SD 11.1). The mean baseline EQ-5D score was 0.5253 (0.5372 for non-switchers (n = 288) and 0.5013 for switchers (n = 144)). The first, second and third year EQ-5D scores for non-switchers were 0.7866, 0.7874, and 0.7998, and for switchers were 0.7072, 0.6815, and 0.7241, respectively. Compared to baseline, all changes were statistically significant ($p < 0.001$). A significant improvement ($p < 0.001$) in EQ-5D scores was observed at 3 years for both primary failures (0.7645, n = 16) and secondary failures (0.7190, n = 128).

Discussion: Anti-TNF therapy for RA produced substantial HRQOL improvement that was sustained for three years. Patients requiring a switch in anti-TNF therapy had lower HRQOL at all time points compared to non-switchers. The difference between groups decreased significantly during the third year as these patients stabilized on effective therapy.

226. THE REGIONAL CONJUNCTIVECTOMY FOR EYE WHITENING OF RED EYE: SAFETY AND EFFECTIVENESS ASSESSMENT

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Objective: We aimed to accomplish the systematic review and evaluation of the Regional onjunctivectomy with postoperative Mitomycin (MMC) for eye whitening, especially with regard to the safety and efficacy.

Methods: A retrospective investigation of the medical records of 1,713 subjects diagnosed with regional conjunctivectomy was conducted from November 23rd 2007 to May 20th 2010, and a telephone survey was conducted on 557 of those subjects, who could be contacted and gave consent. Also, all the qualified studies regarding the Regional conjunctivectomy of conjunctival injection were systemically evaluated using available databases according to predefined criteria. A total of 1 literatures was included in final assessment.

Results: A total of 1,713 patients underwent regional conjunctivectomy. The diagnosis at the time of surgery included 8.8% hyperemia, 23.3% conjunctiva disorder, 14.0% pterygium, 3.5% dry eyes and 1.5% pinguecula. The diagnosis for the remaining 50% of the subjects was either not mentioned or the surgical procedure was for cosmetic purposes. The patients were followed for a mean of 10.9 months (median, 9.1 months). The total complication rate was 82.9%, of which severe complication rate was 55.6% (43.8% fibroproliferation, 4.4% scleromalacia, 13.1% intraocular pressure elevation, 6.2% calcification, 3.6% diplopia) and 28.1% reoperation rate. Because the degree of satisfaction was reported for only 411 out of the total 1,713 subjects, the satisfaction rate of 96.4% is not representative. Also, patients reporting sclera calcification also reported satisfaction with the outcome of the treatment. Thus, the index with respect to the effectiveness could not be used as a meaningful medical result.

Conclusions: Regional conjunctivectomy with postoperative MMC 0.02% (bevacizumab injection) can be useful to treat chronic hyperemic conjunctivae for eye whitening. The safety of the procedure has yet to be verified, evidenced by the high complication and reoperation rates, its use of drugs whose safety has not yet been verified and extensive logadectomy, which can cause sclera ischemia.

236. MEASURING PREFERENCES FOR TEMPORARY HEALTH STATES

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The EQ-5D is recommended by NICE's Diagnostics Assessment Programme for the measurement of preferences for health states. While consistent with methodology across other NICE programmes, little is known of its ability to estimate preferences for temporary health states (< 1 year in duration and transient). This study investigated how accurately the EQ-5D instrument's TTO value set, which uses long duration chronic (10 years and permanent) health state descriptions, was likely to estimate preferences for temporary health states. 28 participants valued multiple scenarios using the lead time TTO. All participants valued 1 week permanent, 1 week transient, 1 month permanent, 1 month transient and 10 years permanent descriptions for EQ-5D-3L states 11122 and 11133. The lead time TTO method was used to adapt the instruments used in the EQ-5D-3L TTO valuation study. Preferences were converted into health-related quality of life weights (HRQoL weights) for statistical analysis. Temporary health states resulted in significantly greater HRQoL weights for both EQ-5D states 11122 and 11133. The greatest difference between the 10 years permanent and the temporary health states HRQoL weight was 0.562 ($p = 0.000$) for state 11133 described as 1 week transient. The transient nature of a temporary health state was shown to increase the HRQoL weight for the health state over and above any change due to the short duration. Preferences for temporary health states are unlikely to be accurately estimated by the EQ-5D. A hypothetical cost utility analysis showed that, ultimately, imprecision in the measurement of preferences for temporary health states has the potential to impact the adoption of technologies within the healthcare system. Alternative methods, for overcoming the challenges of accurately measuring and reflecting preferences for temporary health states in health technology assessments, are discussed. This study aims to provide an illuminating extension to the continued debate around patient preferences.

253. SATISFACTION LEVELS OF USERS, PROFESSIONALS AND MANAGERS WITH THE ACTIONS FOR THE CONTROL OF HYPERTENSION IN REGIONS OF BRAZIL

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Introduction: The Ministry of Health of Brazil established a national system of care for hypertension within the Family Health Strategy. Completed 10 years still there is no clarity about their impacts and outcomes.

Objectives: To evaluate the degree of satisfaction of users, professionals and managers with the Family Health Strategy in the control of hypertension in municipalities in the Northeast of Brail, in 2010.

Methods: Three questionnaires were developed for agents: users, professionals and managers. The questions were structured in eight dimensions, which refer to the basic categories of attention to assessing the quality of health care services (Starfield, 2002): access, gateway, link, service, coordination, family focus, guidance for community and vocational training. Each dimension consisted of structured questions with answers in the Likert scale. To assess the degree of satisfaction among the three agents a composite index was constructed. Decision analysis of these indices were made by statistical tests.

Results: The profile of users was characterized by hypertensive elderly patients, and females with lower education. Satisfaction levels varied significantly among the agents. Users had an optimistic perception, even though their blood pressure levels were out of control.

Discussion: The main results point to a paradox: high levels of satisfaction among hypertensive patients with uncontrolled bood pressure. It is speculated that lower educational level does not contribute to a clear insight to critically evaluate the services that are offered. Professionals and managers seem unaware of the repercussions of their own services for hypertension.

Implications for the health system: To provide indicators of the effectiveness of health programs in the municipalities; to assess the impact of health policies aimed at hypertension; to provide a database for managers in planning and help with strategies to ensure the improvement of the accompaniments of hypertensive users.

257. COMPARATIVE EFFECTIVENESS OF WHOLE BRAIN RADIOTHERAPY VERSUS STEREOTACTIC RADIOSURGERY FOR NEWERLY DIAGNOSED BRAIN METASTASIS

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Objectives: To assess comparative effectiveness of whole brain radiotherapy (WBRT) versus stereotatic radio surgery (SRS) in patients with newly diagnosed brain metastases.

Methods: A retrospective cohort for patients who newly diagnosed brain metastases with primary site of lung or breast cancer and treated with WBRT or SRS in 2 hospitals during 2004-2010 were constructed based on chart reviews. According to radiotherapy modality, characteristics of patient, survival time and control rate were analyzed. Chi-Square test, Log-rank test and ANOVA test used to evaluate difference of various treatment modalities.

Results: A total of 1,559 eligible patients with brain metastases were composed of 1,289 (82.7%) treated with WBRT, 246 (15.8%) treated with SRS and 24 (1.5%) treated with WBRT+SRS. Among treated patients, most frequent primary tumor was non-small cell lung cancer(64.5%). Median survival times treated with WBRT and SRS were 12.7 months and 15.4 months for synchronous patients respectively, also 12.0 months and 14.6 months for metachronous patients respectively ($p < 0.01$). 6-month local control rate treated with WBRT and SRS were 92.5% and 75.6% for synchronous patients respectively, also 84.6% and 68.1% for metachronous patients respectively ($p < 0.01$). Nevertheless, survival time was higher treated with SRS than WBRT, 6-month local control rate for treated lesion was higher treated with WBRT.

Conclusion: The results of this study presented that SRS was done for patients having better prognosis compared to having worse prognosis, however WBRT is superior in terms of local control rate. In addition, more clinical researches including quality of life are needed.

258. TREATMENT PATTERN AND CLINICAL OUTCOMES IN REAL CLINICAL SETTINGS FOR RECURRENT BRAIN METASTASIS

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National Evidence-based Healthcare Collaborating Agency. Republic of Korea.

Objectives: This retrospective study aimed to evaluate treatments patterns and clinical outcomes according to radiotherapy modalities for recurrent brain metastasis in real clinical settings.

Methods: A retrospective cohort re-treatment patients due to progression or recurrence of brain metastasis with primary site of lung or breast cancer and treated with WBRT or SRS in 2 hospitals during 2004-2010 were constructed based on chart reviews. Survival time and local control rate were defined as period from initial retreated date to death date and recurrence at brain metastases lesions or intracranial brain in WBRT and recurrence at treated brain metastases lesions in SRS. According to radiotherapy modality, characteristics of patient survival time, local control rate and number of re-treatment were analyzed.

Results: A total of 307 eligible patients with recurred brain metastases were composed of 88 (26.8%) treated with WBRT, 113 (36.9%) treated with SRS and 105 (34.3%) treated with WBRT+SRS. Median survival times were 3.6 months, 5.9 months and 8.7 months ($p = 0.01$). 6-month local control rate were 97.0%, 96.8% and 98.7% ($p = 0.7$). Mean number of re-treatment of WBRT, SRS, and WBRT+SRS were 1.0, 1.6 and 1.5 respectively, and maximum number of re-treatment were 5 in SRS. Among patients who treated WBRT and SRS as initial treatments, 67.1% and 85.4% treated the same treatment as first treatment for recurrence, respectively.

Conclusion: Whereas the evidence for recurrent brain metastasis patients was not sufficient, this study result presented that retreatment with same treatment modality is common. Further research to develop guideline for re-treatment of brain metastasis is need.

266. RAPID ASSESSMENT METHODS APPLIED TO VACCINE EFFECTIVENESS EVALUATION. A USEFUL TOOL FOR POST INTRODUCTION COST-EFFECTIVENESS ANALYSIS

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Background: Vaccine effectiveness (VE) is a key input in vaccines CEAs, however the most used methods to evaluate it, like case-control studies, are costly and can take long time.

Objective: The feasibility of using cross sectional surveys as a rapid method to evaluate VE was assessed in Colombia.

Methods: Two population surveys were carried out on children < 2 yrs old living in populations where the vaccines were introduced (2009 for rota and 2010 for pneumococcal). A questionnaire was designed to establish vaccination status and the occurrence of syndromes potentially related to each pathogen (acute diarrhea for rotavirus and acute lower respiratory disease (LRD) for pneumococcus). ORs were obtained and interpreted as the risk of have been hospitalized by the syndrome of interest for each vaccine among exposed to such vaccine. VE was estimated as 1-OR.

Results: VE of rotavirus and pneumococcal was assessed in a probabilistic sample of 2140 children < 2 yrs. old from 5 cities, and 2116 children < 2 yrs. old from 4 cities, respectively. Children adequately vaccinated according to their age against rotavirus were 30% (6-67%) less likely to be hospitalized by acute diarrhea, and showed a smaller protection against any use of health service due to acute diarrhea (VE = 12%,0-27%). For pneumococcal, children adequately vaccinated were 32% (9-49,%) less likely to be hospitalized by LRD, and also showed a protection against use of health service due to same syndrome (VE = 25% (8-38%)). Each study was designed and executed in a period time of 5 months at a cost of USD$ 205,000 to rotavirus and USD$ 200,000 to pneumococcal.

Conclusions: Cross-sectional studies seems to be a valuable tool to conduct quick assessment of new vaccines effectiveness in developing countries at a reasonable cost.

303. THE STEPS TO EVIDENCE BASED DECISION MAKING IN SLOVENIA – PATIENT RELATED OUTCOME MEASUREMENT

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With financial crisis and support from Cross Border Directive which introduces HTA in Article 15 Slovenia is following ever more closely the evidence based decision making. The new protocols and regulation have been adopted for medicines and non-drugs products. In 2011 patient reported outcome measures (PROMs) were collected for four health care procedures. They were collected from all providers at the national level, for 20% of national programme. For the first time, quality from the patient perspective was measured and health gain

calculated after surgical treatment using pre and post-operative survey. EQ-5D instrument was used for quality measurements. Additionally, PATH project quality indicators were used for measuring quality of procedures, but those are not to be presented here. The four procedures were hip replacement, hernia, varicose veins and carpal tunnel release. OLS regression model was used to detect any differences among health care providers in quality of the procedures measured by EQ-5D. For each procedure, two dependent variables were regressed on the same set of independent variables. Both variables were defined as a difference of scores before and after each procedure. First version of the dependent variable was defined as the difference between self-reported VAS score, while the second variable was based on the Slovenian EQ-5D value. Results indicate that there are some differences in quality of care among health care providers and also, that the use of Slovenian value set gives better prediction of the measured outcome compared to the self-reported VAS score. The question in Slovenia is whether the PROMs can or should be used as an element for decision making in the next years when allocating budget among programs and providers.

304. ENDOCRINE THERAPY ADHERENCE AND PERSISTENCE AND SURVIVAL AMONG WOMEN WITH BREAST CANCER IN BRAZIL

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Objectives: This work was aimed at identifying explanatory variables of hormone therapy adherence and persistence in women with breast cancer, and evaluating the effect of such variables in breast cancer survival rates.

Methods: Retrospective longitudinal data from a cohort of5861 women with breast cancer, submitted to hormone therapy, was put together through linkage of the Brazilian National Cancer Institute (INCA) datasets, including the control of medicines delivered at its Pharmacy. A logistic regression model was applied to study adherence. Cox proportional hazard models were used to estimate persistence and breast cancer survival.

Results: Assuming at least 80% adherence to treatment, the proportion of treatment adherent women was 75.3%. At the end of the first and the fifth year of treatment, respectively, overall persistence (without at least 60 day interruption) to treatment was79% and 31%, and survival was 94% and 71%. Similarly, better adherence and persistence to treatment, as well as breast cancer survival, were associated with higher education, having a partner, lower cancer stages, being submitted to surgery, having less inpatient care, making outpatient visits to a Mastologist and a Clinical Oncologist, and the need of less exams. Older women were more likely to adhere and to persist to treatment, but those aged 70 years old or more presented higher hazard of death. Alcoholism was associated with lower adherence and persistence, while tobacco use was associated with lower survival. Longer time between diagnosis and the beginning of hormone therapy and cancer family history were, respectively, a risk and a protective factor to treatment persistence and survival. Psychotherapy was protective for adherence and survival. Finally, treatment adherence was positively associated with breast cancer survival, being combined tamoxifen and aromatase inhibitor explicative of lower adherence, while only aromatase inhibitor use was associated with higher hazard of death.

Conclusions: In this cohort, ¼ of the patients did not adhere, only 31% completed the 5-year hormone treatment without an interruption of at least 60 days, and 71% were alive after five years. Socio-demographic, behavioral, clinical and health care aspects explained partially variations in these dependent variables.

332. HEALTH RESOURCE UTILISATION (HRU) ASSOCIATED WITH SKELETAL-RELATED EVENTS (SRES) IN PATIENTS WITH BONE METASTASES (BM): RESULTS FROM A RETROSPECTIVE MULTINATIONAL EUROPEAN STUDY

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Background: Limited data exist on the economic burden of SREs related to BM (radiation/surgery to bone, pathologic fracture or spinal cord compression).

Objectives: To understand the economic burden of SREs by evaluating associated HRU to support future healthcare resource planning and the assessment of treatment options.

Methods: Eligible patients with BM from breast/lung/prostate cancer or multiple myeloma and a history of ≥1 SRE (index) (1 July 2004–1 July 2009) were enrolled in Austria, Czech Republic, Finland, Greece, Poland, Portugal, Sweden and Switzerland. We present HRU associated with SREs for Finland, Greece and Portugal. Data including inpatient stays, outpatient visits and procedures were retrospectively extracted from patient charts from 3.5 months before the index SRE (3 months baseline plus 14 day SRE diagnosis period) to 3 months afterwards.

Results: 364 eligible patients with ≥1 SRE were enrolled across the 3 countries (24%, 28%, 25% and 23% had breast, lung or prostate cancer or multiple myeloma, respectively). Across all tumour and SRE types, mean increase from baseline in number of inpatient stays per SRE was 1.0 (95%CI: 0.7–1.2), 0.7 (95%CI: 0.5–0.9) and 0.6 (95%CI: 0.4–0.7), respectively for Finland, Greece and Portugal, with a mean increase in total length of stay per SRE of 12.0 (95%CI: 8.2–15.8), 8.6 (95%CI: 6.0–11.2) and 11.0 (95%CI: 8.0–13.9) days. Mean increase in number of outpatient visits per SRE was 7.0 (95%CI: 5.9–8.1), 4.3 (95%CI: 3.2–5.4) and 3.7 (95%CI: 2.8–4.6). Mean increase in number of procedures per SRE was 8.4 (95%CI: 7.1–9.8), 8.4 (95%CI: 6.6–10.2) and 6.5 (95%CI: 5.3-7.6). HRU varied across SRE types.

Discussion: Data suggest that SREs are associated with a mean increase of 0.6–1.0 inpatient stays with a mean total duration of 8.6–12.0 days. SREs are also linked to numerous outpatient visits and procedures.

Implications for the health system/professionals/patients/society: Preventing SREs with new bone-targeted agents is important to reduce the economic burden on European healthcare systems.

343. CHALLENGES IN OBTAINING HIGH-LEVEL EVIDENCE ON THE EFFECTIVENESS OF ANIMAL-ASSISTED ACTIVITIES/THERAPY (AAA/AAT) FOR IMPROVING PHYSICAL, SOCIAL, COGNITIVE AND/OR EMOTIONAL FUNCTIONING OF HUMANS

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Animal-assisted activities/therapy (AAA/AAT) aims at improving cognitive, physical, social, emotional well-being, and quality of life of

individuals through their interaction with therapy animals (Delta Society, 1996 https: //www.deltasociety.org/). Promising results of AAA/AAT in promoting health benefits in a variety of settings have been reported, including hospices, elderly nursing homes, hospitals, rehabilitation and oncology units, acute and critical care units, and prisons. However, most of these results have important gaps in their design. The main objective of this study is to discuss the challenges in obtaining high-level evidence on the effectiveness of AAA/AAT for improving physical, social, cognitive and/or emotional functioning of humans. A major gap reported by many authors is the absence of a randomly assigned control group. A control group should have similar characteristics to the AAA/AAT group, but be visited only by therapists/handlers, without the presence of a therapy animal. Small samples may also be an important limitation to these studies. There are also no standards for the optimal frequency, duration, setting and approach for the AAA/AAT activities/interventions (Filan & Llewellyn-Jones. Int Psychogeriatr. 2006). AAA/AAT institutions should provide a list of activities/interventions, and standardize the measures and rating scales applied to assessing outcomes, as also as the methods of data collection. Chandler (2005) suggested gathering both qualitative and quantitative data for AAA/AAT studies. Further rigorous scientific studies on AAA/AAT are needed to address current gaps of existing research, and to provide high-level evidence of the effectiveness of this health technology in comparison to conventional ones, including cost-effectiveness studies, that could support decision-making in health care.

345. IS INDACATEROL MORE EFFICACIOUS AND SAFE THAN SALMETEROL IN PATIENTS WITH MODERATE TO SEVERE COPD? A MINI-HTA

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Introduction: Chronic obstructive pulmonary disease (COPD) is a progressive disorder, associated to an abnormal inflammatory response of the lungs to harmful particles or gases caused mainly by tabagism. It has a significant impact on patients' work, productivity and lifestyle. In Brazil, it's prevalence is 15.8%. The diagnosis, based on spirometry results, is defined by a ratio of forced expiratory volume in one second (FEV1) and a forced vital capacity (FVC) < 0.70.

Objective: To compare the efficacy and safety of indacaterol versus salmeterol in patients with moderate to severe COPD.

Methods: In Nov/2011, PUBMED, EMBASE, TRIPDATABASE, COCHRANE LIBRARY and CLEARINGHOUSE databases were consulted. Randomized clinical trials (RCT) were selected as long as they were not: crossover, open-label nor only placebo-controlled. The selected studies were evaluated according to GRADE and OXFORD criteria as contained in the Brazilian Ministry of Health's Rapid Review Guideline (3rd edition).

Results: Over 58 references were assessed, only two RCTs were included. Both evaluated FEV1 which was superior in the indacaterol group, compared with salmeterol, with a difference between groups of 57 ml and 60 ml, p < 0.05. The adverse events were similar in both studies. The quality of life (QoL), assessed by the St. George's Respiratory Questionnaire, was presented in only one study and showed an improvement in the indacaterol group (-4.2 with p < 0.05).

Discussion: Mortality was not evaluated. Although the intermediate outcome VEF1 showed better performance in the indacaterol group from a statistics point of view, the clinical relevance of this finding is questionable. Regarding the safety profile, the results are scarce, due to a short-term follow-up (< 1/2 years) and a small sample. The QoL was the most relevant result, but more studies should be conducted to confirm this finding.

Conclusions: Indacaterol provides only marginal therapeutic benefits when compared to salmeterol in treating COPD.

581. IMPROVEMENTS OF QUALITY OF LIFE AND CLINICAL SYMPTOMS IN FUNCTIONAL DYSPEPSIA USING MEDICAL AND PSYCHOLOGICAL TREATMENT

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Background: Functional dyspepsia (FD) is defined as central abdominal pain or discomfort that is not caused by structural or organic changes. Its conventional treatments are symptoms based. The disappointing results of such treatments and the role that psychosocial factors play in the severity of symptoms, suggest that FD should be better understood within the biopsychosocial frame.

Objectives: We aimed to determine if there may be any benefit of a combined intervention (medical + psychological) compared with conventional intervention (medical) in the quality of life and symptomatology of FD patients.

Methods: It is a prospective randomized controlled trial. A total of 182 FD outpatients from the digestive services of Galdakao-Usansolo and Basurto Hospitals were allocated to the experimental (combined intervention; n = 91) or control (conventional intervention; n = 91) group of whom 60 and 72 patients completed the self-report questionnaires before and after three months treatment respectively. The quality of life was assessed by Glasgow Dyspepsia Severity Score (DGSS). More score is indicative of worse quality of life. The subjective clinical improvement was also considered. Categorical data was compared using the chi-square test and continuous data by the t-test.

Results: The mean score (standard deviation) in DGSS before treatment was 11.84 (± 3.52) for experimental and 11.44 (± 2.73) for control group (non significant differences were found), while after the treatment the scores were 5.78 (± 3.78) and 7.84 (± 3.97), respectively (p = 0.0029). In the experimental group, 61.7% of patients recognized feeling "A lot or quite better" compared with the 24.6% of the control group (p < .0001).

Conclusions: The combined intervention is an effective treatment for improving the quality of life and symptomatology of FD patients, resulting in a significantly better outcomes compared with conventional intervention. Further longer studies are required to verify if the improvements remain over time.

350. THE POTENTIAL IMPACT OF OBESITY DEGREE ON DIABETES, HEART ATTACK, HYPERTENSION, CHRONIC ANXIETY AND DEPRESSION IN ADULT SPANISH POPULATION

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Background/Objectives: Obesity is considered a major Public Health issue in most developed countries nowadays for its wide

spread across population groups, as well as its contribution to the development of chronic diseases. Our objective was to estimate and better understand the impact of progressively increasing Body Mass Index (BMI) on diagnosed Diabetes, Heart Attack (HA), Hypertension, Chronic Anxiety (CA) and Chronic Depression (CD) in adult population.

Methods: Retrospective analysis of the Spanish 2009 European Health Survey System data base was conducted. Data from population under 18 years old or with BMI under 18.5 or with not reported BMI were excluded. Sample size of 19,880 adults (89.6% of the initial sample) was available for analysis. A logistic regression model was constructed for each of the five dependent variables. Age groups were divided by quartiles. BMI groups were "18.5–24.9", "25–29.9", "30–34.9" (g3) and "35 or more"(g4).

Results: Diabetes prevalence was 7.7%; (OR adjusted for g3: 2.3; 95% CI: 2.0–2.7; OR_g4: 4.2; CI: 3.4-5.3), Hypertension prevalence was 23.6%; (OR_g3: 3.4; CI: 3.0–3.8; OR_g4: 5.8; CI: 4.8–6.9), HA prevalence was 2.8%; (OR_g3: 1.7; CI: 1.3–2.1; OR_g4: 1.6; CI: 1.1–2.5), CA prevalence was 8.2%; (OR_g3: 1.6; CI: 1.3–1.8; OR_g4: 2.3; CI: 1.8–2.9), CD prevalence was 7.9%; (OR_g3: 1.7; CI: 1.4–2.0; OR_g4: 2.7; CI: 2.2–3.4). All the stated OR reached statistical significance ($p < 0.05$ for OR_g4 in HA and $p < 0.001$ for all the rest of them).

Conclusions: The results show how the risk of the examined comorbidities largely increases in those patients with BMI> 35. Considering its potential economical impact on Public Health, it would be required to design and implement effective strategies aimed at the early detection of subjects at risk and the provision of adequate treatment, as well as to establish suitable preventive programmes.

360. ASSOCIATED FACTORS WITH CALCIUM AND BISPHOSPHONATES PRESCRIPTION IN PRIMARY CARE IN MADRID

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Background: Calcium and bisphosphonates has shown efficacy to treat osteoporosis. There are few studies that had analyzed the prescription of these treatments in primary care according to recommendations and guidelines.

Objectives: Establishing the factors that are considering in the prescription of calcium and bisphosphonates in Primary Care (PC) in the Community of Madrid.

Methods: Cross-sectional study using electronic medical records. The database used contains information from 1318020 patients over 24 years with at least one visit to PC during 2006. Patients with a diagnosis of osteoporosis were identified. Descriptive analysis and two logistic regression models were built to describe the relationship between prescription of bisphosphonates and calcium with sex, age, comorbidity, visits to the specialist, drugs and socioeconomical variables. Results are given in the form of odds ratios (OR) with confidence intervals at 95%.

Results: The prevalence of osteoporosis in the study population was 4.4%. Mean age of patients with osteoporosis was 63.8 (SD: 12.5). 23,622 patients (40.3%) were prescribed calcium, and 19,426 patients (33.1%) bisphosphonates. Factors explaining the prescription of calcium and bisphophonates were being women ($OR_{calcium}$: 1.8, (1.7-1.9); $OR_{bisphophonates}$: 1.7, (1.6-1.9)), older than 65 years ($OR_{calcium}$: 1.6, (1.5-1.8); $OR_{bisphophonates}$: 2.2, (1.9-2.4)), less comorbidities ($OR_{calcium}$: 0.9, (0.8-0.9); $OR_{bisphophonates}$: 0.9, (0.8-0.9)). Osteoarrthritis (OR: 1.1, (1.0-1.2)) was significant for calcium model and rheumatologist referrals (OR: 1.5, (1.2-1.7)) for bisphosphonates model.

Discussion: Age and clinical status of patients appear among factors that guidelines mention to influence treatment for osteoporosis, but not factors like sex or being referred to a specialist that seem to be associated with the prescription of this treatments. Prescription of calcium and bisphosphonates for osteoporosis patients appears to be associated not only by clinical, but by socio-economic and socio-demographic factors.

367. CHANGES IN FUNCTIONALITY AFTER HIP FRACTURES DUE TO FALLS IN ELDERLY PEOPLE

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Introduction: Hip fracture is one of the most severe fractures that elderly patients may suffer after an unexpected fall. The goal of this study was to determine the evolution of functionality after those fractures.

Methods: Patients older than 65 years who attended the emergency room (ER) of 7 acute hospitals with a hip fracture due to a fortuity fall were recruited. Patients fulfilled the Barthel and Lawton-Brody questionnaires at the time of the fall, as how they were before the fall, and 6 months later, as well as some other questions on sociodemographic parameters. Descriptive and stratified analysis, by age and sex, were performed, considering the change on the Barthel and Lawton-Brody questionnaires as the outcomes to study.

Results: Preliminary analysis of our data with a recruitment of 976 patients with hip fracture showed an important decline in Barthel (from 85.3 to 63.2 points) and Lawton-Brody (from 4.8 to 3.2) questionnaires scores at 6 months after the fracture. There were not statistically significant differences by sex in the changes in both questionnaires but there were important differences by age categories: for the Barthel there were losses of 11.5 points for those aged 65-74, 16.5 for those between 75-84 and up to 30 points for those older than 84 years ($p < 0.001$); for the Lawton-Brody, there were losses of 1.2 points for those aged 65-74, 1.4 for those between 75-84 and up to 1.9 points for those older than 84 years ($p < 0.001$).

Conclusions: In this very common fracture in elderly, most patients suffer an important deterioration on their functionality detectable at 6 months after the fall which was more important the older the patient was. These results have important implications from the clinical and social services point of view.

379. THE IMPACT OF PUBLIC PROGRAMS ON PREVENTABLE CAUSES OF DEATH IN THE NORTHEAST OF BRAZIL

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Introduction: The analysis of the impact of public health programs is feasible by linking the study of deaths considered preventable with indicators of living conditions. Studies in this area are lacking in one of the regions with the lowest GDP of Latin America, the Brazilian Northeast with 49 million inhabitants, almost 30% of the total population.

Objectives: Measure the impact of health programs on preventable causes such as tuberculosis, HIV and diabetes, through reducible gaps in mortality, for the micro-regions of Northeast from 2000 to 2007.

Methods: Steps performed: 1) Assessment of quality of death records, 2) Measurement of the levels, trends and patterns of mortality from preventable causes, 3) Construction of the indicator "reducible gap in mortality", 4) Use of the regression analysis to identify the relationship between the causes of death and explanatory variables.

Results: In comparing the gaps between micro-regions it was revealed delays in several of them, indicating a lower impact on the development of programs to prevent diseases such as tuberculosis. There was a decrease in the gaps during the time. The stratification of the population by living conditions indicated that the very poor die more, especially by HIV.

Discussion: Analyses show that many deaths could have been avoided, as the living conditions could have been improved. The distance (gap) between the lowest and the highest mortality rate reached about 80%, particularly in the micro-regions more in the north. The regression analysis showed that socioeconomic inequalities used, did not explain significantly the standardized mortality rates for tuberculosis, HIV and diabetes.

Implications for the health system: Identify the most prevalent diseases in the population and which programs were most effective in reducing mortality levels. Support planning for public policies to preventable causes in Northeastern Brazil.

401. CREATION AND VALIDATION OF A SCALE TO ASSESS SEVERITY OF COPD EXACERBATION

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Objectives: Our main goal was to create, and validate, a scale to assess COPD exacerbations that may help emergency physician in their decision making process.

Methods: Prospective cohort study: 1605 patients attending emergency department of six participant hospitals, whose main diagnosis was COPD exacerbation were recruited for the study. Clinical signs and gasometrical parameters at the time of the decision were collected as well as data about outcomes related to the exacerbation during admission or in the week after emergency visit if the patient was discharged. The presence of intensive care unit admission, invasive mechanical ventilation necessity, cardiac arrest and/or death) was considered "very poor evolution". "Poor evolution" was defined as very poor evolution and/or the need of Intermediate Care Admission and/or nor invasive mechanical ventilation during more than 2 days. We explored the influence of each the variable which composed the severity scale in composite end-point variable "poor evolution" as well as the discriminate validity of the scale by means of the Chi-square test.

Results: Significant statistically significant differences were encountered between those who presented poor/very poor evolution and those who didn't, in all the variables which composed the scale, except for hemodynamic stability. On the other hand statistically significant differences were found in percentages of patients who presented very poor evolution among categories of the severity (0.77% mild, 2.89% moderate, 9.28% severe and 7.26 very severe) ($p < 0.0001$). Regarding to those who presented poor evolution, statistically significant differences were also encountered among categories of severity (0.99% mild, 5.28% moderate, 12.37% severe and 18.43% very severe)

Conclusions: Our scale was able to detect patients who were more likely to have poor outcomes after a COPD exacerbation in this study. We are hopeful about the helpfulness of the scale in to emergency physicians in their daily practice.

415. DEVELOPMENT OF PERFORMANCE INDICATORS FOR POST-INTRODUCTION OBSERVATION OF HEALTH TECHNOLOGIES. TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

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Background: Performance indicators are recognized to be valuable tools to measure health care quality. Post-introduction observation performance indicators have been designed to quantify outcomes of new technologies recently introduced in clinical practice in order to resolve uncertainties and indentify quality-of-care problems. The transcatheter aortic valve implantation (TAVI) is associated with important uncertainties about specific target population and long-term complications and durability. It would be important to assess if this intervention reaches an expected level of quality, when it is applied in real world practice, i.e. optimal value for the indicators.

Objective: Development of performance indicators for post-introduction observation of TAVI.

Methods and results: A modified version of the RAND/UCLA Appropriateness Method was used for the development of the performance indicators. A preliminary proposal of indicators was developed from the results of a systematic literature review: definitions, standards, study subgroup, follow-up interval, etc. This list of proposed indicators was appraised by an expert panel consisting of physicians from the National Healthcare System that worked in related specialties. The selected indicators were measures related with the framework (multidisciplinary hospital committee, etc.), process (patient selection criteria, etc) and clinical outcomes (repeat procedure, valve-related hospital readmissions, procedural mortality, survival, quality of life, etc).

Discussion and policy implications: The development and implementation of performance indicators for post-introduction observation is important to ensure the appropriate use of new health technologies, especially when there are important uncertainties regarding their application in real world settings. The information can be used for re-evaluating financing decisions (adjust authorized indications, resources, etc), to design interventions to improve performance or for hospitals to assess their own performance over time to identify areas for improvement. In conclusion, these indicators serve to improve clinical outcomes and achieve an efficient use of resources.

445. IMPROVED CLINICAL PERFORMANCE OF A LOWER EXTREMITY ARTERIAL BYPASS GRAFT PROVIDES ECONOMIC VALUE FOR HEALTHCARE PROVIDERS

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Background: As atherosclerotic disease progresses, synthetic lower extremity arterial bypass grafts may require reintervention to maintain blood flow, and possibly amputation if unsuccessful. The highest rate of reintervention occurs in bypasses to infrapopliteal

arteries. Multiple reinterventions are costly to health care systems and burdensome for patients. Clinical literature shows that the heparin-bonded GORE® PROPATEN® Vascular Graft (GPVG) requires fewer reinterventions compared to standard expanded polytetrafluoroethylene (ePTFE) grafts.

Objectives: Model the cumulative average cost per patient of infrapopliteal bypass using the GPVG compared to standard ePTFE over a 3-year period.

Methods: Costs of bypass procedures, follow-up visits and reinterventions were obtained using Medicare national average cost methodology. Amputation and rehabilitation costs were determined from a clinical publication. Clinical literature was analyzed to yield patency and limb salvage rates for GPVG and ePTFE grafts for 1, 2, and 3 years after infrapopliteal bypass. For each time point, the total cost of the bypass procedure and typical reinterventions performed yielded a cumulative average cost per patient for GPVG and ePTFE bypass.

Results: Analysis of clinical literature showed the GPVG has superior patency and limb salvage rates after infrapopliteal bypass compared to standard ePTFE, resulting in lower cumulative average costs per patient ($19,177, $23,653, and $29,928 at 1, 2, and 3 years, respectively) than ePTFE ($23,476, $33,830, and $44,835 at 1, 2, and 3 years, respectively).

Discussion: As health care costs rise, the economic value of a medical product becomes an increasingly important consideration in addition to its clinical value. The clinical value of the GPVG, reduced reintervention and amputation rates, translates directly to the economic value of reduced cumulative costs over time.

Implications: An increased emphasis on the combination of clinical and economic value has the potential to allow continuous improvement in patient care while providing financially prudent treatment choices for healthcare providers.

449. CONTINUOUS VARIABLES CATEGORIZATION TO APPLY INTO THE DEVELOPMENT OF PREDICTIVE MODELS FOR PATIENTS WITH COPD EXACERBATION

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Background: Important clinical variables collected in a study with COPD exacerbation patients were continuous variables, but either for clinical interpretation as for predictive models construction is preferable to categorize them.

Objectives: The main objective is to categorize arterial blood gases parameters, select robust cut-points and develop a solid predictive model to implement at the Hospital's Emergency departments (ED).

Methods: Prospective cohort study of patients attending the ED with a COPD exacerbation of 16 participating hospitals. A total of 2.877 episodes were collected. We graphically display the relationship between the covariates (pH and PCO2) and the response variable called poor evolution (death, ICU or ICRU admission, IMV and none NIMV) during hospital admission using Generalized Additive Models. The vertical axis of the graph represents the influence the covariate has in poor evolution: 0 no risk; above 0 high risk and below 0 less risk. We propose a category for no risk with a confidence interval around 0, and two categories that represent low and high risk. Moreover, if the relationship between the covariate and the poor evolution increases abruptly at some point, we consider it as a cut-point to distinguish between high and very high risk or low and very low risk.

Results: The relationship between the covariate and the poor evolution, as well as the cut-points is shown in the graphs. PCO2 was categorized as ≤ 45; (45-55]; (55-65); > 65 and PH as ≤ 7.26; (7.26 -7.35]; > 7.35 clinically validated. When using these as predictors of poor evolution the AUCs we obtained were 0.81 and 0.73 respectively.

Conclusion: The categorization that we propose for the variables in the COPD study show significant cut-points that were clinically validated and had very good prediction ability for poor evolution.

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450. ADULT POMPE PATIENT PERCEPTIONS OF DISEASE SEVERITY AND OVERALL IMPACT TO THEIR QUALITY-OF-LIFE: IMPLICATIONS FOR PATIENT CARE

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Background: Pompe disease is a rare, progressive inherited disease. Late onset Pompe, diagnosed in both children and adults, is characterized by progressive deterioration of muscle and respiratory functioning. Individuals with the disease typically progress to severe generalized muscle weakness and require ventilation assistance although the rate of disease progression varies among individuals.

Objectives: While physicians focus on clinical and genetic aspects of Pompe disease, there is a paucity of research on the patient experience. To understand patient perceptions and the impact of Pompe on their quality of life we conducted a survey of diagnosed patients.

Method: Mail and online surveys were conducted with 97 diagnosed patients or their caregivers in the UK, France, Belgium and Japan.

Results: Respondents were asked to self-rate their overall disease severity and impact. Responses divided evenly into three groups (36% less affected; 29% moderately affected and 35% severely affected). However when asked to rate their overall endurance (sleepiness, fatigue, energy) over three-quarters (79%) rated themselves as poor to fair. As well, Pompe was reported to have negative impact on their lives: 65% rated their work/school life as fair to poor, 56% rated their social lives as fair to poor, 41% rated their family life as fair to poor and 41% rated their overall psychological health as fair to poor.

Discussion and implications: Patients diagnosed with Pompe disease report significant impact of the disease on their energy, productivity and social life as well as on their overall psychological health. A treatment paradigm for these patients needs to assess the impact of the disease on their quality-of-life. A care model for treatment should include not only Enzyme Replacement Therapy (ERT) medical treatment but also psychological and social support for patients and families.

456. THE EFFICACY AND SAFETY OF ZOLEDRONIC ACID VERSUS OTHER BIPHOSPHONATES IN PATIENTS WITH PAGET'S DISEASE OF BONE. A MINI-HTA

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Background: Paget's disease of bone (PD) is characterized by an increase in bone remodeling and by an abnormality in the tissue architecture, which leads to important deformities and high risk of fractures. Generally, patients are asymptomatic, although some may manifest degenerative joint wear and pain. The pharmacological treatment aims to diminish bone resorption and the risk of long-term complications; this may be done with biphosphonates. In Brazil,

pamidronate and zoledronic acid (ZA) are registered as treatments for PD. The latter is preferred because needs short infusion time and single annual dose.

Objectives: To evaluate the efficacy and safety of ZA versus other biphosphonates in patients with PD.

Methods: A systematized search was conducted in May/2011 with the goal of retrieving systematic reviews and randomized clinical trials (RCT) in English, Portuguese and Spanish.

Results: Three studies were selected (2 RCTs and 1 combined study of 2 RCTs) which compared ZA to pamidronate, neridronate or to risedronate. All evaluated the therapeutic response based on the normalization of alkaline phosphatase (ALP – bone metabolism marker) and they showed a biochemical remission in less time with ZA. However, in spite of this finding, all the drugs were efficacious in reducing ALP ($p < 0.05$). The 2 RCTs also demonstrated that the pain related to the disease was reduced and that there was no significant difference between the groups regarding the adverse effects (AE).

Discussion: Despite evidence showing better results with the use of ZA, these findings are not clinically expressive, since they do not increase the patient's quality of life (only ALP, a substitute outcome, was considered) - and based on the fact that the other biphosphonates were also efficacious in reducing the marker. The short follow-up time (< 24 months) doesn´t make it possible to evaluate the therapy's true efficacy in the long-term, nor the incidence of serious AE, not allowing for inferences about drug's safety.

Implications: Despite the easy administration of ZA, it will be necessary to evaluate its long-term use, due the results and the high cost to health systems.

458. NURSING CONSULTATION - A HEALTH TECHNOLOGY IN THE PREVENTION OF RISK FACTORS FOR HYPERTENSIVE SPECIFIC SYNDROMES OF PREGNANCY – HSSP

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The prenatal care is an essential resource for the promotion of women's health in pregnancy puerperal cycle, ultimately contributing to the reduction of maternal and fetal morbidity and mortality. Hypertensive Specific Syndromes of Pregnancy (HSSP) is a major cause of maternal morbidity and mortality. Descriptive study with qualitative approach to analyze the impact of nursing consultation on prevention and/or control of risk factors for HSSP, in Fortaleza-CE, with seventeen pregnant women in prenatal monitoring. The women were followed for three months, through nursing consultation. We conducted two interviews - start and end. Organize information into categories and analyzed based on the assumptions of health education and selected literature. The women were aged between 15 and 40 years, brown, three single, four married, and ten in a stable, fourteen attended elementary school, middle school and three, three reported a monthly income less than minimum wage and the other from one. In fifteen the first pregnancy occurred between 15 and 20 years, and two between 20 and 30 years. Two women had high blood pressure in a previous pregnancy and only in the current, four reported family history of hypertension, three complained of emotional conflicts and attributed them to live with family and spouse, and another four reported parenting differently. Only five pregnant women reported some knowledge about HSSP. Pregnant women some risk factors of this disease. To control these, pregnant women generally cited the reduction of salt. According to eight pregnant women, the guidelines were provided by nurses, three, the community worker, and two, citing family and friends. The guidance received in prenatal consultation were related to healthy lifestyle. Pipes carried by pregnant women to prevent and/or control of risk factors for HSSP, were not uniformly practiced. The monitoring of pregnant women through nursing consultation possible changes in attitudes regarding the prevention and control of risk factors for HSSP.

459. ADHESION TO THE ELDERLY HYPERTENSIVE TREATMENT - AN EDUCATIONAL TECHNOLOGY IN HEALTH BASED BELIEF MODEL

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In Brazil has one of the most acute among the aging process, most populous countries. Diseases linked to the aging process leads to dramatic increase in health care costs a major impact on countries' economies. It is estimated that at least 65% of elderly Brazilians are hypertensive. This study aimed to analyze the behavioral changes in elderly hypertensive patients in treatment adhesion, through the application of technology in education based in the Health Belief Model. Search participant developed the Reference Center on Social in Fortaleza-Ceará-Brasil. Participants included twenty seniors. The Educational Technology in Health has been prepared based on the Health Belief Model and consisted of ten meetings that occurred during three months. The interviews had the purpose of assessing the behavior of the elderly in relation to adherence to treatment after the application of technology. Most of the elderly showed a deficit of knowledge about hypertension, as well as on the behavior of control. Older people may feel after the severity forwarded to the memory of facts of everyday life. Fifteen perceived benefits to adhere to measures to control hypertension. Were numerous barriers faced by older people for treatment adherence, such as improper relationship with a team of health care, high cost of medicines. We note that the elderly enjoyed the benefits somehow acquired with adherence to treatment. Finally, the elderly understand the application of technology as something positive for their lives and to control hypertension. These perceived vulnerability and severity of hypertension, the benefits of adherence, the barriers hindering behavioral change, the stimuli for action and the strategies they developed for aiming at a better control of hypertension. Therefore, we emphasize the need for greater scientific production in the area, in order to bolster public health policies in force and meet the needs of the elderly population, which will soon prevail in our country.

462. THE ENVIRONMENTAL HEALTH, THE URBANIZATION AND THE TECHNOLOGY IN HEALTH PROMOTION OF THE URBAN POPULATION

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The world today has reached the level of 7 billion people. More than 50% of this population lives in urban centers, which are found

large environmental changes generated by human activities. We still have the number of elderly has increased considerably. Thus, several studies showed that a large impact of environmental changes affecting the population of children and the elderly, such as air pollution, especially pollution generated by vehicles and biomass burning. Increasingly at certain times of the year the demand for medical care generated by respiratory and cardiac problems in large urban centers for the elderly population has increased. This paper discusses the various technical jobs that studied in large cities link impacts of vehicular pollution on the health of the elderly, analyzed common factors and proposes the adoption of preventive measures and technologies for health that can contribute to the reduction of the search for health services in the elderly population generated by environmental damages. Proposes extensive discussion with the society, through methodologies and protocols for risk communication on the implementation of such "heat islands" in specific regions. Conclusion: With the great environmental hazards in megacities, the large increase of population and urban growth and the elderly, is essential, as revealed in this study, discussion with society and technology adoption of measures regarding chronic diseases and environmental factors.

476. A POPULATION-BASED CASE-CONTROL STUDY OF ENDOSCOPIC SCREENING FOR GASTRIC CANCER IN JAPAN

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Background: Although the incidence of gastric cancer has decreased over the last three decades, it is still the second leading cause of cancer death worldwide. It is anticipated that endoscopy will become a new screening method, but there is insufficient evidence showing that its use reduces mortality from gastric cancer.

Methods: A case-control study was conducted to evaluate mortality reduction from gastric cancer by endoscopic screening in Tottori and Niigata Prefectures, Japan. Cases were defined as persons who had died from gastric cancer in four cities in Tottori Prefecture and Niigata City. Those who died of gastric cancer were identified using death certificates and local cancer registries. Up to six control subjects were matched by sex, birth year (± 3 years), and residence of each corresponding case from population lists in the study areas. The odds ratios (ORs) were also calculated for those who had ever screened by any screening within 12 months before diagnosis compared to persons who had never screened. Conditional logistic-regression models for matched sets were used to estimate the ORs and 95% confidence intervals (95%CIs).

Results: The cases included 292 males and 123 females, and there were 2,313 matched control subjects. Compared to those who had never been screened before the date of diagnosis of gastric cancer, the ORs within 12 months from diagnosis were 0.701 (95%CI: 0.458-1.072) for endoscopic screening and 0.787 (95%CI: 0.527-1.175) for radiographic screening.

Conclusions: The results suggest a 30% reduction in gastric cancer mortality with endoscopic screening compared to no screening within 12 months before the diagnosis of gastric cancer. However, before introducing endoscopic screening in communities, a randomized controlled study is needed to evaluate its efficacy, and consideration of appropriate resource allocation for gastroendoscopy between usual practice and cancer screenings is needed.

540. INTERDISCIPLINARY TREATMENT PSYMEPHY ON PATIENTS WITH FIBROMYALGIA: IMPROVEMENT OF THEIR HEALTH-RELATED QUALITY OF LIFE

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Background: Fibromyalgia (FM) is a persistent disorder that can have a devastating effect on people's lives. Clinical research suggests that an integrated biopsychosocial approach improves outcomes. Despite these results, pharmacological treatment remains the option offered to Spanish patients.

Objectives: To assess whether an interdisciplinary intervention is more effective than usual care for improving the health-related quality of life (HRQoL), and to identify variables that were predictors of improvement in HRQoL.

Methods: In a prospective randomized controlled clinical trial carried out on an outpatient basis in a hospital pain management unit, 153 FM patients were randomly allocated to an experimental group (EG) or a control group(CG). Participants completed the Fibromyalgia Impact Questionnaire (FIQ) at baseline and 6 months after the treatment. The EG received an interdisciplinary treatment (12 sessions for 6 weeks) which consisted of coordinated PSYchological, Medical, Educational, and PHYsiotherapeutic interventions (PSYMEPHY) while the CG received standard-of-care pharmacologic treatment. Descriptive statistics, ANOVA, chi square, Fisher tests and generalized linear models were used for data analysis.

Results: Six months after the intervention, statistically significant improvements were observed in physical functioning ($p = 0.02$), pain ($p = 0.02$) and total FIQ score ($p = 0.04$) in the EG compared to the CG. The number of comorbid physical illnesses was identified as a predictor for improvement.

Discussion: Interdisciplinary treatment improved physical functioning, pain level, and reduced the impact of FM on patient HRQoL. The presence of other physical illnesses was the variable that best predicted this reduction. It is possible that patients who acquired coping skills during the PSYMEPHY treatment applied them in their daily lives, and thus were better able to cope with their other conditions, which would have been reflected in an improvement in HRQoL.

Implications for the health system: Such interdisciplinary interventions may be appropriate for patients referred to hospital pain management units. Our finding offers an incentive to study similar programs.

549. COMPARISON OF CHRONIC MYELOID LEUKEMIA REGISTRIES IN AUSTRIA AND UTAH, USA

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Background: Patient registries provide an important source of observational longitudinal individual-level data for assessing outcomes of treatment.

Objective: The purpose of this research is to compare the data collected, including the type of variables, therapies, and outcomes of treatment, in chronic myeloid leukemia (CML) registries established in Austria and Utah, USA.

Methods: The Austrian CML registry is an online database that allows participating centers throughout Austria to contribute CML patient data. As of March of 2009, 26 centers throughout Austria were participating in the registry. The University of Utah CML Outcomes Research Registry is comprised of data from the University of Utah Health Sciences Enterprise Data Warehouse (EDW) and Utah Population Database (UPDB). The two registries were compared on the basis of their populations, structure, and clinical characteristics.

Results: As of March 2009, the Austrian CML registry included 179 patients. The University of Utah CML registry had 234 patients as of December 2010. The distribution of males and females between the two registries was similar (57.5% male in Austria vs. 59.8% male in Utah, p = 0.64). The majority of patients in each registry were listed as being in chronic phase (CP) at the time of diagnosis or first visit (92.6% CP in Austria vs. 90.2% CP in Utah, p = 0.39). Both registries collected age at diagnosis and other relevant baseline clinical parameters such as comorbidities, BCR-ABL transcript levels, and number of Ph+ chromosomes, and leukocyte count.

Discussion: Similarities between the structure of and populations within the two registries may be reflective of the epidemiology of CML, and similarities among available therapies and technologies, treatment patterns and clinical practice guidelines.

Implications for the health system/professionals/patients/society: Evaluation of the structure and data collected across CML registries can provide valuable insight on best treatment practices and underlying differences in systems of care.

558. LONG-TERM HEALTH-RELATED QUALITY OF LIFE AND COSTS IN CORONARY ARTERY DISEASE

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Background: Information on long-term patient-reported outcomes and secondary care costs of coronary artery disease (CAD) patients treated with varying approaches is scarce.

Objectives: To examine health-related quality of life (HRQoL) and costs of patients initially treated by coronary artery bypass graft surgery (CABG), percutaneuos coronary intervention (PCI) or medical therapy (MT) in the routine setting of a large university hospital.

Methods: Prospective observational study assessing clinical outcomes, change in HRQoL and secondary care costs during an 8-year follow-up in 300 stable, unselected CAD patients entering elective coronary angiography in 2002-2003. HRQoL was determined by the 15D HRQoL questionnaire at baseline and 6 months and 8 years after treatment assignment to either CABG, PCI or MT. Clinical and cost data were obtained from hospital records.

Results: Of the 300 patients, 51 died during long-term follow-up. Mortality did not differ statistically significantly between the groups. Mean (SD) HRQoL score increased from 0.828 (0.953) to 0.861 (0.125) at 6 months after CABG and from 0.813 (0.116) to 0.845 (0.118) after PCI. MT resulted in reduced HRQoL from 0.794 (0.109) to 0.773 (0.163). In patients alive at 8 years, HRQoL in all treatment groups had deteriorated. However, in the CABG and PCI groups, as opposed to the MT group, the statistically significant baseline difference in HRQoL score between the patients and the general population matched for age and sex had disappeared. Mean long-term secondary care costs were 17333 EUR for CABG, 7186 EUR for PCI and 4503 EUR for MT.

Discussion: Although mortality was similar in all treatment groups, long-term HRQoL improved to a higher extent after PCI and CABG compared to MT, but at a significantly higher cost.

Implications: The higher cost of invasive treatment of CAD patients is warranted in light of the better HRQoL compared to patients having received MT only.

570. VALIDITY AND RELIABILITY OF THE INVOLVEMENT EVALUATION QUESTIONNAIRE (IEQ) FOR CAREGIVERS OF PATIENTS WITH EATING DISORDERS

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Background: The Involvement Evaluation Questionnaire (IEQ) was initially developed for the evaluation of the caregiver burden perception of carers of patients with psychotic disorders, but has also been used in other disorders.

Objectives: The aim of this study was to validate it in a sample of carers of patients with eating disorders.

Methods: Prospective study recruiting caregivers of patients with eating disorders, attending the Eating Disorders Outpatient Clinic of the Psychiatric Services at Galdakao-Usansolo Hospital and Ortuella Mental Health Center in Bizkaia, Spain. Caregivers were asked to provide sociodemographic information and to complete several instruments: The Involvement Evaluation Questionnaire, The Hospital Anxiety and Depression Scale (HADS), The Short-Form 12 (SF-12) and The Anorectic Behaviour Observation Scale (ABOS).

Results: The results of the Confirmatory Factor Analysis provided satisfactory fit indexes. All factor loadings were statistically significant ($p < 0.05$) and almost all of the factor loadings were above the criteria of 0.40. Cronbach's alfa coefficients were almost all of them superior to the minimum value of 0.70. The correlation coefficients between the IEQ domains and the other questionnaires were all lower than the Cronbach's alfa coefficients of the IEQ subscales.

Discussion: The IEQ have good psychometric properties and can be used in studies about the burden perception and consequences of caregivers of patients with eating disorders.

Implications for the health system/professionals/patients/society: Instruments prepared to systematically detect the caregiver burden could help clinicians identifying those caregivers that could be suffering more to be able to offer them clinical support.

573. DEVELOPMENT AND IMPLEMENTATION OF A COMPLEX INTERVENTION FOR THE CARE OF OLDER PEOPLE WHO HAVE FALLEN BY PARAMEDICS WITHIN THREE UK AMBULANCE SERVICES FOR EVALUATION IN A RANDOMISED CONTROLLED TRIAL

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Background: The Medical Research Council guidance for the development of complex interventions describes a complex

intervention as one which has several interacting components. Unsuccessful implementation is one of the most frequent weaknesses in such studies; problems can arise during evaluation if an intervention has not been properly developed. SAFER 2 (Support and Assessment for Fall Emergency Referrals), a study linking paramedics to the Community Falls Service, is an example of a complex intervention that has undergone rigorous development.

Objectives: To describe: 1) the methods utilised in development of the SAFER 2 intervention and the resulting complex intervention that arose; 2) the implementation issues encountered within 3 UK ambulance services.

Methods: Development was initially informed by previous studies undertaken in this field; stakeholders' and patients' views were incorporated from qualitative elements of these studies. NICE guidance was instrumental in the development of the intervention in accordance with current UK standards. Specialist sub-groups were set-up to develop specific components of the intervention, while modelling throughout the development phase alongside ongoing stakeholder feedback allowed testing of economic viability and expected affects.

Results: Components of the SAFER 2 complex intervention were identified and defined, including training; protocol; referral process; falls service response and feedback loop. These components were split into those that would be standard among trial sites and those which could be locally defined. Issues encountered during implementation include conflicts with other service developments and operational pressures limiting the availability of paramedics for training. These have been resolved with help from the study steering committee and local implementation teams.

Conclusion: Thorough intervention development and effective implementation are vital to the success of the SAFER 2 study. Evidence is required in the factors that allow wide and effective implementation which will inform future evaluations in this area of emergency medicine research.

Implications for the health system/professionals/patients/society: Guidance for research professionals for developing and implementing a complex intervention in practice.

913. COMPARATIVE EFFECTIVENESS ANALYSES USING SIMULATED TREATMENT COMPARISON (STC)

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Background: Comparative effectiveness data would ideally come from head-to-head trials, but these are rarely available, which demand for simulated comparisons to be initiated. This is done by combining data from that trial with information about the competing interventions for key outcomes.

Objectives: The aim of this STC is to estimate comparative effectiveness versus other interventions had they been included as comparators in a particular trial.

Methods: Predictive equations based on the index trial and comparator trials are constructed to best fit the outcome of interest. Both are based on the characteristics of the populations and treatment options. The equation of the index trial is applied to the placebo arm of the comparator trial predicting their outcome had they been included in the index trial. Then by matching this prediction with the original outcome of index trial placebo patients, the treatment effect between the two active treatments is then estimated.

Results: The relative treatment effect is provided taking into account the differences in the patient population observed between the two studies. Although no confidence intervals can be derived using this method, it is possible to estimate credibility bands around the estimates providing an accurate measure about relative treatment effect.

Discussion: Potential sources of confounding in the results are the historical bias and the residual confounding due to non-observed variables.

Implications for the health system/professionals/patients/society: An STC is a robust addition to the HTA armamentarium that may be utilized to obtain comparative effectiveness information that is unbiased.

926. IMPLEMENTATION OF GUIDELINES ON DIABETES AND CARDIOVASCULAR RISK IN THE BASQUE COUNTRY. A CLUSTER RANDOMISED TRIAL

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Background: One strategy to improve quality of care in patients with diabetes or high cardiovascular risk (CR) is the implementation of evidence-based recommendations. Recently guidelines on these topics have been published, but their effectiveness need to be evaluated in our context.

Objective: To evaluate the effectiveness of a multifaceted intervention aimed at implementing guidelines on diabetes, high blood pressure and dyslipemia.

Methods: A cluster randomised trial. ISRCTN 88876909. Control: mailing of guidelines and presentation sessions in primary care units (PCU). Intervention: Design of a specific, interactive web page containing action-based recommendations and tools. Workshops: 43 PCU in two districts (Gipuzkoa and Bilbao) were randomised. Data from all diabetics, hypertensive patients and coronary risk screening population who attended PCU during the study period were included. The study took place between January 2008 and March 2010. Statistical analysis was performed using SPSS.19. The unit of analysis was the PCU, weighted by the number of patients. The intracluster correlation coefficients were calculated using MLwiN.

Results: Diabetics (N = 40,420): Statistically significant improvements were found for CR assessment (mean difference 28.16%), without differences in HbA1c determination, HbA1c levels, foot examination and basic analysis. Hypertense patients (n = 109,354) Significant mean differences were found for CR assessment (27.55%) and diuretic treatment (20.59%), with no differences for other outcomes (blood pressure, basic analysis, prescription indicators). Dislypemia (N = 129,717 women and 123,384 men): significant mean differences were found for CR screening in both women (13.58%) and men (12.91%) and using CR to start statin treatment (23.09%). Statins prescription in women with low CR decreased significantly (3.07%). There was no difference in statin prescription in secondary prevention.

Discussion/Implications for the health system: A multifaceted intervention focused on clinicians has an effect on some process variables and reduces statin prescription in women at low CR, but it doesn't improve clinical outcomes. The most important changes are seen in areas in which a knowledge gap exist.

590. ORGANIZATIONAL FACTORS AS A DETERMINANT O F DETECTION OF CELLULAR ATYPIA IN CERVICAL CANCER SCREENING ACTIONS

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Cervical cancer is the third most common cancer in woman worldwide. Early detection can be performed by Pap smear tests with

significant impact on morbidity and mortality rates in well organized screening programmes. In Brazil, the disease incidence rates have not significantly dropped despite more than one decade of launching a national programme. This study aims at analysing the contribution of the organizational factors in the detection process of cellular atypia in the cervical cancer screening actions of the Rio de Janeiro State, Brazil. A data sample of 10.0% (n = 65.535) of Pap smear tests held in 2007 was obtained from the Cervical Cancer Information System (SISCOLO in Portuguese). This sample was used to obtain a logistic regression model to explain detection of cellular atypia. The selected predictor variables were related to organizational factors (laboratory of reference – LR, and presence of cervical epithelia in the sample slide – PCES), woman's condition (use of oral contraceptive, bleeding after sexual relation and signs of Sexual Transmitted Diseases) and test results (benign cellular changes and presence of some microorganisms). Receiver Operating Characteristic Curve was applied to define the cut off point for classifying the presence or not of atypia. A sensitivity analysis was developed for the organizational factors. The adjusted model showed sensitivity of 73.0% and specificity of 66.8% with significant coefficients for all factors. The organization factors presented odds ratio of 3.5 (95% CI: 3.2-3.8) for LR and 4.0 (95% CI 3.6-4.5) for PCES. The sensitivity analysis showed an increase of 45.6% in the detection of atypical cells when increasing 19.0% the frequency of LR and 26.0% of PCES. The findings suggested that the organization factors influence the effectiveness of the screening actions in Rio the Janeiro. If laboratory quality process and preparation of the slides are not improved, the incidence of cervical cancer will hardly change in the region.

609. CLINICAL EFFECTIVENESS OF TOTAL HIP AND KNEE ARTROPLASTIES. RESULTS FROM THE CATALAN ARTHROPLASTY REGISTER

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Background/Objectives: The Catalan Arthroplasty Register (RACat) is a population based register designed to assess effectiveness of artroplasties. The aim of this study was to describe patients and process characteristics of total knee (TKA) and hip arthroplasties (THA) in the RACat, and their survival at 3 years.

Methods: Data was collected prospectively from 52 public hospitals through an information-based platform of the Catalan Health Service from 2005 to 2010, including sex, age, reason for intervention, joint, type of surgery (primary or revision), fixation technique (cemented or not, hybrid) and implant brands. Additional information from the hospital discharges dataset was linked to data in the RACat, using the personal identification code of patients. Descriptive analyses on the characteristics of patients and procedures were carried out, as well as survival analysis to examine the length of time between a primary joint replacement and the first revision surgery.

Results: During 2005-2010, 63,428 knee and hip artroplasties were included in the RACat; with a 9.0% and 10.2% burden of revision surgeries, respectively. Completeness of data was 86.6% in knee and 73.2% in hip. Most primary surgeries were TKA or THA (remaining were unicompartimental knee or partial hip interventions) and the reason for surgery was osteoarthritis. The most frequent fixation technique in TKA was cemented (74.0%), and in THA cementless (62.3%). Cumulative risk of revision at 3 years for TKA was 3.7% (3.4%-4.0%) and for THA, 3.1% (2.8%-3.5%).

Discussion: The RACat has improved its completeness and quality of data. It appears to be a useful tool for monitoring the trends of TKA and THA and the prediction of failure and to analyze outcome variations among hospitals or regions. Finally, registers can be understood as an adequate methodological approach to assess health technologies in the field of orthopedic surgery and useful for decision makers.

618. MODELLING THE RELATIONSHIP BETWEEN WOMAC OSTEOARTHRITIS INDEX AND EQ-5D

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Background: Few trials of technologies for treatment of patients with osteoarthritis include preference based outcome measures that can be used to estimate QALYs for economic evaluation. It is therefore essential to estimate the relationship between clinical outcome measures and preference based measures. Several previous studies have used simple statistical methods which have been shown to perform poorly when modelling health state utilities.

Objectives: To examine the relationship between EQ-5D, the widely used WOMAC Index and other explanatory variables and to compare simple statistical approaches with methods developed and applied with success in other disease areas.

Methods: We consider a range of mixed effects model types including the simple linear regression and Tobit models. These are contrasted with a mixture model based on bespoke distributions, using 4 repeated observations from a cohort of Spanish osteoarthritis patients (n = 1768).

Results: The preferred approach is a 5 class mixture model which estimates EQ-5D based on WOMAC summary scores for pain, stiffness and function conditional on age and sex. The linear and tobit models suffer from classic problems of poor fit, particularly at the extremes of EQ-5D. The mixture model has substantially improved fit including at the extremes of the distribution and cannot predict unfeasible values.

Discussion: This study reinforces findings in other disease areas that simple models are not appropriate for modelling EQ-5D. The bespoke mixture model results indicate that WOMAC component scores can be used to estimate EQ-5D.

Implications for the health system/professionals/patients/society: The economic benefits of therapies for patients with osteoarthritis will be underestimated if analysts continue to use inappropriate modelling approaches. Using the bespoke mixture model will provide a more faithful reflection of treatment benefits and may lead decision makers to reimburse different treatments.

686. VARIABILITY IN DRUG PRESCRIPTION IN THE TREATMENT OF ADHD IN THE BASQUE AUTONOMOUS COMMUNITY (BAC), NOT SUPPORTED BY EVIDENCE AND EPIDEMIOLOGIC PROFILES

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Background: Attention Deficit Hyperactivity Disorder (ADHD) is one of the psychiatric disorders that have experienced a greatest

increase in diagnoses in recent years. At the same time, the consumption of the only two drugs with this indication has increased disproportionately and outside of the indications and evidence and safety recommendations, pushing psychological treatment into a second-line approach.

Objectives: To describe the variability in gross rates of methylphenidate and atomoxetine dispensed by primary care unit (PMU) in the BAC and to determine the most prescribing PMUs.

Methods: Ecological, cross-sectional and descriptive study of atomoxetine and methylphenidate use in 131 PMUs in the BAC in 2010, using small area analysis to analyze the variability among PMUs. The most prescribing ones were those with the highest gross rate (DDD/health identification card (HIC)).

Results: The total number of defined daily doses (DDD) of methylphenidate prescribed in 2010 in the BAC was 1,195,275 (median 9,124.4) and atomoxetine 28,699 (median 219.1). Variation rate between percentiles 5 and 95 was 6.25 times for methylphenidate and 35.04 times for atomoxetine. The weighted coefficient of variation between percentiles 5 and 95 was 0.36 and 0.65 for methylphenidate and atomoxetine respectively. The most prescribring PMUs show a gross rate for methylphenidate of 80.65 and for atomoxetine of 4.15.

Discussion and conclusions: Prescription of methylphenidate shows a moderate variability, being even higher in the case of atomoxetine. Epidemiological profiles in PMUs and existing evidence don't justify this variability. These results support the need to explore the causes that could explain the variability in prescription of these drugs among clinicians and could aid in the implementation of standardize measures to support rational and evidence-based drug prescription.

714. NURSE-LED TRIAGE FOR PATIENTS WITH INFLAMMATORY ARTHRITIS REFERRED IN RHEUMATOLOGY

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Background: In patients with inflammatory arthritis (IA), early use of disease-modifying anti-rheumatic drugs substantially improves patient outcomes. Rheumatologists specialize in these complex treatments and should see patients with IA as soon as possible to begin treatment.

Objectives: We evaluated the ability of a nurse-led triage to identify patients with IA and reduce their waiting time, in order to improve process of care.

Methods: A nurse assessed all new referrals to a rheumatology clinic in the Montreal suburban area in 2009 and 2010. Referrals were assigned a priority level according to a complex decision rule based on the written content of the referral, a telephone interview with the patient and, if needed, an adapted joint examination. Patients with potential IA and other acute rheumatologic conditions were prioritized and given an appointment as early as possible. The main outcome measures were validity (sensitivity, specificity) and predictive values of the decision rule as well as waiting time from referral to first visit with rheumatologist.

Results: Of 701 newly referred patients, 79 had a final diagnosis of IA. The decision rule had a sensitivity of 0.76 (95% CI: 0.65 to 0.84), and a specificity of 0.80 (0.76 to 0.83). Positive and negative predictive values were 0.36 (95% CI: 0.29 to 0.44) and 0.96 (95% CI: 0.93 to 0.97) respectively. The median delay between referral date and first visit was 27 days for patients with IA and 114 days for all others.

Discussion and implications for the health system: This nurse led triage correctly identified 76% of patients with IA and resulted in more rapid consultation for these patients. A complete HTA, including evaluation of cost-effectiveness and feasibility is required before implementing this type of triage in Quebec's healthcare system.

715. DISCRETE CHOICE (DC) MODELS TO ESTIMATE THE VALUE SET FOR EQ-5D-5L. (SPANISH PILOT STUDY OF THE EQ-5D VALUATION PROJECT)

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Introduction: The EQ-5D is a generic health related quality of life measure (www.euroqol.org). It has 5 dimensions, each with three levels of severity, and a Visual Analogue Scale. Recently, an extended version of 5 levels, the EQ-5D-5L has been developed, to solve problems with the EQ-5D-3L, such as lack of descriptive richness and restricted discriminatory power.

Objectives: The objective is to find the best method to estimate the EQ-5D-5L value set comparing between Discrete Choice (DC) and Lead Time Trade Off (TTO_{Lead}).

Methods: A survey for the Spanish pilot study included the EQ-5D-5L questionnaire, the VAS, 10 DC tasks, 5 Lead TTO tasks and some specific socio-demographic questions. 400 respondents were recruited, maintaining the structure of the Spanish population in terms of age, sex, and educational level. Three models were estimated. A linear regression model using Lead TTO information was conducted for the anchor points for the worst health state. A conditional logistic model was conducted using DC data. The Lead TTO anchor point was used to rescale the arbitrary scale of the conditional logistic model estimated from DC data. The third model, a rank ordered logistic model, uses DC data plus death questions. To rescale DC_{death} model, the Death state is used as anchor point in 0. Each model was estimated including, for each dimension, only the main effects, (ie, the five levels) using dummy variables representing levels.

Results: TTO_{Lead} model produces lower values than both DC rescaled models, among which slight differences can be detected. The presence of positive coefficients and the non-ordinality between levels in some dimensions indicate some inconsistencies. The dimension with higher impact on index values is *pain/discomfort* on DC_{Death}, while in $DC_{Conditional}$ is *mobility* dimension.

Conclusions: The two approaches, DC_{Death} and $DC_{Conditional}$, are appropriate to estimate EQ-5D-5L value sets, producing similar results.

717. EFFICACY AND SAFETY OF INDACATEROL VERSUS FORMOTEROL IN PATIENTS WITH MODERATE TO SEVERE COPD. THE MINI-HTA

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Introduction: Chronic obstructive pulmonary disease (COPD) is a respiratory disease characterized by progressive limitation of airflow in the airways. In Brazil, the prevalence by age group are: 8.4% (40 to 49 years), 16.2% (50 to 59 years) and 25.7% (> 60 years). Indacaterol is a β2 adrenergic agonist long-acting and registered in the National Health Surveillance Agency (ANVISA) since october 2011.

Objectives: Evaluate the effectiveness and safety of indacaterol versus formoterol in patients with moderate to severe COPD.

Methods: A search was conducted in November of 2011 of the following databases: PUBMED, EMBASE, TRIP DATABASE, the COCHRANE LIBRARY and CLEARINGHOUSE, with the goal of retrieving systematic reviews, randomized controlled trials and health technology assessment in English, Portuguese and Spanish alone.

Results: 58 articles were recovered, but only one met the inclusion criteria for this analysis. In this study, after a follow-up period of 12 weeks, the group treated with indacaterol had a forced expiratory volume in one second (FEV1) greater than 100 ml to the formoterol group ($p < 0.001$). There was an increase of one point of the transition dyspnea index (TDI score) in 63% of patients treated with indacaterol and 53% in the formoterol group ($p < 0.01$). The rate of adverse events was similar in both groups.

Discussion: The study included is a indirect comparison between indacaterol and formoterol, both evaluated against placebo. The difference in FEV1 and TDI score between groups, although statistically significant, has little clinical relevance. There was no difference in the incidence of disease exacerbations or quality of life between the two groups. The outcomes evaluated are intermediate and short follow-up period (52 weeks) which does not allow inferences about the safety of the drug for treatment of a chronic disease.

Conclusions: Not recommended for incorporation of indacaterol in the Brazilian Public Health System (SUS).

719. BURDEN OF SYSTEMIC LUPUS ERYTHEMATOSUS IN PATIENTS WITH HIGH DISEASE ACTIVITY IN EUROPE

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Background: Systemic lupus erythematosus (SLE) is a chronic autoimmune disease. In addition to other clinical parameters, high disease activity can be characterised by the presence of anti double stranded DNA antibodies (ads-DNA) and low complement (C) levels. Here we report on the relationship between ads-DNA and low C and disease severity, resource use and quality of life in patients with SLE.

Methods: Data were drawn from the Adelphi Lupus Disease Specific Programme, a cross-sectional study of patients with SLE in France, Germany, Italy, Spain and the UK in 2010. Using peer reviewed market research methodologies, a convenience sample of rheumatologists, internists and nephrologists completed a record form for the next 5 presenting patients; patients also self-completed a record form. Patients who physicians reported test results for ads-DNA and for low C levels are described, and comparisons between patients with positive ads-DNA positive and low C (DNA+/LOWC) and those without ads-DNA and/or with normal C levels (DNA-/NORMC) were made. Purpose of this analysis is descriptive.

Results: Among 1179 SLE patients (mean age 40.4, 87% female), 251 recorded information on ads-DNA and C levels; 124 patients were DNA+/LOWC, 127 were DNA-/NORMC. More DNA+/LOWC patients were hospitalised in the previous 12 months (36.3% vs 15.0%; $p < 0.001$) with a longer mean stay (12.8 days [SD 17.6] vs 9.1 days [SD 7.1]; $p = 0.4037$) There was a trend towards more physician visits (4.0 [SD 2.9] vs 3.5 [SD 3.1]) for DNA+/LOWC patients ($p = 0.219$). More DNA+/LOWC patients reported problems with pain/discomfort (67.2% vs 51.7%; $p = 0.2507$) and anxiety/depression (48.1% vs 34.5%; $p < 0.05$), while more DNA-/NORMC patients reported problems with mobility (41.4% vs 28.9%; $p = 0.1492$) and self-care (37.9% vs 15.4%; $p < 0.05$) (EQ-5D).

Conclusions: DNA+/LOWC SLE patients appear to require more hospital and physician support and greater proportion experience pain/discomfort and psychological impairment compared with those who were DNA-/NORMC.

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730. BURDEN OF SMOKING ON PRODUCTIVITY IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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Background/Objectives: This study aimed to explore the impact of smoking on productivity in COPD.

Methods: Respondents to the US National Health and Wellness Survey aged 40+ reporting diagnoses of COPD, chronic bronchitis, or emphysema in 2009 or 2010 were included, using 2010 data for individuals completing the survey in both years. Respondents were classified as either current smokers with COPD (n = 1,685) or former smokers (11+ years not smoking) with COPD (n = 1,932). The Work Productivity and Activity Impairment scale assessed productivity, including absenteeism, presenteeism, and overall work and non-work activity impairment. Multivariate generalized linear models were used to predict productivity impairment, with a negative binomial distribution and a log-link function. Covariates included age, sex, race, insurance status, marital status, income, BMI, alcohol use, exercise, and asthma diagnosis. Indirect costs were calculated using the US Department of Labor's 2009 Bureau of Labor Statistics average wages, adjusted for gender and age. These were multiplied by productivity impairment and then annualized to project yearly costs associated with lost productivity.

Results: Multivariable results for productivity data estimated the following differences between current smokers with COPD and former smokers with COPD: absenteeism (3% vs. 1%, $p = .355$.) presenteeism (23% vs.18% $p = .010$), overall work impairment (25% vs. 21%, $p = .043$) and activity impairment (52% vs. 49%, $p = .004$). Calculated mean indirect costs were estimated to be $10,905 vs $7,819 ($p = .002$), or incremental mean indirect costs of $3,096/year for current smokers.

Conclusions: Compared with former smokers quitting 10+ years prior, COPD sufferers currently smoking have similar absenteeism, greater presenteeism and mildly impaired overall work and activity impairment. Estimated incremental costs of productivity decreases are $3,096 per year for current smokers with COPD.

Implications: Results show that despite the progressive, often irreversible nature of COPD, there are clear benefits to patients and society in terms of improved productivity due to quitting smoking.

738. EXPECTED EFFECTS OF EARLY INITIATION OF INHALED CORTICOSTEROID (ICS) AND LONG-ACTING β2-AGONIST (LABA) COMBINATION THERAPY ON HEALTH OUTCOMES IN PATIENTS WITH ASTHMA AND COPD IN GERMANY – CONSENSUS STUDY BY A MODIFIED DELPHI PROCESS

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Background: Uncontrolled asthma and symptomatic COPD with exacerbations are associated with increased healthcare utilisation costs. GINA guidelines recommend adding a LABA to ICS monotherapy in people with uncontrolled asthma. GOLD guidelines recommend

adding an ICS to LABA therapy for symptomatic COPD patients experiencing ≥2 exacerbations a year.

Objectives: To achieve consensus on whether early initiation of ICS/LABA combination therapy (i.e. immediately uncontrolled asthma, or COPD symptoms and/or exacerbations were present) would improve clinical outcomes in asthma patients on ICS and COPD patients on LABA, and lead to reduced healthcare utilisation and costs.

Methods: A modified Delphi process, a validated consensus development methodology using a structured communication process, was employed. There were two stages: completion of a questionnaire to develop 25 statements; and a mediated videoconference to reach consensus on these statements. The panel comprised six General Practitioners and four pulmonologists practising in Germany.

Results/Discussion: The panel agreed that, for the significant share of asthma patients on ICS experiencing symptoms, early initiation of ICS/LABA would improve asthma control. For patients with symptomatic COPD and exacerbations, it was agreed that adding ICS to LABA therapy in a timely manner would lead to fewer exacerbations and reduce symptoms. Early initiation of ICS/LABA was considered to have the potential to prevent a large proportion of hospital, specialist or emergency room visits by asthma and COPD patients.

Implications: Early initiation of ICS/LABA combination therapy in asthma and COPD patients could reduce healthcare resource utilisation and costs. Such reductions could offset the higher cost of ICS/LABA combination therapy and, for German payers, represent an opportunity to control healthcare budgets in the medium-to-long term.

794. FORMAL METHODS FOR DETERMINING SAMPLE SIZE - SURVEY OF SCT MEMBERSHIP

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Background: Central to the validity of a randomised controlled trial (RCT) is a calculation of the number of participants needed (the sample size). This provides reassurance that the trial will identify a difference of a particular magnitude if such a difference exists. Given its importance, determination of this target difference, as opposed to statistical approaches to calculating the sample size, has been greatly neglected. A variety of approaches have been proposed for formally determining what an important difference is (such as the "minimum clinically important difference" approach). However, in practice the target difference may be driven by convenience or some other informal basis. The awareness and use of formal methods in the trial community is unclear.

Objectives: To assess awareness and use of formal methods for determining the target difference and thereby the RCT sample size.

Methods: Members of the Society for Clinical Trials were sent an email invitation to complete an online survey through the society's email distribution list. The survey collected information about the individual responding (e.g. position, affiliation and location). Seven formal methods were identified that could potentially be used. Respondents were asked about their awareness and use of, and willingness to recommend, methods.

Results: 180 responses were received representing 13 countries and a variety of professions and institutions. Awareness of methods varied from 69 (38%) for health economic methods to 162 (90%) for using pilot data. A majority (96, 53%) had used no more than three of the available methods. Recommendation of methods tended to be lower than use except for health economic and reviewing the evidence base methods.

Conclusions: Awareness, use and willingness to recommend varied greatly between methods. Trial specific guidance documentation may increase both awareness and use of formal methods.

803. MEASURE OF PEAK INSPIRATORY FLOW IN PATIENTS WITH DRY POWDER INHALER PRESCRIPTION

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Background: Obstructive respiratory diseases are a frequent cause of hospitalization. Drug treatment is basically done with inhaled medications. One of the most used types of inhalers is dry powder inhalers (DPI); the mechanism is triggered by the inspiratory effort. Patients with moderate and/or severe exacerbations of obstructive diseases cannot be able to properly use the DPI, because of their low inspiratory capacity. The measurement of peak inspiratory flow (PIF) can be done by portable equipment, able to identify which patients are unable to properly trigger the mechanism.

Objective: To evaluate the PFI in patients with prescriptions for dry powder inhaler devices.

Methods: Prospective cross-sectional study. Included adult patients admitted to the Hospital de Clinicas de Porto Alegre who had prescription of DPI type Aerolizer ® from May to September 2011. PFI was measured using a portable device at the patient's bedside and applied checklist through direct observation of inhalation technique. **Results:** were evaluated 77 patients using DPI, 40 (51.9%) were female. The mean age was 63.23 ± 13.24. The diagnosis of respiratory disease were COPD in 50 (64.9%), asthma in twelve (15.6%) and others 15 (19,5%). 23 of 76 patients (30.3%) reported having doubts about the use of inhaled medications. 31 (40.3%) performed inhalation technique properly, while 46 (59.7%) were evaluated as inadequate technique. Twelve patients (15.6%) had PFI values ≤ 60 L/min.

Discussion and implications: Doubts about the inhalation technique were common among users of Aerolizer. It was relatively common the occurrence of PFI below of the measure proposed for the device. However the measure of PFI helps to define the inhalation device for hospitalized patients. Measures are needed to improve the quality of the inhalation technique with DPI in this population.

825. PREDICTORS OF RELAPSES IN PATIENTS WITH MULTIPLE SCLEROSIS TREATED WITH DISEASE MODIFYING DRUGS

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Objective: To identify predictors of relapses in MS patients treated with disease modifying drugs (DMDs), interferon (IFN) or glatiramer acetate (GA).

Methods: The US MarketScan claims database was used to identify MS patients from 2005-2007. Patients previously diagnosed with MS and required to have 6 months of continuous insurance coverage before first DMD use. A relapse defined by a primary MS diagnosis in hospital or corticosteroid use within 7 days following an outpatient

MS diagnosis. Proportional hazard model was used to identify predictors of MS relapse.

Results: 32,083 MS patients identified; 14,753 treated with IFN (N = 9,541, mean age = 45 years and 76.8% female) or GA (N = 5,212, mean 45.6 years and 78.7% female). GA and IFN treated patients had similar relapse rate. Relapse rate decreased with age with a nadir of 43-years, with 20% higher risk for a 25-year patient relative to a 43-year old. Predictors of increased risk of MS relapse included: female gender, HR 1.10, 95% CI, 1.00-1.21; smoker, 1.20, CI, 1.05-1.37; pain, HR 1.31, CI 1.08-1.60; spasticity, HR 1.36, CI 1.10-1.67; arthritis, HR 1.56, CI 1.23-1.99; sleep disorder, HR 1.38, CI 1.16-1.65; allergic rhinitis, HR 1.30, CI 1.10-1.53; urinary tract infection, HR 1.39, CI 1.24-1.57; visit with neurologist, HR 1.32, CI 1.20-1.44; and inpatient admission, HR 2.14, CI 1.93-2.39. Medication possession ratio was a predictor for lower rate of relapse (HR 0.64, CI 0.57-0.73).

Discussion and implications: No difference in relapse rates in MS patients treated with GA or IFN. Relapse decreased with age and reached lowest rate at 43-years. Cigarette smoking and health conditions as pain, arthritis, allergic rhinitis and urinary tract infection were associated with increased relapse. Better medication adherence with DMDs was also noted as an important mitigating factor for MS relapse.

836. PREDICTORS OF DISEASE MODIFYING DRUG USE IN MULTIPLE SCLEROSIS PATIENTS

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Background: Despite the benefits of disease modifying drugs (DMD) in reducing relapses and delaying MS progression, it is not clear which patient groups are more likely to use DMD in real world practice.

Objective: To examine patient characteristics associated with DMD use in clinical practice.

Methods: MS cohort derived from US MarketScan claims database from 2005-2007. Identified patients required to have 6-months continuous coverage prior to first DMD as baseline characteristics. The variables, including age, gender, comorbidities, medical utilization, specialist visits, lifestyle (smoking, obesity), and MS treatment history used to predict use of interferon agents (IFN) or glatiramer acetate (GA) in a logistic regression.

Results: 9,541 first dispensed IFN and 5,212 for GA. 16,434 did not use a DMD in the observation period. During baseline, DMD treated group mean age, 45-yrs vs 46-yrs for non-DMD group, with 76-78% female patients. More full employed patients treated (56%) vs non-treated (37%) group. About 1.3-1.8% had a long term disability claim and 2% needed walking aid or wheelchair in treated vs 3% in non-treated group. About 55% patients visited a neurologist in treated vs 46% in non-treated group. Multivariable adjusted analysis showed: DMD use increased yearly from 2005- 2007. Peak age of DMD use about 34yrs. Observed significant variability in DMD use over geographic regions. Baseline visit to neurologist (OR = 1.36, [1.29-1.44]) and MS relapse (OR = 1.40, [1.25-1.58]) were associated with increased use of DMD, while baseline comorbidity (CCI: OR = 0.81, [0.78, 0.84], depression: OR = 0.81, [0.73, 0.89], and arthritis: 0.68, [0.56, 0.82]) were related with decreased DMD use.

Discussion and implications: While DMD therapy increased over time, about half of patients did not receive DMD treatment in a US managed care population with MS. Presence of comorbid conditions may have a limiting factor for DMD use. Referral to neurologist care appears a mitigating factor for expanded treatment with DMD.

855. ESTIMATING EQ-5D HEALTH STATE VALUES FOR RHEUMATOID ARTHRITIS PATIENTS: A LIMITED DEPENDENT VARIABLE, MIXTURE MODELLING APPROACH

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Background: It is often a requirement of economic evaluation that we have an estimate of treatment benefit in terms of QALYs. Where appropriate instruments have not been included in clinical trials then analysts often estimate the relationship between clinical and preference based measures in an external dataset. This "mapping" is usually undertaken using simple methods that perform badly. We have previously estimated the relationship between function, pain and EQ-5D using a new model based on an adjusted limited dependent variable mixture models (ALDVMM). This approach requires validation and refinement.

Objectives: To replicate and refine methods to estimate EQ-5D tariff values by functional disability, pain, age and sex using a large observational dataset comprising in excess of 16,000 patients (n = 116,707).

Methods: Comparisons of random effects linear, Tobit and ALDVMMs with between three and six latent classes. Model selection in terms of model fit, systematic bias and predictions within the feasible range.

Results: A five class ALDVMM model estimating EQ-5D as a function of HAQ, HAQ^2, pain and age provides a substantial improvement over other approaches. The responsiveness of EQ-5D to changes in HAQ and pain differs substantially between the 5 classes. Class membership can be predicted by sex, disease duration, age, pain and HAQ at baseline.

Discussion: The ALDVMM approach is designed to appropriately reflect the range of challenges that arise from the EQ-5D distribution. Standard models are not as appropriate and fit the data poorly. In RA, data is scarce and may lack credibility for patients in extremely poor health states.

Implications for the health system/professionals/patients/society: The cost effectiveness of technologies for RA patients should be estimated using the ALDVMM since this provides a more accurate representation of treatment benefit.

860. FOUR-YEAR THERAPEUTIC PATHWAYS IN PATIENTS DIAGNOSED WITH MULTIPLE SCLEROSIS

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Background: Multiple sclerosis (MS) is a chronic, progressively disabling disease of the central nervous system.

Objective: Follow MS patients diagnosed and treatment pathways over four years.

Methods: A US MarketScan claims database was used to identify patients newly diagnosed with MS from 2005-2007 during 12 months. MS medications were: Interferon (IFN), glatiramer acetate (GA), immunosuppressants (IS) and no MS specific treatment (No-treatment) followed for four-years. Drug discontinuation was if no MS prescription was dispensed for 90 days after the last day of previous prescription.

Results: 1519 patients identified; about 30% patients initiated IFN after an average of 159 days from the MS diagnosis, 16% initiated GA after 188 days, 4% initiated IS after 507 days. Nearly 50% did not initiate MS treatment four-years after MS diagnosis. Patients started with IFN or GA were younger (45-yrs) and had fewer comorbidities

CCI = 0.3 compared with IS (48-yrs, CCI = 0.8) and No-treatment group (47-yrs, CCI = 0.4). 464 patients who received IFN, 48% continued treatment through four-years, 10% switched to GA after an average of 368 days, 4% switched to IS after 392 days and 38% discontinued after 496 days. Discontinued patients, 46% restarted IFN, 13% started GA or IS. Similar patterns observed for the 239 who initiated GA: 45% continued treatment through four-years, 10% switched to IFN after 429 days, 3% switched to IS after 300 days and 42% discontinued after 421 days. Discontinued GA patients, 55% restarted GA, 9% started IFN or IS.

Discussion and implications: Nearly one-half of managed care insured patients were not treated 4-years after MS diagnosis. Majority treated with IFN or GA and approximately 50% had 4-years of uninterrupted treatment. Medication switches between IFN and GA were 10% in each direction after about 1-yr. About 50% patients who discontinued IFN or GA restarted the drug. Study provided preliminary look of patients without MS treatment 4-years after MS diagnosis.

862. SURVEY ON MANAGEMENT OF METASTATIC HORMONE-REFRACTORY PROSTATE CANCER UPON PROGRESSION DURING OR FOLLOWING FIRST-LINE CHEMOTHERAPY IN FIVE EUROPEAN COUNTRIES

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Background: In Europe, docetaxel is the standard first-line chemotherapy (1L) for patients with metastatic hormone-refractory prostate cancer (mHRPC). Upon progression, either during or after 1L chemotherapy, treatment options are limited.

Objective: This study evaluated how patients who progressed during or after 1L docetaxel between October 2009 and June 2010 were managed.

Methods: A representative sample of 349 physicians (oncologists, urologists) who managed patients with mHRPC were selected from Germany, France, UK, Spain and Italy. Information on the treatments used at the time of progression (during or after the first 6 months following 1L treatment with docetaxel) was provided. Blind characteristics were used in the survey.

Results: Information on 2,870 mHRPC patients was provided of which 2,670 (94%) had received docetaxel in 1L. 1,389 (52%) patients progressed during 1L docetaxel or within 6 months following treatment; of these, 615 (44%) received 2L chemotherapy of agents.

Discussion: Study showed mitoxantrone as the most commonly used agent for 2L treatment of patients who progressed during or after the first 6 months following 1L. Docetaxel rechallenge was uncommon, particularly for patients who progressed within the first 3 months after 1L.

Implications: This survey improves the understanding of the current real-life clinical decision making, having implications for the selection of the comparator for assessments.

870. PATTERNS OF SECOND-LINE CHEMOTHERAPY FOR METASTATIC PROSTATE CANCER IN US

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Background: Patients with prostate cancer progressing from first-line (1L) docetaxel had limited approved treatment options available prior.

Objective: To evaluate patterns of second-line (2L) chemotherapy in a US managed care between 2004 and 2010.

Methods: Patients with metastatic prostate cancer (mPC) treated with 1L docetaxel after July 1, 2004 ascertained from the OptumInsight database. We evaluated type and timing of chemotherapy and relationships between patient characteristics, physician specialty, healthcare costs and geographic regions, 6 months prior to 1L docetaxel and choice of 2L chemotherapy.

Results: Patients (N = 1,173) were identified at onset of 1L docetaxel and followed for 18 months (mean). 451 (38%) received 2L treatment, of which 144 (32%) received mitoxantrone (MITO), 108 (24%) docetaxel rechallenge (RECH), 14% carboplatin, and 12% paclitaxel. Examination of the 2L groups showed that during the 6 months prior to 1L docetaxel, the RECH patients were older (mean, 73 yrs), had fewer hospital admissions (12%), lower comorbidity burden, CCI = 7.4, lower healthcare costs ($10,083), and 78% visited an oncologist; relative to MITO group with 70 yrs, 16% hospital admissions, CCI = 7.5, healthcare costs of $12,074, and 80% saw an oncologist. Median time to MITO from the start of 1L docetaxel was 184 days and 309 days to RECH therapy. Midwest (36%) and West (37%) frequently used MITO than Northeast (26%) and South (31%), while RECH was more frequently used in Northeast.

Discussion: Patients with mPC in US were most frequently treated with MITO or RECH as 2L after 1L docetaxel. MITO was also given sooner than RECH, validating it as a comparator for comparative effectiveness evaluation on new 2L therapy. Rechallenge with docetaxel increased with time and given to patients with lower disease burden than the MITO group.

Implications: The study validates the current real-life clinical decision making in the selection of the comparator for assessments.

885. VALIDITY AND APPLICABILITY OF PREDICTIVE SCORES IN COLORECTAL CANCER SURGERY

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Background: the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) model and its Portsmouth (P-POSSUM) and colorectal (CR-POSSUM) modifications are commonly to predict and audit post-operative mortality and

Table 862. 2L chemotherapy according to time to progression during or after 1L docetaxel

	Time to progression			
Agents received as 2L	**Progression during or within 6 months following the end of 1L (615 patients)**	**Progression during 1L (198 patients)**	**Progression 0-3 months after the end of 1L (195 patients)**	**Progression 3-6 months after the end of 1L (222 patients)**
Mitoxantrone	45%	44%	49%	42%
Vinorelbine IV	22%	22%	17%	27%
Docetaxel	10%	3%	9%	17%

morbidity. Recently, other scoring systems have been developed in different countries in order to improve and expand its applications.

Objectives: To assess quality of evidence of predictive value of the scoring systems in colorectal cancer surgery and their application in the comparison of outcomes among surgeons, units and hospitals.

Methods: The following databases were searched from 1998-2011: Cinahl, Embase, Eric, Medline, y SciELO using terms such as, colorectal cancer, predictive model, surgical scoring systems, POSSUM and ACPGBI. Inclusion criteria: language English, French or Spanish, at least one model on colorectal surgery, outcomes defined morbidity, reintervention or mortality.

Results: 20 original studies were included. They assess the validity of the following models: POSUMM and it derivates P-POSSUM and CR-POSSUM, Association of Coloproctolgy of Great Britain and Ireland (ACPGBI), French Association of Surgery colorectal scale (Association Française de Chirugie, AFC) and the Cleveland Clinic Foundation Colorectal Cancer Model (CCF-CCM) and American College of Surgeons (ACS) National Surgical Quality Improvement Program, among others. P-POSSUM and CR-POSSUM have a better performance in predicting postoperative mortality. Data on other models are inclusive. Internal validity was low to moderate.

Discussion: Different predictive scores have been developed in colorectal cancer surgery, using different approaches and variables. However, they have to be interpreted carefully due to limitations related with internal and external validity.

Implications: Estimating the risk of postoperative adverse outcomes is useful in establishing informed patient consent and shared decision-making, planning treatment and care and also for the purpose of risk adjusted comparison among hospitals.

901. COMPARISON OF SOURCES OF DATA TO GET PREVALENCE OF HOSPITAL-ACQUIRED INFECTIONS IN INTENSIVE CARE UNITS (ICUS) AND ATTRIBUTABLE MORTALITY

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Background and objectives: To compare sources of data to get prevalence of hospital-acquired infections (HAI) in ICU attribute mortality.

Methods: Retrospective cohort undertaken using hospital database from the Premier Perspective of adults admitted with a stay > = 48h in 2007. Three HAI followed: bloodstream infection (BSI), surgical site infection (SSI), Hospital-acquired pneumonia (HAP) including ventilator-associated pneumonia (VAP). Case-subjects with NI, and Control without NI. Inpatient consumption was limited to hospital length of stay (LOS) and inpatient mortality rates. Logistic regression for prevalence odds ratio (OR) used to assess the effects of independent variables as risk factors for the presence or absence of infection.

Results: 5,426,276 patients meeting entry criteria in 2007 in the Premier database, 8.5% experienced HAI. ICU population of 463,491 patients, 119,616 (25.8%) developed HAI. HAP/VAP: 16.6%, BSI: 13.9%, and SSI: 1.4%. Patients with HAI were mostly elderly, admitted via emergency room, a high bed occupation, presented with more severe illnesses, more risk of mortality, and often underwent device procedures as: central-catheter placements (49% vs. 18%) or mechanical-ventilation (42% vs. 15%) compared to patients without NI. The inpatient-mortality rate and LOS were higher in patients with HAI (18.5% vs. 4.5% and 15.8 days vs. 8.1 days), respectively compared to patients without HAI. Central catheters and mechanical ventilations identified as the two main risk factors for HAI with OR = 3.4 CI [3.3-3.4] and OR = 2.8 [2.7-2.8], respectively.

Discussion and implications: HAIs are common and often associated with two main specific risk factors of mechanical ventilations and central catheters, which subsequently lead to longer LOS and higher mortality rates. These findings illustrate the changing nature of hospital patient population over the years that are more vulnerable to nosocomial infections, which demand preventive measures to reduce the prevalence and risk factors of these infections on the elderly.

911. PHARMACOTHERAPY RISKS MANAGEMENT IN INTENSIVE CARE UNIT (ICU) BASED IN BRAZILIAN ORGANIZATION FOR ACCREDITATION (ONA)

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Background: Pharmacotherapy is a valuable therapeutic tool, since it is used properly with knowledge, responsibility and professionalism. However, it can also occur adverse drug events, even with its proper usage, hence the importance of promoting the practice of pharmacovigilance within the risks management program recommended by international health organization, including the Agência Nacional de Vigilância Sanitaria (ANVISA) – the Brazilian Health Surveillance Agency.

Objective: the present study aims to check possible mistakes that can lead to drugs adverse events and plan improvements to provide greater security and quality in pharmacotherapy based on the principles of ONA.

Methods: Analysis of all medical records from May and June of 2011 of pharmacotherapeutic process routinely applied in the ICU of a public metropolitan hospital in São Paulo, by checking dosages, routes of administration, doses, correct patients and possible drug interactions.

Results: There were about 5 big events of pharmacotherapy risks in a week, with non-compliance in the prescription of medicine by not recommended route (15%), wrong solutions for drugs administration (25%), and electrolyte abnormalities caused by drugs (60%). There was no administration of wrong drugs in patients during the study period.

Discussion: Risks management in pharmacotherapy is complex process, so it needs the support and involvement of the hospital's top management and all ICU healthcareworkers; it´s a paramount to applying the principles of the ONA and the training of physicians in pharmacotherapy to ensure greater security and quality of care in the ICU, with greater control over adverse drug events.

Implications for the health system: To avoiding pharmacotherapy adverse events may reduce the time of hospitalization, the cost of treatment, the morbidity and even mortality.

31. DEVELOPMENT OF A SYSTEMATIC REVIEW UNIT OF THE BOTUCATU MEDICAL SCHOOL (FMB), SÃO PAULO STATE UNIVERSITY IN BRAZIL

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Background: One of the aims of the Botucatu Medical School (FMB) is to introduce the principles of Evidence-Based Medicine (EBM) to clinicians, physician residents, graduate and postgraduate medical students, and health professionals. The new model of self-education allows the production of systematic reviews and meta-analyses and to help in the design and conduction of randomized clinical trials at the FMB Clinical Hospital.

Objective: We present the development of a systematic review unit (SRU).

Methods: A systematic review unit was established consisting of a scientist in EBM (RED) trained at McMaster University and worked in the Brazilian Cochrane Centre, two surgeons (SAS, AC), an information retrieval specialist (MB), three clinical physicians (MVR, PB, CRN), and one researcher (DF). Weekly meeting discussion of all members of the SRU is performed to access relevance prior to conducting a systematic review. Systematic reviews and meta-analyses are conducted according to the principles of the Cochrane Collaboration and written based on the PRISMA statement. Furthermore, methodological studies are performed dealing with the problem of lack of clinical trials. All teachers, health professionals and students are welcome to perform systematic reviews. They are trained in EBM by workshops coordinated by Prof. Dr. Regina El Dib.

Results: 22 projects for systematic reviews are currently underway (six are registered in the Cochrane groups). Other three completed systematic reviews were done and one of them paved the way for the successful design and conduct of a pragmatic trial. This trial and review were funded by the National Council for Scientific and Technological Development (CNPq). The other two reviews were also funded by CNPq and by São Paulo Research Foundation (FAPESP). Three clinical trials have been designed according to the reviews protocol.

Conclusions: A SRU increased the production of systematic reviews and clinical trials to help patients make healthcare decisions.

33. EFFICACY OF OFF-LABEL USE OF BEVACIZUMAB FOR RETINOPATHY OF PREMATURITY: A SYSTEMATIC REVIEW

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Objectives: Evaluate the efficacy and safety of intravitreal bevacizumab in retinopathy of prematurity (ROP).

Methods: Systematic review. Participants: one hundred and fifty infants with stage 3+ ROP from published randomized controlled trial.A search strategy was conducted in June 2011 with no language restrictions in Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (1966 to June 2011), EMBASE (1980 to June 2011), LILACS (1982 to June 2011), and the Clinicaltrials.gov to identify randomized or quasi-randomized controlled trials reporting off-label use of bevacizumab in retinopathy of prematurity. We used relative risk (RR) with 95% confidential interval (CI) for dichotomous analysis and we calculated the number needed to treat (NNT) when there was a significance difference. Main outcomes measures: regression and recurrence of retinopathy of prematurity in one or both eyes and adverse events.

Results: The search strategy identified 375 references, however only one study met our inclusion criteria. The study was a prospective, multicenter, randomized, unmasked, phase II trial that compared the efficacy of intravitreal bevacizumab (0,625 mg in 0,025 ml) to conventional laser therapy in reducing the incidence of recurrence in stage 3+ ROP. The rate of recurrence with zone I was significantly higher with conventional laser than with intravitreal bevacizumab (RR 0.15 [95% CI 0.04 to 0.60], p = 0.007). No statistical difference was noted for zone II (RR 0.39 [95% CI 0.08 to 1.90], p = 0.24). However, the diamond effect was also favors bevacizumab regardless the zone classification with a NNT of 5. The overall quality of the study was classified as low risk of bias.

Conclusion: Intravitreal bevacizumab as compared with conventional laser therapy in infants with stage 3+ ROP showed a significant benefit for zone I but not zone II disease. There is urgency for further clinical trials to establish the actual efficacy and safety of bevacizumab in retinopathy of prematurity.

65. EFFICACY AND SAFETY OF ATYPICAL ANTIPSYCHOTIC DRUGS (QUETIAPINE, RISPERIDONE, ARIPIPRAZOLE AND PALIPERIDONE) COMPARED WITH PLACEBO OR TYPICAL ANTIPSYCHOTIC DRUGS FOR TREATING REFRACTORY SCHIZOPHRENIA: OVERVIEW OF SYSTEMATIC REVIEWS

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Background: According to some cohort studies, the prevalence of refractory schizophrenia (RS) is 20-40%.Objectives: Our aim was to evaluate the effectiveness and safety of aripiprazole, paliperidone, quetiapine and risperidone for treating RS.

Methods: This was a critical appraisal of Cochrane reviews published in the Cochrane Library, supplemented with reference to more recent randomized controlled trials (RCTs) on RS. The following databases were searched: Medical Literature Analysis and Retrieval System Online (Medline) (1966-2009), Controlled Trials of the Cochrane Collaboration (2009, Issue 2), Embase (Excerpta Medica) (1980-2009), Literatura Latino-Americana e do Caribe em Ciências da Saúde (Lilacs) (1982-2009). There was no language restriction. Randomized controlled trials, systematic reviews and meta-analyses evaluating atypical antipsychotics for treating RS were included.

Results: Seven Cochrane systematic reviews and 10 additional RCTs were included in this review. The data generally showed minor differences between the atypical antipsychotics evaluated and typical antipsychotics, regarding improvement in disease symptoms, despite better adherence to treatment with atypical antipsychotics. Risperidone was specifically evaluated in patients with RS in one of the systematic reviews included, with favorable outcomes, but without definitive superiority compared with other drugs of proven efficacy, like amisulpride, clozapine and olanzapine.

Conclusions: The findings underscore the difficulty in treating these patients, with high dropout rates and treatment patterns of modest improvement in assessments of effectiveness. Atypical antipsychotics have advantages over typical antipsychotics mainly through their better safety profile, which leads to better adherence to treatment. A combination of antipsychotics may also be an option for some refractory patients.

75. INTERVENTIONS TO REDUCE ACUTE PAEDIATRIC HOSPITAL ADMISSIONS: A SYSTEMATIC REVIEW

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Objective: To compare the effectiveness of interventions aimed at reducing the rate of acute paediatric hospital admissions.

Methods: Design: systematic review. Data sources: Medline, Embase, Psychinfo, The Cochrane Library, Science Citation Index Expanded from inception to September 2010; hand searches of the reference lists of included papers and other review papers identified in the search. Review methods: controlled trials were included.

Articles were screened for inclusion independently by two reviewers. Data extraction and quality appraisal were performed by one reviewer and checked by a second with discrepancies resolved by discussion with a third if necessary.

Results: Seven papers were included. There is some evidence to suggest that short stay units may reduce admission rates. However, there is a general lack of detail in the reporting of interventions and the methods used in their evaluation which preclude detailed interpretation and extrapolation of the results. We found no evidence that the use of algorithms and guidelines to manage the admission decision was effective in reducing acute admission rates. Furthermore we were unable to locate any eligible papers reporting the effects on admission rates of admission decision by paediatric consultant, telephone triage by paediatric consultant or the establishment of next day emergency paediatric clinics.

Conclusion: The rate of hospital admissions amongst the paediatric population continues to rise and there is widespread recognition that this situation is unsustainable. A range of initiatives are being introduced to hospitals in the UK and beyond to reduce acute paediatric admissions. The relative effectiveness of such initiatives, whilst avoiding adverse consequences for the children who are not admitted, is unclear. We found little published evidence upon which to base an optimal strategy for reducing paediatric admission rates. The evidence that does exist is subject to substantial bias. There is a pressing need for high quality, well conducted research to enable informed service change.

83. PREVALENCE OF ATTENTION DEFICIT HYPERACTIVITY DISORDER AMONG CHILDREN AND ADOLESCENTS IN SPAIN: A SYSTEMATIC REVIEW AND META-ANALYSIS OF EPIDEMIOLOGICAL STUDIES

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Objective: Attention deficit hyperactivity disorder (ADHD) is a commonly diagnosed neuropsychiatric disorder in childhood, but the frequency of the condition is not well established in many countries. The aim of the present study was to quantify the overall prevalence of ADHD among children and adolescents in Spain by means of a systematic review and meta-analysis.

Methods: PubMed/MEDLINE, IME, IBECS and TESEO were searched. Original reports were selected if they provided data on prevalence estimates of ADHD among children and adolescents in Spain and were cross-sectional, observational epidemiological studies. Information from included studies was systematically extracted and evaluated. Overall pooled-prevalence estimates of ADHD were calculated using random-effects models. Sources of heterogeneity were explored by means sub-groups analyses and meta-regressions.

Results: Fourteen epidemiological studies (13,026 subjects) were selected. The overall pooled-prevalence of ADHD was estimated at 6.8% [95% confidence interval (CI) 4.9–8.8%] with a prevalence rate of 7.2 cases (95% CI 5.2–9.3) per 1,000 people. There was significant heterogeneity ($P < 0.001$), which was incompletely explained by subgroup analysis and meta-regressions.

Conclusions: Our findings suggest that the prevalence of ADHD among children and adolescents is considerable in Spain and consistent with those estimates previously reported in other countries. This study represents a first step in estimating the burden of ADHD that will be essential to building evidence-based programs and services.

120. ASSESSMENT THE TYPES OF THE LIBERATION TREATMENT FOR MULTIPLE SCLEROSIS

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Background: Multiple sclerosis (MS) is a chronic neurological disease that typically affects young adults. Many investigators believe MS to be an autoimmune disease - one in which the body, through its immune system, launches a defensive attack against its own tissues. In the case of MS, it is the nerve-insulating myelin that comes under assault. Such assaults may be linked to an unknown environmental trigger, perhaps a virus. A recent publication suggested that MS might originate from insufficient blood drainage in certain areas of the central nervous system. The condition was named chronic cerebrospinal venous insufficiency (CCSVI).

Objectives: HTA Department received from Ministry of Health the assignment for a rapid assessment the types of the liberation treatment for MS.

Methods: A computerized search was conducted on English-, Kazakh-, and Russian-languages-published peer-reviewed studies focusing on endovascular treatment of MS.

Results: First and foremost, there was no study which employed a wide range blind randomized design. Although it is obvious that such a design would presently be rather difficult, if not impossible, to implement because of technical complications there is still room for comparisons between different assumption about etiology of MS. In fact, we were unable to reliably determine the main pathology cause of this disease.

Discussion: In this review, we have provided a comprehensive and critical analysis of the published literature on the treatment of MS. We are still unable to define the appropriate cost-effective guidelines for treatment, and have widely adopted an intervention that emerges as relatively ineffective.

Implications for the health system: The relationship between CCSVI and MS presented in this report suggests that the impact of such investigations may be greater than previously assumed. But, nowadays, it is premature to talk about the sufficiency of the scientific evidences for approval of the surgical treatment of MS by the Ministry of Health of the Republic of Kazakhstan.

147. IDH1 AND IDH2 MUTATIONS IN GLIOMAS: A SYSTEMATIC REVIEW

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Background: Gliomas are classified according to the histological criteria by the World Health Organization. However, the classification remains unsatisfactory. In search for objective marker of gliomas, studies on isocitrate dehydrogenase (IDH) 1 and 2 mutations are ongoing.

Objectives: The purpose of this research was to assess the diagnostic, prognostic and predictive values of IDH1 and IDH2 mutations in gliomas.

Methods: A systematic review was conducted to identify relevant articles published until 2011 April. Ovid-MEDLINE, Ovid-EMBASE, The Cochrane Library and the databases of heath technology agencies were searched. The studies on IDH1 or IDH2 mutation status by DNA sequencing analysis were included. The SIGN (Scottish Intercollegiate Guidelines Network) methodology checklists were used for critical appraisal. After data exaction, descriptive analysis was carried out.

Results: The search yielded 921 literatures, 27 articles (18 cohort studies and 9 case series) of which met our inclusion criteria. IDH2 mutations, examined only in 15 studies, were detected in 0-5.8% of gliomas. (a) As a diagnostic marker (7 articles): The specificity of IDH1 mutations in glioma diagnosis (4 studies) or glioma differential diagnosis (5 studies) were 1.00 (95% CI 1.00-1.00) and 0.30 (95% CI 0.19-0.42), respectively. (b) As a prognostic marker (17 articles): IDH1 or IDH2 mutations predicted longer survival in glioma patients. (c) As a predictive marker (4 articles): In one study, IDH1 or IDH2 mutations predicted response to TMZ (temozolomide). However, the other 3 studies reported that IDH1 mutations were not related to the response to chemotherapy using TMZ or PCV (procarbazine, lomustine, and vincristine).

Discussion: Based on the current literature, IDH1 mutations are useful biomarker for diagnosis and prognosis of gliomas. On the other hand, IDH2 mutations occurred rarely, thus did not gave additional information in glioma diagnosis.

151. EFFECTIVENESS OF COMPUTER-BASED COGNITIVE PSYCHOTHERAPIES (CCBT) FOR DEPRESSION

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Background: Medication is the most commonly used treatment option for major depressive disorder since availability of psychotherapies is limited. Computerised cognitive behavioural therapies (CCBT) have been used for the treatment of depressive disorders.

Objectives: The aim of this systematic review was to evaluate effectiveness of CCBT in the treatment of adult depressive patients. Studied outcomes were depressive symptoms, work and ability of function, quality of life, patient satisfaction and costs.

Methods: A systematic literature search from Medline, Cochrane and Ovid was performed. Meta-analysis, systematic reviews, randomised clinical trials and studies on cost-effectiveness were gathered covering period from January 2000 to April 2011. CCBT was compared to all other treatments (face to face therapy, medication, waiting list, treatment as usual).

Results: Nine systematic reviews and 17 RCTs and 4 economical studies were selected out of 169 abstracts. CCBT was more effective in all studies when compared with waiting list and at least as effective as face to face cognitive psychotherapy. Acceptability and satisfaction among the patients was good. Quality of life was similar to that in the control group. CCBT was found to be cost-effective in all studies.

Discussion: CCBT seem promising for the treatment of depression among adults with mild to moderate depression. There is not enough evidence on effectiveness in the treatment of severe depression. The risks of CCBT have not been studied and suicide risk remains as contraindication for use. The impact who is giving the support, the minimum level of support and effectiveness among different patient populations are topics for future search.

Implications: Validation of CCBT program in Finnish language is needed before it can be taken widely in use. The integration of CCBT to other depression treatments should be carefully planned at the local level before taken in use.

152. EFFECTIVENESS AND SAFETY OF PERCUTANEOUS TECHNIQUES FOR THE TREATMENT OF PELVIC RING FRACTURES WITH ILIOSACRAL SCREWS

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Objectives: To determine the effectiveness and safety of percutaneous techniques (PT) for the treatment of pelvic ring fractures with Iliosacral screws.

Methods: A systematic review of the literature was made with a tructured search in the Medline, EMBASE, SCOPUS and Web of Science Databases [limit to December 2010]. Searches were also made in the INAHTA. Criteria for inclusion were: general population, intervention (PT for the treatment of pelvic ring fractures) and outcomes (effectiveness and safety in terms of reduction of morbidity and intra-post operative adverse effects). A critical reading was made of the selected articles. The synthesis of the results was qualitative.

Results: There were 411 references retrieved without duplicates. 33 full text were evaluated and 19 studies included were original papers describing case series. There were 13 case series identified (2 retrospective). All studies used a small number of participants, and recorded differences in surgical technique. The follow-up was in general short and didn´t specify the causes of losses. Intraoperative surgical times ranged between 26 and 87 minutes, and minimal blood losses ranging from 10 to 30 ml. The percentage of suitable consolidation was high (91.3% to 100%). Neurological lesions ranged between 0.6% and 52% in 9 series. Badly positioned screws were recorded with a frequency of between 2.05% and 26% in six of the studies. Material failure was detected at a frequency of between 0.4% and 4% in 5 series, and screw migration occurred in only two studies in 4% and 4.5% of the participants. There were no cases of malunion. The rate of pseudarthrosis was 7.1% and 1.1%. The frequency of secondary displacement ranged between 2.8% and 7.1% in the 9 studies that provided this.

Conclusions: PT in these interventions is an ideally safe and effective way to treat unstable pelvic posterior ring fractures, it has many advantages such as minimal invasion and less complications. Although, quality studies with control groups are needed to allow firm conclusions to be obtained upon which to base recommendations for routine use.

192. SYSTEMATIC REVIEW OF GENERIC SELF-REPORTED HEALTH-RELATED WORKPLACE PRODUCTIVITY LOSS INSTRUMENTS

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Introduction: Health impairment often leads to reduced productivity at work. Many instruments have been developed to measure the impact of illness on productivity at work. This complicates selection of appropriate instruments. Evidence of the psychometric properties is important. The aim of this review is to critically appraise and compare the measurement properties of

generic self-reported instruments that measure health-related workplace productivity losses.

Methods: Four databases were used to systematically search for suitable articles up to 2011: PubMed, PsycINFO, Econlit and Embase. Papers were included that: (a) focus on the evaluation of the measurement properties of generic self-reported health-related productivity loss instruments; (b) define and measure work disability as absenteeism and presenteeism; (c) are available as full text articles in Dutch or English. Afterwards, a uniform checklist called COSMIN was completed to evaluate the general methodological quality based on the: (i) internal consistency; (ii) reliability, (iii) measurement error; (iv) content validity; (v) structural validity; (vi) hypotheses testing; (vii) cross-cultural validity; (viii) criterion validity; (ix) responsiveness; (x) interpretability.

Results: Preliminary results show that several generic subjective instruments could be identified that theoretically could be used in any working population and have sufficient psychometric properties. However psychometric properties differ. The preliminary results imply that recommendations can be made for when to use which instrument. Using these sound instruments, lost productivity costs can be computed. However, users will have to base their decisions on the content of the measurement tool, the target population and the intention of use. This systematic review enables policy makers in (occupational) health care and social insurance to make better informed decisions.

203. PERCUTANEOUS CORONARY INTERVENTION WITH OPTIMAL MEDICAL THERAPY VS. OPTIMAL MEDICAL THERAPY ALONE FOR PATIENTS WITH STABLE ANGINA PECTORIS. MEDICAL EVALUATION

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Background: Medical therapy and percutaneous coronary interventions (PCI) are the most important methods used in the treatment of chronic coronary artery disease (CAD).

Objectives: The evaluation addresses medical efficacy in the use of PCI in CAD patients in comparison to optimal medical therapy alone.

Methods: A systematic literature search was conducted in June 2010 in the electronic databases (MEDLINE, EMBASE etc.) and was completed by a hand search. The medical analysis was based on randomized controlled trials (RCT) with use of current optimal medical therapy. The results of the RCTs were combined using meta-analysis. The strength and the applicability of the determined evidence were appraised.

Results: Only three of the identified RCTs used optimal medical therapy and were included in the meta-analysis. The applicability of the evidence for the endpoints angina pectoris (AP) and revascularisation was moderate, for further endpoints high. The routine use of PCI reduces the proportion of patients with AP attacks in the follow-up up to three years in comparison with optimal medical therapy alone (evidence strength moderate). No difference in effect was found for the investigated critical clinical endpoints death, cardiac death, myocardial infarction and stroke in the follow-up up to five years (evidence strength high).

Discussion: Important methodical problems of the studies are a lack of blinding of the patients and incomplete data for several endpoints in the follow-up.

Implications: The routine use of PCI in addition to the optimal medicinal therapy in patients with stable AP can be recommended for the reduction of the proportion of patients with AP attacks (recommendation degree weak). Otherwise, PCI is to be performed in patients with refractory AP despite of optimal medical therapy (expected in 27% to 30% of patients in five years).

210. PROSPERO: THE FIRST YEAR OF A PROSPECTIVE REGISTER OF SYSTEMATIC REVIEWS

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PROSPERO was launched in February 2011 in response to increasing support for the prospective registration of protocols for systematic reviews. The aims of the register are to help reduce unplanned duplication, to identify and reduce the risk of reporting bias and to encourage transparency in the conduct and reporting of systematic reviews. It is anticipated that this will in time provide an opportunity to improve the quality of systematic reviews and the healthcare decisions that rely on them. PROSPERO was developed in collaboration with an international advisory group and informed by a worldwide consultation to identify the key items for inclusion in the register. The register has been well received with more than 300 registrations from 27 different countries in the first 10 months alone. To inform the next stage in the development of PROSPERO, the utility of the database after one year will be evaluated. The planned evaluation will provide descriptive information about the 'who, where and what' of registration submissions and the use of the website to register ongoing reviews. In addition to feedback from registrants received throughout the year, the results of a planned brief on-line survey of registrants will be presented.

This presentation will outline the registration process and function of the register and then focus on the results of the evaluation. Aggregate details of the submitted records will be presented, together with information on specific registration items of general interest. The preliminary results from the on-line survey of PROSPERO registrants will also be presented, along with ideas for the next phase in the development of PROSPERO.

242. EMPIRICAL EVIDENCE OF UTILIZATION AND PRACTICE OF SELF-PAY SERVICES IN THE GERMAN HEALTH CARE SYSTEM. RESULTS OF A HEALTH TECHNOLOGY ASSESSMENT

Theresa Hunger[a], Petra Schnell-Inderst[a], Katharina Hintringer[b], Ruth Schwarzer[a], Vanadin Seifert-Klauss[c], Holger Gothe[a], Jürgen Wasem[d] and Uwe Siebert[e]

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Background: The German Institute for Medical Documentation and Information commissioned this health technology assessment about individual health services (IGeL). These are medical self-pay services that are not liability of the German statutory health insurance.

Objectives: We investigated empirical data on offers, utilization, practice, acceptance, influence on patient-doctor relationship and economic significance of these services in the ambulatory health care, as well as related ethical, social and legal aspects.

Methods: We performed a systematic literature and internet search for original studies and publications about ethical, social and legal aspects of IGeL. Two independent authors screened the references according to defined criteria and in- or excluded them from the information synthesis.

Results: Of 1344 references, we included 64 articles. 31 of them were publications of original studies on IGeL and 33 were publications on ethical, social and legal issues. Between 19 and 53% of insured persons received IGeL offers by their physician of which three-quarters were actually realized. 10 to 19% of patients actively asked for them. The most frequent IGeL was intraocular tension measurement and accounted for up to 40% of the offered services, followed by ultrasound examinations with up to 25%. Cancer screening and blood or laboratory tests represent great parts of the patients' requests. Ethical, social and legal aspects discussed in this context concern competent patient decision, commercialization of medicine, information requirements, evidence of patient benefit, physician-patient relationship, relation to the statutory health insurance system, social inequality and formal requirements.

Discussion: Since they are wide spread in the ambulatory health care of the statutory health insurance, the provision of IGeL should be more transparent. Independent, evidence-based patient information should be available.

Implications for the health system: Self-pay services need to be considered in the context of the political design of the health care system.

244. RAPID ASSESSMENT OF THE CLINICAL EFFECTIVENESS OF VAGINAL ULTRASOUND SCREENING FOR OVARIAN CANCER OFFERED AS SELF-PAY SERVICE

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Background and objectives: In the context of a health technology assessment (HTA) about self-pay services commissioned by the German Institute for Medical Documentation and Information, the evidence on screening for ovarian carcinoma using vaginal ultrasound (VUS) was investigated as an example for medical services not covered by the German statutory health insurance.

Methods: We performed a systematic rapid assessment of VUS screening. First, we searched HTA reports and systematic reviews and then for randomized controlled trials (RCT) published after the research-period of the latest review/HTA. We included studies with asymptomatic adult women who underwent screening for ovarian cancer with VUS alone or in combination and a comparison group with no screening. Endpoints were cancer related mortality, morbidity, health related quality of life and harm due to screening. The review was performed according to methods of evidence based medicine.

Results: Of 1381 references, we included one HTA report and seven publications of three RCTs. To the date of our report, no mortality data were available. One study detected more stage I and II tumors in the screening group compared to the control group (67% and 44%, respectively; p = 0.2285). The data on diagnostics show that screening induced in a high extent of over diagnosis associated with invasive procedures. The positive predictive value ranges from 0.75% to 2.8%. For each detected invasive carcinoma, between 30 and 35 surgeries were performed in the trials.

Discussion and implications: The benefit of VUS screening for the early-detection of ovarian cancer cannot be judged without patient-relevant outcomes as mortality and quality of life. However, the potential harm caused by unnecessary surgeries is evident. The transferability of the study results to VUS as self-pay service is limited since these are –other than the study populations- also offered to pre-menopausal women in whom more false-positive results are expected.

262. TREATING RHEUMATOID ARTHRITIS WITH ANTI-CD20+B MONOCLONAL ANTIBODY: A SYSTEMATIC REVIEW AND META-ANALYSIS TO EVALUATE EFFICACY AND SAFETY OF RITUXIMAB

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Rheumatoid arthritis (RA) is a chronic autoimmune disease characterized by systemic joint inflammation that often leads to significant disability. Treatment aims to achieve clinical remission, control pain and inflammation, reduce joint damage, and maintain or improve quality of life. Several effective anti-TNF biologic agents have been used alone or with disease-modifying antirheumatic drugs (DMARDs), but some patients have shown an inadequate response. Rituximab (RIT) is a therapeutic monoclonal antibody that selectively depletes CD20+B cells and is been used currently. A systematic review was conducted to access the efficacy and safety of this agent in patients with active RA which have or have not been treated with anti-TNF agents before. The databases PUBMED, LILACS and NCBI were searched until August 2011 to identify articles that reported data on clinical improvement measurements, radiologic progression, patient reported outcomes and adverse events. Five RCTs comparing RIT with DMARDs were included. Treatment with rituximab plus methotrexate (MTX) was more effective in comparison with methotrexate in both patients with anti-TNF treatment failure and naive. At week 24, a higher proportion of patients treated with RIT1000mgx2+MTX achieved American College of Rheumatology responses relating to 20% improvement from baseline (ACR20) comparing with placebo+RIT (RR 2.24 [1.72-2.91]; I^2 40%). ACR50 (RR 3.63 [2.19-6.03]; I^2 44%) and ACR70 (RR 5.28 [2.69-10.38]; I^2 4%), were also better in RIT group. Lower changes in Total Ganant-modified Sharp score, erosion score and joint narrowing scores were observed with RIT plus MTX, and SF-36, FACIT-T and HAQ-DI scores were also better in comparison to placebo+MTX. The incidence of adverse events was similar between groups. Available data support the use of rituximab for the treatment of RA, as it is an effective and safe option for those in which treatment with anti-TNF inhibitors have failed. This review will be important for cost-effectiveness and cost-utility analysis.

295. MODEL-BASED ECONOMIC EVALUATIONS OF DIAGNOSTIC AND THERAPEUTIC STRATEGIES FOR PERIPHERAL ARTERIAL DISEASE: A SYSTEMATIC REVIEW

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Background: PAD is a sign of more widespread atherosclerosis affecting coronary, cerebral and renal arteries and has a potential to cause loss of limb or even loss of life. Asymptomatic and symptomatic PAD patients pose a high economic burden on the health care system and on the society.

Objectives: The objectives of this systematic review are to summarize and compare the findings of model based economic evaluations performed in the field of PAD and to assess the general and methodological qualities of included studies.

Methods: Electronic databases MEDLINE and EMBASE were searched via OVID interface until 31st October 2011. Cochrane database of systematic reviews, Health Technology Assessment database and National Health Services Economic Evaluation database (NHS EED) were searched via Cochrane library. Assessment of the methodological quality of the included studies was performed using a comprehensive 60 points checklist for quality assessment in economic models developed by Philips *et al.*

Results: On application of defined inclusion/exclusion criteria, thirteen model-based full economic evaluations were identified. Eight studies used a Markov model while one study used a combination of a Markov model and a decision tree. Three studies were based on a decision tree and one study did not specify the model type used. Methodological diversity and insufficient information posed a challenge for valid comparison of studies.

Conclusion: The overall assessment of the studies using Philips checklist revealed 'acceptable to low quality' of the included studies. The process of evidence synthesis in the reviewed models is inconsistent. There is a need for transparent, methodologically comparable and scientifically credible economic evaluations. This review recommends that future models should incorporate health states capturing all relevant events related to PAD progression over time providing a broader view of PAD and its effects on the society.

318. EFFECTIVENESS AND SAFETY OF SUTURELESS AORTIC VALVE REPLACEMENT: SYSTEMATIC REVIEW

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Background: Severe aortic stenosis represents a growing worldwide problem. Aortic valve replacement is the treatment of choice but approximately one third of the patients are not candidates for surgery because of high operative risk. Sutureless implantation has the potential to shorten cardiopulmonary bypass time (CPB) and thus constitute an alternative for these patients.

Objectives: The main objective was to assess the effectiveness and safety of sutureless aortic valve replacement in comparison to existing alternatives.

Methods: A systematic search was carried out in the main literature databases (PubMed, Embase, Cochrane, etc). Internet was scanned and manufactures contacted for additional data. All human studies that provided original data on effectiveness and/or safety were included.

Results: the search identified eight published studies that complied with the selection criteria. All were case series; four focused on prosthesis ATS 3f EnableTM and two on Perceval S. Both prosthesis showed good hemodynamic and clinical results. For 3f ATS, 11-17% of the prosthesis had to be replaced at implantation due to inappropriate sizing; 14-33% due to incorrect positioning. The median CPB time was comparable to the standard approach. Paravalvular leakages that required reintervention ranged from 2-17%. For Perceval S, BCP time was approximately 30 minutes shorter that conventional approach, implantation was successful in all patients and relevant leaks were minimum.

Discussion: To date, evidence is insufficient to support sutureless aortic valve replacement in high risk patients. For 3f-Enable, implantation time is not significantly reduced and paravalvular leakages might be a problem. The results for prosthesis Perceval S seem to be promising but these come from two small case series (30 and 32 patients).

Implications for health professionals: Further studies are needed to establish the effectiveness and safety of sutureless aortic valve replacement. Long term date is needed to study durability and results must be compared to conventional and transcatheter techniques.

320. A SYSTEMATIC LITERATURE REVIEW OF RELAPSE IN PATIENTS WITH SCHIZOPHRENIA: DEFINITIONS, DRIVERS AND PREVENTION

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Background: Relapse has devastating repercussions for patients with schizophrenia, including worsening symptoms, impaired functioning, cognitive deterioration and reduced quality of life (Kane. CNS Spectr. 2007;12(suppl 17):21–2; Kane. J Clin Psychiatry. 2007;68(suppl 14):21–2). This progressive decline often exacerbates the burden of the illness on patients and their families.[2] Relapse prevention is identified as a key therapeutic aim (Falkai et al. World J Biol Psychiatry. 2006;7:5–40; NICE Schizophrenia full guidelines CG82 (update) September 2010); however, the absence of widely accepted definition criteria (Leucht & Kane. J Clin Psychiatry. 2006;67:1813–81) considerably hampers achieving this goal.

Objectives: To assess the range and validity of methods used to define relapse in observational or naturalistic settings and capture information on factors that predicted, or influenced, relapse risk.

Methods: A PubMed keyword search (2000–2010) identified articles which discussed relapse (and hospitalization as a proxy of relapse) in patients with schizophrenia. Recent selected congress abstracts as well as national and international guidelines were also reviewed.

Results and discussion: Of the 156 articles identified, 90 defined relapse. 62% (56/90) of these also discussed hospitalization. The majority used hospitalization as a proxy for, or as a component of, relapse, however the duration or type of hospitalization varied considerably. Scales were used to define relapse in 61 instances; multiple scales often appeared within the same definition. Factors predicting relapse were discussed infrequently with their validity being unclear due to varied definitions. There were 98 references to factors that may drive relapse; including non-adherence to antipsychotic medication (22/98), substance abuse (10/98) and stress/depression (11/98). Continuous antipsychotic therapy was associated with reduced frequency and duration of hospitalization, while non-pharmacological interventions were commonly reported as reducing

relapse; however, these were evaluated in patients receiving treatment with antipsychotic medication.

Implications for the health system/professionals/patients/society: Hospitalization is a frequently cited factor used to define relapse and represents a convenient proxy for use in practice. Greater consensus on the definition of hospitalization may help identify factors that predict (and more firmly establish those that reduce) the risk of relapse.

322. NON-ASPIRIN NON-STEROIDAL ANTI-INFLAMMATORY DRUGS FOR THE PRIMARY CHEMOPREVENTION OF NON-GASTRIC CANCER: SUMMARY OF EVIDENCE

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Background: There is evidence that aspirin is effective for the chemoprevention of colorectal cancer. Due to their similar pharmacodynamics, the use of other non-steroidal anti-inflammatory drugs (NSAIDs) has been suggested for other cancer sites. Although this possibility has been discussed in the literature, uncertainty remains about the actual effects of NSAIDs other than aspirin in non-gastric cancer.

Objective: To summarize the best available evidence of the primary chemopreventive effects of non-aspirin NSAIDs for non-gastric cancer.

Methods: We considered eligible narrative or systematic reviews, clinical guidelines and, if they had not been previously included, primary controlled studies that evaluated the effectiveness of non-aspirin NSAIDs in preventing cancer in healthy individuals who are at high risk. Studies were retrieved from the following databases: Guidelines.gov, BMJ Clinical Evidence, TRIP database, UpToDate, MEDLINE, CANCERLIT, Embase, CINAHL, ISI Web of Science and Scopus. Two independent reviewers selected eligible studies. Data were extracted by one reviewer and crosschecked by two others.

Results: A total of 56 studies met the inclusion criteria. Most of these studies were observational. These studies reported conflicting results or no statistically significant associations between the use of non-aspirin NSAIDs and risk of lung, ovary, bladder, prostate, skin and head and neck cancers. In contrast, an increased risk of renal cell carcinoma and a reduced risk of breast cancer were found to be statistically significant. The included studies had methodological limitations, which reduces our confidence in their results.

Conclusions: We did not find sufficient evidence to support the use of the non-aspirin NSAIDs for the primary chemoprevention of a wide variety of non-gastrointestinal cancers. This scenario suggests caution when considering the routine use of non-aspirin NSAIDs. Additional well-conducted controlled studies may provide more conclusive evidence on this issue, but there are concerns about the risks of such exposure.

323. EVALUATION OF ATOMOXETINE EFFICACY AND SAFETY FOR ADULTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD): A META-ANALYSIS

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Background: Atomoxetine is approved for the treatment of adults with ADHD in USA, Mexico and Australia and is currently under assessment in the EU and several Asian countries. Regulatory agencies weight efficacy and safety of medicines under assessment.

Objectives: To assess atomoxetine efficacy and safety for the treatment of adults with ADHD.

Methods: A systematic review and meta-analysis of controlled-clinical trials comparing atomoxetine vs. placebo in adults with ADHD. All-cause treatment discontinuation, reduction of ADHD symptom severity and adverse events (AE)-induced dropouts were collected. Standardized mean difference (SMD) was calculated for continuous outcomes and odds ratio (OR) for dichotomic ones. Data were pooled using the fixed or random effects model depending on the absence or presence of heterogeneity.

Results: Nine studies (3,061 patients) were included; a comorbid disease was an inclusion criteria in 3 of them (635 patients). Mean age of patients was 36.6 and 57.3% were men with combined ADHD subtype (57.6%). Mean atomoxetine dose was 84.6 mg/day. Mean treatment length was 18.1 weeks (range: 10-26 weeks). No study specified if psychotherapy for ADHD was provided. All-cause treatment discontinuation rate was larger with atomoxetine than with placebo (OR = 1.46 [1.25, 1.71], $p < 0.00001$). Atomoxetine was more efficacious than placebo for reducing ADHD symptoms (SMD -0.35 [-0.46, -0.24], $p < 0.00001$). The proportion of patients dropping out due to AEs was higher with atomoxetine (OR = 2.78 [1.96, 3.94], $p < 0.00001$).

Discussion: Our study shows mixed results; while modest improvement of ADHD symptoms was observed with atomoxetine, higher all-cause and AE-induced discontinuation rates were also found.

Implications: The balance between efficacy and safety of atomoxetine in adults with ADHD is not clear. Atomoxetine does not appear suitable as first-line treatment of adult ADHD.

334. MINIMALLY INVASIVE OESOPHAGECTOMY VERSUS OPEN SURGERY: WHERE ARE THE RANDOMISED CONTROLLED TRIALS?

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Background: Oesophageal resection is the main method of curative treatment for cancer of the oesophagus. Despite advances in surgical technology and post-operative care, the survival rate and prognosis of people undergoing oesophagectomy is still poor. The use of minimally invasive techniques in oesophageal surgery offers hope of reduced recovery time due to a reduction in surgical trauma. Although the first reports of thoracoscopic and laparoscopic assisted oesophagectomy emerged some twenty years ago, there is still no consensus that the outcomes are clearly superior to outcomes following conventional open surgery. Increasingly, some surgeons promote the use of minimally invasive techniques for oesophagectomy but questions remain over its safety and efficacy compared with open surgery.

Objectives: To examine the efficacy and safety of for minimally invasive techniques through endoscopy to open surgery for oesophagectomy by performing a systematic review of the literature.

Methods: We conducted a systematic review to compare minimally invasive techniques for oesophagectomy to open surgery. The outcomes of interest for efficacy and safety included mortality, operative complications, recurrence, and quality of life.

Results: No randomised controlled studies (RCTs) were available and therefore the outcome data need to be interpreted with caution. There were 28 included comparative studies but the reporting quality of many of the studies was poor.

Discussion: In light of the poor quality of available studies, we outline the reasons why there are no RCTs for this procedure.

Implications for the health system/professionals/patients/society: Recommendations for future research are discussed. We argue that an RCT is unlikely to be conducted for this procedure but suggest ways that future non-randomised studies could be improved.

342. AN INNOVATIVE METHOD OF PRESENTING STUDY CHARACTERISTICS AND RESULTS IN SYSTEMATIC REVIEWS

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Systematic reviews require the compiling of complex information from many studies. This includes study characteristics and summaries of results. The latter is particularly challenging where meta-analysis is not appropriate. However, clear presentation is essential to aid understanding, interpretation and dissemination amongst expert and lay audiences. The aim of this presentation is to highlight the difficulties that are faced, to describe our experiences with developing a new method, and to provide illustrated examples of the use of the method in two different systematic reviews. We will describe the development and evaluation of a software package that formed part of a PhD in which the use of information graphics in health technology assessment was studied. The software package (GOfER) uses information graphics to display large quantities of information for quick and easy access by the reader. The software is free to use and source-available, so that reviewers can use and build upon these graphical presentation ideas. We will illustrate how a prototype version of a GOfER display has been used in a recent Technology Assessment Appraisal for NICE in the UK and in a systematic review of public health promotion interventions in the workplace.

362. A SYSTEMATIC LITERATURE REVIEW OF RELAPSE IN PATIENTS WITH SCHIZOPHRENIA: THE BURDEN ON HEALTHCARE SYSTEMS

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Background: In patients with schizophrenia, relapse causes worsening of clinical symptoms and cognitive, functional and psychosocial deterioration (Kane, 2007a,b). Relapse prevention is a key therapeutic aim (Kane, 2007; Falkai, 2006) and relapse contributes to the high cost of schizophrenia (Knapp, 2006). The lack of a standardized definition (Leucht, 2006) creates difficulties in assessing rates, durations and costs of relapse.

Objectives: To assess relapse frequency and duration, and their contribution to the cost of schizophrenia.

Methods: A PubMed keyword search (2000–2010) identified articles related to relapse (and hospitalization as a proxy) and estimations of associated costs in patients with schizophrenia. Clinical guidelines and congress abstracts were also reviewed.

Results and discussion: 156 articles were identified; 91 included relapse frequency. The wide variation in relapse frequency in clinical studies (11–96%) depended on factors including patient selection, pharmacological/non-pharmacological interventions, time since diagnosis and study duration. Relapse duration was not specified; 16 publications discussed hospitalization duration, although definitions and mean durations varied considerably (5–110 days). 27 publications discussed relapse costs. Despite a range of methodologies, relapse and hospitalization were associated with significant costs (eg US$15,805 hospitalization costs 6–18 months following diagnosis (Crown, 2001); 1-year hospitalization costs of $4687 (Zhu, 2008)). Costs increased compared with baseline and patients without relapse; relapse increased overall costs (primarily due to hospitalization) by up to four-fold. Partial/non-adherence to medication, a relevant risk factor for relapse, was associated with higher costs. In a retrospective analysis partial adherence increased inpatient costs by 54.5% (Eaddy, 2005). Five publications highlighted the cost-reducing impact of appropriate antipsychotic medication, including savings associated with the use of long-acting injectable second-generation antipsychotics (eg €129.07/month/patient 2 years after switching to risperidone long-acting injectable) (Olivares, 2008).

Implications Relapse contributes significantly to the costs of schizophrenia. Lack of standardized definitions of relapse and hospitalization make comparison between studies difficult. Improvements in partial/non-adherence may reduce the overall burden on healthcare systems.

364. ADALIMUMAB FOR TREATING RHEUMATOID ARTHRITIS: A SYSTEMATIC REVIEW AND META-ANALYSIS

Marina Amaral de Avila Machado[a], Alessandra Almeida Maciel[b], Lívia Lovato Pires de Lemos[b], Juliana Oliveira Costa[a], Ana Luisa Caires de Souza[c], Renata Cristina Macedo[c], Mariângela Leal Cherchiglia[a], Brenda Fernanda Moreira Castro[b] and Francisco de Assis Acurcio[b]

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Rheumatoid arthritis (RA) is a chronic autoimmune disease characterized by synovial inflammation that causes swelling, pain and limitation of motion. Adalimumab (ADA), a fully human anti-TNFalpha monoclonal antibody, is indicated for RA treatment. A systematic review with meta-analysis was conducted to access the efficacy and safety of ADA in patients with active RA. The databases PUBMED, LILACS and NCBI were searched until June 2011 to identify articles that reported data on clinical measurements, quality of life and adverse events. Reference lists from trials and reviews were hand-searched to identify further articles. Seven randomized clinical trials with 2162 patients were included. Two studies were classified as presenting a low risk of bias related to allocation concealment and five trials scored 5 or 6 on modified Jadad scale. Five studies compared ADA 40 mg every other week plus methotrexate (MTX) versus placebo plus MTX. The relative risk (RR) with 95% CI to achieve an ACR20 response until 24 weeks was 2.24 (1.54, 3.25) and at 52 weeks it was 2.40 (2.11, 2.73). The mean difference (95%CI) in the HAQ score at 24 weeks was -0.32 (-0.40, -0.24) and at 52 weeks it was -0.32 (-0.39, -0.24). Two studies compared ADA 40 mg every other week versus placebo. The RR (95%CI) to achieve an ACR20 response was 2.67 (1.89, 3.77) and the mean difference (95%CI) in the HAQ score was -0.31 (-0.42, -0.19) until week 26. All these efficacy outcomes favored the ADA+MTX/ADA groups in the short and long-term treatment. The meta-analysis showed no significant differences between ADA and placebo for safety outcomes. Available data support the use of ADA for the treatment of RA, as it is an effective option. However, it is necessary long-term studies to evaluate safety. This review will be useful for cost-effectiveness and cost-utility analysis.

372. ELICITING PATIENT ASPECTS IN HTA USING QUALITATIVE RESEARCH SYNTHESIS

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Objectives: The objective of this presentation is to discuss how to produce robust scientific evidence about patient aspects. The aim is to demonstrate that qualitative research synthesis can be one relevant strategy in eliciting patient aspects in HTA.

Methods: We explored different approaches of qualitative research synthesis that focus on patient aspects and could be relevant for HTA, health policy design and decision making. The aim of this study was to bring research closer to policy development and decision making, and to facilitate better use of research findings for health and welfare.

Results: We identified four relevant approaches to qualitative research synthesis, namely meta-synthesis, meta-ethnography, meta-study and meta-summary. In order to chose the most relevant synthesis approach, it is important that the researchers look at the following parameters; focus, data generation, approach to data, data analysis and results of the synthesis.

Conclusions: We argue that, before getting started, it is important that researchers have a thorough insight into qualitative research synthesis approaches, experience as a researcher within synthesis, formulated a significant research/policy issue and considered the resources. Qualitative research synthesis has come to stay and it has a considerable potential to answer some of the complex questions about patient aspects in HTA and health policy research.

386. ENDOVENOUS TREATMENT: IS IT THE FUTURE OF VARICOSE VEIN MANAGEMENT? A SYSTEMATIC REVIEW ON RADIOFREQUENCY ABLATION AND FOAM SCLEROTHERAPY

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Background: Chronic venous insufficiency afflicts half of the adult general population and approximately 25 percent have lower extremity varicose veins with the associated symptoms and complications causing significant morbidity. Established at the beginning of the 20th century, the current principles of surgical treatment of varicose veins are increasingly challenged with the advent of endovenous procedures.

Objectives: The objective in this paper is twofold. First, we compare the technology of radiofrequency to conventional surgery for varicose vein treatment. Second, we perform the same comparison between foam sclerotherapy and conventional surgery.

Methods: A systematic review was conducted using the following search engines: Pubmed, Sciencedirect, British Medical Journal, Cochrane Database and Center for Reseach and Dissemination. Websites of Health Technology Assessment agencies were also consulted and english and french publications were considered. Quality of the evidence was assessed by the checklist of Downs and Black (1998) for primary studies and by the AGREE instrument (Appraisal of Guidelines for Research and Evaluation in Europe) for literature reviews.

Results: Based on published data, there is sufficient evidence to consider radiofrequency as a safe procedure with good mid-term results for the treatment of incompetent greater saphenous veins. Concerning foam sclerotherapy, marginal but severe adverse events precludes considering it as a safe procedure. In most publications, medical efficacy of these two endovenous procedures is at least equivalent if not higher than conventional surgery. Further, as opposed to surgery, minor complications were reported less frequently in radiofrequency and foam procedures. These endovenous procedures both incur less cost and allow outpatient treatment, favoring faster recovery time.

Discussion: Comparison of results is difficult because of different inclusion criteria regarding CEAP classification and different follow-up methods and periods and finally because of differences in operator's experience. Therefore, it is desirable to develop a set of guidelines for clinical trials evaluating endovenous ablative methods to ensure a consistent approach in design and reporting of data.

393. QUALITY EVALUATION OF CONTENT-BASED MEDICAL IMAGE RETRIEVAL SYSTEMS: A SYSTEMATIC REVIEW APPLIED TO HTA

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Background: With the growing demand of tools for managing medical images in Health Institutions, there are intense efforts in developing Content-Based Image Retrieval (CBIR) Systems, which provide the relationship of images by their content for the development of Computer-Aided Diagnosis (CAD) applications and others. Once quality is a fundamental requirement, the usage of evaluation methods that ensure these systems work accordingly in clinical practice is increasingly important.

Objectives: To present the results of a Systematic Review (SR), whose goal was to investigate how CBIR systems for medical images have been evaluated regarding Software Quality from a HTA perspective.

Methods: An RS Software Engineering (SE) process was executed. It consisted of Planning, Conduction and Reporting phases. The JabRef v.2.7.2 tool (http: //jabref.sourceforge.net) was used to store and organize the resulting data in each phase.

Results: From a total of 129 studies retrieved, 22 were repeated and 104 were excluded. Three studies matched the established criteria. These were extracted from IEEE, SCOPUS and ACM. All selected emphasized system feasibility in clinical practice, however none assured diagnostic quality in CAD environments, and only one was based on SE-related methodology.

Discussion: The excluded studies focused on image processing and pattern recognition methods and techniques. The scarcity of studies showed a lack of systematic and formal CBIR system evaluations served to surpass functionality limitations (gaps) and effectively introduce these systems in practice. These studies presented performance evaluations of 3D interactive viewing, and new evaluation and functionality/usability paradigms involving computer-human interaction.We concluded that these methods approached specific quality aspects, but failed to approach the existing gaps in CBIR system models thoroughly, limiting it to implementing problems, thus overseeing usability problems from an end-user perspective.

Implications for the health system: It is still remarkable that there are few CBIR system usability-oriented studies from an HTA perspective.

413. CURRENT SITUATION OF PEOPLE WITH DISABILITIES IN PARAGUAY. LITERATURE REVIEW

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The term disability refers to a physical, mental or sensory impairment, permanent or temporary, that limits the ability to perform one or more essential activities of daily life which are caused or aggravated by the economic and social environment. It is estimated that 10% of the world's population has a disability. The majority of this population lives in developing countries with low access to education and employment. In order to describe the current situation of people with disabilities (PWDs) regarding access to education and employment in Paraguay, a literature review was carried out. It was found that the incidence of PWDs ranges between 12 and 20% of the 6,000,000 inhabitants in Paraguay. This group of people has an illiteracy rate of 43%, 57% of PWDs have some school education, 83% have not completed the 6 years of basic school education, 8% have been enrolled in high school and 2% in college. Despite Laws 2479/04 and No. 3585/08 which establish a quota of 5% of public employment positions for PWDs, until 2010 only 580 PWDs had been hired; 80% of PWDs are unemployed or underemployed. PWDs in Paraguay continue to face barriers to formal education and training leading to low academic level specifically a college degree which leads to low access to employment. Among the restricting factors to education, has been architectural barriers, lack of trained teachers and lack of a culture of respect for diversity, in addition to the lack of technological support in the classroom. In order to minimize these barriers, we have proposed a project that will allow not only the access of PWDs to National University of Asuncion, but also ensure their permanence until obtaining a degree.

429. COMBINING TRIAL AND ACCURACY DATA FOR DIAGNOSTIC TESTS: A SYSTEMATIC REVIEW OF FETAL FIBRONECTIN (FFN) TESTING TO PREDICT PRETERM BIRTH

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Background: Ideally use of diagnostic tests should be supported by evidence of clinical benefit. In practice, diagnostic trials are rare and accuracy data along with evidence of an effective intervention are often used as a surrogate.

Objective: To combine trial and accuracy data in a review of fFN testing to predict preterm birth.

Methods: Bibliographic databases were searched from 2000 to September 2011. Trials registers and conference proceedings were also searched. Test accuracy data were summarised using a bivariate model (Reitsma et al, 2005, Harbord et al, 2007).

Results: Searches for trials identified 677 records. Five RCTs were included. All RCTs were poorly reported and rated "unclear" risk of bias across all domains; and focused on the hypothesis that fibronectin testing can reduce interventions without increasing risk of preterm birth. One study reported a significant difference ($p = 0.04$) for the outcome length of hospital stay > 6 hrs in group of patients tested fFN negative. None of the studies found a difference in length of hospital stay. In all included trials, treatment decisions were at the discretion of clinicians, not based on fFN results alone. Test accuracy findings suggested a relatively high false negative rate.

Discussion: The trials provided important information about the consequences when fFN is used in context. If accuracy data were considered alone, the relatively high false negative rate of fFN might suggest that an increase in adverse clinical outcomes would result from using fFN to select patients for intervention.

Conclusions: A full understanding of the role of fFN testing in the care of women with symptoms of pre-term birth requires consideration accuracy data alongside the limited trial data available.

436. DIAGNOSTIC ACCURACY OF PET-CT IMAGING COMPARED TO MRI OR CT IN RESTAGING RECURRENT CERVICAL CANCER: SYSTEMATIC REVIEW OF EVIDENCE

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Background: Cancer of the uterine cervix is a common cause of mortality in women. After initial treatment women may be symptom-free but the cancer may recur within one or more years. It is uncertain whether it is more clinically effective to survey asymptomatic women for signs of recurrence or whether to await symptoms and/or signs before using imaging. This systematic review compared diagnostic accuracy of imaging and is part of a larger project evaluating cost-effectiveness of different patient care options.

Methods: Standard systematic review methods and sources were used to obtain and evaluate relevant diagnostic accuracy studies to May 2010. QUADAS criteria were modified appropriately. Included were any PET-CT, MRI or CT studies compared to the reference standard of histopathological findings or clinical follow up in recurrent cervical cancer. Meta-analysis was carried out in RevMan 5.1 and STATA version 11 where appropriate.

Results: From 7.524 citations, six evaluated PET-CT, two MRI, three CT and one both MRI and CT. All were small and evaluated imaging where recurrence was suspected. The PET-CT studies evaluated local and distant recurrence whereas 5/6 MRI and CT studies evaluated local recurrence only. Meta-analysis of PET-CT studies gave sensitivity 92.2 (95%CI 85.1-96.0) and specificity 88.1 (95%CI 77.9-93.9). MRI sensitivities and specificities varied between 82-100% and 78-100% and for CT between 78-93% and 0-95%. One small comparison study showed more true positives and fewer false negatives for PET-CT compared to MRI and/or CT.

Conclusions: PET-CT has become standard without conclusive proof that it is more beneficial for patients than other imaging methods. Good quality studies need to be conducted comparing the addition of PET-CT to MRI or CT with the same reference standard for test positives and negatives that could be used as input to economic evaluation.

443. SENTINEL LYMPH NODE STATUS IN VULVAL CANCER, DIAGNOSTIC ACCURACY SYSTEMATIC REVIEW

Catherine Meads[a], Sylwia Malysiak[b], Monika Kowalska[b], Anna Zapalska[b], Pawel Chomiak[b], Ewelina Rogozinska[a], Ewa Borowiack[b] and Khalid Khan[a]

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Background: Vulval cancer accounts for approximately 3–5% of all Gynaecological cancers. Groin node metastasis can predict survival but only χasi30% patients with operable disease have nodal spread. Lymph node dissection is associated with considerable morbidity.

Therefore it is important to determine which patients would benefit. The sentinel node is the node that receives lymphatic drainage directly from the vulval tumour so has the highest probability of containing cancer cells. It is uncertain whether the sentinel node is sufficiently predictive of metastatic spread to be clinically useful as sentinel node biopsy causes much less morbidity. This is part of a larger project evaluating cost-effectiveness.

Methods: Standard systematic review methods and sources were used to obtain and evaluate relevant diagnostic accuracy studies to May 2010. QUADAS criteria were modified appropriately. Included were any sentinel node biopsy studies using Technecium 99 or isosulfan blue dye compared to the reference standard of histopathological findings and/or clinical follow up. Meta-analysis was using RevMan 5.1 software where appropriate.

Results: From 2,942 citations, 27 studies were found. There was clinically important heterogeneity in the reference standard used – variation in number of nodes sampled and how they were sliced, staining techniques etc. Sensitivities varied between 67-100% and specificities between 97- 100%. However, technecium 99 and blue dye only detect presence of sentinel node, not metastasis in sentinel node, resulting in a two-stage diagnostic procedure that is difficult to evaluate.

Conclusions: High sensitivity is more important than high specificity because of the consequences of missing malignancy. Clinically it would be advantageous if a malignancy-specific method could be developed to detect groin metastases.

446. A SYSTEMATIC REVIEW OF THE EFFECTIVENESS AND COST-EFFECTIVENESS OF SUBLINGUAL AND SUBCUTANEOUS IMMUNOTHERAPY FOR ALLERGIC RHINITIS IN ADULTS AND CHILDREN

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Background: Hay fever is a global problem with a high prevalence (up to 40%). Severe hay fever uncontrolled by conventional medication can adversely affect quality of life. Immunotherapy has increasingly been shown to be effective in many randomised controlled trials (RCTs). It is uncertain whether subcutaneous immunotherapy (SCIT) or sublingual immunotherapy (SLIT) is more (cost-)effective.

Objectives: To update existing Cochrane reviews on the effectiveness of SLIT and SCIT; in the absence of head-to-head data to conduct an indirect comparison of SLIT versus SCIT; to conduct a systematic review of cost-effectiveness studies; to construct an economic model.

Methods: Validated systematic review methods were employed for study identification, selection, appraisal and synthesis. Double-blind placebo controlled RCTs only were included. Review Manager and WinBugs respectively were used for meta-analyses and adjusted indirect comparisons. Two alternative economic models were constructed.

Results: Twenty-eight new RCTs were identified. Updated meta-analyses of symptom and medication scores confirmed the benefits of SLIT and SCIT compared to placebo in both adults and children and for different types of treatment schedule and allergen (e.g. grass, tree). Results are reported mainly as average mean differences rather than proportions of patients in different states so suitable outcome data has not been identified in the public domain to populate a Markov model.

Discussion and implications: With prevalence of hay fever still increasing in some countries, immunotherapy is an important treatment option, particularly in view of its potential to alter the course of disease and prevent new sensitisations and new cases of asthma. SCIT is more clinically effective than SLIT but it is uncertain whether it is more cost-effective. Full results on indirect comparisons and economic analyses will be available in April 2012.

This work is being funded by the UK NIHR HTA Programme.

453. SYSTEMATIC REVIEW OF THE EFFECTIVENESS OF BOWEL PREPARATION AND ANTIBIOTIC PROPHYLAXIS IN PREPARATION OF ADULTS WITH INVASIVE BLADDER CANCER UNDERGOING RADICAL CYSTECTOMY

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Background: Although no consensus exist among experts, bowel preparation (BP) and antibiotic prophylaxis (ABP) are commonly used as perioperative interventions in radical cystectomy (RC).

Objective: To assess the effectiveness of perioperative BP and ABP in adults undergoing RC.

Methods: A search was performed in Pubmed, Embase, the Cochrane Library, and grey literature to identify systematic reviews (SR), randomized controlled trials (RCTs) and observational studies (OS). Selection, quality assessment, and data extraction from articles were performed by two independent reviewers. Primary outcomes were surgical sites infections and anastomotic leaks. Synthesis review was shared with bladder cancer experts.

Results: 315 studies were retrieved. After quality assessment, one RCT and three OS on BP as well as one SR and one OS on ABP were included. Samples size varied between 62 and 112 for BP and was of 77 for ABP. Studies showed that BP prior to RC with urinary diversion does not demonstrate any significant advantage in perioperative outcomes. A lack of well-designed studies investigating the need for ABP in urologic interventions was observed. No clear interpretation can be done regarding the best ABP regimen (multidose, unidose, no dose) to prevent postoperative complications in patients undergoing RC. Most studies on BP and ABP in RC had several limitations such as retrospective design, few patients in each groups and endpoints not well-defined.

Discussion: According to available evidence, BP for urinary diversion in reconstructive urologic surgery might not be a requisite while no firm conclusion can be drawn for the ABP regimen. Because of the paucity and the low quality of the available studies, further researches are required to support evidence-based clinical pathway in RC. Literature from other major abdominal surgeries, such as colorectal surgery, should also be reviewed to identify knowledge that could be transferred to RC.

457. RADIOFREQUENCY ABLATION FOR LUMBAR FACET JOINT PAIN: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Low back pain (LBP) is the most common cause of disability in young adults. Radio-frequency ablation (RFA), a procedure in which heat is applied to interrupt pain signals in spinal nerves, is a treatment option for chronic LBP. However, the efficacy of RFA has not been documented.

Objective: To determine the short-term and long-term efficacy of continuous RFA for the treatment of lumbar facet joint LBP.

Methods: A systematic review and meta-analysis was conducted. Six electronic databases were searched in all languages (MEDLINE, EMBASE, PubMED, Sportdisc, CINAHL and the Cochrane CENTRAL Registry of Controlled Trials). Articles were included if they were RCTs, original data, involved only human subjects, and reported on the efficacy of RFA for facet joint LBP. The efficacy outcomes of interest were short-term (< 3 months) and long-term (3-6 months) changes in pain using a visual analog 10-point scale (VAS). A random effects model was used to pool the standardized mean difference (SMD). Publication bias was assessed visually using Beggs' funnel plots.

Results: Of the 347 abstracts reviewed, 6 RCTs (n = 312) were included. For short-term pain relief, the SMD was -0.969 (95% CI: -1.746 to -0.192). For long-term pain relief, the SMD was -0.432 (95% CI: -1.016 to 0.152).Statistically significant heterogeneity was found across studies in both the short and long-term analysis (short term: I^2 = 81.2%; long term: I^2 = 81.2%). Publication bias was suggested by the absence of small negative studies in the funnel plots for both time periods.

Discussion: Although RFA is minimally effective for short-term LBP, it does not demonstrate significant long-term reductions in pain. This analysis is limited by the small number of trials and publication bias.

Implications: Larger, blinded trials that are appropriately controlled are required before RFA can be recommended as a long-term treatment option for LBP.

466. IMMUNE CELL FUNCTION ASSAY IN KIDNEY TRANSPLANT RECIPIENTS

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Background: Immune Cell Function Assay (ImmuKnow™, Cylex Inc., Columbia, MD, USA) is a non-invasive functional assay, which directly assess the net state of immune function. In 2002, the assay is cleared by the FDA for detection of cell-mediated immunity in an immunosuppressed population. Immune responses are reported in ng/mL of ATP (adenosine triphosphate) and categorized as strong (≥ 525), moderate (226-524) or low (≤ 225).

Objectives: To determine whether there is sufficient evidence, in relation to clinical effectiveness to use the assay in kidney transplant recipients to monitor clinical status (infection or graft rejection) and guide treatment.

Methods: The searches were conducted via electronic databases including MEDLINE, EMBASE, the Cochrane Library and retrieved 376 non-duplicate citation. Total 13 studies (1 randomized control trial, 12 cohort studies) were included for this review. Two review authors independently applied the extracted data and assessed study quality.

Results: One randomized control trial report that the rapid steroid reduction early after kidney transplantation on the assay in 57 patients contributes to infection control. In several cohort studies, a decreased ATP level correlates with infection or a increased ATP level correlates with rejection in kidney transplant recipients. Also, pretransplant ATP level correlates with progress of infection or rejection. One cohort study report that the assay can help differentiate infected and stable transplant patients and the area under the ROC curve was 0.671 (95% CI 0.552-0.790, p = 0.016).

Conclusions: On the basis of current data, we recommend that the Immune Cell Function Assay can monitor the risk of infection or rejection among kidney transplant recipients and guide treatment.

472. SAFETY OF RENAL TRANSPLANTATION MAINTENANCE IMMUNOSUPPRESSIVE THERAPY: SYSTEMATIC REVIEW AND META-ANALYSIS

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Chronic kidney disease is an important worldwide public health problem. Its progression may lead to the need of renal replacement therapy, such as renal transplantation (RT). Immunosuppressive therapy has evolved much, but the choice of the best maintenance treatment is still complex, mainly because of adverse events (AE) and toxicity. A systematic review of RCTs and observational studies was conducted to access the safety of immunosuppressive therapies used in adult RT maintenance. The databases MEDLINE, LILACS were searched until October 2011. Most reported AE in each treatment strategy were collected; those reported by three or more articles were meta-analyzed using Revman 5.1. Quality was accessed using modified Jaddad scale and Cochrane Protocol for RCTs and Newcastle scale for observational studies. A total of 370 potentially relevant articles were identified and 51 were included for safety analysis; nineteen of them were quantitative analyzed. Most of the included articles were of high quality. Between treatment with cyclosporine (CsA) and tacrolimus (TAC), the first was related with dyslipidemia, Risk Ratio (RR) 0.71 (95%CI 0.57, 0.89; I^2 0%); while TAC was associated with diabetes mellitus (DM), RR 1.29 (1.11, 1.49; I^2 0%). Treatments with TAC + mycophenolate mofetil (MMF)/azathioprine (AZA) presented the same AE profile as the comparing TAC treatments. Between treatments with MMF and AZA, the first one was associated with gastrointestinal discomfort, such as vomiting (RR 1.54; 1.10, 2.15; I^2 0%) and diarrhea (RR 1.49; 1.17, 1.90; I^2 10%). DM was related to sirolimus treatment when comparing with CsA (RR 1.82; 1.14, 2.89; I^2 0%). Most often cohort data supported the findings of RCTs. Available data support that different combinations of immunosuppressants are related to different adverse events. This review will be important for clinicians to select the best maintenance therapy for each patient, since the differences found between groups are relevant.

473. MATERNAL AND INFANT MORTALITY: SYSTEMATIC LITERATURE REVIEW

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Maternal and infant mortality are important problems of public health in Brazil and their rates are still considered high in the context of the level of economic and social development observed in the country. This study is based on a systematic literature review on the theme of maternal and infant mortality draw from three different data bases (MEDLINE, LILACS and PUBMED). The main goal of this systematic literature review was to analyze the variables included in the papers' scope and to select those articles that presented variables pre-defined by the researchers as important to explain infant and maternal mortality. These variables were distributed within six different categories, which are: maternal and infant mortality; infant mortality; access to public health services; mothers' socioeconomic background (at individual and macro level). In order to be selected as object of analysis, the article had to present at least one variable in three different categories. According to the inclusion criteria, 251 articles were pre-selected and analyzed by three different reviewers.

As a result of this analysis 72 articles were selected. Literature reviews about risk factors of maternal and infant mortality are particularly important to contribute to carry out public policies for maternal and infant mortality.

479. BONE GRAFT SUBSTITUTES FOR THE TREATMENT OF TRAUMATIC FRACTURES OF THE EXTREMITIES

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Background: Bone graft substitutes (BGS) are increasingly being used as supplements to standard care or as alternative to bone grafts in the treatment of traumatic fractures.

Objectives: The evaluation addresses the efficacy of BGS for the treatment of traumatic fractures of the extremities.

Methods: A systematic literature search was conducted in December 2009 in electronic databases (MEDLINE, EMBASE etc.) and was completed by a hand search.

Randomized controlled trials (RCTs) were included in the analysis. After assessment of the study quality the information synthesis was performed using meta-analysis.

Results: 14 RCTs were included in the medical evaluation. In the RCT (with elevated high risk of bias) on fracture treatment with bone morphogenetic protein-2 (BMP-2) versus standard care without bone grafting there was a significant difference in favor of BMP-2 for several outcome measures. The RCTs (with high risk of bias) of calcium phosphate (CaP) cements and bone marrow-based composite materials versus autogenous bone grafts revealed significant differences in favor of BGS for some outcome measures. Regarding the other BGS, almost all comparisons demonstrated no significant difference.

Discussion: Although there were some significant differences in favor of BMP-2, due to the overall poor quality of the studies the evidence can only be interpreted as suggestive for efficacy. In the case of CaP- cements and bone marrow-based BGS, the evidence is only weakly suggestive for efficacy.

Implications: The current evidence is insufficient to evaluate entirely the use of different BGS. From a medical point of view, BMP-2 is a viable alternative for treatment of open fractures of the tibia, especially in cases where bone grafting is not possible. Autologous bone grafting is preferable comparing to the use of OP-1. Possible advantages of CaP-cements and composites containing bone marrow over autogenous bone grafting should be taken into account in clinical decision making. The use of hydroxyapatite materials and allograft bone chips compared over autologous bone grafts cannot be recommended.

586. RESPONSE TO ANTI-EGFR MONOCLONAL ANTIBODIES ACCORDING TO KRAS MUTATION STATUS IN METASTATIC COLORECTAL CANCER (MCRC): META-ANALYSIS

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Objectives: Colorectal cancer is the second most frequent tumoral location in Spain (25,600 new cases and 13,500 annual deaths). Mutations in KRAS oncogene predict the lack of response to inhibitory therapies of the epidermal growth factor receptor (anti-EGFR). Routine screening of KRAS gene allows personalized treatment: limiting the use of anti-EGFR therapies to native KRAS patients avoids unnecessary toxicity and a resource savings for the health system. The objective of this study is to estimate the results in health (therapeutic response) derived from determining KRAS mutational status in patients with mCRC in Spain.

Methods: Meta-analysis (random-effects model) of anti-EGFR monoclonal antibody response in mCRC patients after systematic review of publications (response rate for each therapy, prevalence of KRAS mutations, progression free survival and overall survival) referenced in PubMEd until 01/12/2010. Bibliographic search included the following terms: metastatic colorectal cancer, EGFR, Epidermal growth factor receptor, kras, cetuximab y panitumumab.

Results: 28 articles were located (4,266 patients) which included data on response to treatment (22 articles, 3,678 patients, specified how response was measured), according to KRAS mutations, of patients with metastatic colorectal cancer treated with monoclonal antibodies. KRAS mutation was present in 39.7% of the cases studied. The response rate of patients with wild-type KRAS varies from 12.8% to 85.19% versus 0% to 47.00% in mutated KRAS patients (D+L pooled RR 2.812; CI95% 2.052- 3.853).

Conclusions: A diagnostic and therapeutic strategy based on routine KRAS determination in patients with metastatic colorectal cancer and administration of anti-EGFR monoclonal antibodies only to those native KRAS patients optimizes clinical results and avoids adverse effects in patients with KRAS mutations who would not benefit from this treatment.

592. EFFECTIVENESS OF COMPUTED TOMOGRAPHIC COLONOGRAPHY (VIRTUAL COLONOSCOPY) VERSUS COLONOSCOPY FOR COLORECTAL CANCER SCREENING

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Background: Colorectal cancer (CRC) accounts for approximately 210,000 deaths each year in Europe. Although colonoscopy has been a gold standard for CRC early detection, computed tomographic colonography (CTC) has recently been advocated by multiple professional medical societies as an effective alternative for CRC screening. However, CTC effectiveness for asymptomatic colorectal lesions detection remains controversial.

Objectives: To review the available evidence on the effectiveness of CTC versus colonoscopy for CRC screening.

Methods: An electronic search was conducted using the databases Pubmed, EMBASE, Cochrane library and Centre for Reviews and Dissemination, from inception to July 2009. Studies were included if investigations used CTC for CRC screening in asymptomatic populations. Studies were excluded if investigations were conducted for CRC diagnostic or in elderly, high risk or symptomatic populations.

Results: Of the 213 references identified, nine studies were included. The CTC specifity in screening for CRC was high, although it decreased with decreasing diameter of polyp to be detected. The CTC sensibility for detection of polyps less than or equal to 6 mm in diameter was low and heterogeneous, although it was higher for polyps greater than 9 mm in diameter.

Discussion: The main limitation in included studies was the use of CTC as gold Standard. Moreover, the implementation of CTC can be limited by factors related to security, extracolonic findings detection or polyp diameter threshold reference.

Implications for the health system/professionals/patients/society: CT colonography has high specificity but very heterogeneous sensitivity, although in most cases it was not as sensitive or specific as conventional colonoscopy. Thus, CTC could be useful as screening test in specific populations. More studies are necessary.

594. EFFECTIVENESS OF 18-FLUORODEOXYGLUCOSE-POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY IN COLORECTAL CANCER INITIAL STAGING

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Background: Colorectal cancer (CRC) is the third and second most commonly diagnosed cancer in the world in men and women, respectively. The prognostic of CRC is related to the CRC staging in the moment of diagnostic. Computed Tomography (CT) is used widely in CRC preoperative staging. Positron emission tomography (PET) is gaining importance in this field. The PET/CT combination allows complement the functional imaging generated by the PET with anatomical information of CT. Thus, PET/CT has recently been proposed as a technique with potential value in the diagnosis of CRC extension. However, the effectiveness of PET/CT in CRC initial staging is controversial.

Objectives: To review the available evidence on the effectiveness of PET/CT versus CT or MRI in CRC initial staging.

Methods: An electronic search was conducted using the databases Pubmed, EMBASE, Cochrane library, and others from inception to May 2011. Studies were included if the patients included had CRC diagnostic or suspect and the investigations were conducted for PET/CT was performed for CRC staging vs conventional imaging tests (CIT). Studies were excluded if PET was conducted without CT or for CRC diagnostic or in elderly, high risk, or symptomatic populations.

Results: Of the 347 references identified, 5 studies were included. The PET/TC specificity by lesion in CRC initial screening was significantly higher than CIT (MRI and CT). Although sensibility by lesion differences were not significative, it increased with lesions higher 1 cm. Data by patient were incomplete for develop the analysis.

Discussion: The risk of bias in included studies was middle with inadequate gold Standard or the period of time between tests. Moreover, the populations size were limited.

Implications for the health system/professionals/patients/society: PET/CT has high specificity, although in most cases it was not as sensitive as CIT. PET/CT could be useful as screening test in specific populations.

621. EFFECTIVENESS OF INTERVENTIONS FOR IMPROVING ADHERENCE TO ANTIDEPRESSANT MEDICATION. A SYSTEMATIC REVIEW

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Background: Adherence to antidepressant medication is considered a key factor for the successful treatment of depression. However, research has shown that a considerable percentage of patients who are prescribed antidepressant drugs discontinue treatment before recommended or show a poor adherence.

Objectives: To carry out a systematic review on the effectiveness of interventions designed to improve adherence to antidepressant medication in patients with major depression.

Methods: Studies were identified via Medline, Pre-Medline, CINAHL, Embase, PsycINFO, and Cochrane Library databases until July 2011. To be included, studies must be randomized controlled trials analyzing the effectiveness of interventions designed to improve adherence of adult patients with major depression, who were prescribed antidepressant medication. Two investigators independently extracted data and assessed the methodological quality of the studies included.

Results: Once duplicates were eliminated, 1755 references were obtained. From these, 126 were selected for further review, and 27 studies were finally included. A wide heterogeneity was obtained in the type of intervention implemented (multi-component programmes, collaborative care, telephone-based management, pharmacist' training, educational interventions), and methods of evaluate adherence, what precludes a quantitative synthesis of results. About half of the studies showed significant differences favouring intervention, but these effects seem to disappear in the long term.

Discussion: Several interventions have been proven effective in improving adult patients' adherence to antidepressant medication. Further research must analyze what specific components of the programmes are responsible of this effect, and how it could be sustained in time.

Implications for the health system/professionals/patients/society: Improving adherence to antidepressant medication will likely result in better outcomes of depression treatment and less relapse rates, which in turn will reduce the burden of disability and costs associated with the disease.

626. PANITUMUMAB SAFETY PROFILE IN THE TREATMENT OF METASTATIC COLORECTAL CANCER: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Panitumumab is indicated for the treatment of patients with wild-type KRAS metastatic colorectal cancer (mCRC) in first-line in combination with FOLFOX, in second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan), and as monotherapy after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. The aim of conducting a meta-analysis is to gain a better understanding of the overall risk of adverse events (AEs) in patients who received panitumumab-based therapy.

Objectives: To perform a systematic review and meta-analysis to determine the AEs associated with panitumumab in mCRC.

Methods: A systematic review of literature has been conducted focused on the safety, identifying randomized controlled trials (RCTs). MEDLINE, EMBASE, CRD, and the Cochrane Library were searched to 2011 June to identify relevant studies. Two authors independently selected the studies, assessed the quality, and performed the data extraction. Meta-analysis were conducted to assess grade 3/4 AEs. For meta-analysis, Epidat 3.1 software was used and fixed-effects model was considered and in case of heterogeneity, random-effects model was used.

Results: In the systematic review, three RCTs were considered (one study in first-line, and two studies in patients previously treated). Mutant and wild-type KRAS tumors were considered to evaluate safety. A total of 2,626 patients were included. A fixed- effects model was used, except for hypokalemia (I2: 68%). The following grade 3/4 AEs had an increased risk in panitumumab-chemotherapy groups, by meta-analysis, compared with chemotherapy or best supportive care (BSC): skin reactions (RR: 20.30, 95%CI: 13.05-31.57), paronychia (RR: 9.56, 95%CI: 2.86-31.98), diarrhea (RR 1.71, 95%CI: 1.36-2.15), hypokalemia (RR 3.30, 95%CI: 1.32-8.25), and hypomagnesaemia (RR 17.74, 95%CI: 5.56-56.59).

Discussion: In a meta-analysis of RCTs, panitumumab-based therapy, compared with chemotherapy or BSC, is associated with a significant risk of grade 3/4 skin related AEs and electrolytic disorders.

627. EFFICACY OF OSNA ASSAY FOR INTRAOPERATIVE DETECTION OF SENTINEL LYMPH NODE METASTASES IN BREAST CANCER PATIENTS

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Background: The evaluation of axillary nodes in breast cancer patients is used as a method to detect the spread of tumour cells through the lymphatic system and has become one of the main parameters in the prognosis of women with breast cancer. The one-step nucleic acid amplification (OSNA) assay is an automated system for rapid and quantitative detection of cytokeratin 19 mRNA, specific marker of tumour cells, with the reverse transcription loop-mediated isothermal amplification (RT-LAMP) method.

Objectives: To assess the efficacy of the OSNA molecular method compared to conventional techniques that detect sentinel node metastases in breast cancer patients.

Methods: A systematic review of the literature was done. The consulted databases were MEDLINE and EMBASE until July 2011. Others checked databases were CRD, Cochrane Library, INHATA, TEC, Clinical Evidence, ECRI and Hayes. A peer critical reading of studies was done to identify methodological problems. In this way, the quality of scientific available evidence was done.

Results: Eleven studies that assessed the efficacy of intraoperative assay OSNA against others intraoperative and postoperative histopathological methods, were identified. There was sampling bias in all the localized studies. Studies showed a high concordance (91.7% - 98.2% in nodes and 93-93.5% in patients) between the OSNA test and postoperative methods, considered as gold standard. According to data provided by the studies included in this report, the estimated sensitivity of OSNA is within a range from 77.5 to 98.1% in nodes and 77.8-80% in patients, and specificity from 89 to 98.5% in nodes and 96.3-97.2% in patients.

Discussion: Although the limitations of included studies, OSNA assay had a high concordance, sensitivity and specificity compared with postoperative histopathological analysis and greater sensitivity than conventional intraoperative methods.

Implications: Clinical studies are needed to determine the pronostic ability of the OSNA test.

637. HTA OF INTERVENTIONS AND PROCEDURES FOR CARDIOPULMONARY RESUSCITATION

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Background: Interventions and new strategies in cardiac arrest practices try to improve the survival rate.

Objectives: To assess the effectiveness and safety of practices, procedures and interventions for cardiopulmonary resuscitation (CPR).

Methods: A comprehensive review of practices, procedures and recommendations for cardiopulmonary resuscitation in electronic databases (CRD, Cochrane Database, Medline, Clinical Evidence) and websites of national and international organizations was performed. Clinical practice guidelines, systematic reviews and primary studies assessing practices, procedures, equipment and recommendations for cardiopulmonary resuscitation on adults were included. Adult basic and advance life support and electrical therapies with automated external defibrillators (AED) were considered. The quality of studies was assessed through checklists.

Results: Main guidelines and reviews were retrieved as guidelines of International Liaison Committee on Resuscitation (ILCOR) published in October 2010, CPR guidelines from the American Heart Association (AHA), the European Resuscitation Council (ERC), the Resuscitation Council of United Kingdom, the Australian Resuscitation Council (ARC) and the Spanish Resuscitation Council. To assess the quality of the studies ILCOR and AHA levels of evidence were used. The ILCOR and AHA recommendations are based on scientific evidence and expert consensus. The newest recommendation in the 2010 CPR guidelines is the basic life support sequence of steps as "C-A-B" (Chest compressions, Airway, Breathing). The CPR guidelines emphasize on immediate high-quality CPR with effective chest compressions; early defibrillation with an AED for ventricular fibrillation of short duration; integrated post-cardiac arrest care as the fifth link of survival chain; and improved training and education of lay rescuers and healthcare providers. Other interventions during cardiac arrest, like advanced airway placement, drug delivery and vascular access have not yet been proven to increase survival to hospital discharge.

Conclusion and implications: Immediate CPR, with high-quality chest compressions, and early defibrillation are evidence-based interventions that have proven to increase survival to hospital discharge.

643. BELIMUMAB: A TECHNOLOGICAL ADVANCE FOR SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)? REPORT OF A SYSTEMATIC REVIEW AND META-ANALYSIS

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Objective: Belimumab is a new treatment targeted at Systemic Lupus Erythematosus (SLE). We performed a systematic review and meta-analysis of RCTs of use of belimumab for patients with moderate to severe SLE.

Methods: We searched Cochrane Database of Systematic Reviews; the Cochrane Central Register of Controlled Trials (CENTRAL); DARE; EMBASE; HTA Database; Medline; Pre-Medline; Science Citation Index, reference lists and databases of on-going clinical trials. Data were extracted by two independent investigators. Meta-analysis was undertaken using STATA 11. Bayesian random effects meta-analysis was used to predict 95% credible intervals for a new study.

Results: Three RCTs (LO2, BLISS 52 BLISS 76) reported data on 2133 patients. Ethnicity and geographical location of participants and studies varied. All three trials recruited predominantly female patients (χasi90%) and were described as double blind. Adjusted odds ratios for the primary outcome, SLE Responder Index (SRI) (a new composite outcome used in the BLISS studies), showed greater improvement for BLISS 52 (OR1.83 (95% CI: 1.30, 2.59; P = 0.0006)) than for BLISS-76 (OR 1.52 (95% CI: 1.07, 2.15; P = 0.0207)). And BLISS 52 results were more favourable than BLISS-76, for all measured outcomes although tests for statistical heterogeneity were negative. Meta-analysis showed a benefit of belimumab: SRI (OR 1.63; 95% CI: 1.27-2.09).

Conclusions: Meta-analytic pooling of study level results showed a statistically significant benefit of belimumab in SLE. However, in view of the different populations studied at different locations and the

consistently superior results from one trial compared to the other, the generalizability of pooled results should be viewed with caution. Clinical heterogeneity and rigorousness of trial conduct may be important confounders. The possibility that trials undertaken on different populations in different countries might yield different results requires further consideration.

646. EFFICACY OF ALGLUCOSIDASE ALFA IN LATE-ONSET POMPE DISEASE

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Background: Alglucosidase alfa is an orphan drug for Pompe disease.

Objectives: To assess the efficacy of alglucosidase alfa in late-onset Pompe disease.

Methods: A systematic review was conducted. Searches were carried out at the Cochrane Library, CRD databases, PREMEDLINE, MEDLINE, EMBASE and ECRI, until July 2011.Inclusion criteria: Population: late-onset Pompe disease. Intervention: alglucosidase alfa. Outcomes: survival, quality of life, functional status, pulmonary function, muscle strength. Design: meta-analysis, systematic reviews, randomized controlled trials (RCTs), controlled observational studies, uncontrolled intervention studies (UIS) (n> 10 patients). Selection, quality assessment, data extraction and analysis were done by two researchers. Disagreements were resolved by consensus.

Results: Five studies were included: 1 RCT and 4 UIS. Survival: no evidence was found. Quality of life (SF-36): no significant differences were found in any study. Functional status [6-minute-walk-test (6MWD), mean increase]: 28.1 m, p = 0.03 (RCT). Furthermore, statistically significant increases were observed in 3 UIS after treatment. Pulmonary function [% predicted forced vital capacity]: In RCT remained stable after treatment with alglucosidase alfa. However, decreased in placebo group. In UISs also remained stable for most patients. Muscle strength (different tests): no significant differences were found in any study, except in one UIS (a statistically significant increase was observed only in the anterior thigh, but not in overall leg strength). In general, the major benefit of treatment was observed in the less severe form of the disease.

Discussion: Alglucosidase alfa improves functional status (6MWD). However, this improvement has little clinical relevance and great heterogeneity among patients. Alglucosidase alfa doesn't improve pulmonary function, but achieves a stabilization. Its efficacy for other outcomes has not been demonstrated.

Implications for the health system/professionals/patients/society: This review could serve as a basis for developing recommendations for the use of alglucosidase alfa in late-onset Pompe disease.

647. A REVIEW OF ECONOMIC EVALUATION STUDIES ON AMBULATORY MONITORING OF CAPILLARY GLUCOSE IN TYPE II DIABETICS

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Background: Diabetes is considered an important public health problem and its prevalence is rising. Diabetes-related complications can result in high socio-economic costs and represent a significant number of consultations in health care services.

Objective: Conduct a review of economic evaluation studies on ambulatory monitoring of capillary glucose (AMCG) in type II diabetics.

Methods: A literature review was done on MedLine's data base and complemented by searches on various websites. Those articles referenced in the documents analyzed were included, as well as other documents provided by experts. All articles related to efficiency and AMCG costs were included. The methodology's quality was evaluated and a qualitative synthesis of results was done.

Results: Nine articles and one economic evaluation report have been included in the review. Most of the articles involved studies on cost effectiveness with long-term simulations. Since five of the nine articles used Kaiser Permanente's data base and concluded that AMGC was a cost-effective strategy, they can be treated as a single study. The remaining documents found no differences in AMGC use. It should be mentioned that documents that found no differences had lower scores than those showing a beneficial result for diabetes test strips.

Conclusions: A degree of uncertainty exists regarding the question of whether or not it is efficient to use AMCG among persons diagnosed with type II diabetes. More studies are needed to evaluate the efficiency of using AMCG for this population.

Implications: In light of this uncertainty the use of more personalized glucose test strips should be recommended, depending on metabolic control, clinical circumstances and the individual patient's characteristics. In addition, education on diabetes should be included as a key part of this approach.

658. DRUG-ELUTING STENTS VERSUS BARE METAL STENT IN PATIENTS WITH CORONARY ARTERY DISEASE: A META-ANALYSIS

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Background: After the initial success of the use of drug-eluting stents (DES) in percutaneous coronary intervention (PCI), given the dramatic reduction in the rate of restenosis and therefore the need for new revascularizations in comparison with bare-metal stents (BMS), concerns regarding their long-term safety (higher incidence of late stent thrombosis) and effectiveness has emerged.

Objectives: To assess the effectiveness of the use of DES comparing with BMS in patients with coronary artery disease undergoing treatment by PCI.

Methods: MEDLINE, EMBASE, CENTRAL, SCOPUS, SCI, IBECS, LILACS and SCIELO (1990-Feb 2011) were searched. Randomized controlled trials (RCTs) published in English and Spanish were included. Methodological quality of included trials was assessed according to SIGN criteria. Trials were combined by fixed-effects meta-analysis. Outcomes evaluated were death, myocardial infarction (MI), target

lesion revascularisation (TLR), target vessel revascularisation (TVR), major adverse cardiac event (MACE), binary restenosis, late luminal loss and stent thrombosis.

Results: A total of 31 ECA were included in the systematic review but 28 trials contributed to the meta-analysis with at least one outcome, 10 trials (5541 patients) for the comparison paclitaxel eluting stent (PES) vs. BMS and 18 trials (6329 patients) for sirolimus eluting stent (SES) vs. BMS. No statistically significant differences were found in death and MI neither between SES vs. BMS and PES vs. BMS. However, for both comparisons, rates of TLR, TVR and MACE were significantly higher in the BMS group at 1 and 5 years.

Discussion: At present, we are not able to come to a clear conclusion since we are still being carried out analysis for binary restenosis, late luminal loss and stent thrombosis. In-deep analyses with subgroups of patients are also necessary.

Implications: Our findings together with an assessment of budgetary impact of DES on the different health systems will help clinical and funding political decisions.

691. A SYSTEMATIC REVIEW AND META ANALYSIS OF THE CLINICAL EFFECTIVENESS OF CILOSTAZOL, NAFTIDROFURYL OXALATE, PENTOXIFYLLINE AND INOSITOL NICOTINATE FOR SYMPTOM MANAGEMENT OF INTERMITTENT CLAUDICATION

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Background: Peripheral arterial disease (PAD) occurs when atherosclerosis restricts the flow of blood to the arms and legs. The most common symptom of PAD is intermittent claudication (IC), characterized by pain in the legs on walking that is relieved with rest.

Objectives: To assess the clinical effectiveness of cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate for the treatment of IC in people with PAD whose symptoms continue despite three to six months of conventional management.

Methods: Seven key electronic bibliographic databases were searched to April/June 2010. Reference lists of relevant articles were checked. Comparators were placebo, or intervention drugs compared with each other. Outcomes were maximal walking distance (MWD), pain-free walking distance (PFWD), adverse events, cardiovascular events, mortality, and health-related quality of life (HRQoL). Results were synthesised using a network meta-analysis where possible.

Results: Twenty-four randomised controlled trials (RCTs) were identified. In most trials, the comparator was placebo, with one head-to-head comparison of cilostazol and pentoxifylline. The network meta analysis estimates of percentage change in MWD from baseline to 24 weeks for placebo, pentoxifylline, cilostazol and naftidrofuryl oxalate were 27.6%, 41.4%, 59.2% and 106.7% respectively. It was not possible to include inositol nicotinate due to the lack of 24-month data, however the shorter term data did not suggest a significant effect. Adverse events were minor for all drugs (e.g. headaches and gastro-intestinal difficulties). Limited data were available for HRQoL.

Discussion: Meta analysis suggests that naftidrofuryl oxalate is the most effective treatment for increasing MWD in PAD. Most of the trial data only had follow-up periods of 24 weeks.

Implications: Both naftidrofuryl oxalate and cilostazol appear to be effective treatments for the symptomatic relief of PAD.

705. SYSTEMATIC REVIEW AND META-ANALYSES OF LAPAROSCOPIC VERSUS OPEN SURGERY FOR COLORECTAL CANCER

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Background: Colorectal cancer is the second malignant tumour causing mortality in both men and women in Spain. The 5-year survival is above 50%, depending largely on the extent of the disease at the time of diagnosis. Surgical resection with curative intention is the best choice. It has been carried out by conventional open surgery, but the advent of laparoscopic surgery can facilitate recovery avoiding great incisions, without affecting the long-term results.

Objective: The objective of the present report is to assess long term efficacy results of these two interventions in patients with colorectal cancer.

Methods: A systematic review was designed to answer our research question. Randomized controlled trials were searched in Medline, Embase, Scopus, Cochrane Library Plus and Trip databases. Risk of bias and quality was assessed. To summarise quantitative variables meta-analyses techniques were used, using hazard-ratio (HR) meta-analysis for time to event variables. Revman 5.0 was used to perform meta-analyses.

Results: A total of 25 new publications were recruited from 16 randomized clinical trials including more than 4,000 patients. Risk of bias of included trials was mainly associated to no blinding of patients or medical staff. Laparoscopic surgery has longer surgery time (45 min.), and shorter hospital stay (1.38 days), but no differences in mortality and complications could be found. Neither differences were found in recurrence (HR 0.95 CI95% 0.83-1.38), overall survival (HR 1.07 CI95% 0.96-1.20) or long-term complications (Relative risk 0.95 CI95% 0.72-1.27).

Conclusions: Laparoscopic-assisted resection, based on results of more than four thousand patients, has shown results in terms of overall survival and recurrence similar to those achieved by open surgery. Then these two interventions must be considered in colorectal patient, and decision have to be made based in other variables as costs or patient quality of life.

721. A SYSTEMATIC REVIEW OF GUIDELINES TO DOCUMENT THE DESIGN OF A CLINICAL TRIAL IN DIABETES MELLITUS

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Background: The Canary Islands (Spain) has a high prevalence of Type II Diabetes Melllitus (T2DM) (9.4%). This health problem made the Government to promote a community randomized clinical trial (INDICA Study) to assess the effectiveness and cost-effectiveness of two interventions to improve patients and GPs' behaviour.

Objective: To identify high quality clinical practice guidelines (CPG) to define what a "properly controlled T2DM patient" is and to be part of the interventions in the INDICA Study.

Methods: Systematic review of CPGs for T2DM. We searched MEDLINE, MEDLINE in process, National Guideline Clearinghouse and GuíaSalud in March 2011; the search was completed after consulting experts. Selection criteria: CPGs for endocrinologists, GPs or nurses, for treatment and management of T2DM. The CPGs were assessed by means of the AGREE checklist and also according to a group of relevant characteristics for the INDICA Study: adaptability to the Primary Health Care in the region, well known and updated. The language and the availability of a short CPG and algorithm were also assessed.

Results: 230 references were screened by a panel of 10 experts. Nine general CPGs and 12 specific CPGs were included. The CPGs with the highest scores were NICE and SIGN. The panel chose the NICE's CPG for INDICA Study based on its methodological quality, its actualization and its knowledge among GPs in the region. The adaptation of the CPG to the context (and previous implemented policies) was discussed among researchers; some recommendations from the ADA were incorporated.

Conclusions and implications: The best CPG for INDICA Study was the NICE's. The experience and the results reinforce the decision to base the design of a clinical trial on the best evidence obtained after a systematic review of the literature. However, when there are several high quality guidelines, the election has to incorporate the external validity.

728. EDUCATIONAL INTERVENTIONS FOR PRIMARY CARE HEALTH PROFESSIONALS TO IMPROVE HEALTH CARE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW

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Background: In the context of the design of a clinical trial on diabetes (INDICA study), we performed a systematic review of the literature.

Objectives: To determine the effectiveness of educational group interventions targeting primary care physicians and/or nurses with the aim of improving the health of patients with type 2 diabetes.

Methods: Medline and Premedline were searched (june 2011). Eligible studies included randomized or quasi randomized controlled trials, controlled before-after studies and previous systematic reviews. Methodological quality of the included studies was assessed according to SIGN criteria.

Results: Ten studies (6 RCTs) met all inclusion criteria. Only two studies were considered with a low bias risk. The intervention was more often provided by a specialized nurse (4 studies). Most interventions were multifaceted with a follow-up period of at least 12 months. There was diversity among the analyzed variables in each study. 'Quality of care provided', 'Self-perceived quality of life' and 'auto referred satisfaction' were the areas with the most frequent statistically significant improvements (4/5 studies), (2/3 studies) and (2/3 studies) respectively. Most of the studies showed no statistically significant improvement for clinical parameters in the intervention group; HbA1c (%) and blood pressure (3/8 studies) and total cholesterol (1/6 studies) were the most frequently improved.

Discussion: Our findings suggest that educational group interventions to primary care professionals are not effective improving clinical parameters in patients with diabetes type 2 at short and medium-term follow-up period but they improved the quality of care provided. However, evidence is scarce, heterogeneous and not very high quality. This made it difficult to draw definitive conclusions from this body of research.

Implications: The results of this systematic review have been taken into account for the design of the INDICA study. We propose it can be useful for future researches and the planning of health policies for improving diabetes.

733. EFFICACY AND SAFETY OF THREE ORPHANS DRUGS: AGALSIDASE ALFA, IDURSULFASE AND VELAGLUCERASE

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Background: Rare diseases are those that affect a very small number of people in relation to the general population. The European Union considers as a rare disease when the prevalence is less than 5 cases per 10,000 inhabitants. Most rare diseases begin in childhood, affecting more than one organ, present a diagnostic challenge and have a chronic and disabling clinical course. This type of diseases associated with the concept of orphan drugs, used to treat these diseases, which generally have a very high cost. In Uruguay requested the inclusion in the "Formulario Terapéutico de Medicamentos (FTM)" of three orphan drugs that are the Agalsidase alfa, Idursulfase and Velaglucerase used for the treatment of Anderson-Fabry disease, Hunter disease and Gaucher's disease respectively. If these drugs are included, should be financed by mandatory health providers.

Objectives: Determine whether the available scientific evidence on efficacy and safety of agalsidase alfa Idursulfase and Velaglucerase is enough to include these drugs in the FTM of Uruguay.

Methods: There were three different searches in major biomedical scientific databases with the following keywords: "agalsidase alfa AND Anderson- fabry disease", "Idursulfase disease and Hunter," "velaglucerase AND Gaucher disease". Filter was used by clinical trials, meta-analysis and review.

Discussion: We found seven studies, five were randomized controlled trials; two were open-label studies. The number of patients involved in each study is very low, making a total of 248 patients. None of the studies reported serious adverse events. The efficacy outcomes were not given to long term. Three ongoing extension studies should provide more data of safety/efficacy.

Implications for the health system: The available scientific evidence is very limited for each of these drugs. The absence of alternative treatment for these diseases makes each one of these drugs a potential effective treatment that should be confirmed in future research.

737. COSTS OF MULTIPLE SCLEROSIS IN LATIN AMERICA AND THE CARIBBEAN: SYSTEMATIC REVIEW OF THE LITERATURE

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Background: Multiple sclerosis (MS) is the second most common cause of neurological disability in young adults. Limited information is available about the cost of the disease in Latin America and the Caribbean (LAC). The objective of this study was to assess health economic data of MS in LAC.

Methods: We conducted a systematic review of the literature from 1990 to 2011. Outcome measures included: mean cost of drug modifying disease (DMD), mean cost of treatment of relapses (steroids and hospitalization), mean cost of disease by stage stratified by EDSS and mean cost of rehabilitation.

Results: Nine hundred and thirty nine citations were identified. Seven studies from 3 countries (Brazil, Argentina and Colombia) met predetermined inclusion criteria after full-text review. The studies were heterogeneous in several aspects. The mean cost of DMD treatment was reported to be of USD 35,000 per patient-treated for 2004 in Argentina and the total MS expenditure of DMD rose from U$D 14,011,700 in 2006 to U$D 122,575,000 in 2009 in Brazil. In Sao Paulo, DMD accounted for 12.9% of high cost medication supplied by the public sector in Brazil. The mean length of hospitalization related to MS was 7.7 days being the mean cost of hospitalizations reported of USD 386 for 2009 in Brazil. The mean direct and indirect cost of disease by stage stratified by EDSS was evaluated in one Colombian study. Patients cost ranged between USD 10,543 (EDSS 8-9.5) and USD 25713 (EDSS 3-5,5). Indirect costs markedly increased for the EDSS 8-9.5 patients. No information was retrieved on rehabilitation.

Conclusions: This study represents the first systematic review of the costs of MS in LAC. Few studies and with low methodological quality deal with this issue in LAC, so further research about the economic burden of MS in LAC is needed.

739. PROGNOSTIC ACCURACY OF EXERCISE ECG AND CT CORONARY ANGIOGRAPHY TO PREDICT MAJOR ADVERSE CARDIAC EVENTS (MACE) IN PATIENTS WITH SUSPECTED ACUTE CORONARY SYNDROME (ACS): A SYSTEMATIC REVIEW

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Background: Accurate risk stratification of patients presenting to the emergency department with suspected ACS is important. Exercise ECG (ExECG) and Computed Tomography Coronary Angiography (CTCA) are non-invasive tools commonly used to diagnose Coronary Artery Disease in patients with stable symptoms. They are used less frequently for the management of patients presenting to the emergency department with suspected ACS.

Objectives: To assess the prognostic accuracy of ExECG and CTCA to predict major cardiac events (MACE) in patients with suspected ACS.

Methods: A systematic review to assess the prognostic accuracy of ExECG or CTCA for predicting MACE, defined as including at least cardiac death and non-fatal MI, at at least 30 days follow-up in adults presenting to the emergency room with suspected ACS. Nine electronic databases and bibliographies of previous systematic reviews were searched.

Results: Seven studies of CTCA and 13 studies of ExECG were identified. Meta-analysis found, for CTCA, a relative risk for MACE of 3.1 (0.3-18.7) for positive and intermediate scans versus negative scans and 5.8 (0.6-24.5) for positive versus intermediate and negative scans. For ExECG, an increased risk for MACE of 8.4 (3.1-17.3) for positive and inconclusive versus negative tests and 8.0 (2.3-22.4) for positive versus inconclusive and negative tests was found.

Discussion: MACE rates were low in patients with negative tests, and generally modest in patients with positive tests. Many were process events (Percutaneous Coronary Intervention or Coronary Artery Bypass Graft), which may reflect physicians acting upon positive results. Low overall event rates may be a result of selected low risk study populations.

Implications: CTCA and ExECG offer potentially useful non-invasive methods to stratify risk in patients with suspected ACS. However, currently there is insufficient evidence to recommend their routine use. Larger trials generating more events are needed.

746. LEFT VENTRICULAR ASSIST DEVICE TYPE HEARTMATE II AS DESTINATION THERAPY FOR ADULT PATIENTS WITH END-STAGE HEART FAILURE: A SYSTEMATIC REVIEW OF CLINICAL EFFECTIVENESS

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Background: While cardiac transplantation remains the best treatment for patients who have end-stage heart failure (HF), not all patients are eligible for transplantation. The continuous-flow left ventricular assist device (LVAD) HeartMate II (HM II) is a very costly emerging technology increasingly used as permanent therapy ("destination therapy") in transplantation-ineligible patients with end-stage HF. The Quebec Ministry of Health requested an evaluation of this technology by INESSS, an independent body that supports decision-making with systematic literature reviews, field evaluations and outcomes research.

Objectives: To assess the effectiveness of HM II as destination therapy for adults with end-stage HF ineligible for cardiac transplantation.

Methods: A systematic literature search was performed in electronic databases for English/French-language articles published from 2008 to 2011 and completed with LVAD registries, manufacturer web sites, grey literature, and current trial registries. Study selection, data extraction and quality assessment were done by two independent reviewers using standardized appraisal tools. A synthesis of the data was presented to a group of medical experts.

Results: A single randomized controlled trial, one prospective case series and one retrospective report from a registry were included. The methodological quality of the studies was low to moderate. HM II was associated with improved survival, functional status and quality of life at 1 year in HF patients who were ineligible for cardiac transplantation. HM II was associated with a lower rate of complications than the previous generation of pulsatile LVADs.

Discussion: Despite the limited quantity and quality of evidence, HM II may be a clinically effective treatment for patients deemed ineligible for cardiac transplantation and otherwise facing a grave prognosis. Further research is needed to assess longer-term (> 1 year) effectiveness.

Implications: These **r**esults provide important information for decision-makers regarding the appropriate implementation of this technology in Quebec.

759. ARE PICCS A GOOD OPTION FOR CHEMOTHERAPY ADMINISTRATION? A SYSTEMATIC REVIEW

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Background: Peripherally Inserted Central Venous Catheters (PICCs) have been used to deliver outpatient courses of intravenous therapy. They function as a central catheter allowing drug infusion, parenteral nutrition and blood sampling. PICCs are easy bedside

insertions in the basilic or cephalic vein without need for general anesthesia and surgery room, that can be performed by trained nursing staff. Because of the high satisfaction reported by patients and caregivers using PICCs, their use has considerably increased in hospital and ambulatory medicine during the last two decades. Moreover, PICCs are cheaper than tunnelled catheters or implantable ports.

Objectives: This study aims to evaluate PICCs in terms of safety, quality of life (QoL) and economical costs compared with other catheters currently used for chemotherapy administration.

Methods: Comprehensive searches have been carried out for each review question using a range of databases (PUBMED, EMBASE, SCOPUS, CINAHL, UpToDate, THE COCHRANE LIBRARY); Database of Abstracts of Reviews of Effects (DARE); NHS Economic Evaluation database (NHS EED) and resources for evidence-based clinical practice guidelines (NGC, NICE, TRIP). Selected studies will be retrieved and assessed for quality prior starting the review.

Results: They are unavailable at present. However, we are expecting to find scientific evidence that documents advantages such low complication rates at insertion, fewer problems derived from prolonged use, higher QoL due to a better preservation of the patient's venous capital, and time and costs savings.

Discussion: PICCs are replacing central venous catheters (CVCs) and peripheral catheterization for the administration of chemotherapy in many countries, but not in Spain. This study will allow us to draw recommendations about using PICCs, CVCs or peripheral catheterisation.

Implication for the health system/professionals/patients/society: Choosing the best evidence-based available administration system will enhance patient's safety and QoL.

790. SYSTEMATIC REVIEW OF METHODS FOR SPECIFYING THE TARGET DIFFERENCE IN RANDOMISED CONTROLLED TRIALS (DELTA REVIEW)

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Background: To determine the sample size for a randomised controlled trial (RCT), a (target) difference between treatments is typically specified, which the RCT is designed to detect. This provides reassurance that the study will likely detect this difference (where it exists) with the required level of statistical precision. One common approach is to specify a difference that is regarded as being clinically important. Determining an appropriate sample size by specifying the target difference is of crucial importance as too large or small a study could be unethical, wasteful or lead to a potentially misleading conclusion. Within the medical field, various methods have been proposed to formally determine target differences, but their relative merits are unclear, and the availability and suitability of alternative methods from non-medical fields is unknown.

Objectives: To systematically review the medical and non-medical literature to identify methods to specify the target difference for use in RCTs.

Methods: Electronic searches of biomedical and non-medical databases were performed. Studies reporting a method that could be used to specify the target difference were included. Titles and abstracts were screened prior to full-text assessment.

Results: The search identified 11,386 potentially relevant studies; 1,274 were selected for full-text assessment. Seven methods were identified: anchor, distribution, economic evaluation, effect size, opinion-seeking, pilot study and reviews of the evidence base. Anchor, distribution and effect size methods were most commonly used.

Discussion: A variety of methods were identified, though each had important variations in application. Some methods require strong assumptions to be made before application to an RCT setting. Further research evaluating usage and optimal implementation is needed.

810. EFFICACY AND SAFETY OF INSULIN GLARGINE IN THE TREATMENT OF ADULTS WITH TYPE 1 DIABETES MELLITUS: A META-ANALYSIS

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Background: Insulin glargine is commonly prescribed for the management of type 1 diabetes mellitus, although there are doubts regarding its optimal use. A meta-analysis was conducted to compare clinical outcomes of insulin glargine with NPH insulin in the treatment of type 1 diabetes in adults.

Objectives: The aim of this meta-analysis is to evaluate the use of insulin glargine regarding the incidence of hypoglycemia events rate and glycemic control compared with human insulin.

Methods: We searched MEDLINE, LILACS and the Cochrane Controlled Trials Registry. Two reviewers independently assessed the methodologic quality of the included studies as well as collected data. Disagreements were solved by consensus. The effect measures used were rate ratio for hypoglycemia (total, nocturnal and severe) and standardized mean difference (SMD) for glycated hemoglobin at the end of follow-up. Data was pooled by the DerSimonian and Laird random effects model and heterogeneity was assessed with the I-squared statistic.

Results: We included 9 randomized controlled trials in the analysis. Most of the studies were of short to medium duration and of low quality. The pooled rate ratios and 95% confidence intervals of total, nocturnal and severe hypoglycemia were 1.013 (0.888 to 1.157), 0.872 (0.694 to 1.097) and 0.834 (0.578 to 1.204), respectively. The pooled SMD for glycated hemoglobin was -0.239 (-0.522 to 0.044).

Discussion: This meta-analysis showed no benefits of glargine relative to NPH in terms of reducing hypoglycemia and glycemic control. Long-term high-quality studies are needed to assess vascular complications and cost-effectiveness.

Implications for the health system: Given its higher cost compared with human insulin and the lack of statistically significant additional benefits, stronger evidence is required to implement health-care policy concerning treatment of diabetic patients with insulin glargine.

822. SYSTEMATIC REVIEW OF EFFICACY AND SAFETY OF OMALIZUMAB IN THE TREATMENT OF SEVERE ALLERGIC ASTHMA

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Background: Omalizulab (OMZ) has been available in Brazil for less than five years. There is controversy about the cost-effectiveness of OMZ as an adjunctive therapy to conventional asthma treatment.

Objectives: To evaluate the effectiveness of OMZ as adjunctive therapy to conventional treatment of severe allergic asthma in adolescents and adults.

Methods: Studies published in the last 15 years in Cochrane Library, Pubmed/Medline, Lilacs, REBRATS, CRD, NHS databases were considered, in English, Spanish or Portuguese. Meta analyses, systematic reviews, controlled clinical trials, national and international health surveillance agencies databases and technological bulletins were included. The following outcomes were considered: exacerbation rate, death rate, hospital admissions and emergency visits. Studies with follow-up period shorter than 24 weeks, as well as comparative analyses with treatments not approved in Brazil were excluded.

Results: Were included 8 studies, being 8 clinical trials, one metanalysis and one technology assessment. OMZ is more effective than placebo in patients with allergic asthma not controlled with inhaled corticosteroid therapy, reducing approximately one exacerbation per year. There is no consistent evidence of benefits in hospital admissions and death rates.

Discussion: The magnitude of the OMZ effect is low. Most of the studies present methodological problems, including outcomes that cannot be considered clinically relevant. Conventional treatment of control groups can be considered insufficient in the majority of the studies, for only a small number used long-acting beta agonists associated with inhaled corticosteroid as a criterion for severe asthma, and only a small proportion of patients received oral corticosteroid on a regular basis, according to step 5 GINA. Efficacy and safety data about medium and long-term use are scarce.

Implications for the health system/professionals/patients/society: OMZ inclusion in Brazil's Public Health System is not recommended due to low benefits, safety issues and high cost.

852. PREVALENCE OF HYPERTENSION AMONG BRAZILIAN ELDERLY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Prevalence of hypertension in the elderly Brazilian population has been investigated only through telephone surveys.

Objective: To estimate the pooled prevalence of hypertension in elderly subjects, from studies conducted in Brazil between 1980 and 2010.

Methods: A systematic review and meta-analysis was undertaken. Population-based cross-sectional and cohort studies carried out on probabilistic samples, published between 1980 and 2010 were identified. Two blinded reviewers conducted independent searches in PubMed, EMBASE, LILACS and Scielo databases. In PubMed, Mesh Terms used were: Majr AND Hypertension Prevalence AND Brazil. Additionally, unpublished teses and dissertations were also retrieved. Hypertension was defined as average blood pressure ≥ 14090 mmHg –the Joint National Committee (JNC) criterion– or use of antihypertensive drugs. Self-reported hypertension in household and telephone surveys was also evaluated. Elderly individuals were defined by age ≥ 60 or ≥ 65 years, depending on the criterion used in the studies. We used the Comprehensive Meta-Analysis software to calculate pooled prevalence through random effects model.

Results: Searches retrieved 602 articles, excluding overlapping results. The title and abstract screening excluded 444 articles, the full-text reading another 158, leaving 18 eligible studies, comprising containing 14346 individuals. The prevalence of hypertension from 1980 to 2010, according to JNC criteria was 67.5% (95%CI: 65.5 -69.4%; n = 2214). In the 2000-2010 period, the prevalence of self-reported hypertension was 48.7% (46.4 -51.0%, n = 3705) in household interviews and 56.1% (50.2 -61.7%, n = 6044) in telephone surveys.

Discussion: This study confirmed high prevalence of hypertension among the elderly and striking differences between prevalence rates obtained by blood pressure measurement and self-reported hypertension, with underestimation of actual prevalence by the latter.

Implications: This was the first systematic review designed to estimate the prevalence of hypertension among Brazilian elderly. Our results may serve as reference and a basic tool to public health policy makers in the country.

856. SCREENING FOR BREAST CANCER WITH DYNAMIC ANGIOTHERMOGRAPHY: A SYSTEMATIC REVIEW

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Background: Breast cancer is a leading cause of death in women around the world. Early detection is regarded as promising strategy for a more favorable outcome. For screening purposes, mammography is accepted as a gold-standard approach, at least for women older than 50-years. However, there is some discussion regarding its disadvantages: high costs, pain and exposition to X-Ray etc. Recently dynamic angiothermograph (DA) was suggested as an alternative screening method for breast cancer. It encompasses a qualitative approach based on the interpretation of patterns of functional blood flow in the breast.

Objective: To evaluate systematically the scientific evidence about the usefulness of DA as a screening method for breast cancer.

Methods: We searched for studies published in English, Spanish and Portuguese. Searches were performed electronically in these databases: Medline, Embase, Web of Science, Lilacs, Google Scholar, Cochrane Registry of Controlled Trials and ClinicalTrials (from inception to 01/10/2011), using the following research terms: thermograph, breast, cancer, diagnosis, temperature, blood, angiogenesis, neoplasms, microcirculation, mammography, screening, mastectomy, surgery e mortality. The outcomes of interest were mortality, morbidity, sensitivity, specificity and/or costs.

Results: From 36 studies initially identified, only three met inclusion criteria. All three were case series, and included 712 women. No study has reported the outcomes of interest. They have important methodological limitations (they do not have control group, there was no randomization or blinding procedures and there was potential conflict of interests).

Discussion: There are few studies about DA in breast cancer screening and they have major limitations. In face of these findings, we concluded that the quality of scientific evidence about DA is very low.

Implications for the health system: Although a promising technology, at this moment there is no scientific evidence to support the adoption of DA as a breast cancer screening method. Further large-scale clinical trials are warranted.

875. AMBULATORY MANAGEMENT VERSUS HOSPITALIZATIONS IN INFANT MORTALITY RATES OF PREGNANCIES COMPLICATED BY DIABETES OR HYPERGLYCEMIA: A SYSTEMATIC REVIEW

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For many years, Gestational Diabetes Mellitus (GDM) has been defined as any degree of glucose intolerance with onset or first recognition during pregnancy. Although most cases resolve with

delivery, the definition applied whether or not the condition persisted after pregnancy and did not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. The objective of this study was to search for evidence to determine the best treatment (ambulatory or hospital care) in diabetic pregant women. Type of study: A systematic review of clinical trials. Search strategy: The following electronic databases were searched: Pubmed, CENTRAL, Embase, Scielo and Lilacs. The date of the most recent search was September 4, 2011. Three studies, involving 736 participants, were included. There was no statistically significance different between ambulatory management versus hospitalization with regards mortality in any of the subcategories analyzed: perinatal and neonatal deaths (RR 0.65; 95% confidential interval [CI] 0.11 to 3.84; p = 0.63); neonatal deaths (RR 0.29; 95% CI 0.01 to 6.07; p = 0.43); and infant deaths (RR 0.29; 95% CI 0.01 to 6.07; p = 0.43). This systematic review offers up-to-date but limited evidence supported by three studies regarding the effects of ambulatory management versus hospitalization in GDM or hyperglycemia. The studies showed clinical and methodological differences. Ambulatory management ought to be the first choice for the treatment of diabetics women during pregnancy because it is a combination of effective and inexpensive procedure compared to hospitalization. However, the results of this review confirmed the need for further randomized clinical trials (RCTs) and ensure a greater understanding on both precision and cares during the prenatal period.

916. SUBLINGUAL VERSUS SUBCUTANEOUS IMMUNOTHERAPY FOR RHINITIS AND/OR ASTHMA: A SYSTEMIC REVIEWS

Hyun Jin Song, Sun Young Park, Yea Ji Jung, Joo Yeon Park and Sangjin Shin

National Evidence-Based Healthcare Collaborating Agency (NECA). Republic of Korea.

Objectives: An aim of the systematic review was to compare clinical outcomes by route of administration of Immunotherapy for symptom medication score (SMS), symptom score (SS), medication scores (MS), adverse reactions (AR), lung function, and quality of life (QoL) for rhinitis and/or asthma.

Methods: We searched MEDLINE, EMBASE, the Cochrane Library, Koreamed, KISS, Kmbase, KiSTi, and additional sources for articles comparing outcomes between Sublingual immunotherapy (SLIT) and Subcutaneous immunotherapy (SCIT) among patients with rhinitis and/or asthma through 3 November 2011. All studies were assessed to identify randomized controlled trials with reporting at least one clinical outcome. We extracted variables related to the study design, setting, participants, and clinical end points. A random-effects model was used to combine trials and to perform analyses using standardized mean difference (SMD), and Relative risk (RR).

Results: 8 studies were included, with 337 patients in 6 RCTs suitable for meta-analysis. Compared with SCIT, SLIT significantly reductions in SMS requirements (SMD -0.87; 95% confidence interval [CI], -0.58, -0.16), MS (SMD -1.55; 95% CI, -2.40, -0.71) and lung function (PEFR) (SMD -0.79; 95% CI, -1.44, -0.15). SLIT were associated with no detectable differences in SS (SMD 0.34; 95% CI, -0.43, 1.12), systemic AR (RR 0.77; 95% CI, 0.54, 1.09), local AR (RR 0.23; 95% CI, 0.03, 1.99), total AR (RR 0.17; 95% CI, 0.01, 3.23), lung function (FEV1) (SMD -0.04; 95% CI, -0.53, 0.45), and QoL (SMD -1.91; 95% CI, -14.64, 18.46) compared with SCIT.

Conclusions: SLIT reduced rhinitis and/or asthma medications and improves PEFR in one trial respectively. No significant differences between SLIT and SCIT were observed in rhinitis and/or asthma in adverse reactions, FEV1, and quality of life.

918. SAFETY AND EFFICACY OF SUBLINGUAL IMMUNOTHERAPY: COMPREHENSIVE META ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

Hyun Jin Song, Yea Ji Jung, Joo Yeon Park, Sun Young Park and Sangjin Shin

National Evidence-Based Healthcare Collaborating Agency (NECA). Republic of Korea.

Objectives: To estimate the relative safety and effectiveness of Sublingual Immunotherapy (SLIT) with rhinitis and/or asthma by performing systematic review of randomized controlled trials (RCTs).

Methods: We performed an electronic search (MEDLINE, EMBASE, the Cochrane Library, Koreamed, KISS, Kmbase, KiSTi) and hand search of studies of SLIT through 3 November 2011. We included randomized, placebo controlled studies published in patients with rhinitis and/or asthma and reporting at least one clinical outcome including symptom medication score (SMS), symptom score (SS), medication score (MS), adverse reactions, lung functions, and quality of life (QoL). Meta-analysis was performed to stratify based on ages, allergens, and treatment durations using the Standardized Mean Difference (SMD), and Relative Risk (RR) using random effect model. Allergic rhinitis and asthma patients' data were analyzed separately.

Results: 111 RCTs were identified, with 53 rhinitis and 14 asthma studies suitable for meta-analysis. In allergic rhinitis, SLIT, compared with placebo, significantly reductions in SMS requirements (SMD -0.86; 95% CI, -1.60, -0.13) SS (SMD -0.54; 95% CI, -0.71, -0.38), MS (SMD -0.58; 95% CI, -0.81, -0.36). In asthma, the SLIT was associated with a significant reduction in SS (SMD -0.84; 95% CI, -1.51, -0.17) and MS (SMD -0.37; 95% CI, -0.65, -0.09), without increasing SMS compared with placebo (SMD -0.18; 95% CI, -0.83, 0.47). Local adverse reactions were significantly higher in the SLIT group for rhinitis. SLIT were no differences adverse reactions, lung function (PEFR), QoL.

Conclusions: SLIT reduced rhinitis and/or asthma SMS requirements and improves FEV1. No significant differences were observed in rhinitis and/or asthma in adverse reactions, PEFR, and QoL without local adverse reactions in patients with allergic rhinitis.

919. SYSTEMATIC REVIEWS OF SUBCUTANEOUS IMMUNOTHERAPY FOR ALLERGIC RHINITIS AND/OR ASTHMA

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National Evidence-Based Healthcare Collaborating Agency (NECA). Republic of Korea.

Objectives: The objective of this study was to estimate the relative impact of subcutaneous immunotherapy (SCIT) on symptom medication score (SMS), symptom score (SS), medication score (MS), adverse reactions (ARs), lung functions (FEV1, PEFR), and quality of life (QoL) in allergic rhinitis and/or asthma patients by performing systematic review of randomized controlled trials (RCTs).

Methods: We searched MEDLINE, EMBASE, the Cochrane Library, Koreamed, KISS, Kmbase, KiSTi, and related sources for SCIT among patients with rhinitis and/or asthma through 3 November 2011. We included randomized, placebo controlled studies published in patients with rhinitis and/or asthma and reporting at least one clinical outcome. A random effects model was used the Standardized Mean Difference (SMD), and Relative Risk (RR) to combine trials to perform separated allergic rhinitis and asthma patients.

Results: We included a total of 45 RCTs in the review.11 studies for rhinitis and 10 for asthma studies were suitable for pooling in meta-

analyses. In allergic rhinitis, SCIT, compared with placebo, significantly reductions in SMS requirements (SMD -0.57; 95% CI, -0.91, -0.22), symptoms (SMD -0.92; 95% CI, -1.41, -0.42), and medication requirements (SMD -0.49; 95% CI, -0.91, -0.07). In asthma, the SLIT was associated with a significant reduction in symptom medication scores (SMD -1.13; 95% CI, -1.72, -0.54), without increasing SC and MS compared with placebo. Systemic and local ARs were significantly higher in the SCIT group for rhinitis and local ARs for asthma. SLIT were no differences local ARs, lung function (FEV1, PEFR) for asthma, and QoL for rhinitis.

Conclusions: SLIT reduced rhinitis SMS requirements without asthma. ARs were higher SCIT without local ARs for asthma. No significant differences were observed in lung functions, and QoL.

924. INSULIN PUMPS FOR PATIENTS WITH DIABETES TYPE 1

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Background: Insulin is commonly administered by way of multiple daily subcutaneous injections (MDIs). An alternative approach involves administering insulin continuously using continuous subcutaneous insulin infusion (CSII) pumps commonly known as insulin pumps. It has been proposed that CSII may result in greater stability of blood glucose levels and reduce the probability of too-high or too-low blood sugar levels.

Methods: A systematic review of CSII in patients with diabetes mellitus type 1 compared with MDI has been undertaken and included in the "Managing diabetes mellitus type 1" clinical practice guidelines.

Results: Although a total of 14 systematic reviews were found, the evidence available is limited as it comes from low-quality trials and clinical series. These studies suggest that insulin pumps provide no relevant clinical advantage for patients who achieve good glycaemic control with intensive MDI therapy. The use of insulin pumps may have an impact in patients who are unable to achieve a satisfactory level of glycaemic control despite the correct use of MDIs and therefore suffer from disabling hypoglycaemias. As far as efficiency is concerned, the incremental cost-effectiveness ratio is € 29,947/QALY (data from 2005).

Discussion: Treatment using a continuous subcutaneous insulin infusion pump is not a universal option for all diabetes mellitus type 1 patients. An appropriate selection of candidate patients should therefore be performed taking into account their metabolic control, risk of acute complications and greater economic cost.

Implications for health system/professionals/patients/society: The appropriate choice of patients with continuous subcutaneous insulin infusion pumps optimises both their effectiveness and the use of health-care resources.

925. HOW SHOULD ERECTILE DYSFUNCTION IN TYPE 1 DIABETES PATIENTS BE TREATED?

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Background: Erectile dysfunction (ED) is the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. It is a microvascular or neuropathic complication that may appear in diabetic patients and is associated with depression, anxiety, loss of self-esteem and has a major impact on the quality-of-life of both patients and their partners, thereby affecting interpersonal relationships.

Methods: The clinical practice guideline "Management of diabetes mellitus type 1", which is to be published in 2012, analyses the clinical management of microvascular complications in diabetes. In this regard, systematic reviews of the scientific evidence regarding the efficacy, safety and patient preferences for each of the following interventions have been undertaken: sublingual apomorphine; phosphodiesterase-5 (PDE-5) inhibitors; intraurethral treatments (alprostadil with or without prazosin); intracavernosal injection of vasoactive agents (alprostadil, papaverine or phentolamine); vacuum devices for inducing erection; penile prosthesis; psychological interventions.

Results: Treatment with phosphodiesterase inhibitors, particularly when associated with group psychotherapy, was found to provide the best results as regards the treatment of ED in terms of efficacy, safety and patient preference, followed by intracavernosal alprostadil and mechanical devices such as prosthesis and vacuum devices.

Implications for health system/professionals/patients/society: Good quality evidence that allows the clinical management of ED in patients with type 1 diabetes to be defined is available.

927. DIABETES MELLITUS TYPE 1 AND PREGNANCY

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Background: Diabetes may have important consequences for both the pregnant woman and the foetus or newborn. It is therefore important to provide diabetic women and health-care professionals with the best available scientific information in order to avoid such detrimental effects.

Methods: The clinical practice guideline "Management of diabetes mellitus type 1", which is to be published in 2012, analyses clinical management during pregnancy: its planning, the evolution of chronic complications, metabolic targets and contraception. A systematic review of the available scientific evidence concerning these topics has therefore been undertaken.

Results: The main recommendations resulting from this study are as follows: Pregnancy in women with diabetes mellitus type 1 should be planned until appropriate glycaemic control is achieved and to evaluate the possible appearance of retinopathy and nephropathy both prior to and during pregnancy. Such women should be informed that any decrease in HbA_{1C} below 6.2% reduces the risk of congenital malformations and they should be recommended not to exceed a level of 6.9%. Situations in which pregnancy is not recommended: HbA_{1C} levels above 8%; Severe nephropathy (plasma creatinine > 2 mg/dl or proteinuria > 3 g/24 hours and/or difficult-to-control HTA). Ischaemic heart disease. Severe proliferative retinopathy with poor visual prognosis. Severe autonomic neuropathy. A copper IUD is recommended as the safest contraceptive method in women with diabetes mellitus type 1. All these recommendations have a recommendation strength B.

Implications for health system/professionals/patients/society: The severe consequences of poor metabolic control in women with diabetes mellitus type 1 require clear, high-quality evidence-based recommendations.

928. THE FREQUENCY OF RETINAL SCREENING IN PATIENTS WITH DIABETES MELLITUS TYPE 1

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Background: Retinopathy is responsible for the highest morbidity in patients with diabetes mellitus. The vast majority of patients who develop a diabetic retinopathy (DR) remain asymptomatic until an advanced stage (macular oedema and/or proliferative diabetic retinopathy), at which point treatment may have little effect.

Methods: During preparation of the CPG "Management of diabetes mellitus type 1", a systematic review of the optimal frequency with which DR screening should be performed in patients with diabetes mellitus type 1 was undertaken.

Results: Four studies (369, 367, 368, 366) found that the risk of developing retinopathy increased with time since diagnosis, age and HbA1c levels (366, 367), and that 86% of patients with no retinopathy at the baseline examination remained retinopathy-free after 2 or 3 years of evolution (368, 369).

Discussion: Although some clinical practice guidelines recommend annual retinopathy screening, this study suggests that a lower frequency (every 2 or 3 years) can be used in the demonstrated absence of retinopathy.

Implications for health system/professionals/patients/society: Performing retinopathy screening every 2 or 3 years in the absence of retinopathy at the baseline examination will benefit the patient (lower number of journeys, medical visits and lost work or study time) with no increase in the risk of not detecting a retinopathy, and will also benefit health services as a result of the lower care load and subsequent freeing-up of medical and administrative time that can be invested in other activities.

941. ASSESSMENT OF THE EFFECTIVENESS OF EXERCISE PROGRAMS FOR FALLS PREVENTION IN THE ELDERLY - A REVIEW OF REVIEWS

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Background: Falls and their consequences, such as fractures, contribute a significantly to the morbidity of elderly people. Therefore fall prevention ranges high among preventive measures for the elderly.

Objective: The assessment of the effectiveness of exercise programs for fall prevention presented here is part of a comprehensive assessment (granted by DAHTA) which is intended to support rational decisionmaking with regard to the application of different measures for falls prevention.

Methods: The assessment consists of a systematic overview of the literature based on systematic reviews (SR) and randomized controlled trials (RCT). The searches in 31 literature databases cover the publication period from 2003-2010. Trials with ≥ 30 participants, ≥ 3 months of follow-up and prospective falls registration were included into the assessment. Their methodological quality was assessed using a modified version of the Cochrane Collaborations "Risk-of-Bias-Tool". All analyses are predominantly based on data that could be retrieved from publications of SR. Because of marked clinical heterogeneity results were summarized in a stratified qualitative manner.

Results: Only 37 out of 100 RCT from 11 SR satisfied the predefined inclusion criteria – which precluded the utilization of pooled effects estimates from the SR. Eight further RCT were identified by electronic literature searches. The qualitatively summarized results indicate that multidimensional exercise programs, if they are executed continuously, may be effective for preventing falls in the healthy elderly. At the same time opposite results are reported for the fragile elderly population.

Conclusions: Results have to be interpreted against the background of a potentially impaired methodological quality of primary studies – to assess their quality turned out to be problematic following a "review of reviews" approach. Compared to the results of other reviews the stratified qualitative summary of results arrives at more imprecise but more differentiated conclusions than those reviews that present metaanalyses of heterogeneous studies.

47. EVALUATION OF TECHNOLOGIES IN HEALTH: THE PROCESS OF IMPLANTATION IN THE ISRAELITA ALBERT EINSTEIN HOSPITAL- BRAZIL

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The evaluation for incorporation of new technologies in health is a process of inquiry and analysis of all the possible clinical, economic consequences that eventually can impact in the health services. In Brazil the activities in this field had been initiated in the decade of 80, assuming increasing role in such a way in the half academic how much in the public politics. Routinely new technologies of treatment are incorporated by the diverse professionals of form many times sped up and same before enough evidences that they prove its security, effectiveness and effectiveness. The use of information on costs and benefits of the interventions in health can assist in the establishment of priorities for the allocation of resources in health. In this intention, the supplement direction identified the necessity of a structuralized process that evaluates the incorporation of new technologies in the area of the health, aiming at to keep the Institution in the border of the technological innovation. The Committee of ATS is formed by the Executive Direction of the Hospital and its partners. As results, we have: to receive the best treatment available considering the degree from clinical evidence and cost effectiveness. To reach the standards and goals determined for the Ministry of Health recognized being for the community as pioneering in the ATS in privates of health institutions, assisting the Secretariats of Health and the Ministry of Health to promote the best available funds allocation of and to improve the welfare general of the Brazilian population.

90. AUCKLAND CITY HOSPITAL: FACILITATING THE PROCESS WITH THE NEW CLINICAL PRACTICE TOOLKIT

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Background: The Clinical Practice Committee (CPC) was established in 2005 within Auckland District Health Board to undertake hospital-based HTA. Submission and scoring processes continue to evolve through continuous improvement. Effectiveness within the organisation can be measured by evaluating management responsiveness to technology proposals in determining whether a technology is implemented.

Method: In order to assess such proposals, information provided by the applicants must be comprehensive and supported by colleagues. It had become apparent to the CPC that although its own rapid HTA process was becoming well established, "work up" within the clinical departments was still variable. A retrospective analysis of correspondence was undertaken.

Results: By December 2011, 51 health technologies had been assessed but only 25% (n = 13) contained sufficient information in the original submission. Requesting further information led to inevitable delays in being able to undertake the technology assessment.

Conclusions: Applicants could benefit from a *New Clinical Practice Toolkit* which has been designed by the CPC to provide assistance during the early stages. The toolkit provides a generic step-by-step process for any clinical team contemplating the introduction of *any* new clinical practice, as per the requirements of the Auckland District Health Board policy: Innovation and New Clinical Practice. The Toolkit steps cover the preliminary department-based discussion, technology information gathering, determination of the lead operator or "clinical lead", a CPC informal review, consultation, a formal CPC review (if required) and final implementation panning. Each phase has its own downloadable checklist with guidance provided via the Toolkit page of the CPC intranet site. The process is designed to be led by the relevant Clinical Director (CD) since the benefits for the patient group, the department and the organisation, must be recognised by the CD in the first instance.

91. AUCKLAND CITY HOSPITAL: CONSISTENT UTILISATION OF A QUALITY OF EVIDENCE SCORING TOOL

Caroline McAleese and Stephen Munn

Auckland District Health Board. New Zealand.

Background: The Clinical Practice Committee (CPC) was established in 2005 within Auckland District Health Board to undertake hospital-based HTA. Submission and scoring processes have evolved through continuous improvement since.

Method: Effectiveness within the organisation can be measured by evaluating management responsiveness to scores assigned to technology proposals in determining whether a technology is implemented. Not all proposals lead to a score being awarded. The impact of not invariably awarding a score is analysed.

Results: By the end of 2011, 51 health technologies had been assessed and 36 scored. Demonstrating a relationship between score and implementation was compromised by not scoring 15 proposals. For those scored, there was a clear relationship between CPC advice and management response (advice not taken in only 2, or 6%). Of the 15 not scored, reasons given were: multiple patient groups (6), lack of information (1), lack of evidence (2), low cost (2), pending national assessment (1) or reason not given (3). For these, the relationship between CPC advice and management response was still clear (advice not taken or unknown in just 3 of the 15, or 20%).

Conclusions: Although ADHB management usually acts upon CPC advice, regardless of whether applications are scored, the ability to demonstrate a statistical relationship between CPC score and management implementation is compromised if the scoring tool is not consistently applied in all applications, since the sample size is reduced and/or risk of bias is introduced. Ranking of dissimilar proposals cannot be made as effectively if not all are objectively assessed. Consistent scoring and objective assessment of all submissions now occurs. These changes include the requirement for only one patient group per submission and an amendment to the scoring tool to include lower scores when evidence doesn't exist.

146. THE MEDICAL EQUIPMENT INCORPORATION IN HOSPITAL: CURRENT STATUS AND HTA USE TO IMPROVE IT

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In hospitals there is the largest concentration of health technologies, especially those of greater complexity and cost. Hospitals deal with complex decisions about the introduction of new important medical equipment. Then, clinical engineering is continuous looking for tools and approaches that allow a better measurement of the real impact of medical equipment in the organizational context in which it is or will be used. The aim is present a stage of the mapping of the current decision making process regarding the medical equipment incorporation in hospitals in Santa Catarina-Brazil. For this purpose, the activities related to this subject were monitored in three spheres. The clinical engineering team was searched, mainly through the Local Centers of Clinical Engineering (LECE), established in public hospitals. By the LECE, the decision making process was investigated from the hospital viewpoint thorough the professionals that are active in the process inside the hospitals. Finally, there was the research in the Santa Catarina State Department of Health (SES-SC) to include activities that are of state competence but can influence the local level. It was verified that the requests, for medical equipment with the technology is known in the hospitals, are addressed to LECE. The clinical engineer adds its judgment and forwards the request to the hospital director, who in its turn, also, add its opinion and forwards the request to SES-SC, who has the final decision about the equipment incorporation or not. If the request for medical equipment is about some technology that the hospitals do not have or had, the requests do not pass through LECE. In this case, some hospitals use a kind of a form to collect some information about the new equipment. The clinical engineering could improve the medical equipment incorporation process, through tools to assist the medical equipment assessment, mainly with the use of the Health Technology Assessment (HTA). Hospital based HTA models could be put in practice to maximize the use of HTA in hospitals and their benefits with the clinical engineering participation as a facilitator of this process.

208. HOSPITAL RESOURCE USE FOR TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

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Background: Transcatheter aortic valve replacement (TAVI) is an established technology allowing treating patients with severe aortic valve stenosis which are not candidate for surgical replacement. The procedure can be performed via transfemoral (TF) or transapical (TA) access.

Objectives: To assess the hospital resource impact of this technology at our institution, as compared with the planned pathways.

Methods: All patients treated by either TA-TAVI or TF-TAVI were included. Patients' characteristics and resource use were derived from the hospital database, and compared with the planned pathways (3 days in intensive care unit out of a 9-day length of stay).

Results: A total of 68 patients (37 female and 31 male) of mean age of 80 years (range 54-95) were treated by TA-TAVI over a 3-year period, and 22 patients (14 female and 8 male) of mean age of 86 years (range 73-94) by TF-TAVI over 2 years. As compared with TA-TAVI patients, TF-TAVI patients were older (86 ± 5 vs 80 ± 9 years, $p = 0.002$), had a lower Euroscore (19 ± 10 vs 38 ± 15, $p < 0.001$), but similar valve area and left ventricular function. Operative time was longer in TF-TAVI patients (135 ± 27 vs 100 ± 32 minutes, $p < 0.001$), but total complication rates were similar (25%). Intensive care unit stay was required only in the first 4 TF-TAVI patients, but in all TA-TAVI patients for an average of 3.3 days (median 1 day, maximum 30 days). Hospital stay was also shorter in TF-TAVI patients (7.8 ± 3.0 vs 15.5 ± 10.6 days, $p < 0.001$), but 30-day mortality rates were similar (10%).

Discussion: TA-TAVI and TF-TAVI patients have similar severity of cardiac condition, but different global risk, as TA-TAVI patients suffer

from a more severe general condition. Hospital resource use for TAVI is smaller in TF-TAVI as compared with TA-TAVI patients.

Implications for the health system: From a hospital management's perspective, TF-TAVI should be preferred whenever technically feasible.

344. THE FEATURE OF PREVENTABLE ADVERSE EVENTS IN HOSPITAL IN BRAZIL

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Oswaldo Cruz Foundation. Brazil.

Objective: To analyze the features of preventable adverse events (AEs) in hospitals in Brazil.

Methods: Descriptive analysis of secondary data from a retrospective cohort study to assess the occurrence of AEs in three hospitals in the State of Rio de Janeiro.

Results: The proportion of patients with preventable AEs was 66.67% (56/84) (95% CI: 56.37 to 76.95). The incidence of patients with preventable AEs was 5.08% (56/1103) (95% CI: 3.77 to 6.37). The causes that led to preventable AE were proportionally: 16 (24.62%) due to a care associated infection; 13 (20.00%) due to a surgical and/or anesthetic complications; 12 (18.46%) due to a delay or failure to diagnose and/or treatment; 12 (18.46%) due to a pressure ulcers, 5 (7.69%) due to a venipuncture complications; 4 (6.15%) due to a fall and 3 (4.62%) due to a medication. The preventable AEs were responsible for over 373 days of hospitalization.

Conclusions: The retrospective studies have shown the results of the frequency of AEs, however some of these events are not preventable. To understand better the frequency and causes of preventable AEs may contribute to the development of policies to prevent AEs or mitigate the risk.

391. PROFILE OF MANAGEMENT OF INCORPORATION AND EVALUATION OF TECHNOLOGIES IN BRAZILIAN HOSPITALS

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Ministry of Health. Brazil.

Background: The incorporation of technologies in health in brazilian hospitals is usually preceded by an evaluation carried out by multidisciplinary committee, as the Commission of Pharmacy and Therapeutics that evaluates medications. However, these committees do not always use methods recognized by health based on evidence. In spite of this, the use in hospitals can influence the demand for incorporation of the technologies in the health care system in Brazil, which is examined by the Ministry of Health by means of the National Committee for Incorporation of Technology in Public Health System (CONITEC).

Objectives: Establish a profile of management of incorporation and health technology assessment (HTA) in teaching hospitals in Brazil.

Methods: Study of the type investigation. In December 2011 the January 2012, has been distributed questionnaire electronic structured for members of the Brazilian Network of Sentinel Hospital.

Results: 56 hospitals in all regions of Brazil responded to the questionnaire, 87% of them teaching. Of the respondents, 55% claim to have structure to ATS, but 61% do not have fees or services that set on the incorporation of technologies. Among those who have, 79% evaluate the drugs, 54% equipment and 49% medical and hospital supplies, and only 12% assess procedures. Believe they are capable of observational studies (16%), clinical (15%), systematic review (9%), economic evaluation (9%) and budget impact (9%), mostly to the areas of cardiology, surgery and cardiovascular, obstetrics and gynaecology, infectious diseases, orthopaedics and traumatology.

Discussion: It was observed that the lack of use of methods of ATS in Brazilian hospitals for purposes of incorporation of technology. There are alarming data for a country that wants to make a rational use of technologies, but they can be changed with the new Brazilian law (12,401/2011), which defines the criteria for incorporation into the Public Health System, as well as the educational work that the CONITEC has done.

485. HOSPITAL HTA FOR A ROBOTIC SURGERY SYSTEM IN SWITZERLAND – AN EVIDENCE-BASED DECISION TOOL

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Background: The department of urology of a medium-sized regional hospital in Switzerland faces the decision whether to invest into a new robotic surgical system.

Objectives: Provision of an evidence-based, hospital-specific basis for decision-making for the hospital management. It is a comparison between robotic-assisted laparoscopic prostatectomy and open radical prostatectomy in patients with prostate cancer.

Methods: The hospital HTA consists of different chapters covering all topics that drive the decision-making process in a hospital: effectiveness, safety, profitability, organisational impact, market potential, legal framework and ethical concerns. It consists of methodical approaches derived from an HTA mixed with elements from a business plan.

Results: Measures considering effectiveness and safety need to be treated with caution, because evidence-level is low and results often inconsistent. Compared to open surgery, peri- and post-operative outcomes are mostly advantageous for robotic surgery. Results of long-term health outcomes (e.g. urinary continence, erectile function) are ambiguous. Positive surgical margin (measure of cancer control) is lower with robotic surgery. Costs of surgery with the robotic system are around 50% higher than open surgery. Cost savings are possible due to shorter length of stay in hospital. Additionally, robotic surgery results in a higher reimbursement by attracting more privately insured patients. Robotic surgery system density in Switzerland is high compared to other European countries. This could be a problem for reaching high number of cases and involves the risk of overtreatment. However there is market potential in other surgical fields such as gynaecology or heart surgeon using the da Vinci surgical system.

Implications for the hospital: In order to be attractive for employees and patients and to be competitive in the hospital market, investing into robotic surgery is recommended under given assumptions.

534. ASSESSMENT OF MEDICAL EQUIPMENT IN THE MATERNITY UNIT AT A DISTRICT HOSPITAL IN SOUTH AFRICA

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Background: District hospitals in South Africa provides a comprehensive package of promotive, preventive, curative and

rehabilitative reproductive health services for women which are not available in PHC facilities. These services require special equipment and personnel that are unavailable in these health facilities. Specific life saving medical equipment must be available for routine and emergency management of maternal and neonatal complications.

Objectives: To determine the availability and related cost of medical equipment used in the maternity ward at Mecklenburg Hospital.

Methods: A cross sectional study design was used to review past records over a period of one year. The setting of the study was in maternity ward of Mecklenburg Hospital in Limpopo Province.

Results: The majority of the capital equipment in the maternity unit was still relatively new. The Unit is non-compliant with all the lists (WHO, South African District Health Service Package DHSP) and NCCEMD) for vacuum-extraction. In addition, the Unit does not have equipment needed for steam-steriliser and ICU-beds as recommended by WHO. In terms of the DHSP list, additional exceptions were forceps. There was a single ultrasound machine, 5 CTG machines and a single operating theatre. The mean number of days to receive the order for consumables was 7.4 days (SD 4.6 days and range 1-12 days). The study calculated the total asset value of capital (R767,303.66) and minor (R146,164.50) medical equipments based on purchase price. Total cost of consumables was R1052.76 (R 87.73/month). Although 10 Procurement meetings were held during the study period, no additional capital medical equipment was procured.

Conclusions: The study highlighted that the Unit was overall compliant with WHO list as well as national guidelines (NCCEMD and DHSP lists). The study also identified gaps which would require more detailed and prospective study to improve the services and clinical outcomes in the Unit.

556. ANALYSIS OF THE ORGANIZING MODEL FOR RESTORATION: EVALUATION OF THE IMPACT THROUGH HEALTH TECHNOLOGY ASSESSMENT IN THE AZIENDA OSPEDALIERO-UNIVERSITARIA OF UDINE

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Background: The present study applies the HTA method in analyzing the hospital food service, comparing the "cart" and the "tray" services. To date, no data are available in the Literature on which of the two methods is preferable.

Objectives: To identify tools for a rationalization and improvement of restoration process.

Methods: We reviewed the Literature on HTA data-banks and on the organization of restoration in the hospital setting. We conducted the analysis on prevalence (time/work of catering process) and compared the "cart" and "tray" models on the HTA dimension. We evaluated the perceived service quality in the patients of our Institution and in a regional hospital.

Results: The "tray" system ensures a spare of time in delivering food to the patients, but requires greater resources and is perceived as of "average to low" quality. In the ethical-social and safety analysis, some caring and managing activities era not ensured as time and employment are required to maintain the higher standards of care.

Discussion: The comparison of different HTA dimensions supports the choices of appropriate resources' use. The switch from the "cart" to "tray" food model does not cause a loss of competence, but ensures a spare of time, to be employed in the care and safety of the patients.

Implications for the health system and patients: There is a need to define the level of reinvestment of the time regained from the "lost care" in assisting patients, particularly in managing and monitoring depending patients' alimentation. To maintain high standards of food safety requires attention and time from operators. The time the caregivers spend in patient's care and support has a social cost that deserves to be considered in the health system.

623. STUDY OF THE INTRODUCTION IN A PATHOLOGY SERVICE OF A CYTOHISTOLOGIC SLIDES DIGITAL SCANNING AND ANALYSIS SYSTEM

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Background: The system has a place in pathology as final link in the chain of the process that leads to the production of the slide sample and its diagnosis.

Objectives: Being that technology still considered not quite mature, this study is intended to detect pros and cons in terms of logistics, cost and actual benefits.

Methods: Study has been developed by following the Danish MINI HTA methodology: research in the international literature to detect existence of previous studies and trials with some models of scanners on the market have been carried out.

Results: The market solutions are being rapidly developing: scanning speed is increasing and simpler and powerful software tools for image processing are delivered. The worldwide telepathology network is already available and useful for "second opinion" and "e-learning" services.

Discussion: The technical improvements growing on are obvious advantages in a pathology support service but there are still significant limitations that prevent the slide scanning systems take off. Among these: the cost of a slide scanner, the burden for the safe management of a data-sensitive database, the huge size of digital images that limits their transmission and storage performances, the lack of adoption of communication international standards for the images transmission and the unavailability of a medical-compliance standard certification for whole system.

Implication for the health system/professionals/patients/society: Cytohistologic slide scanner is a technology that, thanks to either the digital format of slides and an image processing CAD software, can assist the pathologist facilitating the diagnosis and improving its quality. The simple recovery and retrival of images simplify the physician job and the telepathology reduces greatly processing time.

663. COMBINED POSITRON EMISSION TOMOGRAPHY AND COMPUTED TOMOGRAPHY IN RADIATION THERAPY PLANNING FOR HEAD AND NECK CANCERS: A HTA FOR EVIDENCE-BASED HOSPITAL DECISION MAKING

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Background: Use of combined positron emission tomography and computed tomography (PET-CT) in radiation therapy (RT) planning has recently gained popularity for cancer management but the health benefits remain unclear.

Objective: A HTA was performed to assess the effectiveness and safety of PET-CT in RT planning for head and neck cancers and assist hospital decision-making.

Methods: Systematic reviews (SRs), evidence-based practice guidelines, randomized controlled trials (RCTs), observational studies, and case reports of incident between 2000 and September 2011 were retrieved from multiple databases. Studies with sample size < 20 were excluded. Selection, quality assessment and data extraction were performed by two independent reviewers. Synthesis review was shared with an interdisciplinary group of experts.

Results: Two SRs including two observational studies, one practice guideline, and 14 observational studies (updated search) were included. Lack of uniformity between studies in contouring methods and image acquisition were noticed. Among these studies, PET-CT was associated with change from curative to palliative treatment in up to 25% of patients and led to changes in gross tumor volume (GTV) in 50% to all patients. No data was available to evaluate the clinical benefits related to these changes. Because of scarce results, no conclusion can be drawn regarding the impacts on mean target volumes and normal tissue exposure. Use of PET-CT appears to be safe according to data retrieved in these studies and the small number of incidents reported.

Discussion: PET-CT in RT planning for head and neck cancers may be equally or more effective than CT to estimate the GTV. However, uncertainties remain regarding long-term clinical outcomes. The main recommendation is to use PET-CT in RT planning for head and neck cancers as part of field evaluation with an assessment of the evidence including prospective collection of relevant information in a local register of cancers.

713. COST-EFFECTIVENESS OF PRESENTATION AND DELAYED TROPONIN TESTING FOR ACUTE MYOCARDIAL INFARCTION

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Objectives: To estimate the cost-effectiveness of delayed troponin testing for myocardial infarction (MI), as recommended in current guidelines, compared to troponin testing at presentation.

Methods: We developed a decision analytic model to estimate the cost-effectiveness of diagnostic strategies for MI, measured as the incremental cost per quality-adjusted life year (QALY) gained by each strategy compared to the next most effective alternative. Delayed troponin testing (10-12 hours after symptom onset) was compared to standard and high sensitivity troponin testing at presentation and no testing.. We tested three different scenarios regarding delayed testing, in relation to the delay between results being available and a decision being made: The "doctor on demand" scenario, in which medical staff were available 24 hours a day to make a disposition decision within one hour of the results being available. The twice daily ward round scenario, in which medical staff were only available at twice daily ward rounds to make disposition decisions. The once daily ward round scenario, in which medical staff were only available at one daily ward round to make disposition decisions.

Results: In all scenarios tested presentation high sensitivity troponin testing was the most effective strategy with an incremental cost-effectiveness ratio (ICER) below the £20,000/QALY threshold. Delayed troponin testing was only likely to be cost-effective if a discharge decision could be made as soon as a negative result was available and the £30,000/QALY threshold was used.

Conclusions: Delayed troponin testing is unlikely to be cost-effective compared to high sensitivity troponin testing at presentation in most scenarios. The implication of our analysis is that the current guidelines recommending 10-12 hour troponin testing does not appear to promote cost-effective use of hospital resources, unless services are in place to allow rapid decision-making once delayed test results are available.

747. IMPACT OF A HOSPITAL BASED HTA UNIT. THE EXPERIENCE OF THE HOSPITAL CLINIC BARCELONA (SPAIN)

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Background: The Hospital Clínic (HCB) is a Tertiary Hi-tech Hospital located in Barcelona that provides attention to 7 million citizens and employs 3971 workers with a budget of 460 m€. In 2009, a Hospital based HTA Unit was created within the Innovation Directorate to support the decision making process on investments regarding innovative Health Technologies (HTs). The objective of this work is to analyse the impact of this hospital based HTA Unit in its 3 years of life.

Methods: Descriptive analysis in terms of process of work, characteristics of HTs being assessed, economic impact for hospital, and satisfaction of professionals who have been involved in the HTA process, including final decision-makers.

Results: Since its creation, 14 HTs have been assessed; including big-ticket HTs (e.g. surgical robot), medium (e.g. Deep Brain Stimulation for Parkinson Disease) and small size (i.e. Multigene Assay test for Breast Cancer), together with procedures (e.g. Amniotic membrane transplantation for treatment of venous leg ulcers). All these HTs summed up a total investment cost of 6.5 m€ and resulted in an opportunity cost of 4.5 m€. The unit has also advised on the appropriate indication of 35 costly drugs for 45 clinical conditions, leading to more appropriate use as well as to cost reduction. Preliminary results on satisfaction show a positive perception of the unit among hospital professionals.

Conclusion: The work performed by the Hospital based HTA Unit is answering informational needs of professionals and is contributing to rationalize/optimize investment decisions at our hospital.

Implications for the health system: Hospital professionals perceive the hospital based HTA as a valuable tool for promoting consensus in decision-making regarding the introduction of HTs at our hospital. We suggest that having a hospital based HTA program helps in optimization of hospital resources and can contribute to the sustainability of a health system.

867. CEFAZOLIN PROPHYLAXIS REVIEW AND ANTIBIOTICS USE IN PATIENTS SUBMITTED TO BARIATRIC SURGERY IN A BRAZILIAN PUBLIC HOSPITAL

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Background: In Brazil 3,195 bariatric surgeries (BS) were performed (R$ 15.7 million to Brazilian's Health System/2008). Surgical site infection (SSI) is one of the main BS complications. According to the literature there is no protocol to antibiotic prophylaxis.

Objectives: To analyze available scientific evidence to define whether the use of cefazolin prophylaxis reduces the risk of SSI in morbidly obese patients submitted to BS and to present the initial results of evaluation of the use of antibiotics and related post-surgical complications.

Methods: Databases searched: Cochrane Library, Medline, Embase, and Lilacs. The use of antibiotics (name, class, dose, time and period

of administration) was evaluated carrying out a non-controlled cohort study.

Results: Twenty four abstracts were retrieved and reviewed by two researches. Title and scope excluded three studies. From the remaining 21 studies, sixteen were not adequate to the objective and the remaining five were analyzed using full text. Two additional studies were included after examining the references. The average periods of hospitalization and time of surgery were 4.9 days and 4.06h, respectively. In seven surgeries the antibiotic used in prophylaxis was cefazolin; three, cefoxitin. Seven cases had the moment of antibiotic administration registered, four patients, after de incision and one, simultaneously. Six patients received antibiotics for 24 hours after surgery.

Discussion: Cefazolin remains the antimicrobial agent most commonly used for prophylaxis of SSI in BS. However, there is a paucity of well conducted studies to support this use. Results from our preliminary study reveal that the regimens are variable and not standardized. Related issues to be settled include the agent, dose and time of administration.

Implications for the health system/professionals/patients/society: Our results provide a scenario where the use of different antimicrobial agents in different regimens brings a risk of widespread antimicrobial resistance and waste sources of national public health system.

13. PERFORMANCE ASSESSMENT OF GA DISTRICT MUTUAL HEALTH INSURANCE SCHEME, GREATER ACCRA REGION, GHANA

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Ghana established National Health Insurance Scheme (NHIS) in 2004 to replace out-of-pocket payment which created financial barrier to health care access to the poor and vulnerable. However, the NHIS was fully implemented in 2005 and has since faced operational challenges such as delays in issuance of membership cards to registered members and payment of providers claims. The study assessed performance of the Ga District Mutual Health Insurance Scheme over the period, 2007-2009 and provided recommendations to improve on its operations. Desk review method was employed to review membership, revenue, expenditure, and medical claims data of the Scheme. A household survey was also conducted in the Madina township using self-administered semi-structured questionnaire to determine community coverage of the Scheme. The results showed membership coverage of 22.6% and community coverage of 22.2%. About one-third of the registered members were paying premium to the scheme which affects revenue. Financially, the Scheme depended largely on subsidies and reinsurance from National Health Insurance Authority (NHIA) for 89.8% of its revenue. Approximately 92% of the total revenue was spent on medical bills. About 99% of provider claims were settled beyond the stipulated four weeks period. This poses financial challenge to healthcare providers and may force them to take measures that defeat the purpose of the scheme. There are downward trends in membership coverage and revenue from contributions, and lengthy delays in claims settlements. Establishment of district schemes in the Ga East and Ga West sub-districts will be necessary to improve membership coverage and revenue mobilization from the informal sector. Whilst the claims are being vetted, it will be important for the Scheme to advance part-payment to healthcare providers to ensure continuous provision of services to insured members.

36. COST-EFFECTIVENESS OF ANEMIA TREATMENT IN DIALYSIS PATIENTS IN BRAZIL

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Background: Anemia is the most common abnormality found in chronic kidney disease (CKD). It's more severe in dialysis patients, in which the disease is advanced. It increases the morbidity and the mortality of CKD patients and it is also responsible for their reduced quality of life. Anemia's main cause in CKD is the deficiency of erythropoietin. Its treatment is based on the administration of erythropoiesis stimulating agents.

Objective: This study sought to determine the cost-effectiveness of anemia treatment in dialysis patients for Brazilian Public Health System. Two alternatives were compared: the *Continuous Erythropoietin Receptor Activator*, CERA, recently registred in Brazil, and another one, provided nowadays by the National Health System, Epo-rHu (Recombinant Human Eythropoietin).

Methods: A Markov cohort of dialysis patients treated with CERA and Epo-rHu for four years was used to perform the base case analysis. The model outputs were QALYs and costs. The quality of life associated with each drug was measured by interviews applied to health care professionals. These interviews were previously submitted and approved by the local ethics committee. A sensitivity analysis was applied to the model to test it, varying the values of drugs dosage, costs, discount rate and effectiveness.

Results: The average quality of life assigned by health care professionals to the patients treated with Epo-rHu, CERA and to kidney transplant receptors were respectively 6,3, 7,8 and 9,3. The model showed that Epo-rHu treatment was more cost-effective than CERA treatment. The cost-effectiveness ratio of Epo-rHu therapy was R$ 21.052,00. In addition, the cost per QALY gained of CERA therapy was R$ 72.974,00.

Conclusions: Anemia treatment with CERA is associated with improvement in quality of life compared to Epo-rHu therapy. However, the new drug is not more cost-effective than the drug provided by the Brazilian Public Health System.

38. TENOFOVIR, INTERFERONS ALFA; ENTECAVIR; LAMIVUDINE AND ADEFOVIR FOR TREATMENT CHRONIC HEPATITIS, IN PATIENTS WITH HBEAG-REACTIVE AND NON REACTIVE WITH ABSENCE OF CIRRHOSIS: A COST-EFFECTIVENESS ANALYSIS

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A cost-effectiveness and budget impact of treatments given to adults infected with hepatitis B HBeAg-reactive and non reactive with absence of cirrhosis was performed by comparing the non-treatment with tenofovir, interferons alfa 2a and 2b; entecavir; lamivudina and adefovir. The Markov model developed engineered the development of hepatitis B in a cohort of 1,000 patients for a period of 30 years for the various states of disease development. Therapy based on lamivudine proved to be the most effective strategy, ie, in the treatment of HBeAg-reactive individuals had the lowest cost per quality-adjusted life 530.21 US $/QALY. Following the

recommendations of the World Health Organization, tenofovir has the cost effectiveness favorable, because 555 US $/QALY does not exceed the threshold of acceptability of up to three times the GNP/percapita. 5% discount tax was applied. The sensitivity analysis performed for the parameters: discount rate, probability of response to the order tracking and overall cost of drug therapy, lamivudine showed that, as noted in the initial result is the most effective strategy. The result would only be favorable to tenofovir, if the unit value of lamivudine was ≥ US $ 1.48 in patients with hepatitis B HBeAg-reactive and non reactive.

102. COST EFFECTIVENESS ANALYSIS OF TWO DIFFERENT ALTERNATIVES FOR THE RAPID DIAGNOSIS OF MULTIDRUGRESISTANT TUBERCULOSIS

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Background: Tuberculosis is a disease that causes 9 million cases every year worldwide, out which 2 million die. Multidrugresistant tuberculosis (MDR-TB), defined as *Mycobacterium tuberculosis* resistance to at least Isoniazid and Rifampicin, first line treatment medicines, represents the greatest thread for the control of the disease.

Objective: To compare cost and effectiveness of the traditional technique for the diagnosis of MDR-TB (proportion method) and the thin layer agar culture.

Methods: This study was carried out in the Corporacion para Investigaciones Biologica's (CIB) mycobacteria unit. For the estimation of the value of each test, the lab's implementation and execution costs for each test were taken into account (institutional perspective). Validity was evaluated in terms of sensitivity, specificity and time taken to give results. A decision analysis model (TreeAge) was used to compare the evaluated alternatives in terms of cost affectivity.

Results: The cost of the proportion method was US $71. The mean measurement time for the report is 49 days. The cost of the rapid agar thin layer test was US $18, and had a mean measurement time of 14 days. Sensitivity and specificity were valued as similar in both techniques.

Discussion: *M. tuberculosis* Resistance to Isoniazid and Rifampicin diagnosis method based in the agar thin layer culture is cheaper, has a higher effectiveness valued in less days needed to give the final result and has a similar sensitivity and specificity to the traditional method.

Implications for the health system: Using thin layer agar culture for the diagnosis of TB-MDR will allow a faster diagnosis of patients breaking the chain of infection. And because of its cost it could be applied to more patients in a limited source environment.

106. THE IMPACT OF PRESUMED CONSENT LAW ON ORGAN DONATION: AN EMPIRICAL ANALYSIS FOR LONGITUDINAL DATA

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Background: Human organs for transplantation are extremely valuable goods and their shortage is a problem that has been verified in most countries around the world, generating a long waiting list for organ transplants. This is one of the most pressing health policy issues for governments. To deal with this problem, some researchers have suggested a change in organ donation law, from informed consent to presumed consent. However, few empirical works have been done to measure the relationship between presumed consent and the number of organ donations. The demand for organ transplants is large and has been increasing over time, and the shortage of human organs is a pressing issue to policy makers and governments. This issue has motivated researchers to study the determinants of organ donation rates and the magnitude of their impact on the supply of organs. A particular debate has arisen in this context: the matter of legislative default on cadaveric organ donation.

Objective and methods: The aim of this paper is to estimate that impact, using a new method proposed by Koenker (2004): quantile regression for longitudinal data, for a panel of 34 countries in the period 1998-2002. The data come from the Transplant Procurement Management Organization (TPM), the World Health Organization (WHO), World Bank (WB) and the Sociedad Latinoamericana de Nefrología e Hipertensión (SLANH). The sample contains 34 countries over 5-year period (1998-2002).

Results and implications: The results suggest that presumed consent has a positive effect on organ donation, which varies in the interval 21-26% for the quartiles [0.25; 0.5; 0.75], the impact being stronger in the left tail of the distribution. Health expenditure has an important role on the response variable as well, the coefficient estimate varying between 42-52%.

109. ECONOMIC IMPACT AND EPIDEMIOLOGY OF CERVICAL CANCER IN AMAZONIC REAGION (STATE OF RORAIMA - BRAZIL): UNIFIED HEALTH SYSTEM APPROACH

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Objective: Evaluating the incidence, magnitude and the direct economic impact of uterus cancer (CCU) in Roraima (Brazil's Amazon region), and analyze the socio-economic and epidemiological profile of patients with this disease. The questions to be answered in this essay are: 1) which the incidence and the economic impact of the CCU in the State of Roraima? 2) which the socio-economic and epidemiological profile of the carriers of the CCU in this State?

Methods: Retrospectively reviewed all the cases of patients with CCU. 4 records have been analyzed the pathology laboratories (public and private, representing the entirety of laboratories carrying out histopathological analysis. The average age of oncological patients was 55.7 years BP (± 16.4). The annual cost per patient with cancer of the cervix was R $ 8,711 (approximately $ 5,070).

Results: The socio-economic profile of patients with CCU in Roraima reveals that the disease affects a population socially excluded group, economically disadvantaged, with low schooling, who are unaware of preventive programs, Government and who rarely or never performed the trace (PAP test).

Discussion: The unfavourable socio-economic profile of women with cervical cancer in Roraima (Brazil) leads us to conclude that the inefficiency of preventive programs to reach and educate women at risk for the disease, special populations such as the indigenous and those with low educational level and profile of social exclusion is related to high morbidity from cervical cancer in Roraima. Indigenous peoples are a group of increased risk for CCU. Peculiar characteristics as early initiation of sexual activity, sexual intercourse without barrier and the low adhesion to existing preventive programmes (PAP test), by cultural issues, or by limited access, can contribute to the high prevalence of HPV infection. We highlight the important contribution of indigenous women aldeas to the magnitude of the CCU in the State of Roraima.

Implications: The high economic impact of cervical cancer to society fosters the deployment of new preventive technologies from the standpoint of cost-effectiveness, in particular aiming at more susceptible populations.

123. THYROID DISEASE IN WOMEN AFTER EARLY SPONTANEOUS ABORTION: A CLINICAL EFFECTIVENESS AND COST-EFFECTIVENESS OF SCREENING

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Background: Numerous studies have investigated whether thyroid disease is associated with increased rates of pregnancy loss, infertility and perinatal death (eg. Rao et al., Indian J Med Sci. 2008;62(9): 357-61). However, there is insufficient evidence to recommend for or against screening for thyroid disease in women after spontaneous abortion (SpA), and no reports on cost study are available for this group of patients (compare Thung et al., Am J Obstet Gynecol. 2009;200(3): 267.e1-7, Dosiou et al., Eur J Endocrinol. 2008;158(6): 841-51).

Objectives: To assess the suitability of screening for thyroid disease as standard care in women after SpA – from the perspective of women´s reproductive health.

Methods: A total of 300 women were interviewed by a single investigator after SpA: women with treated thyroid disease (group 1) and women with untreated thyroid disease (group 2). At present, we are calculating the direct and indirect costs of screening using the methods of cost analysis in relation to adverse pregnancy outcomes (recurrent SpA, infertility, fetal death, preterm birth, caesarean section).

Results: We are currently working on a health economic model to determine the cost-benefit ratio of screening for thyroid disease in women after SpA and to calculate the consequent profitability. Final results will be presented during HTAi2012.

Discussion: We expect no significant difference in costs between groups. Nevertheless, the results will help us to solve the dispute between gynecologists and endocrinologists whether to perform screening for thyroid diseases in women after SpA.

140. MODELLING FOR COST-EFFECTIVE DECISION MAKING

Graeme Roberts and Graeme Roberts

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Background: The proliferation of HTA submission guidance and methods for good modeling practice, albeit good in principle, may have the unwanted effect of increasing the cost of the decision making process without substantially aiding it. Evidence from an economic model often provides some of the evidence on which a reimbursement or funding decision is taken. The models should be simple yet adequate enough to inform the process. However the focus when developing a model tends to be towards fulfilling the requirements of the NICE reference case or to conform to guidelines on good modelling practice such as those being developed by ISPOR members. That these are available is a good thing, however an unintended effect is models are developed that are overly complicated for their intended use. Either they do not meet the needs of an intended audience or they obscure what may be a straightforward value statement. In most evaluations there are only a few key drivers that may need to be addressed and where results indicate one technology is dominant, there is no difference in cost-effectiveness or it is well within accepted WTP thresholds a simple model may suffice. Of course we should then ensure that the model is robust but not all sections of the guidance may be relevant. Cost and time for development and review increase with model complexity. By ensuring we develop appropriate models we can keep costs to a minimum, reduce review time, queries and expedite reimbursement and funding decisions.

Conclusions: When developing an economic model the first steps must be to define the decision problem and the level of evidence and then develop an appropriate and validated tool. The existence of guidance should not preclude the use of the most neglected decision tool, our brain.

145. COST UTILITY ANALYSIS OF CHRONICAL RENAL DISEASE IN BRAZIL: RENAL TRANSPLANTATION AND HEMODYALYSIS

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Background: Brazil has the most public of transplants and occupies the second place (behind only the United States) in number (absolute) of surgeries of this size, with emphasis on the kidney transplant.

Objectives: Analyse the cost utility of treatment of of chronical renal disease, comparing renal transplantation and hemodyalisis for a middle income country, like Brazil.

Method: Cost Utility and QALY. Use of Markov Model. The time horizon was 10 years. It was done a sensibility analysis of the results.

Results, discussion and implications: A cost-utility analysis was conducted to assess which treatment, renal transplant or hemodialysis, has a lower cost rate per quality-adjusted life years. The result obtained corroborates the international evidence, which indicates renal transplant as the most cost effective strategy. In the case of this study, the cost-utility ratio for renal transplant and hemodialysis was US$ 11,157/QALY and US$ 25,110/QALY, respectively. In spite of renal transplant being the dominant strategy, the scarcity of organs hinders this strategy to be widely used, reducing in this way, the efficiency gain in the allocation of scarce resources.

153. ECONOMIC BURDEN OF ATTENTION DEFICIT/ HYPERACTIVITY DISORDER (ADHD): COSTS ASSOCIATED WITH CHILDHOOD AND ADULT ADHD IN THE UNITED STATES

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Background: ADHD, traditionally thought of as a condition of childhood, can persist into adulthood with associated symptomatology and impairments (Kessler et al. *Am J Psychiatry* 2006;163(4): 716-723). Previous reviews have not examined costs across all sectors and populations affected by ADHD.

Objective: This review uses a societal perspective to examine comprehensively the ADHD-related incremental costs for children/ adolescents and adults in the US.

Methods: MEDLINE, PsycINFO, EMBASE, and ERIC databases were reviewed for primary US-based studies published between 1/1/1990 and 6/30/2011 on costs in children/adolescents and adults with ADHD

and their family members. Only studies in which mean annual incremental costs per ADHD individual (compared with non-ADHD controls) were reported or could be derived were included. Nineteen studies met the inclusion criteria (health care costs [n = 13], productivity costs [n = 9], education costs [n = 3], justice system costs [n = 2]) (some studies included more than one sector). Per-person costs were adjusted to US$2010 and converted to annual national excess costs of ADHD based on 2010 US census population estimates, ADHD prevalence rates, and employment rates by age group.

Results: The overall national annual incremental cost of ADHD ranged from $143 to $266 billion. The majority of costs were attributable to adults ($105-194 billion) compared with children/adolescents ($38-72 billion). The main ADHD-related cost drivers for adults were productivity and income losses ($66-225 billion), while those for children/adolescents were within the healthcare ($21-44 billion) and education ($36-69 billion) sectors. Costs to families of individuals with ADHD (in the health care and productivity sectors) were also substantial ($33-43 billion) contributors to overall costs.

Discussion: Our results highlight the large share of societal costs associated with ADHD as it progresses into adulthood, and its influence on costs incurred by family members of individuals with ADHD.

Implications: Despite a wide range in the magnitude of the cost estimates, this analysis indicates that ADHD has a substantial economic impact in the US.

160. ECONOMIC EVALUATIONS OF SOCIAL CARE INTERVENTIONS: BUSINESS AS USUAL?

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Background: Traditionally HTA agencies such as NICE make recommendations on the use of health technologies. Recently NICE's remit has extended to social care. Increasingly the consensus is that integrating health and social care is fundamental to driving up the quality of patient care.

Objectives: A review of the empirical literature was undertaken to examine economic evaluation methods for assessing social care interventions. It sought to identify whether the evaluation of these services poses particular methodological challenges, and to explore how they may be addressed.

Methods: Thirteen health, care and economic bibliographic databases were searched to identify relevant literature, and experts were consulted. Data on study characteristics and key economic evaluation methods were extracted.

Results: 29 studies were reviewed fully following assessment of 6,082 abstracts. Evidence from the review suggests a general lack of clarity in methodological considerations and reporting of the decision problem, perspective of the analysis and decision making context. Methodological challenges exist in the measurement and valuation of outcomes and informal carer time, assessment of multi-sector implications and equity. Most studies (79%) included more than one outcome. A variety of measures were used, even when evaluating the same intervention, complicating cross-study comparison. Informal care was evaluated in 38% of studies. All valued time using the human capital approach however a number of different wage estimates were used. 90% of studies included costs falling on the health care sector. Other, broader costs were included in 84% of studies. Equity was referred to in one study.

Discussion: The review highlights key methodological challenges for the economic evaluation of social care interventions and reflects on lessons to be learnt in undertaking these analyses.

Implications: Additional methodological development and greater clarity on methods for assessing the cost-effectiveness of care interventions will facilitate analysts' ability to undertake useful evaluations for informing decision making.

180. SHOULD CHRONIC HEPATITIS B BE TREATED AS EARLY AS POSSIBLE?

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Background and objectives: We studied the cost-effectiveness of tenofovir and entecavir in e antigen positive (CHBe+) and negative (CHBe-) chronic hepatitis B patients in Belgium.

Methods: Using a multicenter survey including 544 patients we measured patient quality of life (EQ-5D questionnaire) and attributable direct health care costs by clinical disease stage, i.e. inactive carrier, CHBe+/- non-cirrhotic, CHBe+/- compensated cirrhosis, decompensated cirrhosis, hepatocellular carcinoma (HCC), liver transplant (< 1 and > 1 year). Natural disease progression was studied in 278 untreated patients in a single center. A static, probabilistic Markov model was constructed to follow hypothetical cohorts of patients: 40 year old CHBe+, 40 year old CHBe- and 50 year old with compensated cirrhosis. We chose natural history as comparator since lamivudine is no longer considered an appropriate first line treatment.

Results: We did not find an improvement in quality of life when viral load was reduced under treatment. Transition rates to liver cirrhosis were found to be age-dependent. Because both drugs appear equally effective and because of the lower price of tenofovir in Belgium, tenofovir dominates entecavir. Further results focus thus on the tenofovir versus no treatment strategy. The incremental cost-effectiveness ratio (ICER) of tenofovir for a 20 years time horizon is more favorable for Caucasian cirrhotic patients (mean ICER 29,000 €/QALY) compared with non-cirrhotic patients (mean ICER 110,000 and 131,000 €/QALY for CHB e+ and e-, respectively). Within the non-cirrhotic patients the ICER decreases with increasing patient age at start of treatment (from 30 to 50 years).

Discussion: Based on cost-effectiveness considerations, our results suggest that antiviral treatments such as tenofovir should be targeted at patients with cirrhosis or at risk of rapid progression to this disease stage. Results of long term models for tenofovir or entecavir treatment of CHB need to be interpreted with caution as long term trials with hard endpoints are lacking. Especially the effect on HCC remains highly uncertain.

193. INVESTIGATING VARIATION IN THE UPTAKE OF PROSTATE CANCER SCREENING IN EUROPE

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Background: Prostate Specific Antigen (PSA) testing as part of a Prostate Cancer control strategy is the subject of much debate. It is perhaps unsurprising therefore that considerable variation exists in uptake of the test. This paper examines variations in the uptake of PSA testing across Europe and the role of individual and contextual

variables in explaining this. Particular attention is paid to the role of income inequality and the primary care system in operation.

Methods: Data were taken from Eurobarometer 66.2 "Health in the European Union" 2006 on self-reported uptake of PSA testing in the preceding 12 months. Data related to men from 29 European countries aged 40 and over (N = 7515). Three age cohorts were constructed based on results from previous clinical trials. A series of logistic regression analyses were undertaken examining the role of individual characteristics across and within countries.

Results: A range of individual characteristics were found to be statistically significant predictors of uptake including education (OR 1.88***), marital status (OR 1.42***) and smoking status (OR 0.55***). Socio-economic status (SES) was also statistically significant in the cohort aged 40-54 and the cohort aged 55-69. Variations across countries in uptake were evidenced. Importantly, a significant role was accorded primary care and income inequality in explaining variations in uptake.

Conclusions: Uptake of PSA testing varies considerably within and across European countries. Differences within states relate to the characteristics of individuals offered tests and differences between states relates to the extent of income inequality evident and the system of primary care in operation. Given the significant welfare loss implicit in the variations evident, the role of primary care and income inequalities in explaining variations warrant greater attention.

204. PERCUTANEOUS CORONARY INTERVENTION WITH OPTIMAL MEDICAL THERAPY VS. OPTIMAL MEDICAL THERAPY ALONE FOR PATIENTS WITH STABLE ANGINA PECTORIS. HEALTH-ECONOMIC EVALUATION

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Background: Medical therapy and percutaneous coronary interventions (PCI) are the most important methods used in the treatment of chronic coronary artery disease (CAD).

Objectives: The evaluation addresses cost-effectiveness in the use of PCI in CAD patients in comparison to optimal medical therapy alone.

Methods: A health economic modelling was performed with the clinical assumptions derived from the conducted meta-analysis of randomized controlled trials (RCTs) with use of current optimal medical therapy and economic assumptions derived from the German Diagnosis Related Groups 2011. The strength and the applicability of the determined evidence were appraised.

Results: The meta-analysis was based on three RCTs with use of optimal medical therapy, which were identified through the systematic literature search. The routine use of PCI reduces only the proportion of patients with AP attacks in the follow-up up to three years in comparison with optimal medical therapy alone (evidence strength moderate). The applicability of the evidence for the endpoints AP and revascularisations is moderate, for further endpoints high. The average difference in the total costs for PCI in comparison with optimal medical therapy alone, which was calculated in the modelling, was found to be 4,217 Euro per patient. The incremental cost-effectiveness ratio per life-year of a patient with avoided AP attacks was estimated to be 24,805 Euro (evidence strength moderate).

Discussion: Important methodical problems of the underlined RCTs are a lack of blinding of the patients and incomplete data for several endpoints in the follow-up. The determined incremental cost-effectiveness ratio per life-year of a patient with avoided AP attacks was appraised not to be cost-effective.

Implications: From the health economic point of view the routine use of PCI in addition to an optimal medical therapy in patients with stable AP cannot be recommended.

215. HEALTHCARE BUDGET IMPACT OF INTRODUCING PANITUMUMAB FOR FIRST- AND SECOND-LINE TREATMENT OF METASTATIC COLORECTAL CANCER IN THREE EUROPEAN COUNTRIES

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Background: The European indication for the monoclonal antibody (mAb) panitumumab in patients with wild-type *KRAS* metastatic colorectal cancer (mCRC) was recently expanded to include combination treatment in first-line with FOLFOX and in second-line with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan).

Objectives: To assess the economic impact of including panitumumab as a first- or second-line therapy option for patients with wild-type *KRAS* mCRC from the perspective of payers in France, Italy, and Spain.

Methods: We created a budget impact model of the introduction of panitumumab, which assumed that over the 3-year time horizon panitumumab will increasingly be used in place of cetuximab in combination therapy regimens. Target population size in each year and average patient weight and body surface area for mAb and chemotherapy dosing were estimated for each country. Drug utilization was based on the number of vials required to achieve target dose, with up to 5% dose reduction permitted to reduce mAb wastage. Country-specific unit costs were multiplied by utilization of mAb, adjunct chemotherapy, and patient management.

Results: In both first- and second-line therapy, total direct medical costs of treating the target population decreased with the introduction of panitumumab, primarily attributable to reduced costs of mAb and patient management from lower frequency of administration. For first- and second-line therapy combined, total net cost savings in years 1, 2, and 3 were, respectively: €3,134,244, €6,805,166, and €10,157,851 for France; €7,854,377, €12,317,180, and €14,539,746 for Italy; and €3,596,400, €5,633,132, and €7,378,238 for Spain.

Conclusion: Introducing panitumumab as a reimbursed treatment option for first- and second-line treatment of patients with wild-type *KRAS* mCRC is potentially cost saving, with an estimated 3-year net budget savings of €20,097,261, €34,711,302, and €16,607,771 in France, Italy, and Spain, respectively.

240. SENTINEL LYMPH NODE BIOPSY LESS EXPENSIVE THAN AXILLARY LYMPH NODE DISSECTION IN EARLY BREAST CANCER STAGING

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Background: Sentinel lymph node biopsy may adequately stage the axilla in breast cancer with less morbidity compared to axillary clearance.

Objectives: As part of the information needed for recommendations making, we aimed to compare the cost of systematic axillary lymph node dissection and sentinel lymph node biopsy –with axillary dissection only if the sentinel node contains metastases-, with or without intra-operative histological examination.

Methods: Unit costs collected in a French national study were included in a model simulating the cost of 3 strategies: 1) axillary lymph node dissection, 2) sentinel lymph node biopsy followed by

distant axillary lymph node dissection in case of positive sentinel lymph node and 3) sentinel lymph node biopsy with intra-operative histological examination and axillary lymph node dissection for positive cases. A multivariate probabilistic sensitivity analysis was conducted on identification rate, complication rates, sensitivity, specificity and length of hospital stay.

Results: The sentinel lymph node biopsy is less costly than axillary lymph node dissection in the early stages of breast cancer. Intra-operative histological examination of sentinel lymph node significantly reduces the cost of the procedure.

Discussion: Data on molecular intra-operative examination couldn't be integrated in the present study as no French cost data were available. In a systematic review, no survival difference could be demonstrated between the three strategies in early stage of breast cancer and quality of life was found to be better with sentinel lymph node biopsy than with axillary lymph node dissection. Nevertheless, more data are needed to integrate these results in a cost-effectiveness analysis.

Implications for the health system/professionals/patients/society: The study confirms the interest of sentinel lymph node biopsy in early stage of breast cancer. The cost comparison helps to determine the choice of the intervention alongside other arguments as women's preference, efficacy and safety.

250. TARGETED VERSUS UNIVERSAL PREVENTION: OPTIMAL RESOURCE ALLOCATION TO REDUCE THE BURDEN OF COPD

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Introduction: Chronic obstructive pulmonary disease (COPD) is a major cause of mortality and morbidity. The aim of this study is to analyze the optimal allocation of resources over smoking cessation programs aimed at smokers in the general population, smoking cessation for smokers with COPD and pharmaceutical maintenance treatment for COPD patients. Allocations will be evaluated for the resulting health benefits and effects on healthcare costs.

Methods: A COPD disease progression model was used to estimate the long-term costs and health benefits of five different implementation strategies: Smoking cessation during years 1 to 4 for COPD patients or the general population; the same options offered during years 5 to 8, and more maintenance medication during years 1 to 8. The optimal budget allocation was examined by maximizing total health benefits by changing the allocation of resources to different strategies.

Results: The ICERs of the five strategies compared to care as usual varied from €2,400 per QALY for smoking cessation offered to all smokers to €11,600per QALY for additional maintenance medication for COPD patients. At budgets below €0.45 billion the most cost-effective strategy is smoking cessation in the non-diseased smoking population during years 1 to 4. Until budgets of €0.75 billion, it will be possible to offer smoking cessation in the general population during years 5 to 8. Only when both smoking cessation in the non-diseased population strategies have been implemented at their full capacity, it becomes worthwhile to introduce smoking cessation for COPD patients, followed by additional maintenance medication.

Discussion: The results show that if the aim of health care policy makers is to obtain maximal total QALYs for a given COPD-budget, investing in smoking cessation is preferable over more sophisticated maintenance therapy for existing COPD patients. For any given budget, the disease burden of COPD can be reduced if sufficient resources are allocated towards smoking cessation.

259. FINANCIAL, TIME AND EFFICIENCY ASSESSMENT OF PHYSIOTHERAPEUTIC BED AND MANUAL MASSAGE TECHNIQUES

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Background: One regularly finds new medical devices on the market that are ment to replace work of health care staff. The paper shows a possibility for physiotherapists to change their work using the CERAGEM massage bed, the only bed approved as a medical device in the Czech Republic.

Introduction: The paper compares efficiency, financial and time demands of the CERAGEM physiotherapeutic bed (represents an automatic massage technique), and manual reflex massages done by a physiotherapist in patients with a vertebrogennal illness.

Methods: The evaluation of the effectiveness included 60 patients selected in line with the recommended indications of CERAGEM massages. Half of them received 5 procedures of the CERAGEM massage followed by 5 procedures of the manual reflex massage. The second half received the massages in a reverse order. The patients were interviewed by a single person in order to evaluate subjective and objective criteria describing the health status of the patients. These evaluations were combined in a scale showing the improvement of patients´ health state. The results were compared by the Wilcoxon two-sample test. Cost effectiveness of both techniques was compared on the basis of fixed costs.

Results and discussion: The results showed the usage of automatic massage beds for patients with muscle stiffness and back impaired mobility convenient. Differences in the efficiency of both therapy forms proved for various health aspects. Financial savings were compared using different cost items (acquisition, labour, overhead costs). The best cost-effectiveness proved in the case that the health care facility has 4 CERAGEM beds serviced by one support person, instead of 4 physiotherapists in case of manual massages. In the conditions of the Czech Republic, the main benefit appeared to be labour cost savings when utilizing the massage beds.

267. ECONOMIC EVALUATION OF PROSTATE CANCER SCREENING TEST AS A NATIONAL CANCER SCREENING PROGRAM IN KOREA

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Background: Prostate cancer (PC) incidence is rapidly increasing in Korea: from 12.5 per 100,000 in 2003 to 23.1 in 2008. The professional societies have requested to add Prostate Specific Antigen (PSA) test in the National Cancer Screening Program (NCSP), but it started a controversy in Korea and neutral evidence on this issue is required more than ever.

Objectives: The purpose of this study is to provide economic evaluation evidence to the decision makers of the NCSP.

Methods: A cost-utility analysis was performed on the adoption of PSA screening program among the men aged 50-74-years in Korea from the healthcare system perspective. Several data sources were used on the modeling of PSA introduction to the current NCSP, including general health screening data from a university hospital (1998-2010), National Cancer Registry (2000-2009), claims data from Health Insurance Review and Assessment Service (2005-2009), and cause of mortality from the National Statistical Office (2000-2009). To solicit the utility index of PC by each stage in Korea, a face-to-face interview for general men aged 40 to 69 was conducted using Time-Trade Off (TTO) method.

Results: As a result, the increase of cumulative effects (QALYs) when adopting the PSA national screening program compared to current situation was estimated at 0.00017 and the ICER was analyzed as about 79 million KRW. In addition, the best case scenario assuming maximum mortality gain and the best improved cancer stage distribution with 100% examination rate from the PSA national screening initiation showed ICER about 64 million KRW. Extensive sensitivity analyses were performed on the incidence rate, screening rate, cancer stage distribution, utility index, and treatment costs but the results of sensitivity analysis were consistent with the default analysis.

Conclusions: Under the current circumstances with low incidence rate of PC in Korea, the national screening of PC was not cost-effective. Therefore, we concluded that adopting national PC screening program would not be suggested until further evidence, especially sufficient incidence rate, is provided in the future.

281. THE COSTS AND EFFECTIVENESS OF LONG-TERM AND SHORT-TERM PSYCHODYNAMIC PSYCHOTHERAPY AND SOLUTION-FOCUSED THERAPY IN THE TREATMENT OF DEPRESSIVE AND ANXIETY DISORDERS DURING A FIVE-YEAR FOLLOW-UP

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Background: Various psychotherapies are used extensively in the treatment of depressive and anxiety disorders, but still we have relatively little comparative knowledge on the cost-effectiveness of therapies of different lengths.

Objectives: The aim of this study is to compare the costs and effectiveness of long-term psychodynamic psychotherapy (LPP) with two short-term therapies – short-term psychodynamic psychotherapy (SPP) and solution-focused therapy (SFT) – in the treatment of depressive and anxiety disorders during a five-year follow-up.

Methods: In this study, which is part of the larger Helsinki Psychotherapy Study, 128 patients suffering from depressive or anxiety disorders were randomized to LPP, 101 to SPP and 97 to SFT. Depressive symptoms were measured using the Beck Depression Inventory and the Hamilton Depression Rating Scale, and anxiety symptoms using the Symptom Check List Anxiety Scale and the Hamilton Anxiety Rating Scale. All direct health care costs due to depressive and anxiety disorders were taken into account. The analysis was based on the intention-to-treat population.

Results: All four health indicators showed statistically significant reductions in psychiatric symptoms in all treatment groups. Symptoms decreased slower in the LPP group but taking into account the whole five-year follow-up there were no notable differences in the effectiveness of the three therapies. The difference in costs, however, was significant as the mean direct costs of both the SPP and the SFT group were less than half of those of the LPP group. This was due to the fact that LPP itself cost much more than SPP or SFT.

Conclusions: If one looks only at psychiatric symptoms, the cost-effectiveness ratios of SPP and SFT are most likely better than that of LPP. Further research is needed on areas regarding other outcome domains, e.g. functional capacity and need for auxiliary treatment, before firm conclusions about the cost-effectiveness of these therapies can be made.

308. A HEALTH TECHNOLOGY ASSESSMENT OF TRANSIENT ELASTOGRAPHY IN ADULT LIVER DISEASE

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Background: Liver disease affects two million Canadians. The standard of care for diagnosing and monitoring liver disease is percutaneous liver biopsy (LB); an invasive procedure with risks and complications. Transient elastography (TE) is a non-invasive ultrasound-based alternative. The objective of this study was to assess the efficacy of TE compared to LB for adults with 5 common types of liver disease (hepatitis B, hepatitis C, non-alcoholic fatty liver disease, cholestatic disease and transplant patients).

Methods: We conducted a systematic review of peer-reviewed and grey literature from 2001 to June 2011. Included studies were prospective diagnostic cohort studies evaluating the accuracy of TE using LB as the comparator. An economic model was developed to estimate the cost per correct diagnosis gained with LB compared to TE. Moderate and severe fibrosis and cirrhosis stages were considered.

Results: Fifty-seven studies were included in the review. The diagnostic accuracy of TE for the 5 clinical subgroups had sensitivities ranging from 0.67-0.92 and specificities ranging from 0.72-0.95. LB, compared to TE, was associated with an additional $1,427 to $7,030 per correct diagnosis gained. The model was sensitive to the sensitivity, specificity and prevalence of fibrosis. TE is less effective and less expensive than LB. To recoup the upfront cost of a TE machine and annual maintenance, assuming a 7 year lifetime for the machine, approximately 67 biopsies would need to be avoided per year (417 in total over 7 years).

Conclusions: TE is an accurate and cost-effective method for diagnosing patients with moderate fibrosis, severe fibrosis or cirrhosis.

Implications: System implementation of TE should be considered for diagnosis of liver disease.

341. COST-EFFECTIVENESS OF A CHRONIC CARE MODEL FOR COMMUNITY-DWELLING FRAIL OLDER ADULTS: DESIGN OF THE ECONOMIC EVALUATION OF ACT (FRAIL OLDER ADULTS: CARE IN TRANSITION)

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Background: Health care utilization in industrialized countries is increasingly driven by the needs of vulnerable older persons. Efficient care models targeting current challenges in elderly care are needed to warrant the financial tenability of health care systems. The Chronic Care Model (CCM) aims to provide coherent, proactive and patient-centered care. We hypothesize that implementing the CCM for

community-dwelling older adults will lead to financial savings by substitution to primary care and delay in hospital and long-term care admissions, due to early recognition of health problems.

Objectives: To evaluate the cost-effectiveness and -utility of the CCM for community-dwelling frail older adults compared to usual care.

Methods: *Design*: Prospective (2-year) economic evaluation from a societal perspective alongside a stepped wedge cluster RCT. Study population: Dutch community-dwelling frail older adults (N = 1147) and their primary informal caregivers. *Intervention:* Half-yearly geriatric assessments of care needs will be performed by practice nurses using the Resident Assessment Instrument (RAI), resulting in a tailored care plan. Complex situations are reviewed in a multidisciplinary meeting (including the patient's general practitioner). All professionals involved are directed by a central CCM team, which encourages coordination between care organisations. *Measurements:* Effect measures at 6, 12, 18 en 24 months include functional status (Katz Index) and quality of life (EQ-5D). Costs include health care utilization by both the older adults and their informal caregivers, and the costs of development and implementation of the CCM. Resource use is measured using cost diaries and will subsequently be valued using Dutch cost prices. *Analysis:* Bootstrapping will be used to analyse cost-effectiveness. Cost-effectiveness planes and cost-effectiveness acceptability curves will be estimated.

Results: Results are expected in the second half of 2013.

Implications: This study will show whether implementing the CCM for community-dwelling older adults is cost-effective compared to usual care.

351. ECONOMIC IMPACT ANALYSIS OF STERILIZATION OF RIGID ENDOSCOPES WITH STERRADTM VS. STEAM IN SPAIN

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Background and objectives: The increasing penetration of endoscopic techniques in surgical procedures has resulted in a more frequent use of rigid endoscopes (RE). Several studies have reported significant reductions in the number of damaged RE and repairs when reprocessed with Sterrad™ instead of Steam. The aim of this study was to analyze the economic consequences of RE sterilization with Sterrad™ versus Steam from a hospital perspective.

Methods: A dynamic excel-based decision-analytic model was developed. Published literature was used to estimate the two key variables (% of RE damage with Steam as well as with Sterrad™). A two-way sensitivity analysis was conducted (varying the two key variables up to ± 25%, thus generating 121 different scenarios). Input data for the model collected as an average from four Spanish hospitals were: 1,000 RE sterilization units (StU) annually, 2,000€ cost for every RE repair and 0,56€ in consumables/StU with Steam. 11,99€ in consumables/StU with Sterrad™ was calculated based on list prices and an average of 2.5 RE per sterilization cycle. The analysis covered a one year time horizon and assumed 100% utilization for each sterilization technology.

Results and discussion: A 21% budget impact decrease was achieved with Sterrad™ versus Steam, leading to 11,870€ in annual savings. The more costly sterilization process (11,986€ versus 560€ per year) was clearly more than compensated by the reduction of 23,296€ in RE repair costs. The sensitivity analysis showed in 100% of the scenarios that Sterrad™ was cost-saving compared to Steam. **Conclusions/implications for the hospital:** This analysis adds a new component of support for the sterilization of rigid endoscopes with Sterrad™ by demonstrating that it is cost-saving compared to reprocessing with Steam. Despite the conservative approach of the model which may be in favour of Steam, use of Sterrad™ led to savings of 21% in the hospital budget.

363.A LIFETIME COST-EFFECTIVENESS ANALYSIS OF THE RECOMMENDED ANTIHYPERTENSIVE DRUG CLASSES IN FRANCE

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Introduction: The French guidelines for the management of arterial hypertension recommend the assessment of the cardiovascular risk, based on the patient's age, sex, cholesterol level and systolic blood pressure (SBP) and, depending on this risk, a treatment with either of the antihypertensive drug classes (angiotensin converting enzyme [ACE]-inhibitors, angiotensin receptor blockers [ARBs], beta-blockers, calcium channel blockers [CCB], thiazide diuretics).

Objectives: To assess the cost-effectiveness of the recommended antihypertensive classes from the French 'All-Payer' perspective.

Methods: A lifetime Markov model was developed using 1-month (in the first year) and 1-year cycles. Newly diagnosed patients were starting a first line monotherapy. The initial 10-year cardiovascular risk was evaluated via the Framingham equation adapted to France (Laurier 1994). Expected SBP reductions and relative risks of cardiovascular events vs. placebo, provided by the most recent meta-analyses, were applied. Patients switched to a bitherapy, then tritherapy, if they failed to reach a target SBP (140 mmHg) or in case of non-persistence (class-specific data from national pharmacy database). An annual discounting of 4% was applied to costs and outcomes.

Results: In 65-year-old men with initial SBP of 150 mmHg, the lifeyears gained vs. placebo ranged from 0.23 (beta-blockers followed by beta-blockers/ACE-inhibitors) to 0.36 (CCB followed by CCB/ACE-inhibitors). Based on probabilistic sensitivity analyses, all treatment sequences were significantly more effective and less costly than placebo (total costs from 9,341€ [ACE-inhibitors] to 9,650€ [ARBs] vs. placebo 9,940€), except those based on beta-blockers (10,033€). There were significant costs differences between beta-blockers and the other antihypertensive classes, but not between the other four classes. The relative risks of cardiovascular events and initial risk level were driving the model results.

Conclusions: All anti-hypertensive drugs seem cost-effective compared to placebo. However there were no differences between 'non-beta-blockers' classes, so that those drug classes can be equally defined as efficient first line treatment options.

373. SYSTEMATIC REVIEW OF DA VINCI SURGICAL SYSTEM ECONOMIC EVALUATIONS

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Objective: To perform a systematic review of economic evaluation comparing DaVinci surgical system with open or conventional laparoscopic surgery.

Methods: Databases included: Pubmed, Embase, Tripdatabase, CRD (DARE, NHS and HTA) and Cochrane Library Plus. Searches were last updated on October, 2011. We calculate the difference of costs expressed as a percentage for robotic surgery compared to laparoscopic or open surgery.

Results: 53 studies have been located with cost data. Only one study performed an analysis of the type cost-effectiveness presenting costs per birth for tubal reanastomosis. Other studies included cost analysis. Robot acquisition cost amounted to $1,650,000. Annual maintenance costs is $149,000. Use of robot varied from 100 to 364 cases annually. The amortization of the device was between 5 and 10 years. Equipment costs ranged between $1,126 and $2,210 per intervention. Intervention time was longer using robotic surgery increasing costs. Length of hospital stay was lower for robotic surgery lowering postoperative costs. Compared with laparoscopic the 16 indications accounted higher costs for robotic surgery, cost increases ranging from 7% to 703%. Comparing robotic surgery with open surgery, 11 types of surgery had higher costs for robotic surgery (increase between 14 and 91%) but 7 types of surgery had lower costs for robotic surgery: pancreatectomy, carotid artery bypass, gastric bypass, adrenalectomy, radical cystectomy, pediatric Nissen fundoplication and hysterectomy.

Conclusions: Compared with laparoscopic surgery all indications accounted higher costs for robotic surgery with increases between 7% and 703%. Compared to open surgery 11 types of surgery had higher costs for robotic surgery but 7 types of surgery had lower costs for robotic surgery: pancreatectomy, carotid artery bypass, gastric bypass, adrenalectomy, radical cystectomy, pediatric Nissen fundoplication and hysterectomy. It would be desirable the development of full economic evaluation presenting the incremental cost-effectiveness of robotic surgery compared to open surgery and laparoscopic.

399. COST-UTILITY ANALYSIS OF THE INTRODUCTION OF THE VACCINE AGAINST HUMAN PAPILLOMA VIRUS IN SPAIN

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Background: Human Papilloma Virus (HPV) vaccination programmes started in Spain in 2008. Results of the published cost-effectiveness studies of HPV vaccination are not directly applicable to our context. Relevant aspects remain uncertain regarding effectiveness and health impact of HPV vaccination.

Objectives: To evaluate the cost-utility of the introduction of the quadrivalent HPV (16,18,6,11) vaccine combined with cervical cancer opportunistic screening compared to only opportunistic screening in Spain.

Methods: A lifetime Markov analytical model was developed to calculate the cost per additional quality adjusted life-year (QALY) gained by the introduction of the vaccine combined with opportunistic screening compared to only opportunistic screening. The cohort members were 11 years old girls who receive three doses of vaccine at the beginning and a booster dose 10 years later. The vaccination coverage considered was 77.2%, according to the 2011 reported data in Spain. The perspective adopted was that of the Spanish National Health System. One-way and multiway sensitivity analyses were developed to manage uncertainty.

Results: The base-case resulted in an average cost of 1,413 € at the option of vaccination plus screening and of 1,186 € at the option of only screening. The average utility was 27.2524 QALYs at vaccine plus screening and 27.2459 QALYs at only screening. These data gave rise to an ICER of 34,776 € per additional QALY gained. The probabilistic sensitivity analysis found that 95% of the 10,000 Monte Carlo simulations resulted in ICERs between 31,041 and 39,766 € per additional QALY gained. Duration of protection and vaccine efficacy were the variables that most affected ICER results.

Discussion: Consideration of the introduction of the vaccine against HPV in Spain as a cost-utility option depends largely on the ICER threshold taken as reference. Other relevant factors that affected cost-utility were duration of protection and vaccine efficacy.

404. A COST-EFFECTIVENESS ANALYSIS OF A PRIMARY CARE-BASED TELEMONITORING INTERVENTION FOR HOME CARE PATIENTS WITH HEART FAILURE AND CHRONIC LUNG DISEASE. THE TELBIL STUDY

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Background: The cost-effectiveness of home-based telemonitoring interventions remains an important issue for the implementation of this technology.

Objectives: To evaluate a primary care-based telemonitoring intervention in economic terms compared to usual care through a cost-effectiveness analysis.

Methods: A 12-month follow-up primary care-based randomised controlled trial was carried out to assess the impact of a telemonitoring intervention aimed at home-care patients. The perspective of the analysis was undertaken from a healthcare provider and the time horizon was of one year. Only direct unit costs per patient were calculated. The specific costs that were taken into account include: costs directly associated with the telemonitoring intervention, with the home care and those related to the impact of the telemonitoring program on the necessary resources for the provision of patient care. The QALYs, calculated from the EQ-5D generic questionnaire, were used as a measure of effectiveness and were estimated by calculating the area under the curve. Additionally, the baseline utility was controlled using a regression-based adjustment. The ICER was calculated to determine which approach was more cost-effective. To determine the uncertainty of the assessment, a sensitive analysis was carried out using the non-parametric bootstrapping to calculate 95% confidence intervals (CI) (percentile method).

Results: For a sample of 58 patients, the costs and QALYs of the telemonitoring intervention were 12,997€ (95% CI: 8,319€-18,570€) and 0.36 (95% CI: 0.31-0.41) versus 15,228 (95% CI: 3,131€-36,677€) and 0.30 (95% CI: 0.10-0.49) for usual care. The ICER was of -34,768€/QALY (95% CI: -564,059€/QALY – 1,120,111€/QALY).

Conclusions: The deterministic result showed that the telemonitoring intervention was both cheaper and more effective than usual care, namely was dominant. Nevertheless, the confidence interval calculated by bootstrapping for the ICER, also showed a large uncertainty. Therefore, it would be necessary to carry out further analysis to confirm these results.

405. ORGANIZATIONAL AND PHARMACO-ECONOMIC IMPACT OF NEW STRATEGIES TREATMENT FOR THE MACULAR EDEMA WITH RETINAL VEIN OCCLUSION (RVO)

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Background: The retinal vein occlusion (RVO) is a leading cause of vision loss and the prevalence is about 0.2% in the Europe.

Objectives: The aim of this study is to assess, trough HTA analysis, the new different approaches therapy (Intravitreal implant of dexamethasone, intravitreal injection of ranibizumab or bevacizumab) in the treatment of macular edema with RVO in the wide area of Udine.

Methods: We made bibliographic researches, in the main healthcare and HTA databases to evaluate the efficacy, safety of the different treatments. The economic evaluation includes the costs of technology, administration and organization. The incidence of the disease in the wide area was used to calculate the economic and the organizational impact in the next 5 years.

Results: The trials GENEVA (dexamethasone), BRAVO and CRUISE (ranibizumab) and the prospective studies found in the literature (bevacizumab) show that the different therapeutic strategies provide a clinical advantage over the current gold standard. A single implant of dexamethasone increases of 5 letters 6 months; ranibizumab increases, an average gain of 12-18 points in 6 months, in monthly administration. Other evidences suggest that bevacizumab produces similar results.

Discussion: Considering the patient annual cost, these therapeutic strategies are different in: 1) the drug (ranitizumab: 11135 €, dexamethasone: 1722 € and bevacizumab: 101 €), 2) the administration (ranitizumab: 2303 €, dexamethasone: 433€ and bevacizumab: 2303€) 3) the follow-up (e.g. ophthalmologic exams – optical coherent tomography - fluorescein angiography)(ranitizumab: 762 €, dexamethasone: 532 € and bevacizumab: 762€).

Implications for the health system/professionals/patients/society: The budget impact analysis will allow us to program the use of economic and organizational resources for the diagnosis, the treatment and the follow up of patients suffering from macular edema with RVO.

427. THE ANNUAL DIRECT MEDICAL COST OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS AND COSTS DRIVERS (LUCIE STUDY): ITALIAN RESULTS

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Objectives: To determine the annual direct medical cost of the management of adult patient with ANA positive SLE.

Methods: LUCIE is a multicenter, observational, retrospective study carried out in 5 European countries (Italy, Germany, UK, France and Spain). SLE patients characteristics, disease severity, flares rate, health care consumption (laboratory tests, biopsies, imaging tests, medications, specialist visit, hospitalisations) were collected retrospectively over a 2-year period (Jan 2008-Jun 2010). The Italian NHS perspective was considered when estimating the average annual direct cost using official cost database. Cost predictors associated with SLE and flares management were identified by multivariate regression models.

Results: 4 Italian SLE centres participated in the study, and included 96 consecutive patients: mean age 42.9 ± 11.7 years, 85.4% females. The mean SLE duration was 12.6 ± 7.2 years, the mean SELENA-SLEDAI score, an index of SLE activity, was 6.3 ± 5.9. On average, SLE patients had 0.65 ± 0.60 flares/year. The annual unadjusted mean direct medical cost of SLE patients was €2,513. The minimum and maximum (€238 and €15,536 respectively) showed the wide range of costs directly related to the different profiles of disease severity and activity. In severe patients the cost was 1.4 times higher than in non-severe patients: €2,905 vs €2,104 ($p = 0.031$). Medical treatment represents the largest component of the average annual direct cost of SLE patients (61.4%) and was 1.5 times higher in severe patients (€1,842 vs €1,231, $p = 0.007$). The mean 2-year cost of patients with flares was 2.4 times higher than the cost of patients without flares (€6,420 vs €2,718, $p < 0.001$). The number of severe flares showed a statistical significant relationship with cost ($p = 0.0487$). Each additional flare increased of €594 the mean annual direct medical cost.

Discussion: The annual direct medical cost of active SLE is significant especially for patients experiencing severe flare and is mostly driven by the cost of medication.

447. COST-EFFECTIVENESS OF ALENDRONATE FOR OSTEOPOROSIS POSTMENOPAUSAL IN BRAZIL

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Osteoporosis is a common disease in the elderly, characterized for low bone mineral density and affect million women worldwide. The main consequence of osteoporosis is an increased incidence of fractures, notably at the hip, which increases as woman ages. The disease results not only in morbidity for the patient, with a risk of mortality following fractures of the hip, but also in the consumption of scarce health resources. The aim was to assess the cost-effectiveness of alendronate compared to not treat in women with postmenopausal without previous fractures at 50 years old, from a Brazilian public health system's perspective. Using Markov model, we constructed hypothetical cohort of 40 years for osteoporosis postmenopausal patients. The outcome of treatment efficacy was hip fractures risk. The cost was expressed in U.S. dollars (2010) and effectiveness in life years (LY). At the end of cohort, 21.9% from women would have died vs. 22.4% (no treat). The cost-effectiveness ratio of alendronate and no treatment was US$198.32/LY and US$6.98/LY, respectively. The incremental cost-effectiveness ratio was US$24,333.68/LY and is below the threshold recommended by World Health Organization (three times the Brazilian GDP per capita; US$32,561.64). The use of medication to women at 50 years old is cost-effective to prevent hip fractures. Further studies are needed to strengthen this evidence, to evalue fractures in other sites and other medications and its economic impact.

451. RAPID REVIEW FOR RARE DISEASES TREATMENTS – THE CASE OF PEGVISOMANT FOR ACROMEGALY

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Background: Under the standard methods of health technology assessment (HTA) incorporating economic evaluation, orphan drugs do not usually prove to be cost-effective. Adding their high cost, it meant that funding and patient access may be limited in the Brazilian Public Health System (SUS). Acromegaly is one example, with annual

incidence of 3-4 cases/million and prevalence of 40-90 cases/million. There is a new drug, pegvisomant, which presents a relative efficacy at a high cost.

Objective: To identify the best pharmacoeconomics evidence for pegvisomant in acromegaly and to review the knowledgment transfer to support a rapid economic review of rare diseases under the perspective of SUS.

Methods: In the case of the rare disease acromegaly a search was conducted on October 18th, 2011 using 'cost'/exp OR cost AND effectiveness AND ('pegvisomant'/exp OR pegvisomant) AND ('acromegaly'/exp OR acromegaly) in Medline (PubMed), EMBASE, Virtual Health Library (BVS), Center for Reviews and Dissemination (CRD), The Cochrane Library.

Results: Only the study "Clinical effectiveness and cost-effectiveness of pegvisomant for the treatment of acromegaly: a systematic review and economic evaluation" was identified and selected. The study was conducted in the United Kingdom, where health costs are different from the Brazilian structure.

Discussions: The study´s evidence indicates that pegvisomant is not cost-effective to treat patients with resistant agromegaly. In Brazil the cost of each dose in the public health system is about 25% more expensive than the UK, and so is the cost of labor.

Implications for research: The need of economic assessment transferability as a tool to support the management of political decisions, especially to high cost technologies and rare diseases, are not set as priority in the research fostering agenda of the SUS.

465. THE ECONOMICS OF STRUCTURED SELF-MONITORING OF BLOOD GLUCOSE (SMBG) IN NON-INSULIN-DEPENDENT TYPE 2 DIABETES MELLITUS - LESSONS TO BE LEARNED FROM THE STRUCTURED TESTING PROGRAM (STEP) STUDY

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Background: In poorly controlled type 2 diabetes, the structured treatment group (STG) of the STeP study improved HbA1c control with less test strips employed in comparison to enhanced usual care that included unstructured SMBG (active control group (ACG)).

Objectives: Answer key economic questions for decision makers: Is an initial investment necessary that needs refinancing in later years? Is structured SMBG efficient?

Methods: Combining STeP-outcomes with U.S.-costs (in USD) of diabetes and its consequences by utilizing a well-established Markov model, a cost-effectiveness-analysis was developed from the perspective of U.S. third party payers over life-time.

Results: Improving HbA1c levels leads consistently to improved life-expectancy (LE) and cumulated quality adjusted life-years (QALYs). Improvements in LE against baseline are clinically relevant as patients in their mid-fifties are expected to live 0.46 to 0.60 years longer. The nominal (discounted) life-time cost range from USD 114,203 (70,899) in STG patients to USD 116,442 (72,447) in the ACG. STG dominates both ACG and STeP baseline cohorts in undiscounted and discounted cost-per-life-year (CLYG). STG patients not being previously active testers at baseline are predicted to live 0.5 years longer. Their nominal (discounted) life-time costs amount to USD 118,670 (72,321). STG previously not active testers dominate the not active testing baseline in undiscounted cost-per-life-year (CLYG). An additional USD 292 is noted for discounted CLYG.

Discussion: As cost-effectiveness is already reached in the first treatment year no initial investment needs to be refinanced over time. A maximum price of USD 1.26 per strip represents the efficiency break-even point of structured versus unstructured testing (STG vs. STeP baseline) in discounted CLYG.

Implications for the health system: With due caution needed when considering modeling studies, diabetes treatment using structured vs. unstructured SMBG according to STeP represents a cost-effective approach to improve diabetes care.

467. LEFT VENTRICULAR ASSIST DEVICES (LVADS) AS A BRIDGE-TO-HEART TRANSPLANT (BTT) FOR PATIENTS WITH END-STAGE HEART FAILURE. A HOSPITAL-BASED HTA

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Background: LVAD has been proposed as a life-saving alternative to conventional therapy (mainly pharmacological with intravenous inotropes) for patients awaiting heart transplant (HT). However, its high price (97.000€) could have an important impact upon the cardiology department, making its adoption unfeasible. A hospital-based HTA was performed to aid managers in their final investment decision.

Methods: Cost-effectiveness analysis comparing LVAD to conventional treatment was performed. The analysis used a Markov Model, which extrapolates survival, utility and resource use over the total lifetime of a hypothetical cohort of patients under both strategies. Clinical data on effectiveness and safety was obtained from a systematic review. Cost data was provided by the economic directorate of hospital. Ethical, legal and organizational impact upon the hospital was also approached.

Results: Six studies meet the inclusion criteria, showing that LVADs improve survival significantly. Adverse events of LVAD are a serious concern. The economic evaluation shows that LVAD has an incremental cost-effectiveness ratio of 62.000€/QALY. The average cost for treating a patient 1 year while waiting for the HT was 143.057€ and 21.046€ for a LVAD-implanted and conventionally treated patient, respectively.

Discussion: Clinical evidence indicates that LVADs are clinically more effective than conventional treatment as a BTT, although it is not cost-effective (criterion based on a 30.000€/QALY thresholds) for our hospital. The cost per process of care is also high compared with current practice. Therefore, LVAD is not recommended for "usual care" in our hospital. However, the higher effectiveness and other strategic elements could promote its indication in selected patients.

Implications: Implantation of LVADs as a BTT lacks justification in terms of cost-effectiveness at our hospital. The hospital-based HTA tool can play an important role in efficient decision-making regarding the adoption of health technologies.

480. NATIONAL INSTITUTE FOR HEATLH AND CLINICAL EXCELLENCE (NICE) SINGLE TECHNOLOGY APPRAISAL (STA) PROCESS: - A PROCESS CASE STUDY OF CHRONIC IDIOPATHIC (IMMUNE) THROMBOCYTOPENIC PURPURA (ITP)

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The NICE/STA process was developed to inform rapid decision making for new and novel pharmaceutical drugs. A manufacturer submission demonstrates the value for money argument for reimbursement by the NHS and is critiqued by an independent Evidence Review Group (ERG). This paper draws from manufacturers' and ERG reports from two technology appraisals, romiplostim

–TA221– and eltrombopag –TA205–, for treatment of chronic ITP. NICE appraisal committees issued guidance rejecting eltrombopag (October, 2010, awaiting patient access scheme decision) and recommending romiplostim (April, 2011). We use this case study to discuss methodological challenges of the STA process. There were inconsistencies in how evidence was presented and incorporated into the modelling process between manufacturer submissions. This was particularly evident in the model structure for underlying disease process and treatment sequences. Although both models extrapolated clinical efficacy from placebo controlled trials, the link between trial outcomes and final events differed: romiplostim focussed on increasing platelet counts whilst eltrombopag focussed on reducing bleeding events. Both measures of outcome should be highly correlated however each model provided conflicting results. Indirect comparisons based on platelet count data favoured romiplostim; comparisons based on bleeding events favoured eltrombopag. As only limited comparator data were available to the manufacturer and ERG, it was not possible to robustly synthesise a comparison using the available data. We conclude that the STA process was suboptimal in this instance where two drugs were undergoing appraisal simultaneously. All drugs licensed for chronic ITP should ideally have been compared in a decision analytical model as part of the NICE multiple technology appraisal (MTA) process. The implications of our conclusions can be extrapolated to all drugs under assessment by NICE, and careful consideration is required as to whether these drugs should be evaluated using the STA or the MTA process.

482. DECISION MODELLING USING TIME ON TREATMENT DATA: EVALUATING THE SURVIVAL BENEFIT OF NILOTINIB VERSUS IMATINIB IN PATIENTS WITH CHRONIC PHASE CML

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Background: The ENESTnd randomised controlled trial demonstrated that nilotinib in newly diagnosed Philadelphia chromosome positive (Ph+) chronic phase chronic myeloid leukaemia (CML) has clinical superiority in terms of molecular and cytogenetic response over imatinib. However the exact relationship between improvements in major molecular response (MMR), complete cytogenetic response (CCyR) and improvements in long-term survival is as yet unknown.

Objectives: (1) to evaluate the survival benefit of first-line nilotinib compared to first-line imatinib for the treatment of Ph+ chronic phase CML, and (2) to develop a decision analytic model which avoids the uncertainty of using surrogate response outcomes in economic evaluations.

Methods: A decision analytic model of first-line nilotinib compared to first-line imatinib was constructed for newly diagnosed chronic phase Ph+ CML patients. Time on treatment data from the ENESTnd trial was used to model the effectiveness of nilotinib and imatinib. This approach allows the explicit modelling of all treatment failures (patients who fail to achieve or lose response, experience intolerable adverse events or those who discontinue treatment) and provides a measure of those that continue to benefit from treatment.

Results: The mean undiscounted survival was estimated to be 11.80 years in the nilotinib arm compared to 10.44 years in the imatinib arm; a difference of 1.36 life-years (LYs). Using a discounting rate of 3.5%, patients will accrue an additional 0.88 LYs in the nilotinib arm compared to the imatinib arm.

Conclusions: The results suggest that nilotinib produces substantially greater long-term survival than treatment with imatinib. The use of time on treatment data avoids the need for surrogate response outcomes and their associated uncertainty.

487. COST- UTILITY OF THE VACCINE AGAINST THE HUMAN PAPILOMA VIRUS IN PERUVIAN WOMEN

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Objectives: To estimate the cost-utility of the vaccine against the Human Papiloma Virus (HPV) in peruvian women after the application of the vaccine at 10 years of age.

Methods: A cost-utility analysis was performed using the Markov´s hidden model in a hypothetical cohort of peruvian women, based on the information on epidemiological parameters, costs associated to uterine cervical cancer (UCC) and the efficacy and costs of the vaccine against the HPV. The vaccination costs were estimated from the Peruvian Ministry of Health perspective and were compared against the quality-adjusted life years (QALYs), using a discount rate of 5%.

Results: The annual cost of the vaccination was USD 16,861,490, for the Papanicoau screening it was USD 3,060,793 and the costs associated to the UCC were USD 15,580,000. The incremental cost utility ratio (ICUR) was 6,775 USD/QALY.

Conclusions: Vaccination against HPV can be cost-utility compared to not vaccinating.

488. COST UTILITY OF PREVENTIVE STRATEGIES FOR BREAST CANCER IN WOMEN IN PERU

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Objectives: Estimate the cost effectiveness of strategies to reduce mortality from breast cancer in women in Peru.

Methods: We performed a cost effectiveness analysis using Markov model, based on information from epidemiological parameters, costs associated with breast cancer and the effectiveness and costs of mammography and chemoprotection tamoxifen interventions. Intervention costs were estimated from the perspective of the Ministry of Health of Peru and compared with the years of quality-adjusted life (QALY) using a discount rate of 5%.

Results: The annual cost of the intervention with mammography was $ 13'047,050.82, for intervention with tamoxifen was $ 4'705, 800. The incremental cost effectiveness ratio (ICER) was $ 20,581/ QALY

Conclusions: None of the interventions prove to be cost effective.

489. COST ANALYSIS OF RAPID METHODS FOR DIAGNOSIS OF MULTIDRUG RESISTANT TUBERCULOSIS IN DIFFERENT EPIDEMIOLOGIC GROUPS IN PERU

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Objectives: To evaluate the costs of three methods for the diagnosis of drug susceptibility in tuberculosis, and to compare the cost per case of Multidrug-resistant tuberculosis (MDR TB) diagnosed with these (MODS, GRIESS and Genotype MTBDR plus ®) in 4 epidemiologic groups in Peru.

Methods: In the basis of programmatic figures, we divided the population in 4 groups: new cases from Lima/Callao, new cases from other provinces, previously treated patients from Lima/Callao and previously treated from other provinces. We calculated the costs of each test with the standard methodology of the Ministry of Health, from the perspective of the health system. Finally, we calculated the cost per patient diagnosed with MDR TB for each epidemiologic group.

Results: The estimated costs per test for MODS, GRIESS, and Genotype MTBDR plus® were 14.83. 15.51 and 176.41 nuevos soles respectively (the local currency, 1 nuevos sol = 0.36 US dollars for August, 2011). The cost per patient diagnosed with GRIESS and MODS was lower than 200 nuevos soles in 3 out of the 4 groups. The costs per diagnosed MDR TB were higher than 2,000 nuevos soles with Genotype MTBDR plus ® in the two groups of new patients, and lower than 1,000 nuevos soles in the group of previously treated patients.

Conclusions: In high-prevalence groups, like the previously treated patients, the costs per diagnosis of MDR TB with the 3 evaluated tests were low, nevertheless, the costs with the molecular test in the low-prevalence groups were high. The use of the molecular tests must be optimized in high prevalence areas.

502. BURDEN OF DISEASE OF DIABETES MELLITUS – CONSEQUENCES FOR CAPACITY PLANNING

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Objectives: For health care planning epidemiological data to define the population at risk is necessary. This information is therefore used for capacity planning of the healthcare system infrastructure. It is used for modelling of the change of service utilization due to the aging of the population. And it is the basic of the estimation of health care need based on real life data.

Methods: First we gathered anonymised claims data of all Austrian social insurance companies of the years 2006 and 2007. Secondly we categorized all persons, where claims for pharmaceutical treatment were settled, to ICD9 groups. So we generated a rough epidemiological overview showing the most common health problems with prevalence and incidence, their regional, gender and age distribution. Thirdly we prioritized the field of diabetes mellitus. This disease belongs to the ICD9 group 250 – 259 (2007: 506.311 persons). The prevalence therefore is 6.1% of the official population and 5.2% of the social insurance population.

Results: The difference between these populations and methodologies is important. The DM population coming from a selection of medications by experts contains 351.707 (302.823 DM II respectively – second source) people. The health survey estimates 353039 people with diabetes according to the questions used. The register of type I diabetes showed 1316 children in 2007, the expert approach 1257 and the ATCàICD categorization 3799 entries. The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. As this is not a specific epidemiology for Europe another study reports that the ratio of previously undiagnosed diabetes ranges from 1: 2 in the U.S.A. to 1: 1 in Europe. It is estimated that in Europe, 12% of people aged 60 years or above are treated for diabetes, another 15% have undiagnosed diabetes and, in addition, about 30% have IGT.

509. COST-CONSEQUENCES EVALUATION OF POC TEST FOR CD4 CELLS IN BRAZILIAN HEALTH SYSTEM

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Background: The Brazilian response against AIDS has been seen as a success story and it is frequently cited as a model for other developing countries facing the AIDS epidemic. In Brazil, the CD4 tests are performed in centralized laboratories, but the expansion of ART program into rural areas, such as Amazon region, brings the necessity to improve the laboratory logistics to carry out patients needs.

Objectives: To estimate the related costs of introducing POC test for CD4 cells in Brazilian Health System and identify scenarios and benefits of the introduction of POC test for CD4 cells.

Methods: A costing instrument was designed to collect cost data related to ART treatment. The costs related to both tests (standard and POC CD4) were collected and compared. In addition, a sort of different scenarios and benefits related to the introduction of POC test for CD4 cells were identified and organized in different group of information (geographic, logistics, etc.).

Results: The analysis of costing instrument data denotes a similar estimated costs for each CD4 test strategies. In terms of financial resources, the cost analysis demonstrated that the introduction of POC CD4 test can be a feasible strategy, and also can reflect in the quality of ART treatment, especially in Amazon region.

Discussion: As well as in other developing countries, in Brazil the CD4 lymphocytes counts are used as a tool for monitoring the disease progression and the effectiveness of ARV treatment for AIDS patients. It is not uncommon to identify delays in CD4 testing results in the central laboratories and it can result in loss of patients who do not return or who die before initiating treatment. With the introduction of POC CD4 test is expected a reduction of problems related to logistics and geographic aspects related to the Brazilian health system.

Implications for the health system/professionals/patients: The introduction of POC CD4 test can alleviate testing burdens at centralized laboratories and also it can improve CD4 test access in rural areas, such as Amazon region.

537. ECONOMIC BURDEN OF COMMUNITY-ACQUIRED PNEUMONIA AND INVASIVE PNEUMOCOCCAL DISEASES IN ELDERLY: THE ITALIAN SITUATION

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Background: Streptococcus pneumoniae (Spn) is the most common cause of Community-acquired pneumonia (CAP) and invasive pneunmococcal diseases (IPD) in the elderly population.

Objectives: The objective of the analysis was to estimate the economic burden of disease caused by Spn in Italy by considering people aged > 65 years.

Methods: A cost of illness analysis was performed from the Italian National Health Service (NHS) perspective. Therefore, only direct

medical costs were taken into account. The main cost drivers were as follows: diagnosis, visits to GPs, drugs, hospitalizations. Regarding epidemiological and economic data input, incidence rates were taken from the national literature and unit costs (€2010) from national tariffs. The literature search, conducted between July 2000 and July 2011, was performed by consulting PubMed e Ovid. Search terms used were as follows:" Streptococcus pneumoniae", "invasive pneunmococcal diseases", "Community-acquired pneumonia", "cost", "economic".

Results: The current analysis showed that hospitalization represents the main cost driver. Regarding visits to GPs, annual average cost was €53.9 per patient (€1.267.458 population). Regarding diagnosis, annual average cost was €52,82 per patient (€1.242.062 population). Regarding drugs, antibiotic prescription absorbs a significant amount of resources (€2.257.440 annually/patient). Furthermore, the overall hospitalization costs due to Spn was €175.837.848 annually.

Discussion: The analysis showed that the total cost due to Spn diseases was more than €180 million annually. Nevertheless, this value does not consider costs related to sequelae due to IPD and CAP, because of a lack of data at national level. Therefore, it would be necessary to conduct further analyses with the aim to investigate also these costs in order to give a comprehensive picture of the costs related to Spn diseases.

Implications for the health system/professionals/patients/society: Considering the high costs due to streptococcal diseases it would be necessary to consider the implementation of vaccination strategies in the elderly population.

538. COST-EFFECTIVENESS OF DENOSUMAB VERSUS ZOLEDRONIC ACID (ZA) FOR THE PREVENTION OF SKELETAL-RELATED EVENTS (SRE) IN PATIENTS WITH BONE METASTASES (BM) FROM CASTRATION-RESISTANT PROSTATE CANCER (CRPC) IN SWEDEN, SWITZERLAND AND PORTUGAL

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Background: Prevention of the painful, debilitating and costly skeletal consequences of BM is an important goal of therapy.

Objectives: Assess the cost-effectiveness of denosumab (120mg Q4W) versus ZA (4mg Q4W) in the prevention of SREs in men with CRPC and BM in Sweden, Switzerland and Portugal based on results reported in a phase III, head-to-head, randomised, double-blind clinical trial (ClinicalTrials.gov: NCT00321620).

Methods: A three-state Markov model was developed. In the absence of available real-world SRE rates, ZA SRE rate was estimated from the clinical trial and used together with the trial-based treatment effect (1st and subsequent SRE rate ratio) for densoumab versus ZA to estimate the denosumab SRE rate. Overall survival was similar between the treatment arms and assumed equal in the models. For extrapolation beyond trial duration, overall survival was estimated using generalised gamma parametric distribution. Analyses were based on a lifetime horizon. SRE-related utility decrements were derived from a time-trade-off study. Treatment costs, SRE-related costs and administration costs were based on local data. Costs and outcomes were discounted at 3%.

Results: Denosumab was dominant versus ZA, due to fewer SREs, higher QALYs and lower total costs. Incremental QALY gains of 0.041 were predicted, with total cost savings per patient of € 2,946, €7,555, and €1,053 in Sweden (9.1 SEK/€), Switzerland (1.20 CHF/€) and Portugal, respectively. Deterministic and probabilistic sensitivity analyses confirmed the robustness of results. Probabilistic analyses indicate that denosumab offers overall cost-savings with a probability of 1.0 in Sweden and Switzerland and 0.95 in Portugal.

Discussion: Denosumab is dominant versus ZA, offering superior efficacy with fewer SREs, improved QALYs and lower total cost. The results are based on the use of trial-based SRE rates, potentially underestimating the annualised SRE rates and value of densoumab.

Implications for the health system/professionals/patients/society: Denosumab represents good value for money in the prevention of SREs in CRPC patients with BM.

541. COST-EFFECTIVENESS ANALYSIS OF INDACATEROL VERSUS FIXED-DOSE COMBINATIONS (FORMOTEROL + BUDESONIDE AND SALMETEROL + FLUTICASONE) FOR PATIENTS WITH COPD IN COLOMBIA

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Background: Indacaterol 150 µg is a once-daily, long-acting-beta$_2$-agonist (LABA) used for the treatment of chronic obstructive pulmonary disease (COPD). Its cost-effectiveness has not yet been evaluated against fixed-dose combinations drugs consisting of a LABA combined with an inhaled corticosteroid.

Objectives: The main objective was to estimate the cost-effectiveness of indacaterol 150 µg compared to salmeterol/fluticasone 50/500 µg (SAL/FLU) and formeterol/budesonide 9/320 µg (FOR/BUD) in the Colombian setting. A second analysis was undertaken against tiotropium (TIO).

Methods: A previously published Markov model was utilized. Its structure reflected the initial improvement and progressive reduction in Forced Expiratory Volume in 1 second (FEV1) experienced by COPD patients. Health-states in the model were distinguished by FEV1% predicted according to the 4 GOLD-severity stages using pre-bronchodilation values. Each state consisted of sub-states accounting for treatment discontinuation. Efficacy was based on the initial improvement in FEV1, either taken from a published mixed-treatment-comparison (SAL/FLU and FOR/BUD) or from a randomized controlled trial (TIO). Colombian direct costs and life tables were incorporated in the adaptation, and performed from a healthcare payer perspective, discounting future costs (in Colombian pesos COP and US-dollars at purchasing power parity (Int$)) and benefits at 5%.

Results: Within a 5 and 10 years horizon, indacaterol 150 µg was estimated to be dominant; thus saving COP 0.8 million (Int$574) and 1.0 million (Int$709) versus SAL/FLU and COP 1.6 million (Int$1,229) and 2.0 million (Int$1,517) versus FOR/BUD, and increasing the number of life-years. The number of quality-adjusted-life-years (QALYs) gained after 5 and 10 years was 0.006 and 0.010 versus SAL/FLU and 0.012 and 0.021 versus FOR/BUD. The incremental-cost-utility-ratio against TIO was COP 1.4 million (Int$1,069) and 4.2 million (Int$3,124) per QALY after 10 and 5 years respectively.

Discussion: The results indicate that by replacing SAL/FLU or FOR/BUD with indacaterol there are possible cost-savings for the Colombian healthcare system, especially since the Colombian COPD (spirometric) incidence is estimated to be 8.9%.

542. BUDGET IMPACT ANALYSIS OF THE USE OF DIRECT LATERAL INTERBODY FUSION (DLIF) TREATMENT IN SPINAL FUSION SURGERY

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Background: Spinal fusion surgery for the treatment of degenerative spinal diseases is a widespread and costly malady. Direct Lateral Interbody Fusion (DLIF) allows for complete discectomy, distraction, and interbody fusion without the need for an approach surgeon. Several reports have reported the safety of the approach, and the short term clinical benefits. However, no published studies to date have reported the budgetary impact the use of DLIF treatment.

Objectives: To evaluate the budgetary impact of spinal fusion surgery with DLIF treatment compared with standard anterior spinal intervertebral fusion treatment.

Methods: A budgetary impact analysis was done comparing the budget impact of DLIF treatment with standard Anterior Lumbar Interbody Fusion (ALIF) treatment. Inputs were cost of spinal surgery cost with additional cost of intervertebral cage, length of stay and the rate of re-operation. Baseline cost data and resource utilization came from Health Insurance Review & Assessment Service Agency (HIRA) and National Health Insurance Corporation (NHIC). Likely utilization of the DLIF treatment, the length of stay and the rate of re-operation were determined from epidemiological and clinical evidence.

Results: For DLIF treated patients, savings due to reduced hospitalizations and shorter length of hospital stay were $1,889 and 2.9 days respectively. Subtracting the cost of DLIF treatment from the standard care projected net saving of $1,619,609 yearly.

Conclusions: Addition of DLIF treatment to usual care in this model analysis resulted in a net cost saving compared with standard treatment. Substantial cost savings were realized, regardless of variation in additional cost of intervertebral cage and length of stay.

547. ROBOTIC ASSISTED RADICAL PROSTATECTOMY (RALP) WITH "DA VINCI SURGICAL SYSTEM": CLINICAL OUTCOME, AND COSTS

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Background: Robotic Assisted Radical Prostatectomy (RALP) is one of the more costly urological innovations. Prices ranging from 693.866 € to 1.734.66 € for each unit, without taking into account costly maintenance and the use of additional consumables.

Objectives: We evaluated the outcomes, and costs comparing RALP vs open retro-pubic radical prostatectomy (RRP) performed in our Hospital.

Methods: We compared 54 RALP, and 50 RRP in terms of costs (amortization, maintenance service, consumable equipment, surgical and anesthesia equipment), and clinical outcomes (length of Hospital Stay, continence and potency rate). To evaluate if the tariffs for reimbursement cover the cost of RALP we used the break even point technique, for which identifying the point where the total revenue is just sufficient to cover the total cost.

Results: RALP evidenced lower hospitalization ($p < 0.01$), higher early continence rate ($p < 0.01$), and better potency rate in nerve sparing procedures ($p < 0.01$). Single case costs were 10.481 € for RALP, and 4.469 € for RRP respectively. The point where the total revenue is sufficient to cover the total cost is 367 RALP.

Discussion: Our analysis shows that, RALP's costs are higher than RRP, as in the Literature, (7.780 € for RALP, and 6.355.84 € for RRP respectively).

Conclusions: To balancing cost-effectiveness we suggest to increase the number of patients treated byRALP. The major limitations of our study are that costs of surgery, anesthesia, and operating room occupancy can be different from each hospital.

Implication for the health system/professionals/patients: Although RALP shows a good outcome for patients, its low use can lead to waste of scarce resources by the health care system.

550. A MODEL TO EVALUATE AN ORAL ONCOLOGY TREATMENT COMPARED WITH A TRADITIONAL TREATMENT ACCORDING TO THE HEALTH TECHNOLOGY ASSESSMENT (HTA) APPROACH: CAPECITABIN VS 5-FLUOROURACIL

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Background: In Italy colorectal cancer is among the leading causes of death. Every year, 240 new colorectal cancer patients are treated with chemotherapy at the University Hospital of Udine (AOUD). Endovenous 5-fluorouracil (5-FU) is the *gold standard* in the treatment of the metastatic disease.

Objectives: We compared oral capecitabin with 5-FU among AOUD colorectal cancer patients, through a multidimensional analysis.

Methods: Efficacy and safety were evaluated through literature review using the main medical, pharmacological, and HTA databases and the AOUD *HTA Engine*. To assess quality of life, the FACT-C questionnaire is being administered to AOUD patients. To assess the organizational impact we examined both literature and ad hoc collected data. We also compared the costs (technology, preparation, administration) of capecitabin and 5-FU (FOLFOX 4 and FOLFIRI 6 protocols).

Results: Capecitabin was at least as effective as 5-FU, even in terms of survival, with a better safety profile.

Discussion: According to preliminary data collected in AOUD from 3 patients treated with capecitabin and 10 with 5-FU, the first appeared more satisfied of how they faced their disease; also, they seemed to work and sleep better than the others. Adverse events were reported by 2 patients treated with capecitabin (leading to a telephone call to the oncology ward and to an Emergency Room access) and by 7 patients with 5-FU (leading to 3 telephone calls to the oncology ward, 2 pharmacological treatments, 1 unplanned oncologic visit, and 1 hospital admission). The cost of a treatment cycle was 395.84€ for capecitabin, 255.41€ for FOLFOX 4, 303.93€ for FOLFIRI6.

Implications for the health system: Oral capecitabin resulted a potentially advantageous alternative to endovenous therapy for many patients and for the hospital organization.

554. ECONOMIC EVALUATION OF TREATING MODERATE TO SEVERE RHEUMATOID ARTHRITIS PATIENTS WITH ADALIMUMAB: A COST UTILITY ANALYSIS BASED ON AN OBSERVATIONAL STUDY IN GREECE

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Background: Because of significant differences in national health care systems results of existing pharmacoeconomic analyses need to be independently tested across a spectrum of different countries to confirm the applicability of their findings. We sought to evaluate the treatment of patients with moderate to severe RA with adalimumab, both in terms of health outcomes and costs in Greece.

Methods: A cost utility analysis was performed based on a 52-week, multicenter, single-arm, observational study for the health economic evaluation of treatment with adalimumab compared with traditional treatment in Greek patients with RA. In total, 76 patients out of 124 enrolled, completed the study and were present at all 4 visits (at baseline and 3, 6, and 12 months). During each visit, patients completed the EuroQol-5 Dimension (EQ-5D) questionnaire and reported all costs incurred during the preceding 3 months. The health outcomes were measured in terms of quality-adjusted life years (QALYs) based on the EQ-5D derived utilities. The costs were calculated based on the local unit costs multiplied with the volume of each resource used for each patient.

Results: The QALYs and costs reported after 1 year of administration of adalimumab were compared to the equivalent QALYs and costs reported at baseline. The total direct costs were €201,355.6 at 12 months and €20,920.05 at baseline. The relevant QALYs were 47.18 and 33.94 at 12 months and baseline, respectively. The resulting incremental cost-effectiveness ratio (ICER) was €13,628.06 per QALY.

Conclusions: Compared with traditional treatment, treatment with adalimumab is associated with an ICER of €13,628.06/QALY which is significantly less than the threshold of €50,000/QALY and better health outcomes. Adalimumab is a cost-effective treatment in Greek patients with moderate to severe RA.

564. USE OF QALY IN DIFFERENT CLINICAL SITUATIONS

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Introduction: Quality-Adjusted Life-Years (QALYs) are increasingly used in the evaluation of health interventions and have been recommended by NICE for use in cost-effectiveness analyses of health technologies. However, the assigned algorithm underlying conventional cost-effectiveness analysis has been criticized on the basis of theoretical arguments and empirical studies.

Objective: To identify attributes which are potentially useful for the estimation of equity weights or relative social values of health gains, measured in QALYs.

Methods: A review of the literature was made. The search was conducted in the usual databases of articles on health economics, supplemented by a manual review of references.

Conclusions: The evidence shows that citizens are willing to relinquish the maximization of health gains for society in order to benefit certain population groups, depending on the characteristics or attributes studied in this work. Severity is considered one of the most important factors to be taken into account in making healthcare decisions. The existence of a "threshold", or minimum level, is noted at which severity is important and which may be at 30% of normal health. The benefits of treatment are generally considered to be of high importance, second only to severity. There is less support for the prioritization of patients with less potential for improvement. The evidence regarding *age* shows that there is limited support for its use as a rationing criterion. The population may favour the dissemination of additional gains over a larger number of people, provided that the size of the gain is large enough. The evidence regarding other attributes is scarce and ambiguous: direction of change in health, cost of the intervention or personal characteristics of beneficiaries.

640. BUDGET IMPACT ANALYSIS OF MAJOR DEPRESSION AFTER CYP450 GENOTYPING WITH BRAINCHIP TESTIN SPAIN

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Background: Approximately 30-40% of patients with major depressive disorder (MDD) do not respond to antidepressant medication. It has been observed that those treated with the same drug dose show differences regarding therapeutic response and adverse effects occurrence. These differences can be explained by genetic biomarkers, as genes encoding CYP450 isoenzymes, which are involved in antidepressant drugs metabolism. BrainChip test screens the polymorphisms of these enzymes allowing to predict the individual response to pharmacological antidepressant treatment.

Objectives: To develop a budget impact model to analyze the addition of BrainChip test before drug prescription in MDD after first line treatment failure in Spain.

Methods: A Markov model was developed after simulating regimen therapy changes derived from BrainChip test addition. Clinical parameters were collected from literature reviews, and health resource use and costs were adapted to the Spanish context. Results were analyzed under the National Health System (NHS) perspective after the 1st, 2nd and 3rd year after BrainChip addition. A 3% discount was considered for effects and costs (euros 2011).

Results: 24,308 out of 64,713 patients could receive an alternative therapy based on the results of BrainChip information. Adding BrainChip to the NHS could yield to 13.6 million euros savings (6.8% of the budget) for three years considering direct costs, and 194.4 million euros in terms of total costs (direct and indirect).

Discussion: BrainChip may reduce health care costs in the management of MDD for the NHS.

Implications for the health system: Regimen changes in antidepressant therapy that improve the efficacy for the system.

644. TECHNOLOGY ASSESSMENT OF COMPUTER-ASSISTED PAP TEST SCREENING IN ITALY: NOW AND IN THE HPV TEST AND VACCINE ERA

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Background: Cervical cancer is a disease which is highly controllable through screening. In Italy the target population for cytological screening (25-64 years) is about 17 million, about 6 million women to be screened every year according to the three year interval recommended by Italian Guidelines and including follow up and repeated smear for unsatisfactory samples.

Objective: to assess the introduction of computer screening into routine practice, considering various scenarios: conventional and liquid-based slides, fully automatic instrumentation (Becton Dickinson FocalPoint Slide Profiler and Hologic ThinPrep Imaging System) and semiautomatic scanner (Hologic Integrated Imager I-Squared).

Methods: a Working Group, including researchers from the largest centres already using instrumentation, was selected. The centres completed a questionnaire on organisational ethical-social problems, operating procedures and annual workload. The cost data were obtained directly from the companies concerned. The scope of the report and final draft were submitted to a Consulting Committee of the various stakeholders.

Results: The break-even point was found to be 49,000 cases/annum if traditional slides are used, while liquid-based slides can reach the theoretical maximun capacity of the machine, 70,000 cases/annum. Efficiency increases when volume of slides per year and productivity per screener increase. Computer-assisted cytology reduces screening time by about 2/3 for conventional slides and by less than 1/2 for liquid-based slides. Acceptance of the new instrumentation by the cytoscreeners is good and the learning curve is very short.

Discussion: Computer-assisted automated scanning may be introduced only if there is a need to increase the volume of slides screened to cover the screening target population but there are not sufficient human resources available. Changes in HPV epidemiology as vaccinated women reach screening require caution. Furthermore, primary screening with HPV tests will drastically reduce the need for Pap test reading.

Implications for the health system: In most situations the introduction of computer-assisted automated Pap-test will mean additional costs.

648. HOSPITALIZATION COSTS ANALYSIS OF SPINAL FUSION PROCEDURES: COMPARISON OF MAST AND OPEN SURGERY SURGICAL APPROACH

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Background: Most spinal fusion procedures can be performed according to different surgical approaches: MAST™ (Minimal Access Spinal Technology) and Open surgery (OS). MAST™ aims at reducing surgical trauma, blood loss and post-operative pain compared to OS as well as reducing hospital length of stay (LoS) and accelerating patient's return to normal activities.

Objective: To compare hospitalization costs associated with the two surgical approaches (MAST™ vs. OS) in patients with degenerative spinal disorders.

Methods: The study was performed according to a micro-costing approach in two Italian hospitals in which the learning curve could be considered completed. Patient care pathways for both surgical approaches were mapped through interviews with medical staff and the resource consumption during hospitalization was valorized considering direct and indirect costs (staff time, diagnostic tests, drugs/consumables, operating room and general expenses) and according to hospital perspective. Unit costs were collected from hospital accounting and standard tariff lists. Costs were compared between pathways from admission to the follow-up after discharge.

Results: In both hospitals MAST™ was associated with less overall resource use mainly due to a shorter post-operative LoS (2 vs 4 days), less blood loss and less demanding wound care. If the pre-hospitalization and follow-up phases resulted in similar resources consumption, significant differences emerge in surgery and post-surgery episodes. There was a 67% decrease of costs in consumables, 31% in general/common costs. These offset the higher cost for spinal implants and saved 7% overall compared to OS. The total cost associated with MAST™ corresponds to 76% of an average DRG tariff of 10,000€ in Italy.

Discussion: This study confirms the economic benefits associated with MAST™: despite higher initial investment (instrumentation, learning curve), it is an effective and cost-saving alternative to OS. The information can be used in the assessment of minimally invasive options from the hospital perspective.

653. COST-EFFECTIVENESS ANALYSIS OF TELESPIROMETRY IN A PRIMARY HEALTH-CARE ENVIRONMENT

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Background: The use of ICTs in spirometry quality assurance programmes would prevent unnecessary costs to the health system by improving their quality.

Objectives: To perform a cost-effectiveness analysis of a telemedicine project in spirometry (telespirometry) quality assurance programmes in the primary health-care field.

Methods: A cost-effectiveness analysis comparing a telespirometry procedure (TSP) with a normal spirometry procedure (NSP) was performed on the basis of a nine-month multicentre trial undertaken by the Pneumology Department at Cruces Hospital to analyse the effectiveness of telemedicine in spirometry quality assurance programmes. The perspective of this study was that of the Basque Health System funder. The effectiveness was estimated as the mean proportion of forced spirometries (FSs) of quality A and B performed for both the TSP and the NSP in 15 primary health-care centres during the study period. The direct costs to the Basque Health System, namely the software, human resources, training (for both performing the FS procedures and handling the telespirometry software) and spirometry costs, were considered. The incremental cost-effectiveness ratio (ICER) was determined and a univariate sensitivity analysis performed.

Results: The ICER is €56.08 for each additional A+B-quality spirometry using the TSP procedure. The univariate sensitivity analysis indicates that a 15% increase in the effectiveness reduces the ICER in €2 per each additional A+B quality spirometry and on the contrary, a 15% decrease in the effectiveness increases as €7 per additional A + B quality spirometry.

Conclusions: Telespirometry results in a better use of the scarce resources available in our health system by avoiding unnecessary costs whilst improving quality.

667. EFFICIENCY OF CORAIL HIP SYSTEM FOR PRIMARY TOTAL HIP ARTHROPLASTY IN SPAIN

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Objectives: The CorailTM Hip System, a hydroxyapatite coated cementless implant, has demonstrated its high efficacy and safety for primary total hip arthroplasty (THA) for over 20 years. The aim of our study was to estimate incremental health care benefits and costs of the Corail™ Hip System compared with other cementless hip designs (standard) in Spain.

Methods: A probabilistic Markov model was built in order to compare costs and outcomes associated with Corail™ hip and standard in a hypothetical cohort of potential THA. Outcome probabilities and effectiveness, expressed in Quality of Adjusted Life years (QALYs) gained, were derived from literature. All data was validated by local clinical experts. Analysis were built under the National Health System perspective and it was considered a 3% discount for effects and costs (euro 2012). Time horizon was lifetime. Deterministic and probabilistic analyses were performed.

Results: Corail™ provided a gain of 0.009–0.021 QALY after 10 years and 0.075-0.39 at lifetime. Corail™ Hip System for THA compared with the standard resulted in €1,999 per revision avoided and €2,691 per QALY gained considering a time horizon of 10 years. The result was dominant in favour of Corail™ when a time horizon of 20 years or lifetime was considered for all the scores. There were no significant differences between sexes. Sensitivity analysis also suggested that Corail™ economic profile improved when the time horizon of the model was extended. A probabilistic sensitivity analysis confirmed the findings of baseline results, showing that Corail™ was cost-effective in 74% of cases at lifetime (threshold of €30,000/QALY).

Conclusions: Preliminary results showed that Corail™ Hip System is a cost-effective option in THA compared with the rest of cementless hip trademarks available in Spain.

668. BREAST CANCER: QUALITY IN HEALTHCARE AND REDUCTION OF COSTS? MISSION: POSSIBLE!

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Background: In breast cancer therapy, diagnostic-therapeutic pathways may differ among different centres. The approach of the General Surgery Unit of the University Hospital of Udine differs from the most frequent pathways because includes stadiation through magnetic resonance imaging (MRI) for all patients and sentinel node biopsy (SNB) analysis made through extemporaneous exams. This approach, despite of wider initial costs allows, in some cases, to avoid further interventions.

Objectives: We evaluated the cost of our diagnostic-therapeutic pathway in breast cancer versus the costs of the different available approaches.

Methods: We studied patients who underwent surgery for breast cancer in our department in the last 5 years (2006-2010); analyzed variables are: execution of MRI, type and duration of surgery, duration of hospitalization. In case of mismatch MRI/basic exams (mammography, ultrasonography) or positive SNB, we indicated the necessary second surgery or the axillary lymphadenectomy. We considered the costs of every single procedure and then their sum, hypothesizing then the application of other different pathways to the same group of patients, calculating each cost.

Results: Treated 767 patients, 489 quadrantectomies (63.7%) and 278 mastectomies (36.3%). Positive SNB in 90/559 cases (16.1%). Therapy modification after MRI happened in 63 cases (10.1% of 619 MRI). A single MRI costs 323€, hospitalization 570€/day. Operatory room cost/minute is 9,4€/quadrantectomy, 8,9€/mastectomy. SNB biopsy cost is 112€ if extemporaneous, 107€ if deferred. Further surgery due to MRI exam not executed costs 5,394€, postponed axillary lymphadenectomy costs 4,081€. The entire cost of our pathway was 3,825,890€, the cost of pathway with extemporaneous analysis of SN but without MRI for all patients would have been 3,973,722€ and the cost of pathway without MRI and extemporaneous analysis of SN would have been 4,339,588€.

Discussion and implications: Data seem to show that our pathway, which allows to avoid further surgery, reduces health care costs.

669. RENAL TRANSPLANTS AT CEARÁ: HOSPITAL AND COSTS INDICATORS AT 2008-2011 - BRAZIL

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Introduction: The severe renal disease (SRD) is a worldwide problem of Public Health. In case of renal lesion advanced, it submits the patient to replace renal therapy. The renal transplant is indicated to SRD, being the patient in dialysis or in pre-dialysis phase. The high cost of renal transplant and the pressure of society by attendance of patients porters of SRD justify the realization of this study.

Objective: To describe hospital indicators of renal transplant and its related costs at Ceará, during 2008 through 2011.This work was dispensed by Ethics and Research Board of Ceará University State, so it treats basically of data rising of electronic media.

Methods: Quantitative, descriptive, observational study having as resource the data bank of Hospital Information System of Only System of Health. It was extracted informations from Ceará, 2008-2011. The State was divided into three great areas: Fortaleza, Cariri and Sobral.

Results: It prevails patients of male gender during all the four years. Age tax of sickening by 20 to 49 years old. It identified more frequency of renal transplant with deceased donor (M = 134, 5). It noticed the increasing values of costs with renal transplants in four years and two greater regions. It observed, in 2011, at Fortaleza, an increase in overall costs around 44% compared to 2008. At Cariri the increase was 119%.

Conclusions: It verified the prevail of renal transplant in patients of male gender in productive age. The number of renal transplant has increased in that period, especially in deceased donor, surely justified by the politics of organs´ captation. According national data it registers the increase of costs related to these procedures.

Implications: The increase number of renal transplants and its high costs resound in public politics of health and reinforce the need of betterments in preventive medicine and control by main co-morbidities that take to renal falency.

681. ECONOMIC ASPECTS OF INTRODUCING FIRST TRIMESTER ULTRASOUND SCREENING IN PREGNANCY

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Background: As part of prenatal care, a publicly financed routine ultrasound scan is currently offered to all pregnant women in the

second trimester. An additional scan in the first trimester has the potential to better detect cases of monochorionic twins, congenital heart defects and Down syndrome. Whether or not the current recommendation should be expanded to include an early scan is currently a heated debate in Norway.

Objectives: To assess the cost-effectiveness and cost consequences of expanding the screening programme to include a first trimester ultrasound.

Methods: Based on discussions with clinicians, two options were considered realistic to add on to the current recommendation: ultrasound in the first trimester with nuchal translucency (NT) or combined NT and blood sample. We developed a decision tree that followed pregnancies until a diagnosis was confirmed. Costs were collected from national tariffs and diagnostic accuracy from the systematic review part of this HTA.

Results: The alternative that maximises the number of detected cases, the first trimester combined test, is likely to be the most cost-effective strategy assuming a willingness to pay per detected case of more than € 51 000. This strategy is likely to double the running costs associated with ultrasound and foetal diagnostics compared to the current recommendation.

Discussion: The actual utilization of ultrasound and foetal diagnostic procedures does however seem to be higher than the levels estimated in the strategies in the model. It is therefore not evident that an expanded public programme will lead to an increase in the running costs associated with ultrasound and foetal diagnostics in Norwegian obstetric care.

Implications for the health system/professionals/patients/society: The decision of whether or not to implement early ultrasound rests heavily on other factors besides economics. However, if such a decision is made, our results may contribute to identifying the most efficient strategy.

702. AVOIDABLE COSTS OF PHYSICAL TREATMENTS FOR CHRONIC BACK, NECK AND SHOULDER PAIN WITHIN THE SPANISH NATIONAL HEALTH SERVICE: A CROSS-SECTIONAL STUDY

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Background: Back, neck and shoulder pain are the most common causes of occupational disability. They reduce health-related quality of life and have a significant economic impact. Many different forms of physical treatment are routinely used. The objective of this study was to estimate the cost of physical treatments which, despite the absence of evidence supporting their effectiveness, were used between 2004 and 2007 for chronic and non-specific neck pain (NP), back pain (BP) and shoulder pain (SP), within the Spanish National Health Service in the Canary Islands (SNHSCI).

Methods: Chronic patients referred from the SNHSCI to private physical therapy centres for NP, BP or SP, between 2004 and 2007, were identified. The cost of providing physical therapies to these patients was estimated. Systematic reviews (SRs) and clinical practice guidelines (CPGs) for NP, BP and SP available in the same period were searched for and rated according to the Oxman and AGREE criteria, respectively. Those rated positively for [greater than or equal to] 70% of the criteria, were used to categorise physical therapies as Effective; Ineffective; Inconclusive; and Insufficiently Assessed. The main outcome was the cost of physical therapies included in each of these categories.

Results: 8,308 chronic cases of NP, 4,693 of BP and 5,035 of SP, were included in this study. Among prescribed treatments, 39.88% were considered Effective (physical exercise and manual therapy with mobilization); 23.06% Ineffective; 13.38% Inconclusive, and 23.66% Insufficiently Assessed. The total cost of treatments was 5,107,720 Euros. Effective therapies accounted for 2,069,932 Euros.

Conclusions: Sixty percent of the resources allocated by the SNHSCI to fund physical treatment for NP, BP and SP in private practices are spent on forms of treatment proven to be ineffective, or for which there is no evidence of effectiveness.

720. AN ECONOMIC EVALUATION OF BLOOD GLUCOSE METERS FOR MONITORING INDIVIDUAL BLOOD GLUCOSE AND DETECTING TRENDS AND PATTERNS IN BLOOD GLUCOSE LEVELS

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Objectives: To estimate the long-term cost-effectiveness ratio (ICER) and budget impact analyses (BIA) of self-monitoring systems of blood glucose (SMBG) equipped with a device to detect glycemic trends in comparison with other models not equipped with this device.

Methods: Cost-effectiveness analysis based on clinical effectiveness data from literature and Spanish-specific costing. A Markov transition model will be used to calculate the incremental cost-effectiveness ratio (ICER) for SMGB versus the more conventional method. The model will include main events resulting from poor, short-term monitoring of blood glucose levels (hypoglycemia). The study population will include patients diagnosed with type I and type II diabetes that are being treated with insulin. The time horizon will be a patient's lifetime and the perspective will be the Spanish National Health Service (SNHS), thus only the direct costs related to monitoring blood glucose levels and complications resulting from poor self-monitoring will be included. The BIA will be done to estimate the cost of including the new technology in the SNHS taking into account data related to prevalence, hypoglycemia, and consumption.

Results: The results will determine whether or not this new device for detecting glycemic trends is cost-effective for the national health system, as well as the budget impact of its implementation. Results will be reflected in terms of cost/years of life gained.

Discussion and implications for the Health System: The self-monitoring of capillary glucose levels provides valuable information to persons diagnosed with diabetes. Such tools enhance a patient's ability to control his or her blood sugar levels, a key factor also associated with the reduction of morbidity and mortality in this group. The health system should evaluate devices designed to ensure the adequate metabolical control of this group and improve educational efforts for patient awareness. Furthermore, the frequency of self-monitoring glucose levels must be established individually according to the patient's particular characteristics and pathology.

725. A NEW ECONOMIC MODEL TO ASSESS COST-EFFECTIVENESS OF DRUG ELUTING STENTS VERSUS BARE-METAL STENTS

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Background: Restenosis is still a major problem after percutaneous coronary intervention (PCI). Drug eluting stents (DES) have been shown to reduce the incidence of this complication. However, DES have a significantly higher price than bare-metal stents (BMS), though long-term costs might be reduced due to the avoidance of reinterventions.

Objectives: This study assesses the cost-effectiveness of DES versus BMS from the Spanish National Health System perspective.

Methods: A decision analytic Markov model was developed to compare BMS versus DES for eligible population above 55 years old. Conceptually, the model assumes that patients are either well or death. "Wellness" of patients is achieved after an intervention to allocate a new stent (up to three interventions are allowed in the model) or after performing a coronary bypass. Patients may die as a result of any of these interventions, complications related to their coronary disease, as well as for any other cause. Model probabilities were derived from a meta-analysis on the latest published data from clinical trials. A life-time horizon and annual cycles were chosen. The national health system (NHS) perspective was used for the analysis. The measure of effectiveness was quality-adjusted life year (QALYs) and both QUALYs and costs were discounted (3%).

Results: Compared with BMS, DES reduce life-time costs by € 3,879.87 (DES: € 22,649.85; BMS: € 26,529.72) and increased QALYs by 0.723 (DES: 18.217, BMS: 17.494). Only by using a time horizon of 1 year did BMS show a lower cost than DES (€ 8,998.35 versus € 9,317.89), though not better effectiveness (BMS: 0.744 QUALYs, DES: 0.755 QUALYs).

Conclusions: According to the results of the study, the use of DES is more efficient in the long term when compared to the use of BMS.

749. PRECISE STUDY: TWO-YEARS EXPERIENCE WITH SPINAL CORD STIMULATION IN ITALY

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Background: Spinal Cord Stimulation (SCS) is considered to be a (cost-) effective treatment option when drugs fail to control neuropathic chronic pain, and in particular Failed Back Surgery Syndrome (FBSS).

Objectives: PRECISE study aims to confirm SCS effectiveness in the Italian clinical practice, and to evaluate its impact on resource consumption and costs related to patient management in order to provide Country-specific data for health-policy makers in Italy.

Methods: An observational, pre-vs-post data collection was developed in 9 Italian Hospitals. Enrolled patients responsive to a screening test were implanted and thereafter interviewed every 6 months up to 24 months post-implantation. Data collection included: pain intensity, disability, quality of life, direct and indirect costs. Costs [EUR 2009] were evaluated in three different perspectives: Patient, NHS, Society.

Results: Out of the 80 patients initially enrolled and screened, 72 were implanted and 55 completed the 24-months follow-up (FU). Mean pain intensity decreased from 7.4 ± 1.4 to 4.1 ± 2.5 and 45 (82%) patients reported an improved functionality at 24-month FU if compared to the baseline accordingly to the Oswestry Disability Index. EQ-VAS increased from 39 to 63 and all SF-36 domains significantly improved. With respect to the baseline, costs decreased for the patients and the Society as a whole. Including SCS related expenditures, monthly per-patient total costs incurred during the second year of FU were the following: € 142.35 (NHS), € 88.27 (Patient) and €285.69 (Society). Before implantation, with CMM alone, monthly per-patient costs were: €187.24 (NHS), €188.92 (Patient), €512.27 (Society).

Discussion: SCS appears to be effective in controlling pain, improving functionality and re-gaining a better quality of life. Economic results suggest a positive impact of the therapy in patient management costs.

Implications for the health system/professionals/patients/society: SCS could be considered for a wider adoption in the Italian NHS.

763. COST PER PATIENT AND BUDGET IMPACT PREDICTION OF DENOSUMAB VERSUS ZOLEDRONIC ACID (ZA) IN PREVENTION OF SKELETAL-RELATED EVENTS (SRE) IN PATIENTS WITH BONE METASTASES (BM) FROM SOLID TUMOURS IN SWEDEN AND PORTUGAL

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Background: SREs (spinal cord compression, pathologic fracture or surgery or radiation to bone) are painful, debilitating and costly to healthcare systems. Phase III head-to-head clinical trials in breast cancer, prostate cancer and other solid tumours demonstrated that denosumab is superior to ZA in the prevention of SREs (ClinicalTrials.gov: NCT00321464, NCT00321620, NCT0033075).

Objectives: To assess the cost per patient per year and predict budget impact, assuming patients are switched to denosumab (120mg Q4W) from ZA (4mg Q3W-Q4W), in the prevention of SREs in patients with BM from solid tumours in Sweden and Portugal.

Methods: The analyses included medication, patient management, administration and SRE-related costs. In the absence of real-world SRE rates, ZA and denosumab SRE rates were derived from the clinical trials. A one-year time horizon was assumed.

Results: The estimated cost per patient per year for ZA was €9,691 in Sweden (9.1 SEK/€) and €7,848 in Portugal. Treatment switch from ZA to denosumab was predicted to generate cost savings of €1,823 in Sweden and €797 in Portugal per patient, per year. The overall cost savings for denosumab are driven by predicted SRE-related cost reductions and lower costs associated with subcutaneous versus intravenous administration. For every 1,000 patients switched from ZA to denosumab the predicted total annual cost saving is €1.8M in Sweden and €0.8M in Portugal. Sensitivity analyses confirmed the robustness of results.

Discussion: Denosumab offers superior efficacy in patients with BM from solid tumours and lower treatment costs per patient versus ZA. Cost savings are predicted in the Swedish and Portuguese healthcare systems following treatment switch from ZA to denosumab.

The results are based on the use of trial-based SRE rates, potentially underestimating the annualised SRE rates and the value of denosumab.

Implications for the health system/professionals/patients/society: Denosumab is cost saving and should represent good value for money in prevention of SREs in patients with BM from solid tumours.

764. ECONOMIC EVALUATION OF IMMUNOSUPPRESSIVE DRUGS USED IN KIDNEY TRANSPLANTATION IN A CLINICS HOSPITAL, UNIVERSITY MEDICAL SCHOOL IN SÃO PAULO

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Background: Kidney transplantation begun in Brazil since 1960, in 2009, 4259 procedures were performed. The Chronic rejection is the main cause of graft loss. Standard immunosuppressant clinical guidelines prescribe: cyclosporine+azatioprine + corticosteroids, or alternatively substitute cyclosporine by tacrolimus, and azathioprine by mycophenolate mofetil or sirolimus.

Objective: Economic evaluation of immunosuppression for patients in first and fifth year after kidney transplantation.

Method: Retrospective, descriptive study of patients' medical records transplanted between 2004 and 2009 in the Clinics Hospital, São Paulo University Medical School. A sample of 30% of all patients was randomized into 2 groups. Group A: 5 years of immunosuppression treatment was evaluated amid 30 transplanted in 2004. Group B: evaluated one year immunosuppressive therapy on follow-up of 60 transplantees in 2009. A cross-section period from January 1st to December 31, 2009, was assessed in both groups, using 2009 values and exchange R$1.00 = US$1.00.

Results: Similar demographic data, age 46.8 ± 13.77 and 45 ± 16.65, male ratio 66% and 50%, white race 67% and 73%, 92% and 98% under haemodialysis pre-transplantation, respectively in Group A and B; as well as the prevalence of immunosuppression induction with non depleting antibodies (80% and 68%) and maintenance with combinations of drugs: prednisone, mycophenolic acid (mycophenolate mofetil/sodium) and tacrolimus. The average daily cost of immunosuppressants for each patient in the Group A was US$ 12.64 ± 7.44 maintenance and for those transplanted in 2009, Group B, it was US$ 30.32 ± 10.24; (p = 0.0022). Survivors at the 5th year immunosuppression post-transplantation used 50% less drugs as compared with those in the first year in 2009.

Conclusions: Required immunosuppression proved to decrease along follow-up. Itemized therapy and local acquisition costs have promoted better kidney transplantation program planning, favor Registry-like studies and prepare basis to ascertain cost-effectiveness of emergent and costly pharmaceuticals, often used in combinations.

776. USE OF ANTI-MICROBIALS IN PATIENTS HOSPITALIZED IN INTENSIVE AND SEMI-INTENSIVE CARE UNITS IN TERTIARY PUBLIC HOSPITAL OF CEARÁ-BRAZIL

Waldelia Maria Santos Monteiro[a], Regina Claudia Furtado Maia[b], Solange Cecília Cavalcante Dantas[a], Adriana Rocha Solon[a], Bráulio Matias de Carvalho[a] and Marcelo Gurgel Carlos da Silva[b]

[a]Secretaria de Saúde do Estado do Ceará. Brazil. [b]Universidade Estadual do Ceará. Brazil.

Introduction: The assistance in Intensive Care Unities (ICU) is constantly challenged by systemic infections that result in increase of morbidity and mortality, at time of hospitalization and at costs with health.

Objective: To describe the consume of anti-microbials in UIT and semi-intensive in public hospital, relating it to severity and costs´ score.

Methods: Observational, transversal study through reports of consume of ATM of Pharmacy´s service and data bank of Board of Hospitalar Infection´s Control. It was considered the ATM administered by parenteral via in patients of 4 ICU and semi-intensive at 2011 year, in public hospital, majored in heart-breath diseases. The variable used were Daily Doses Defined by 100 rooms-day, score of severity ASIS (Average Severity of Illness Score) and costs in dollar (USD).

Results: It was available U$1,436,479.00 to all classes and presentations of ATM at hospital. The cost of ATM inject to unities available was U$ 513,508.22, where the carbapenems got a higher cost with 40.7%, followed by anti-fungi (20.8%). The poliximina got the greater consume in DDD, with 390 DDD/100 rooms-day. Regarding the severity score, the heart-lung ICU got highest score (ASIS = 3.9). At general unities´evaluation, the main valors were: poliximina (126.7), glicopeptide (124.7) and carbapenens (114.3).

Conclusion: The costs analysis with anti-microbials showcased percent and currencies values elevated, having as main classes carbapenems, anti-fungi and poliximina. The criteria of correct use of anti-microbians is not easy to be established and the high consume of poliximina reveals the difficulty of bacterial multi-resistance at ICU studied.

Implications: The microbial resistance promotes economic impact to public health system, with excess of costs, unbalancing resources commonly rare, as well as, rise the risk of exposure to severe infections in community.

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784. A COST-UTILITY ANALYSIS OF UNINVESTIGATED DYSPEPSIA MANAGEMENT IN COUNTRIES WITH HIGH PREVALENCE OF HELICOBACTER PYLORI

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Background: Uninvestigated dyspepsia is highly prevalent in western countries, accounting for 8% of the primary care visits. Cost-efectiveness studies of UD management were conducted mainly in countries with low H.pylori prevalence.

Objectives: Describe the cost-utility ratios of the main alternatives for managing uninvestigated dyspepsia in areas of high prevalence of Helicobacter pylori.

Methods: An analytical model describing the natural history of uninvestigated dyspeptic patients according to Rome III was built. Etiology of dyspeptic symptoms, utilities, prevalence of Helicobacter pylori, treatment effectiveness and study resource utilization and costs were measured in a large clinical trial conducted at Brazil (HEROES trial). Long-term transition probabilities in a time horizon of 5 years were established through literature review. Five strategies were considered: immediate endoscopy; test proton pump inhibitor (PPI) empirical test and endoscopy, test and treat; PPI and empirical treatment with antacids. Probabilistic analysis was performed and the results were expressed as major acceptability curve.

Results: Antacid and PPI strategies have been dominated by empirical strategy IBP/Endoscopy. The incremental cost-effectiveness of immediate endoscopy strategy was US$3068. The test and treat strategy was dominated by immediate endoscopy strategy.

Discussion: In a very low-income setting use of PPI for 3 months followed by endoscopy for refractory patients was the most cost-effective strategy. According the cost-per-QALY threshold recommended by World Health Organization, for countries with annual per capita income higher than a thousand US Dollars, immediate endoscopy was a cost-effective approach.

Implications for the health system/professionals/patients/society: According our data, in highly prevalent Helicobacter pylori middle-income countries, immediate endoscopy was a cost-effective strategy at a cost of US$3068 per QALY. This result contrasts with findings of developed countries with low prevalence of H.pylori where test and treat strategy has been advocated.

786. ECONOMIC EVALUATION OF DABIGATRAN IN ITALY

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Stroke is the most frequent event related to embolic Atrial Fibrillation. In Western countries it is estimated an annual cost of € 3,000, which, on the Italian population, (756 000 subjects) causes a potential expenditure of € 2.268.000.000 (about 2% of total public health expenditure) The purpose of this study is to assess the cost-utility ratio of dabigatran etexilate (Pradaxa) in comparison with warfarin and no treatment in patients with atrial fibrillation (AF) in Italy. The cost-utility was performed using a bayesian Markov model which consists of 23 primary health states (15 permanent and 8 temporary). The cost-utility analysis followed a third party payer perspective. Clinical data were derived by weighting the results of RE-LY study and were adapted to the Italian organizational context. The preliminary results (the price of the drug will be negotiated with aifa in 2012) show an incremental costs per life year gained (LY) and an incremental cost/QALY, which are below the international standards of sustainability. Concerning the comparison with the to warfarin therapy the ICER is € 21,239/LY (< 80 years) and € 19 041/LY (80 + years) or € 20,512/QALY (< 80 years) and € 19 192/QALY (80 +). Concerning the comparison with no treatment the ICER is € 7,190/LY (< 80 years) and € 5535/LY (80 +) or € 7,217/QALY (< 80 years) and € 5301/QALY (80 +). The sensitivity analysis shows how, in the case of comparison with no treatment, the ICER is lower of € 30,000/QALY for 65% < 80 which are administered a dose of 150 mg. This probability rises to 95% for individuals < 80 which are administered a dose of 110 mg. Compared with warfarin the probability of dabigatran to be cost effective are 100% for < 80 individuals and 50% for > 80 individuals. In conclusion dabigatran is showed to be a cost effective solution for patients with AF.

787. COST-EFFECTIVENESS OF SIROLIMUS FOR MAINTENANCE TREATMENT OF KIDNEY TRANSPLANTATION

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Immunosuppressive drugs are essential for the maintenance of renal transplantation. Sirolimus (SRL), a rapamycin inhibitor, can replace in a regimen of calcineurin inhibitors, cyclosporine (CsA) or tacrolimus (TAC), or one of antimetabolites, azathioprine (AZA) or mycophenolate mofetil (MMF). According to the protocols, the immunosuppressive regimens should be composed with a steroid, usually prednisone (P). The aim of this study was to evaluate cost-effectiveness of the schemes using sirolimus in maintenance renal transplant. For the cost-effectiveness analysis it was used the Markov model, assuming a hypothetical cohort of patients for each of the following regimens: CsA+SRL+P, TAC+SRL+P, SRL+MMF+P and TAC+MMF+P used as comparator. The hypothetical cohort was established based on the characteristics of renal transplant recipients in Brazil and the duration was 20 years. It holds patients of both sexes with average age of 38 years. In the model, the health stages of transplant recipient could be: healthy alive transplanted (initial state of health), acute rejection, dyslipidemia, skin cancer, CMV infection, graft loss followed by dialysis and death of the patient. Estimates of effectiveness and costs of the health stages were obtained from the literature. The cost was expressed in U.S. dollars and effectiveness in life years (LY). A comparison of the alternatives was performed using incremental cost-effectiveness ratio (ICER). It was observed that scheme TAC+SRL+P presented the highest effectiveness with 16LY. TAC+MMF+P showed the best ICER result. The strategies SRL+MMF+P was dominated, TAC+SRL+P and CsA+SRL+P showed incremental effectiveness of 0.6 and 1.0LY with costs U$: 56.369 and U$: 35.060 respectively. These costs were much higher than the limits of willingness to pay allowed by World Health Organization (three times the Brazilian GDP per capita). Considering a scenario where only these schemes were available, it is concluded that TAC+MMF+P proved to be the most cost-effectiveness.

798. COST-EFFECTIVENESS OF NUCLEOS(T)IDES ANALOGUES FOR CHRONIC HEPATITIS B IN BRAZIL

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Chronic hepatitis B is a disease of high prevalence; 350 million of cases worldwide and one million deaths per year are estimated. The aim was to assess the cost-effectiveness of adefovir dipivoxil, entecavir, lamivudine and tenofovir for the treatment of chronic hepatitis B in adults without HIV coinfection, from a Brazilian public health system's perspective. Using Markov model, we constructed hypothetical cohort of 40 years for HBeAg-positive patients and other to HBeAg-negative patients. The outcome of treatment efficacy in HBeAg-positive patients was HBeAg seroconversion. In HBeAg-negative patients was considered viral DNA bellow 400 copies/mL. The cost, expressed in U.S. dollars, was estimated according to the literature and official data from the Brazilian government, and was evaluated for the year 2011. The effectiveness was expressed in life years (LY). Considering the clinical responses, entecavir and tenofovir showed better results compared to adefovir dipivoxil and lamivudine for treatment efficacy, protection for disease's complications and development of viral resistance. Treatment with adefovir dipivoxil showed higher cost and lower effectiveness. In HBeAg-positive patients, treatment with lamivudine has demonstrated higher cost and lower effectiveness compared to entecavir and tenofovir. The lowest cost-effectiveness ratios were for entecavir in HBeAg-positive patients (US$2,289.29/LY) and lamivudine for HBeAg-negative patients (US$3,541.71/LY). For HBeAg-negative patients, the incremental cost-effectiveness ratio of entecavir (US$8,048.54/LY) is below the threshold recommended by WHO (three times the Brazilian GDP per capita; US$32,561.64). Sensitivity analysis showed that variation in the cost of drugs may become tenofovir cost-effective alternative in comparison to entecavir. However, there are few published clinical trials that evaluated clinical outcomes of these treatments. Considering the published studies on the treatment of chronic hepatitis B, entecavir and tenofovir are recommended alternatives for the treatment of chronic hepatitis B in Brazil. Further studies are needed to strengthen this evidence.

799. ASSESSMENT OF THE DEMAND AND THE FINANCIAL IMPACT OF THE ISOTRETINOIN IN SPECIALIZED COMPONENT OF PHARMACEUTICAL SERVICES (CEAF) IN 2011, MINAS GERAIS (MG), BRAZIL

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Background: Isotretinoin, medicine used to treat severe acne has been the subject of various studies to investigate the relationship between therapy and psychiatric disorders. At the same time, the demand has been growing this item in the National Health System (SUS) which incorporated the drug since 2001 and its use is standardized by SUS.

Objectives: The aim of work was to quantitatively evaluate the demand Isotretinoin of in the year 2011 and the financial impact of this item in the total distributed in Component Specialized Pharmaceutical Services –CEAF (program for access to medicines under SUS).

Methods: Survey demand data and distributed financial value of Isotretinoin 20 mg of 2011 in SIGAF-(Computerized Management of the State Pharmaceutical Assistance Minas Gerais) in relation to the total amount distributed to all items of CEAF.

Results: In 2011, the demand of the Isotretinoin was 9374 new patients, the second-placed; iron hydroxide 100 mg, 3111, budesonide + formoterol 400/200 mcg was placed third with 2177. The total amount distributed was equivalent to 8,715 million dollars, 8% of total expended with 196 medicines that make up the CEAF.

Conclusions: Isotretinoin was the most requested in 2011 in CEAF, three times higher than the second and 4 times higher than the third. At the same time, spending on this medicine is relevant, considering the percentage of the total spent on all CEAF's medications. This represents 11.6% of the total amount spent in the State of Minas Gerais with the treatment of cardiovascular diseases, chronic diseases most prevalent in Brazil according to WHO. Considering the known risks and the lack of conclusive studies on other adverse effects of Isotretinoin, the results highlight the need for closer monitoring of patients and control this medicine, in order to avoid the rampant consumption and irrational.

805. THE COST-EFFECTIVENESS OF BUCCOLAM® (LICENSED OROMUCOSAL MIDAZOLAM) FOR THE TREATMENT OF ACUTE EPILEPTIC SEIZURES IN THE UK; A TWO MODEL SOLUTION

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Background: Buccolam (licensed oromucosal midazolam) is indicated for the treatment of prolonged, acute, convulsive seizures in children and was the first product to receive a paediatric-use marketing authorisation (PUMA) in September 2011. In the UK community setting two treatments are used; unlicensed oromucosal midazolam (widely recommended by physicians) and rectal diazepam, the only licensed treatment but rarely used by parents and carers.

Objectives: A model was constructed to support a submission to the Scottish Medicines Consortium by ViroPharma Limited, assessing the cost-effectiveness of Buccolam for prolonged acute convulsive seizures initially occurring in the community setting.

Methods: A hybrid model has been developed including; a time to event simulation for the frequency/location of occurrence of prolonged seizures, and a decision tree model which assesses the treatment pathway when a child has a seizure. The associated cost and health related quality of life (HRQL) impacts are then calculated. Data were obtained from a variety of sources including clinical effectiveness estimates from McIntyre et al. 2005, a Delphi panel, hospital audit, and a survey of parents of children with epilepsy (to ascertain current practice). Costs were taken from published sources.

Results: Over six years, compared to unlicensed oromucosal midazolam, Buccolam showed a reduction in costs of £2,046 and increase in HRQL by 0.005 QALYs. Compared to rectal diazepam Buccolam showed a cost reduction of £8,516 and HRQL improvement of 0.036 QALYs. Buccolam remained dominant across a range of scenario analyses.

Discussion: Treatment with Buccolam is cost-saving compared to rectal diazepam through a reduction in the need for ambulance call-outs and hospital stays. Compared to unlicensed oromucosal midazolam through reduced drug costs and wastage.

Implications: When considering different comparators there may be different value drivers (here, efficacy and wastage). For complex

models, different data sources (including primary data collection) may be required.

812. DIRECT AND INDIRECT COSTS OF SCLEROSIS MULTIPLEX IN SLOVAK REPUBLIC

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Background: There was no HTA study of Multiple Sclerosis in the Slovak Republic till now.

Objectives: The overall economic burden caused by multiple sclerosis in Slovakia was calculated. The societal and health insurance perspective was used to perform the study.

Methods: This study had the goal to discover direct costs and indirect costs based on the extracted data from the state General Health Insurance and Social Insurance and using official economic country indicators. Data not available from official structures were obtained from patient survey conducted by written questionnaire.

Results: Total annual cost in 2010 for 6.100 patients diagnosed with MS in Slovakia was €54.723.591. Direct costs (€22.994.834) represented 42% of total costs, disease-modifying drugs resulted as the most expensive component (€12.641.052) followed by hospitalizations and diagnostics (mainly MRI). Indirect costs exceed the direct costs (€31.728. 757). The highest share of indirect costs represented loss of productivity (79%), followed by disability pensions (18%) and sick leave wage compensation (2%). The cost of loss productivity due to sick patients and invalidity pensioners was €25.207.512. The total average cost per patient was €8.971. Slovak health insurances data showed an evidence of 6.100 diagnosed and dispensed patients. Majority of patients from our survey had EDSS score 0-3 and 4-6.5. Patients average age were 39 years, while females accounted for 74%.

Discussion: Multiple sclerosis causes a high economic burden in Slovak healthcare system. Total annual direct and indirect cost due to MS in 2010 was €54.723.591. Indirect costs represent more than half of total MS costs and therefore should be considered in assessing the cost effectiveness of new coming innovative MS therapies.

Implications for the health system: This study can be the first step for future studies to optimize healthcare utilization and disease management.

826. COSTS ON THE ACTIVE PHARMACOVIGILANCE OF ANTIRETROVIRALS MEDICINES USED IN EXPERIENCED PATIENTS: APPLICATION OF THE ABC METHOD

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Background: About five million people worldwide have access to antiretroviral drugs for the treatment for HIV infection. Studies suggest that few countries have the structure, systems and resources to implement actions for pharmacovigilance. In this context, Brazil presents itself as a strategic scenario with the role of regulatory and monitoring post-marketing surveillance of drugs played by the Agência Nacional de Vigilância Sanitária (ANVISA) and universal access to antiretroviral drugs through the Sistema Único de Saúde (SUS). In addition, the literature suggests that only limited information about the costs involved for the implementation and institutionalization of pharmacovigilance programs, especially in outpatients.

Objectives: Estimate the costs involved in active surveillance of adverse events of antiretroviral medicines used in experienced patients in two referral centers in Brazil. Specific objectives: estimating the cost of pharmaceutical care in referral centers; Map a system of active surveillance of adverse events to antiretroviral drugs used in experienced patients; Estimating the costs of implementing the actions of active pharmacovigilance of antiretroviral adverse events.

Methods: Exploratory descriptive study using the ABC method (Activity Based Costing) and evaluating activities of pharmaceutical care in two referral centers. A projection was made for pharmacovigilance activities. Perspective: Health system.

Results: Preliminary results show that in a referral center, the cost of pharmaceutical services is approximately R$ 8641, 26. It is estimated that 35% of the time is spent on activities for pharmacovigilance.

Discussion: The study seems to highlight important elements for the implementation of programs of pharmacovigilance of antiretroviral drugs in experienced patients.

830. EXPENDITURES IN OUTPATIENT CARE BEFORE AND AFTER THE BARIATRIC SURGERY

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Background: Bariatric surgery (BS) is the best approach for treatment of patients with morbid obesity, in which is possible to reverse or improve comorbidities associated to obesity. Notwithstanding, the surgical procedure is not free of complications, and requires a long term monitoring.

Objectives: to compare the expenditures in outpatient care before and after the bariatric surgery of morbid obesity patients.

Methods: a retrospective cohort study was carried out including database of patients who have sought an outpatient care to treat morbid obesity and have performed a bariatric surgery, in a referral general public hospital in southern Brazil**.**

Results: 200 patients were enrolled in this study. Females represented 85.5%, mean age 45.4 (± 10.8) years and white race 92.5%. The body mass index (BMI) ranged from 35.6 to 80 kg/m^2. Before surgery there were 2.9 (SD 1.1) years of follow up, whereas after surgery a follow up of 2.52 (SD 2.0) years was conducted (p = 0,001). The expenditures per patient before the surgery, was US 547.70 and US 361.34 after this procedure. The specialties more frequently accessed before the bariatric surgery were psychology (24%), general endocrinology (21.4%), nutritional care (19.3%) and specialized care for morbid obesity (6.2%). In the postoperative was specialized care for morbid obesity, including endocrinology, nutritional care and psychology (58.9%).

Discussion: Bariatric surgery remains a selective procedure by demographic characteristics (age, sex and race). The reduction of expenditures in outpatient care after surgery was higher (34%) p < 0,001. As expected, the specialized follow-up of outpatients care for patients undergoing bariatric surgery was more frequent in the postoperative period. Bariatric surgery has shown to be able to lower costs in outpatient care among individuals with morbid obesity.

Implications for the health system/professionals/patients/society: This research allowed understanding the clinical determinants of the postoperative expenditures. It can help to manage better the resources and improve quality in the patient care.

833. MULTIPLE REGRESSION FOR IDENTIFICATION OF RISK FACTORS LINKED TO THE DEVELOPING OF CHRONIC COMPLICATIONS OF TYPE 1 DIABETES – ECONOMETRIC ANALYSIS

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Diabetes has been a challenge for health decision makers, due to its epidemic incidence and prevalence, about 200 million people all around the world. Brazil estimates 7,6% Brazilian people lives with diabetes, prevalence of 14 million people, and this number is continuously growing up. Between them, 5% might have type 1 diabetes (T1DM). Actually, diabetes has been the disease associated to the biggest burden of disease rate in Brazil. There are several chronic micro and macrovascular complications related to diabetes, like retinopathy, neuropathy, nephropathy, and cardiovascular disease. Nowadays, not all the factors related to the development of these complications were identified. It should be very interesting to identify the relation between some factors and the upset of these complications. Concerning this, utilization of a multiple linear regression model as part of an econometric analysis seems to be an effective tool to explain the influence of variables on the prevalence of chronic complications in T1DM people. A multiple linear regression model has been used, as follows: $y = \beta_0+\beta_1x_1+\beta_2x_2+\beta_3x_3.. +\varepsilon$, where y is the prevalence of complications. The explain variables included in the model are: gender, age, time of disease, A1c, diet, exercises, hypoglycemia events, and type of therapy. Coefficients have been obtained from the application of questionnaires, based on these variables. Questionnaire form is being applied to a first sample of 300 people with T1DM by email. Results are going to supply statistical information to the model that will be used to calculate the cost-effectiveness of treatment options for T1DM in Brazil. In the Ministry of Health of Brazil, there is no regulatory law about drugs and devices that should be coveraged for people with T1DM. We hope that this regression analysis should help the users and the policy makers with the best available evidence on how to care about diabetes.

848. PRACTICAL IMPLICATIONS OF OPTIMIZING STERILIZATION ON PLASMA TECHNOLOGY OF HYDROGEN PEROXIDE IN THE HOSPITALS OF THE SECRETARY OF HEALTH STATE OF CEARÁ, BRAZIL

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Background: Sterilization is the destruction of all viable forms of microbial life, through the application of physical, chemical and physico-chemical. It is a necessary requirement to provide security of the materials used in health care. For critical articles and thermosensitive compatible technologies is one of the low-temperature sterilization Plasma Hydrogen Peroxide (PPH). When the hospital does not have an alternative safe to do so, has turned to outsourcing. The Commission for Health Technology Assessment (CHTA) of the Health Department of the State of Ceará, Brazil (SESA-CE) through an analysis of the costs with the outsourcing of the service proposed to optimize the technology available at the General Hospital of Fortaleza (HGF) centralized sterilization of thermosensitive from other hospitals in the network.

Objectives: To evaluate the financial impact of outsourcing services for low temperature sterilization in hospitals in the SESA/CE and centralize this service in HGF.

Methods: a review of contracts with private enterprise, raising prices of service and evaluation of technical capacity in HGF.

Results: The annual amount paid by hospitals to the private company was contracted 274,551.17 USD. By centralizing the HGF was reduced to an annual amount of 175,598.99 USD for the four participating hospitals.

Discussion: From this decision it was found that HGF is fit structure, processes and provide suitable results to meet the participating hospitals.

Implications for the health system/professionals/Patients/society: full use of technology, annual savings of approximately 98,953.25 USD and safety in the use of material assistance in the procedures of health.

850. COST-EFFECTIVENESS ANALYSIS OF THE 7TH REPORT OF THE US JOINT NATIONAL COMMITTEE ON HYPERTENSION AND THE 6TH BRAZILIAN GUIDELINES FOR SYSTEMIC HYPERTENSION RECOMMENDATIONS' COMPARED TO THE STATUS QUO ON PRIMARY CARDIOVASCULAR PREVENTION: METHODS

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Background: Brazil has a health care system inspired in the UK NHS. Differently than the NICE guidelines, Brazilian clinical practice guidelines are determined by medical professional societies with no attention to the cost-effectiveness of the recommendations, which are currently reported in the VI Brazilian Guidelines for Hypertension (BGH 6). Hypertension affects approximately 28% of the Brazilian adult population, but there are no cost-effectiveness analyses evaluating the cost-effectiveness of the VI BGH. Moreover, given the paucity of resources assigned to health care in Brazil, cost-effective analyses on clinical guidelines are crucial to maximize health benefits for the population.

Objective: To establish the cost-effectiveness of the strategies recommended in the VI BGH and the 7th US Joint National Committee on Hypertension compared to the *status quo* (usual care) on primary cardiovascular prevention and life years saved (LYS).

Methods: A decision tree will be constructed over a time frame of 10 years. Total cost will be accounted in Brazilian Reais, converted to US dollars, and as a percentage of mean household income and the nation's GDP. Cost evaluation will include direct (outpatient visits, tests, and pharmacological treatment) and indirect (transportation, meals, patient's and family's productivity loss) financial costs, assuming the patient and the public health system perspectives. End points for effectiveness will be occurrence of first MI or stroke and all-cause mortality (used to estimate LYS). All data required will be retrieved through systematic review on PubMed, Brazilian (BVS) and Latin-American (LILACS) data bases. Outcomes will be estimated by well-established cardiovascular risk calculators (e.g. the Framingham score) and prospective studies. Monte Carlo simulations will be employed for sensitivity analyses. The strategies will constitute

independent branches of the tree and will follow all the guidelines' recommendations concerning diagnosis, staging and pharmacological treatment of hypertension. The *status quo* will serve as base-case scenario.

869. DIABETES AND PREGNANCY: COST-EFFECTIVE OF HOSPITALIZATION COMPARED TO OUTPATIENT CARE

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Pregnancies complicated by diabetes are associated with an increased risk of maternal and neonatal complications. The most serious maternal complication is the risk of developing type 2 diabetes within 10-12 years after birth. Perinatal complications include macrosomia and its increased risk of birth trauma and intrapartum hypoxia/asphyxia, high C-section rates, delayed pulmonary maturation and its consequent risk of respiratory distress syndrome, and metabolic disorders at birth. All these conditions worsen neonatal prognosis and increase perinatal mortality and the costs of prenatal care. The objective of this study was to determine the cost-effective of hospitalization compared with outpatient management of pregnant women with diabetes or mild hyperglycemia attending the Center for the Investigation of Perinatal Diabetes of Botucatu Medical School Hospital, São Paulo State University (CIPD/BMSH–Unesp). The study was a randomized study, to analyze maternal and perinatal outcomes of pregnant women with diabetes and mild hyperglycemia attending the CIPD/BMSH – Unesp. Pregnant women who have an indication for hospitalization were randomized into two groups: outpatient management and accompanied with hospitalizations. The patients selected for ambulatory received individual guidance for controlling glycemia in predetermined day, with the blood glucose monitor to obtain the average glycemic load. The hospitalized patients had their glycemic control carried out at the Hospital. The costs of diabetic patients in an outpatient were significantly less than hospitalization. Maternal and perinatal outcomes were similar between the groups. Cost-effective analysis showed that outpatient management was more economically advantageous than hospitalization. The work implies the identification of treatment enabling greater satisfaction and comfort to the patient, and at the same time is economically advantageous to the institution and for Brazilian Unified Health System (SUS) as well as contributing to research in the area of Health Technology Assessment (HTA) in Brazil.

873. COST-EFFECTIVENESS OF TRAP TO CAPTURE THE DENGUE ADULT VECTOR IN THE CONTEXT OF THE PUBLIC HEALTH SYSTEM, IN BRAZIL

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The Brazilian´s Government data show a rising trend in the number of cases of dengue in all regions of Brazil in 2011, 254,734 cases reported until March. Resources have been invested in strategies of elimination the *Aedes aegypti*. However, the efficacy of those approaches is still controversial. So, innovative methods of control adult mosquitoes are being developed and applied. Objective: To estimate the cost-effectiveness of trap to capture the dengue adult vector as compared to the usual program of dengue control, from the perspective of the Public Health System, in Salvador/Bahia, Brazil. The effectiveness was obtained from the longitudinal epidemiological study conducted in the Peninsula Itapagipana in Salvador. The primary outcome was the incidence of dengue in children aged zero to fourteen, followed by 12 months. The procedures performed were listed according to criteria of the Ministry of Health of Brazil and the costs were obtained from the SIGTAP/SUS and Price Bank of the Ministry of Health of Brazil considering only direct medical costs. The cost of the trap was determined according to the manufacturer. An analytical model was developed to compare the cost-effectiveness of the interventions. The dengue incidence was 11.43% in the houses with trap and 15.55% on without trap, showing a 26.5% reduction in disease incidence. The cost/year of the trap was approximately R$259.20, the cost/days of treatment for Dengue Classic was R$287.76 according with SIGTAP and for Dengue type A was R$174.50. This analysis showed that the intervention without trap was considered dominant over the one with trap, what represented a saving of resources for the National Health System. The sensitivity analysis to assess the consistency of this result is ongoing. To help health managers in making coherent and rational decisions about the incorporation of this new technology, it is important to consider the disease severity.

880. COST EFFECTIVENESS STUDY OF DIRECTLY OBSERVED TREATMENT ON PULMONARY TUBERCULOSIS PATIENTS AT SALVADOR CITY ON 2008

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In Brazil it was estimated 80,000 new TB cases occurring annually. This study aims to estimate the cost effectiveness of DOTS treatment strategy compared to unsupervised treatment as the endpoint. Visits were made to health units for data collection. Exploratory analysis and logistic regression were performed. Costs were estimated through cost accounting procedures at the public sector perspective. Values were tested through a sensitivity analysis with variations in costs of exams. Of a total of 2,611 cases of active pulmonary tuberculosis reported in 2008, 61% were men, 62% attended from 5th grade through high school completion. Logistic regression analysis showed a positive association with low education and supervised treatment Cost of DOTS was adopted as the daily cost of care of a health care given to a patient, considering that 50% of patients receive home visits to monitor the drug intake and 50% goes to the health unit to take medicine. Estimated cost to DOTS treatment per day and the cost of conventional treatment was R$ 1.04, and R$ 0.96 per patient, respectively. Conventional treatment of patients showed 77% effective with respect to the result of healing; supervised DOTS treatment had a ratio of 62%. Cost effectiveness for DOTS was R$ 836.07 and a conventional treatment was estimated at R$ 428.75. There was a statistically significant association between DOTS and poor education, alcoholism and mental illness, suggesting the occurrence of offering DOTS strategy for vulnerable groups. Nurses had about 30 hours of dedication to the program, even when they were not exclusive to care for patients with tuberculosis, which is a positive fact since these professionals perform patient care activities with TB. The alternative measure of DOTS as a guarantee of completion of the treatment of patients with the diagnosis of healing appeared to be cost effective.

882. IMPACT EVALUATION OF THE BETAPLUS® SUPPORT-PROGRAM FOR PATIENTS WITH MULTIPLE SCLEROSIS, IN COLOMBIA

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Background: Multiple sclerosis is a highly disabling chronic illness. The current treatment achieves only delay its progression. In Colombia for over 10 years, nearly 2500 patients receiving interferon beta for treatment within the Betaplus support-program funded by the pharmaceutical industry, which seeks to ensure adherence and improve the quality of life of patients.

Objectives: Evaluate the impact of the Betaplus support-program in patients with multiple sclerosis in Colombia taking changes in the quality of life of patients as indicator.

Methods: The impact on quality of life was evaluated for a 343-patient sample who participated in the program, at least for a year, in two modes (full and basic). SF36 questionnaire was applied to measure variations in terms of physical and mental health. Using a linear regression model it was assessed the relationship between different variables and the two forms of participation. The basic mode group was taken as control group. The data were analyzed in cross-section, every 6 months.

Results: The evaluation showed that the program in its full mode improves physical health (16% more) and mental health (13.6% more) per year remaining in the program. It was established that the effect diminishes within time. Mental health does not differ at 5 years for both modes of analysis. No significant changes were identified based on age or sex of patients.

Discussion: Since now the MS is not curable, is a therapeutic target the best quality of life of patients. The existence of a comprehensive care program would enhance the effects on the patient. The low costs of these activities against the cost of medicines and the benefits obtained in terms of mental health patients received justify this type of program and not just treatment.

Implications for the health system: The development and implementation of programs to support patients with chronic diseases such as multiple sclerosis should be part of state policy, which could enhance the effect of drugs applied to the result of improved quality of life.

887. PATTERNS OF BIOLOGIC THERAPY AND ASSOCIATED COSTS IN RHEUMATOID ARTHRITIS PATIENTS INITIATING TUMOR NECROSIS FACTOR ANTAGONISTS OVER TWO-YEARS

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Background: There is a need to understand treatment patterns for patients with Rheumatoid arthritis (RA) who are treated with biologic agents as tumor necrosis factor alpha (TNFα) antagonists to optimize therapy.

Objective: To examine the treatment patterns and costs associated with switching for patients.

Methods: Patients who initiated etanercept, adalimumab or infliximab during 2007-2008 were identified using *MarketScan® Research Databases* of paid US insurance claims. All patients had a six-month continuous medical and pharmacy benefits coverage prior to initiation and for 24-months afterwards. Patients with Crohn's disease, psoriasis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis or inflammatory polyarthropathies other than RA were excluded. Treatment patterns of TNFα antagonists discontinuation, switching and overall costs were examined.

Results: A total of 3719 patients were identified as initiators of etanercept (N = 1783), adalimumab (N = 1249) or infliximab (N = 687). Most patients remained on their initial treatment (etanercept, 74%; adalimumab, 70%; infliximab, 73%). Patients continuously treated over 24 months, without a 90-day gap, ranged from 38-52% (etanercept, 42%; adalimumab, 38%; infliximab, 52%). Between 11-17% of total population had an early treatment break (i.e., discontinued/switched to another biologic within 90 days after first treatment). Most patients who switched went to similar routes of administration (65-73% for SC-to-SC; 67% for IV-to-IV). The only differences in comorbidity, as measured by Charlson comorbidity index (CCI), were for those who switched first to a non-TNFα antagonist; they had a higher CCI than their counterparts (mean: 2.4 vs. 1.8 at year 2, $p < 0.001$). Patients who switched had higher costs at 24 months than those who did not, excluding index treatment only patients (mean = $59,978, N = 824; mean = $44,556, N = 2668; $p < .0001$ respectively).

Discussion: RA patients who initiate TNFα antagonists and need to change therapies incur higher cost. When patients switch, initial routes of administration are largely maintained.

Implications: Consideration should be given when switching treatments for these patients.

895. WHAT DRIVE THE ECONOMIC BURDEN OF HEALTHCARE CONSUMPTION IN INTENSIVE CARE UNITS (ICU): RETROSPECTIVE ANALYSIS FROM A U.S. HOSPITAL DATABASE

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Background and objectives: To determine the prevalence of three types of hospital-acquired infections (HAI) known drivers of high economic impact in ICU from a US hospital database.

Methods: A retrospective study using hospital database from the Premier Perspective of adults admitted to an ICU with a stay ≥ 48h from 2007-09. The three HAI assessed were: bloodstream infection (BSI), surgical site infection (SSI), and hospital-acquired pneumonia (HAP) of ventilator-associated pneumonia (VAP). Economic impact assessed using inpatient mortality rate, length of stay (LOS) and cost for inpatients.

Results: Data collected on 463, 491 patients with 511,815 stays (Mean, 1.10 stay/patient) in ICU following entry criteria in 2007; 91.5% had only one stay over the year. ICU patients, mostly elderly (53.3%) were concerned on mechanical ventilation (21.9%) and central catheter (26.2%) use, which are high risk factors for HAI. Among the stays, 26.7% were concerned with the prevalence: 16.9% for HAP/VAP, 14.5% for BSI, 39.7% for sepsis and 1.5% for SSI. The inpatient-mortality rates were higher for HAP/VAP with 16.7%, followed by 13.9% for BSI and 10.9% for SSI. SSI showed the highest LOS (23.4 days), followed by HAP/VAP (15.2 days) and BSI (12.7 days). One-day ICU costs (USD) were similar throughout the three HAI (BSI: 2,621, SSI: 2,582 and HAP/VAP: 2,362). An increase in inpatient mortality was observed in patients with HAI (13.2% vs. 1.1%) and an increase in LOS (12.5 days vs. 6.9 days) compared to patients without HAI. Costs/day were less in stays for patients with HAI (2583.9), compared to stays without HAI.

Discussion and implications: The prevalence and burden of HAP/VAP, BSI and SSI in ICU are high and associated with higher economic impact. The increase in mortality rates and longer LOS findings as the drivers of higher ICU costs, indicate the need for specific measures to reduce the prevalence of these types of HAIs.

923. INFORMAL PAYMENTS IN HEALTH SECTOR IN MONGOLIA

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Out-of-pocket payment (OOP) is a major form of health system financing and an important component of comprehensive National Health Accounts estimation. The main goals of this study are (*a*) to estimate the amount of informal payments made in the Mongolian health sector according to Mongolian National Health Account (MNHA) classification, and (*b*) to provide evidence to support the decision making process. Qualitative and quantitative surveys were conducted to estimate the amount of informal payments and ey findings are as follows: -2537 participants were involved in the quantitative survey. 1279 (50.4%) participants made out-of-pocket payments and the remaining 1258 (49.5%) participants paid nothing to receive health services. -A total of 88,000 USD in OOP were paid by 1279 participants per capita OOP was 68 USD. -Of the 88,000 USD of OOP, 56,000 USD (63%) were informal payments and 33,000 USD (37%) formal payments. -According to MNHA classification, 92.9% of payments was paid for inpatient care and 7.1% was paid for outpatient curative care, which were the highest amounts by service types. Payments were made in the form of cash, donation and presents to health providers. The least was paid for curative day cases, long-term care and prevention care (0.03%). -According to the qualitative survey the amount of informal payments made to medical professionals varied depending on qualification and position of provider. The highest informal payments were paid by patients from rural areas to receive health care services in big city, but a relationship between customer income and amount of informal payment made was not found. Comprehensive policy action is needed that not only ensures financial protection for individuals but also broad incentives across health care providers in order to improve quality of health care and health professionals' motivations.

154. ECONOMIC EVALUATIONS OF TREATMENTS FOR INTRACTABLE EPILEPSY: A METHODOLOGICAL REVIEW

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Background: Intractable epilepsy is associated with significant morbidity, impaired quality of life, mortality and substantial costs. The increasing number of treatment options and the high costs associated fostered the development of economic evaluations in the area of refractory epilepsy. Economic evaluations are used in governmental decision-making. As influential decisions depend on these economic evaluations, it is therefore important that the quality is unquestionable.

Objectives: This study aimed at providing an overview and a quality check of published full economic evaluations of interventions for patients with intractable epilepsy in order to inform those seeking to assess the economic impact of epilepsy treatment.

Methods: Only studies meeting the criteria of a full economic evaluation in refractory epilepsy, published in English from January 2000-October 2011 were included. Those were identified via PubMed and the Centre for Reviews and Dissemination Databases.

Results: Eventually, 12 articles were included in our review of which the methodological quality on several issues was assessed. These issues were (1) the perspective from which the analysis was performed, (2) the type of economic appraisal and the study design, (3) the outcome measures of costs and consequences and the associated time horizon in which these outcomes can be expected, (4) discounting costs and outcomes, (5) and performing comprehensive sensitivity analyses.

Discussion: We systematically checked the included articles on the previously mentioned issues and found that it was often poorly described, overlooked, or not taken into account at all. We agreed with previous reviews on the difficulty to compare results of economic evaluations in epilepsy due to heterogeneity in methods and concepts used.

Implications: The quality of economic evaluations, which are intended to inform decision-makers at all levels (government, health systems, individuals), is overall still poor. The quality could simply be improved by following the existing guidelines.

174. EFFICIENCY OF PERITONEAL DIALISYS VERSUS HEMODIALISYS

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Background: Patients in end-stage-renal disease (ESRD) should receive renal replace therapy. There are three major treatment modalities: hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation. The best strategy is kidney transplantation, however, the number of kidney donors is insufficient to meet demand. The costs of treatment with HD are very high and a great volume of literature about safety and efficacy of DP recommend its use.

Objectives: To assess the economic aspects of dialysis treatment in ESRD patients to demonstrate the efficiency of DP versus HD.

Methods: A systematic review of literature of economic evaluation studies was carried out. The main databases used were Medline, Embase, Cochrane Library, CEA Registry, and CRD. A combination of MESH terms as "hemodialysis", "peritoneal dialysis", "costs and cost analysis", and "quality-adjusted life year" was used. Inclusion criteria were comparative studies between dialysis methods within economic information about cost, cost-effectiveness analysis (CEA), cost-utility analysis(CUA), cost-benefit analysis (CBA), and budget impact analysis (BIA). Outcomes measured were costs, costs per life year gained, cost per quality adjusted life year (QALY). A quantitative summary of results was developed. Quality of articles has been measured according to the checklist of economic studies proposed by CASP.

Results: 439 references were identified, after selection process, 20 studies were included in the review that were classified as 8 cost analysis, 3 BIAs, 3 CEAs, and 6 CUAs. Forty different comparisons were developed, with an average percentage of saving of 22% in favour of PD. The incremental cost-effectiveness ratios were under the usual threshold of 30,000€ per QALY.

Discussion: There is enough evidence to confirm that PD is cost-effectiveness versus HD in economic terms, although both technologies are not always substitutes, but sometimes complementary.

Implications for health system: Health authorities should promote higher use of PD, as it would save important resources.

283. QUALITATIVE MOLECULAR TESTS FOR CONFIRMATION OF THE DIAGNOSIS OF HEPATITIS C IN SEROPOSITIVE PATIENTS: A SYSTEMATIC REVIEW

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Hepatitis C represents a serious Public Health problem. In approximately 80% of cases, the disease becomes chronic and the diagnosis can sometimes be made before the disease becomes severe. In 1993, the Brazilian government adopted a screening system with

serological kits for hepatitis C diagnosis in blood donors. However, a positive screening should be confirmed with another type of test since they do not distinguish active infection from past infection. So, molecular tests are very important to establish actual viremia and the hepatitis c diagnosis. Many guidelines throughout the world recommend the molecular test in various settings, including the confirmation of HCV in seropositive people. There are different qualitative molecular tests available for detecting HCV. The aim of this study was to conduct a systematic review of the accuracy of these different tests for confirmation of the diagnosis of HCV in seropositive people. We searched MEDLINE, SCOPUS and the Cochrane Library. QUADAS was the tool used for quality assessment of the studies. The search resulted in 1222 articles for evaluation. Only 2 studies were included in the systematic review, according to the established inclusion and exclusion criteria. Both COBAS AMPLICOR and AMPLICORtests had high sensitivity and specificity in one of the studies. The second study, presented accuracy data regarding an "in house" PCR test, which presented overall accuracy of 75%. Although we identified many articles in our search, the vast majority addressed analytical sensitivity, therefore not meeting our criteria, especially because they did not present accuracy data according to an established a gold standard. Furthermore, the 2 studies included did not present a good methodological quality according to QUADAS. These findings show the urgent need of studies with appropriate design for extraction of accuracy data of molecular tests.

492. THE VALUE OF INFLUENZA VACCINATION: AN ASSESSMENT FROM THE ECONOMIC POINT OF VIEW

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Background: Influenza epidemics are responsible for considerable mortality and morbidity rates, especially among elderly and high risk groups, and vaccination is the main effective strategy for primary prevention.

Objectives: The aim of the study was to analyze the economic impact of influenza vaccination with a particular focus on elderly and high risk groups, independently from age.

Methods: A search of cost-effectiveness and cost-utility analyses of influenza vaccination in comparison with no intervention was carried out on PubMed from January 1990 to May 2011. Economic analyses were considered eligible only if they addressed elderly and high risk groups. The quality of selected articles was assessed through Drummond's checklist.

Results: Sixteen cost-effectiveness analyses and four cost-benefit analyses were selected, with a quality judged fairly good. Influenza vaccination appeared to be cost-effective and sometimes cost-saving among elderly, also in terms of deaths averted and years of life gained. Among children at risk, vaccination was shown to be cost-saving from the societal perspective and less costly than other preventive measures, with a cost-benefit ratio of 6.4. Among high risk groups vaccination was cost-effective in all studies but one with respect to patients younger than 65: for adult cancer patients it was either cost-effective (Incremental Cost-Effectiveness Ratio of US$224.00 per Quality Adjusted Life Years gained) or cost-saving, averting total costs by US$ 2,107 and US$ 6,338 from the health care and societal perspective respectively.

Discussion and implications: Influenza vaccination has a very high economic value, as it allows to allocate resources efficiently and to guarantee a better health state also by avoiding severe complications among elderly and high risk groups. Anyway, the standardization of methods of evaluation would permit the comparability and transferability of results of different studies. The saving of indirect costs should be also considered in addressing economic implications in Public Health.

673. SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS OF DABIGATRAN ETEXYLATE FOR THE STROKE PREVENTION IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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Introduction: Dabigatran etexilate is the first available oral direct thrombin inhibitor for the prevention of stroke in atrial fibrillation.

Objectives: The objective of this report is to conduct a systematic review of published economic evaluations of dabigatran etexylate in the stroke prevention in patients with non-valvular atrial fibrillation.

Methods: Bibliographic research in reference database of scientific literature, selection and critical analysis of economic evaluations. The inclusion criteria were as follows: any type of full economic evaluations (especially to include results of cost per life-year gained quality-adjusted (QALY) and ICER results), those focused on dabigatran and its use in the study indication for stroke prevention in atrial fibrillation and limited to English or Spanish language. The databases searched were: MedLine, combining free text search ("dabigatran etexilate") and thesaurus using the MESH terms ("Anticoagulants","Atrial fibrillation","Stroke/prevention and control", and "Cost-Benefit analysis"). The Bibliographic review was completed in systematic reviews databases (Cochrane Database and DARE) and specific economic evaluation databases also (National Health System, Economic Evaluation Database, EURONHEED (Centre for Reviews and Dissemination, Centre for Health Economics at York University), Canadian Australian and Sweden Health Technology Assessment Agencies and NICE publications. Critical analysis will be done by two independent reviewers using a checklist adapted from that proposed by Drummond and the Ministry of Health from Spain.

Results: Within the results of the search in Medline, 8 publications were selected for critical analysis, meeting the inclusion criteria. To these were added the latest report from NICE and the CRD/ERG Report. In total 13 economic evaluations will be analyzed. The final results will be obtained for critical analysis by March 2012.

Conclusions: The specific conclusions will be drawn once the critical analysis of economic evaluations is performed

Implications for the health system: It helps decision making for effective management of health resources.

804. SYSTEMATIC REVIEW OF MODELS ASSESSING THE COST EFFECTIVENESS OF BIOLOGICS IN RHEUMATOID ARTHRITIS

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Background: A number of decision-analytic economic evaluations, comparing both the costs and consequences of biologic therapies for the treatment of rheumatoid arthritis (RA), have been published.

Objective: To assess the structural and methodological aspects of published cost effectiveness models associated with the use of biologic therapies in rheumatoid arthritis.

Methods: A systematic literature search was performed using the databases (Pre-) MEDLINE, EMBASE, the Cochrane Database of Systematic Reviews and Health Technology Assessment, and NHS EED (Economic Evaluation Database) from the literature published from January 1996 to January 2012. To be included, studies had to evaluate the cost effectiveness of a biologic (or a treatment sequence involving biologic therapy) for the management of RA.

Results: A total of 38 studies were identified, the majority of which included cost-utility models (n = 33) that used cost per quality-adjusted life-year gained as the primary outcome. Modeling approaches employed across the studies included decision trees, Markov models, discrete event simulations and other mathematical and simulation models with time horizons ranging from 6 months (n = 2) to lifetime (n = 20). Ten different countries were represented by the 38 studies. All of the models used societal and/or healthcare provider/payer perspectives. In addition, all of the studies used at least one of the following to assess clinical severity: the Disease Activity Score (DAS), Health Assessment Questionnaire (HAQ) Disability Index, the American College of Rheumatology (ACR) response criteria.

Discussion: There was significant heterogeneity in the structure and methodology of the models reviewed. A lack of long-term head-to-head outcomes studies involving the biologics may help explain some of the differences in time horizons, modelling approaches and assumptions utilized in these studies.

Implications: Findings from this review will help inform future modelling studies, including areas for improvement and future research initiatives, and hopefully improve reimbursement and coverage decisions surrounding the use of biologics in RA.

171. QUANTIFICATION OF UNCERTAINTY IN EQ-5D UTILITIES FOR THE UK

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Background: The EQ-5D is a widely used, NICE recommended questionnaire for self-reported health related quality of life (HRQL), with a corresponding set of utility values for the UK. The mean EQ-5D utilities are currently assumed known with complete certainty. However, the Decision Support Unit (DSU), which elaborates on NICE Methods guidance, recently encouraged quantification of uncertainty in these utilities due to uncertainty in the regression parameters of the EQ-5D.

Objectives: We perform this recommendation from the DSU, given the lack of published research in this area.

Methods: The covariance matrix of the regression parameters for the EQ-5D valued health states for the UK is available on the DSU website. From this matrix, 10,000 sets of regression parameters were simulated. Using these parameters, the standard error of the mean utility for each health state and the correlations between means were calculated. To quantify additional uncertainty in the population mean utility attributable to uncertainty in the EQ-5D utilities, we estimated the population mean and its standard error for a sample of EQ-5D responses from real and plausibly simulated datasets, separately.

Results: The simulated standard errors of the mean utilities are similar across all health states, approximately 0.01. The relative contribution to uncertainty in estimated population mean utility due to uncertainty in EQ-5D utilities concerns factors including sample size and within-sample utility variance.

Discussion: Although this quantification implies that uncertainty in utilities from the EQ-5D regression parameters may be greater than the uncertainty due to finite patient populations, it is small compared to other sources typically encountered in cost-effectiveness analyses.

Implications for the health system/professionals/patients/society: This study helps improve estimation of uncertainty in the cost-effectiveness of health technologies, and hence whether a given health technology should be publicly-funded.

194. DESIGN OF A TRIAL-BASED ECONOMIC EVALUATION ON THE COST-EFFECTIVENESS OF EMPLOYABILITY INTERVENTIONS AMONG WORK DISABLED EMPLOYEES OR EMPLOYEES AT RISK OF WORK DISABILITY: THE CASE-STUDY

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Background: In the Netherlands, absenteeism and reduced productivity due to work disability lead to high yearly costs reaching almost 5% of the gross national product. To reduce the economic burden of sick leave and reduced productivity, different employability interventions for work disabled employees have been developed. Within this study, called 'CASE-study' (Cost-effectiveness Analysis of Sustainable Employability), five different employability interventions directed at work disabled employees with divergent health complaints will be analysed on their effectiveness and cost-effectiveness. This paper describes a consistent and transparent methodological design to do so.

Methods: Per employability intervention 142 participants are needed whereof approximately 66 participants receiving the intervention will be compared with 66 participants receiving usual care. Based on the intervention-specific characteristics, a randomized control trial or quasi-experiment with match-criteria will be conducted. Notwithstanding the study design, eligible participants will be employees aged 18 to 63, working at least 12 hours per week, and at risk of work disability, or already work disabled due to medical restrictions. The primary outcome is the duration of sick leave. Secondary outcomes are health status and quality of life. Outcomes will be assessed at baseline and then 6, 12 and 18 months later. Economic costs will consist of healthcare costs and cost of lost production due to work disability, and will be evaluated from a societal perspective.

Discussion: The CASE-study is the first to conduct economic evaluations of multiple different employability interventions based on a similar methodological framework. The cost-effectiveness results for every employability intervention will be published in 2014, but the methods, strengths and weaknesses of the study protocol are discussed in this paper. To contribute to treatment options in occupational health practice and enable the development of guidelines on how to conduct economic evaluation better suited to this field; this paper provides an important first step.

241. METHODOLOGICAL CHOICES FOR HEALTH ECONOMIC EVALUATION AT THE FRENCH NATIONAL AUTHORITY FOR HEALTH (HAS)

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Background: With the 2008 Social Security Financing Act, the French National Authority for Health (HAS) was given a new competence, in health economic evaluation.

Objectives: In this respect, HAS developed a methodological framework to define principles, methods, and guidelines for health economic evaluation.

Methods: A literature review including a comparative analysis of existing guidelines produced by other health technology assessment agencies was performed. Based on this review, principles and methods were discussed at several meetings between health economists from both academia and HAS, during 2009-2010. A workshop with representatives from NICE and IQWIG was organised at HAS in July 2010 to discuss the positions of these agencies. A first draft of the guidelines was opened for public review. A second draft was produced on the basis of the comments received. The final document, validated by the Health Economics and Public Health Committee and the HAS Board, was published online in November 2011.

Results: The comparative analysis of existing guidelines and discussions between NICE, IQWIG, and HAS, indicate that methodological choices for economic evaluation are clearly determined by these agencies' respective roles. Likewise, the HAS guidelines define the principles and methods required for any cost-effectiveness evaluation that HAS conducts, initiates or assesses. To maintain a balance between scientific and operational requirements, some of the guidelines are systematically required, while others are preferred ones, which may not be followed if this choice can be justified.

Discussion: The positions taken by HAS are based on the current state of science. Yet, as economic evaluation methods are improving and scientific debates evolving, these guidelines will need to be revised regularly.

Implications for the health system: The HAS guidelines should strengthen the role of health economic evaluation in France, at a time when new regulations on drugs and medical devices coverage are being defined.

339. A COMPARISON OF THE RELIABILITY OF THREE PREFERENCE-BASED QUALITY OF LIFE INSTRUMENTS (EQ-5D, ICECAP-O, ASCOT) IN COMMUNITY-DWELLING FRAIL OLDER ADULTS

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Background: In economic evaluations the EQ-5D is widely used to assess health-related quality of life (hr-QoL). However, the focus on health does not correspond with current developments towards integrated health- and social care systems and with older people's experiences, who consider other aspects of life just as essential. In complex care situations involving older adults, the aim is to improve or sustain general quality of life (also referred to as 'well-being'), which includes prevention of and coping with consequences of health problems, autonomy, social functioning, dignity, and enjoyment in life. Two recently developed preference-based generic quality of life instruments have taken these considerations into account: the ASCOT and the ICECAP-O. Not much is known yet about the measurement properties and suitability of these instruments compared to the EQ-5D in the setting of community dwelling frail older adults in the Netherlands.

Objectives: As first in a series of studies we compared the test-retest reliability of two preference-based quality of life instruments (ICECAP-O and ASCOT) with the EQ-5D in community-dwelling frail older adults.

Methods: Quality of life in approximately 130 Dutch community-dwelling frail older adults (participants in the ACT study) was assessed using Dutch translations of the instruments. This measurement was repeated within 7-14 days after the first measurement.

Results: Results about the stability of the total scores and of choices for answer categories within each dimension of the measurement instruments are available in May 2012.

Implications: The results of the test-retest show which of the three instruments is most reliable in community-dwelling older adults. Combined with the results of our further clinimetric and feasibility studies the results contribute to the selection of more relevant and appropriate outcome measures for future economic evaluations in complex care settings aimed at improving or sustaining generic quality of life, rather than hr-QoL alone.

666. PROSPECTIVE COST-BENEFIT ANALYSIS OF A DECISION SUPPORT SYSTEM BASED ON INTEGRATIVE BIOCOMPUTATIONAL SIMULATIONS

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Background: HTA has rarely been applied to the clinical/socio-economic impact of complex, multi-interventional technologies like computer modelling of human patho-physiology.

Objectives: The European Osteoporotic Virtual Physiological Human (VPHOP) project creates a patient-specific clinical decision support system (CDSS) allowing for improved diagnostics/treatment. Prospective assessment of such systems by advanced HTA is mandatory because they transform clinical decision making with far reaching impact on health systems/patients.

Methods: The methodological elements of the adapted CBA are: Realistic process model of currently implemented osteoporosis treatment pathway(s), measurement of inputs, costs, outcomes; Process model of new CDSS elements to estimate implementation and service costs; a new pathway (model) aligned with the foreseeable optimal use of the new technologies' front-end and back-end services, outcome estimates.

Results: Using the preliminary CDSS, for each set of individual patient data 1,650 simulations p.a. for a 10-year horizon were run estimating bone fracture risk and impact of treatment options to avoid fractures. Estimates suggest that, for a typical annual cohort of 5,000 patients screened, improved diagnostic and treatment accuracy would avoid 200 fractures, a 8% improvement. Taking the long-term costs of fractures avoided into account, a positive benefit/cost ratio was achieved, indicating that costs of CDSS would be justified.

Discussion: Our approach is capable of contributing information for decision makers funding/accelerating the diffusion of complex, integrative health technologies having potentially extensive impact on care pathways and patient-centred care.

801. CHOOSING A CHECKLIST FOR QUALITY ASSESSMENT OF ECONOMIC EVALUATION STUDIES FROM INCORPORATION'S REQUESTS IN CONITEC - BRAZILIAN MINISTRY OF HEALTH (MOH)

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In 2011 it was published the Law No. 12,401 which created the National Committee for Incorporation of Technologies in Public

Health System (CONITEC) in the Brazilian Ministry of Health (MoH). This law states that the decision-making about incorporation of health technologies should be based not only on efficacy and safety evidences, but also in economic evaluation (EE) studies. Moreover, CONITEC has 180 days to analyze the requests for incorporation and make a decision about incorporation or not. Therefore, CONITEC had to define a methodology to evaluate the quality of EE studies, enabling quick and complete assessment of the requests. Two validated checklists (BMJ, 1996 and Philips, 2004) were chosen by an EE expert and a workshop was held to evaluate their applicability in the CONITEC scope. Technicians of CONITEC and other areas of MoH, with experience in HTA, joined the workshop. A second workshop was held to apply the checklists to a real request submitted to CONITEC. Philips' checklist was considered more complex and complete in relation to issues about quality of effectiveness studies used in EE. However, since CONITEC has already had a guideline for methodological quality assessment of effectiveness studies, and because it is easier, the BMJ checklist was chosen. At the end of the two workshops, the BMJ checklist was translated into Portuguese and comments were added to each question in order to standardize the assessment and explain how to get the answers and what kind of information should be considered in each question. The use of HTA in decision-making about incorporation of health technologies is a new practice in Brazil, especially with regard to EE. The rational incorporation of new technologies, based on high methodological quality EE studies, represents an advance in the Brazilian Public Health System.

903. QUANTITATIVE ANALYSIS AND COST ASSESSMENT OF MAJOR SURGICAL PROCEDURES FROM A SUPPLEMENTARY HEALTH INSURANCE IN BRAZIL

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Introduction: Health Systems' management requires constantly evaluation and monitoring. Usually, it should be empowered by outstanding information to support the decision-making. The establishment of patterns of procedures coverage, by a Supplementary Health Insurance, is necessary to improve audit processes of hospitalization expenses. In this study we apllied statistics concepts of EDA – Exploration Data Analysis – created by John Turkey. Also, we counted on computer science's concepts from Data Warehouse – invented by Bill Inmon – and Data Marts – developed by Ralph Kimbal. These technologies enabled us to explore information to bring about patterns and detect databases background knowledge.

Methods: 49 surgical procedures were selected for analysis, in a 12-months period in 2010. The covered population accounted for approximately 89.000 beneficiaries. A retrospective cross-sectional study was carried to identify quantitative and costs standards of surgical procedures with high incidence. It was based on the service descriptions, quantification and valuating to form a Procedure Data Mart (Data's Cube). It was built listing the following data: procedures, ICD-10 code, patients ID, insurance policy, health care providers. Scanning techniques and data visualization were applied, resulting in charts that enabled researches developing and automatic analysis. This tool provides a quick looking and easy data exploration, exposing surgical procedures arrangements and patterns, systematically organized by the burden health care procedures.

Results: It resulted in automatic surgical procedures analysis, mainly for those with high incidence. Also, produced templates that allowed cost provisioning, audit processes improvements and hospital`s bills' payment optimization. This approach assists procedures' reimbursement management once it enables the costs' standards assessment. It provides clear quantification and easily points out outliers, resulting in a smart instrument of surgical procedures surveillance. Likewise, it can be employed to quality control, providing adverse events tracking through outliers analysis. This application may assist health care management and its costs, consistently and continuously.

26. HEALTH TECHNOLOGY ASSESSMENT: THE VENETO ARSS EXPERIENCE ON LARGE MEDICAL EQUIPMENT EVALUATION AND AUTHORIZATION PROCESS

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Health care system costs are steadily increasing and they are reaching levels beyond the actual possibilities of livelihood. Therefore, to carefully evaluate each individual investment is now a priority. There is a particular spending increasing in technology sector, often not supported by clinical needs. The tendency would be to chase the market and want the latest news, but it is clear that this approach is not economically sustainable. The ARSS and the Veneto Region have therefore started an evaluation and authorization process for large equipment purchase. In this document we illustrate methods and profitable results of our experience, showing in detail the main key points of this process: 1) Region Hospitals large equipment census creation and maintenance; 2) Allocative appropriateness criteria identification and systematic review; 3) Hospitals roles classification: the Hospital Network concept; 4) Simplified purchase authorization applications forms differentiated on replacement/replacement with upgrading/new acquisition case; 5) ARSS technique investigation before the meeting, based on multi-disciplinary methods of the Health Technology Assessment; 6) Regional Commission (CRITE) purchase authorization.

32. A NEW APPROACH TO DEAL WITH THE ABSENCE OF CLINICAL TRIALS IN SYSTEMATIC REVIEWS: A PROPORTIONAL META-ANALYSIS OF CASE SERIES STUDIES

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Background: Evidence-based medicine is defined as the link between good scientific research and clinical practice and it uses existing and available scientific evidence, with good internal and external validity, to apply its results in clinical practice. Systematic reviews are criticized for frequently offering inconsistent evidences and absence of straightforward recommendations. Their value seems to be depreciated when the conclusions are uncertain or based on less than the highest grading of evidence. For these reasons the need to create strategies to deal with the absence of clinical trials is crucial.

Objective: To describe a new method of evaluating case series studies in health care when there is absence of clinical trials.

Methods: We provide illustrations from recent experiences and discuss the impact of the level of evidence in the clinical practice. Proportional meta-analysis was performed on surgical outcomes from the clinical question taking as example to illustrate this new approach.

Results: As demonstrated by the example, this method is an alternative design to provide some evidence of the intervention under evaluation and plotting all available case series.

Conclusions: We describe a new method to evaluate case series in health care reviews. This method is extended to be used in the

absence of clinical trials, mainly, for surgical procedures. The use of this method leads to substantial gains in the scientific community as it supports the clinicians and surgeons in their clinical practice. This alternative method can help surgeons, physicians and health professionals for decision making in health care while clinical trials are ethically unacceptable or methodologically biased. It´s not a replacement for the gold standard randomized clinical trial, but an alternative for clinical research.

77. UTILITY OF A SCORING TOOL FOR COMPARING DISSIMILAR HEALTH TECHNOLOGIES

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Background: Auckland District Health Board (ADHB) administers both hospital and community health services in central Auckland, New Zealand. It has a budget of $USD 1.3 billion per year and runs the largest hospital in the country with over 7000 employees. Prior to 2005, new health technologies were introduced to ADHB in haphazard fashion without formal review. In that year a committee (the Clinical Practice Committee [CPC]) was constituted of senior clinicians with good analytical skills and HTA infrastructure was added to the secretariat to allow all substantial new proposals to implement health technology to be evaluated. To assist in the comparison of dissimilar technologies a scoring tool was developed that allocated points based on the quality of evidence to support the safety, efficacy and cost-utility of the new technology and on the likely financial impact on the institution (cost-saving technologies being awarded the highest points)

Methods: The activity of the CPC was reviewed after six years and scores correlated with management decisions and ultimate implementation outcomes.

Results: In the 6 year period from July 2005-June 2011 the CPC held 94 meetings and reviewed 39 new technologies and 13 other requests (including disinvestment evaluations). It was not possible to score all technologies but the table below describes the spread of scores and the resulting management decisions about implementation. The correlation is significant (p = 0.014) in spite of the small numbers analysed.

Score ranges	< 30 (n = 11)	30-60 (n = 15)	> 60 (n = 5)
Implemented	9%	33%	60%
Pending funding	9%	60%	40%
Rejected	82%	7%	0%

Conclusions: Given the competition for resources within a tertiary care hospital, it is gratifying to see that after HTA techniques are applied to applications for resources to implement new health technologies and an appropriate scoring tool is used to compare dissimilar submissions, management decisions become more closely evidence-based.

139. A METHODOLOGY FOR HEALTH TECHNOLOGY ASSESSMENT IN THE LOCAL HOSPITALS' SYSTEM. A CASE STUDY AT THE DIGESTIVE ENDOSCOPY DEPARTMENT IN FLORENCE

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Introduction: The health model is a complex system in which interact multiple factors including the continuous growing use of biomedical technologies in the clinical activity. Hence a continuous evaluation of devices in healthcare is necessary and accomplished through a multidisciplinary scientific approach known as Health Technology Assessment (HTA) which determines the impact of using a specific medical device, drug therapies, procedures and services on healthcare. This paper aims to provide to the technology decision makers in health care a decision support system for analyzing the impact of technology on safety.

Methods: The assessment of risk related to the use of technology consisted of the application of a set of indicators which estimated the safety for both the patient and the medical personnel when using medical equipment or medical device. The methodology was composed by two main steps: Definition and organization of the Key Performance Indicators with the estimation of the Safety Risk Indices and the Development of the Decision Support System with the implementation of the extra function "simulation mode." The safety evaluation was carried out to different levels: 'Equipment', 'Hospital department', 'hospital' and 'Local Health System.' The system was applied to the digestive endoscopy department in Florence which included four health structures - the main university hospital and three hospitals belonging to the Florence Health System.

Results and discussions: The analysis showed how the most critical device was the trolley servant of endoscopes with a high risk level while the simulation mode, which reported the possible outcomes coming from the application of a specific type of intervention, considered a correct and proper use of Personal Protective Equipment by medical personnel. This led the risk levels passing from a high to a medium level. Further developments regard the completion of the system by including economic and organizational analysis.

186. EVALUATION OF HTA PROCESSES FOR MEDICAL TECHNOLOGIES IN AUSTRALIA WITH REFERENCE TO ESTABLISHED PRINCIPLES OF HTA

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Background: Principles have been established to inform the development and implementation of realistic and rigorous methods of HTA processes (Drummond et al. IJTAHC, 2008;24:244–58). These have been used to benchmark international HTA agencies to determine whether they 'supported' and/or 'implemented' these principles (Neumann et al. IJTAC. 2010;26:71-8). Following a comprehensive review of HTA processes in Australia (Review of Health Technology in Australia, 2009), the Medical Services Advisory Committee (MSAC) revised the application and evaluation processes to address long-standing concerns from applicants regarding transparency, timeliness and process inefficiency.

Objective: To evaluate the revised MSAC processes with reference to established principles of HTA best practice.

Methods: Experience gained from the first pilot evaluation under the revised MSAC framework is used to compare to established principles of HTA best practice.

Results: Deviating from HTA Principles, the revised MSAC framework does not: consider a wide range of relevant evidence and outcomes; incorporate appropriate methods for assessing costs and benefits; produce a timely decision; facilitate an unbiased and transparent exercise due to the lack of publically available submission and economic guidelines.

Discussion: Although public declarations indicate that MSAC *'supported'* several of the fundamental HTA principles, experience

from the pilot evaluation of the revised process reveal a generalised failure to effectively *'implement'* the established principles.

Implications: Whereas the explicit goals and scope of the MSAC reform are aligned with HTA best practice, the failure to effectively implement established HTA principles serves to erode trust in the transparency, objectivity and consistency of the evaluation process and undermines confidence in the legitimacy of the MSAC recommendations. From an applicant perspective, concerns remain regarding timeliness, consideration of a range of appropriate evidence and outcomes, undue emphasis on overall budget impact and the lack of guidelines. The effect of this departure from accepted best practice include delayed patient access to cost effective medical technologies, negative impact on health outcomes and delayed economic benefit to Australian society.

195. ANALYSIS OF TECHNOLOGIES IDENTIFIED THROUGH THE EARLY AWARENESS AND ALERT SYSTEM -SINTESIS-NEW TECHNOLOGIES-: STUDYING THE POSSIBLE GAPS IN SOME MEDICAL SPECIALTIES

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Background: The Early Awareness and Alert System (EAAS), SINTESIS-new technologies, aims to provide decision makers with information on the potentially most significant new and emerging technologies, excluding drugs. One of the major concerns of EAAS is to miss significant technologies.

Objectives: To analyse medical specialties of technologies identified through the EAAS in the last three years, and to study possible gaps in some medical specialties.

Methods: Descriptive study. We calculated percentage frequency distribution of medical specialties of the technologies identified through our EAAS. A comparison between specialties of technologies identified by the EAAS and medical specialties corresponding to the Cleveland Clinic top 10 medical innovations for the period 2009-2011 was made.

Results: Twenty-nine medical technologies were identified through SINTESIS-new technologies from 2009 to 2011. These technologies belong to 12 medical specialties. The most frequent specialties were Neurology & neurosurgery: 21.4% of technologies; Cardiovascular & vascular disease: 17.9%; Gastrointestinal & liver disease: 10.7%; and Gynaecology & Pregnancy: 10.7% of technologies. According to the Cleveland Clinic top 10 medical innovations for the period 2009-2011, the medical specialties most often associated with innovations were Cardiovascular & vascular disease, Respiratory disease & thoracic surgery, and Gastrointestinal & liver disease, followed by Gynaecology & pregnancy, and Ear nose & throat. SINTESIS-new technologies did not identify any technology from the specialty of Respiratory disease & thoracic surgery.

Discussion/Implications for the health system: SINTESIS-new technologies identifies new and emergent health technologies from relevant medical specialties, but there are some gaps in medical specialties closely related to innovations such as that observed for Respiratory disease & thoracic surgery. Proactive identification in this area could improve the effectiveness of our Early Awareness and Alert System.

196. HEALTH SERVICES UTILIZATION ESTIMATES: BRAZIL CASE STUDY FOR PNEUMOCOCCAL DISEASE

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Background: Developing health services utilization estimates for pneumococcal disease (PD) is complex and challenging. Pneumococcus may be associated to various clinical syndromes, which, on the other hand, may also be related to different pathogens.

Objective: to estimate health services utilization due to PD for pneumococcal conjugate vaccine (PCV) economic evaluation.

Methods: Data from the Brazilian Health Information Systems and literature review were used to estimate health services utilization (inpatient and outpatient care) by under-5 children in 2004 (before introduction of PCV in Brazil). Estimates of hospital admissions, medical visits, diagnostic tests, and medication due to meningitis, sepsis, pneumonia, and acute otitis media were developed.

Results: During the study period, 968 hospitalizations for pneumococcal meningitis were registered in the Hospital Information System (SIH-SUS) and 289 were estimated occurring in the private sector, totalizing 1 257 hospitalizations; 741 hospitalizations for pneumococcal sepsis in the public sector and 221 were estimated for the private sector, totaling 962 hospital admissions. There were 355 072 hospitalizations due to all cause pneumonia reported in the SIH-SUS and additional 106 060 hospitalizations in the private sector were estimated, totalizing 461 132 hospitalizations. Ambulatory care and epidemiological surveillance data systems and national literature were used to estimate 2 514, 1 924, 330 327, and 5 462 770 outpatient events for meninigitis, sepsis, pneumonia and acute otitis media, respectively.

Discussion: The utilization of secondary data from health information systems and literature review allowed the development of national health services utilization estimates of PD for PCV economic evaluation in Brazil.

Implications for the health system: Strengthening health information systems is an essential element in the implementation of health care system policies and management and health care population impact, and also very necessary for evaluating and monitoring the results of specific interventions on health care utilization and quality and population health.

202. FOCUSED COLLABORATION ON COMMON SEGMENTS OF AN HEALTH TECHNOLOGY ASSESSMENT IN FRANCE AND FINLAND

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Background: The EUnetHTA POP database allows real-time overview of ongoing projects across HTA Agencies in Europe. With the Finnish (FinoHTA) and the French (HAS) Agencies working simultaneously on the topic of Carpal Tunnel Syndrome (CTS) between 2011-2012, common areas of interests were mutually identified and agreed on, allowing for a topic-focused collaboration.

Objectives: Foster work efficiency, accuracy and relevancy by cross-examination of focused topics within the scope of overlapping projects.

Methods: Objectives and methods for the Finnish and French HTA projects on CTS were shared and compared. After identifying common areas of interests, a collaborative approach was defined and followed through with its implementation.

Results: In France, the topic of interest was appropriateness of surgical decision-making in CTS, while Finland was performing a technology assessment on the usefulness of an electroneurogram device for CTS. The role of electroneurography (in diagnosis, severity assessment and as a management tool for CTS) defined as a common research question. We agreed to (1) share literature search strategies and results, (2) assess published guidelines and systematic reviews covering the common research question using the same quality appraisal tools, (3) inquire with HAS French expert working group on questions identified by FinoHTA (core model) (4) discuss issues and conclusions arising from our assessments. This collaborative process was included in the methodological section for each respective national report.

Discussion: Fruitful short-term collaborations may be implemented on well-defined limited topics among Agencies working simultaneously on overlapping projects. Such collaborations could be defined as segmental information sharing when relevant according to project timeframes. This requires real-time monitoring of ongoing work processes across Agencies.

Implication for the health system: Such collaborations improve quality of reports. EUnetHTA tools may help identifying areas of concrete collaborations.

214. GENERAL METHODOLOGICAL ISSUES IN COST-EFFECTIVENESS ANALYSIS INSPIRED BY THE ASSESSMENT OF DASATINIB, NILOTINIB AND IMATINIB FOR FIRST LINE CHRONIC MYELOID LEUKAEMIA

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Background: In 2011-12, the cost-effectiveness of imatinib, dasatinib and nilotinib for 1st-line chronic myeloid leukaemia in the UK was evaluated by NICE.

Objectives: We discuss three methodological issues which strongly influence the estimated cost-effectiveness of these drugs. These issues are also important for the cost-effectiveness of many other drugs and medical devices.

Methods: We discuss the pros and cons of the following competing methods. (1) Estimation of overall survival: Method A: estimated as the cumulative duration of 1st-, 2nd- and 3rd-lines of treatments. Method B: estimated from the surrogate responses: complete cytogenetic response and major molecular response. (2) Cost-effectiveness of subsequent treatments: the cost-effectiveness of 1st-line drugs are substantially affected by the cost-effectiveness of subsequent drugs. Method A: traditional method of modelling estimated costs and QALYs of subsequent drugs. Alternatively, minimise impact of cost-effectiveness of subsequent treatments by either Method B: setting per patient costs and QALYs of subsequent treatments equal between treatment arms, or Method C: cap the cost-effectiveness ratio whilst on subsequent treatments at the willingness to pay threshold. (3) Future drug prices: This is an important issue given that the patent for imatinib will expire soon, in 2016, after which its price may fall substantially. Method A: use the current list prices of all drugs in the future, as required by NICE. Method B: assume constant drug prices until patent expiry, at which time assume a fixed price cut. Assuming a modest 25% price cut on patent expiry, the ICER for nilotinib vs. imatinib increases substantially, from £36,000 to £54,000 per QALY.

Implications for the health system/professionals/patients/society: This study informs important methodological issues which apply to many health technologies. The study ultimately contributes to more accurate assessments of the cost-effectiveness of health technologies, and hence whether a given technology should be publicly-funded.

220. USE OF RECORD LINKAGE TECHNIQUES FOR IDENTIFYING WOMEN DATA IN A CERVICAL CANCER INFORMATION SYSTEM

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The Cervical Cancer Information System (SISCOLO in Portuguese) has two main files, containing data on the histological and cytological exams of women enrolled in the cervical cancer screening programme. In SISCOLO the women are not uniquely identified, which limits the use of indicators based on the woman. This study aimed at integrating the files of SISCOLO in order to identify the exams associated with each woman. Data from the Rio de Janeiro State, Brazil, from June 2006 to December 2009 were used. Each file was linked with itself and with the other through record linkage techniques based on Fellegi-Sunter method, implemented by a computer program that used the woman's name, birthdate and woman's mother's name as comparison variables. For each pair of compared records, a score was attributed by the program and every pair above a certain threshold was classified as belonging to the same woman. This approach allowed the identification of the records belonging to the same woman in both files. The quality of the integration was evaluated by taking random samples of pairs of records for each linkage process and comparing the classification obtained by the program with that established by a human observer (gold standard). The integration identified 6,236 women (out of 7,477 records) in the histology file, 1,678,993 women (out of 2,030,074 records) in the cytology file and 5,324 women in both files. The integration process presented sensitivities above 90% and specificities and precisions near 100%. This study showed that the integration of the SISCOLO through record linkage techniques may contribute to the estimation of indicators based on the woman and that a similar approach may be used in other production databases.

237. HEALTH TECHNOLOGY ASSESSMENTS (HTAS) PERFORMED ON TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) IN EUROPE: HOW DO THEY COMPARE?

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Objectives: The aims of this study were to compare the methods, results and conclusions of European HTAs published on TAVR and to investigate the impact of these HTAs on funding arrangements.

Methods: A systematic search (up to Dec 2011) of medical and HTA agency databases was conducted to identify any published HTA reports that examined aortic valve replacement using a transcatheter intervention.

Results: 12 HTAs and one Interventional Procedural Guidance (IPG) on TAVR were retrieved from 2005 to 2011 in 8 countries. The included HTA's evaluated a wide range of evidence from RCTs to individual case reports. Cost-effectiveness analyses (CEA) were undertaken in 2 HTAs (Spanish, Belgian). TAVR was cost-effective in both HTAs only for patients with AS who are deemed inoperable, with cost per quality-adjusted life year (QALY) ranging from 27,000 to 37,400 Euros. Time horizon for the 2 CEA's varied from 5 years (Spain) to lifetime

(Belgium). Favorable conclusions were given in 5 HTAs; favorable conclusion led to a positive recommendation for use of TAVR at a regional (Galicia, Spain; Venito Italy) hospital (Quebec, Canada) and national (HAS, France) level. Interestingly, funding arrangements for TAVR in some countries are not aligned with the conclusions and recommendations made by the HTA bodies. For example, the Austrian HTA body did not recommend the use of TAVR for patients with severe AS, yet TAVR is funded under DRG arrangements from January 2012. In Belgium TAVR is funded under hospital budgets despite the negative recommendation published by KCE.

Conclusions: TAVR has shown to be cost-effective in certain patient populations, yet a number of HTA agencies remain conservative in recommending this therapy. Interestingly, reimbursement and funding arrangements for TAVR in some countries do not appear linked to HTA conclusions. Further analysis is required to understand how this disconnect impacts patient access to TAVR.

238. HOW AND WHEN TO POOL DATA IN META-ANALYSES TO MAKE THE RESULTS CLINICALLY MEANINGFUL

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Background: Meta-analyses can be useful in deciding whether or not an intervention is feasible. However, it is subject to discussion which data should be included. An inclination to pool as much data as possible to get a sturdy estimate must be balanced against a possible increase in heterogeneity and difficulties in interpretation of the results within the clinical context. Based on issues that aroused during our preparation of a HTA report, Thromboprophylactic treatment with rivaroxaban or dabigatran compared with enoxaparin or dalteparin in patients undergoing elective hip- or knee replacement surgery, we highlight different choices we had to make.

Objective: The objective is to raise the awareness regarding choices that has to be considered when pooling data from different studies and its possible impact on the results and interpretation. We use the comparison of rivaroxaban to enoxaparin, in prevention of deep venous thromboembolism (DVT) in patients undergoing elective total hip replacement surgery as an example.

Methods: Data were extracted and pooled in different ways to give risk ratios (RR) and 95% confidence intervals (CI).

Results: Pooled data from 5 studies, regardless of doses and treatment duration, gained RR 0.46 (0.26-0.84). However, if the effect estimate is limited to the doses and treatment durations representative for clinical use within EU countries only one study remains, with a RR 0.28 (0.16-0.49). On the other hand, instead of narrowing the focus one might want to expand to pool data regardless of hip- or knee replacement therapy.

Discussion: Always adjust the meta-analysis according to the research question. Use of subgroups may facilitate getting an overview of the data, interpretation and extrapolation to similar research questions.

Implications for the health system/professionals/patients/society: Openness regarding which data is included in meta-analyses is necessary for optimal interpretation of results.

248. ASSESSING THE IMPACT OF HEALTH TECHNOLOGY ASSESSMENT ON THE AUSTRIAN HEALTHCARE SYSTEM

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Objective: In Austria, research in Health Technology Assessment (HTA) has been conducted since the 1990s. The aim of this study is to analyse whether the HTA reports of the Institute of Technology Assessment (ITA) and the Ludwig Boltzmann Institute for HTA (LBI-HTA) have had an impact on the Austrian Health Care System.

Methods: We applied qualitative and quantitative empirical research methods, such as interviewing, download analysis, questionnaire, retrospective routine data analysis and media analysis. Data were analysed according to a conceptual framework, considering seven impact categories (awareness, acceptance, process, decision, practice, final outcomes, enlightenment) and different target groups.

Results: A rising number of downloads and single HTA reports with high media interest were identified. Interviews showed that HTA reports have increasingly been used for investment and reimbursement decisions, as well as for the preparation of negotiations. Economic impact was indicated by decreased expenditures due to HTA recommendations. Overall, knowledge about evidence-based medicine increased and, in places, an 'HTA culture' can be recognised. Yet, several decision-making processes occur at all levels without the use of HTA.

Conclusions: The analysis demonstrated an impact within all pre-defined categories; however, it depends on the system level and its target groups. HTA reports are primarily used by hospital management, (social) insurances and the Austrian Ministry of Health. Nevertheless, there is still potential to increase the impact of HTA. Therefore, in Austria the inclusion of HTA in decision-making processes needs to move from a voluntary basis to a mandatory one.

254. LOCATING SEX SPECIFIC DATA IN HEALTH INTERVENTION RESEARCH: VALIDATING PUBLISHED FILTERS

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Background: Health technologies may be most effective when context (environment, needs and behavior) is factored into development and implementation. Literature search filters designed to retrieve demographic-specific outcomes such as age, race, and gender can facilitate the identification and incorporation of this data into health technology assessments.

Objectives: The objective of this study was to explore the effectiveness of published search filters in identifying sex specific data in health promotion intervention studies indexed in MEDLINE.

Methods: We devised literature searches to retrieve studies in MEDLINE on uptake of and attitudes towards colorectal cancer screening, nutritional labeling and influenza vaccination. Studies were screened for the presence or absence of sex-specific outcomes data; those reporting this data comprised our "gold standard". We calculated the sensitivity and precision of 3 sex-specific filters (MeSH, Montgomery and Moerman), previously validated with clinical studies, against our "gold standard".

Results: Overall filter sensitivity across topics was: 14.52% (MeSH), 54.41% (Montgomery) and 49.52% (Moerman). Overall precision was: 50.95% (MeSH), 39.31% (Montgomery) and 39.80% (Moerman). Sensitivity and precision were less than that reported in clinically based validations. Two MeSH terms in combination - female[MeSH] or male[MeSH] - yielded the greatest combined sensitivity (94.57%) but the lowest overall precision (23.97%) than that of any other term. Sex factors[MeSH] achieved the greatest precision (51.34%) of any term, MeSH or textword.

Discussion: We recorded lower sensitivity and precision results than in previous studies. This may reflect a more transparent reporting of sex-specific data in clinically based studies. Although it is possible to achieve high degrees of sensitivity in MEDLINE using sex-specific filters, precision is sacrificed.

Implications: Database search filters, validated or not, may result in missed studies. This research highlights both the need for this awareness and the importance of supplementing database searching with other methods of study identification.

268. LOCATING STUDIES FOR RAPID HEALTH TECHNOLOGY ASSESSMENTS: DO WE REALLY NEED TO SEARCH EMBASE?

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Background: Comprehensive and efficient literature searches provide the foundation for health technology assessments (HTA). Previous research has highlighted the inadequacy of EMBASE indexing which frequently retrieves many irrelevant studies. Additional searching and screening out irrelevant references impacts the timelines associated with the production of rapid HTAs.

Objectives: The objective of this study was to determine what evidence exists to support the inclusion of EMBASE as a core database in rapid reviews.

Methods: We conducted a retrospective analysis of 21 full and 4 rapid HTAs published since 2007 by 3 Canadian HTA agencies. Topics ranged from the purely clinical (eg: drug-eluting stents) to HTAs with broader social implications (eg: spousal violence). MEDLINE was searched for the clinical, economic and social implications studies included in these reviews. EMBASE was searched to identify studies not found in MEDLINE.

Results: Clinical studies in MEDLINE ranged from 37.5% to 100% with an average across HTAs of 89.56%. Clinical studies identified solely in EMBASE ranged from 0% to 37.5%, with an average across HTAs of 5.69%. EMBASE contributed most significantly to HTAs on sex offender treatment (37.5%), lymphedema (33.33%) and occupational stress (20%). Similar results were found for studies included in the social and economic components of HTAs. Notably, 11 HTAs did not include any EMBASE-specific clinical studies and 3 of 4 rapid reviews did not include any studies unique to EMBASE, clinical or otherwise. For HTAs with significant social implications most non-MEDLINE studies were found in PsycINFO.

Discussion: MEDLINE retrieved the majority of studies included in all HTAs. The importance of including EMBASE varied across HTAs. In some instances, databases other than EMBASE yielded a greater percentage of relevant results.

Implications: Although often considered a core database in HTA production, the value of including EMBASE in rapid reviews is debatable.

273. POTENTIAL OF NATIONAL HEALTH SURVEILLANCE AGENCY DATA SOURCES FOR EARLY AWARENESS AND ALERT ACTIVITIES IN BRAZIL

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Early Awareness and Alert (EAA) activities in Brazil are in initial stage and the search for local sources of data on emerging and new technologies is needed to establish a Brazilian EAA system within the scope of the Unified Health System (SUS in Portuguese). This survey aimed at evaluating the potential of data sources of the National Health Surveillance Agency (Anvisa in Portuguese) to be used in EAA activities. Four of the Anvisa's data sources were considered: clinical research, drug registration, medical device registration and drug price regulation. Each of these sources has specific forms that should be completed by a company in different phases of the marketing authorization process. These forms, available at Anvisa's website, were analysed regarding the usability of their data for EAA activities. The survey target data was about description of the new technology, clinical evidence on efficacy, potential risk to patient, evidence on safety, current clinical practice and potential impacts on patients and health system. Interviews were carried out with the staff responsible for two of data sources to clarify the process and the flux of information. The first two topics were requested by the four data sources. The potential risks to patients were described in all but the drug price regulation. The two latter topics were requested by the drug economic regulation form. These findings revealed that the data available for regulatory purpose could be a potential source of data for EAA activities in Brazil, however there is a need for verifying the consistence and the practicalities of the use of these data. The most challenging task will be to guarantee the access to these sources for EAA activities with the consent of all the stakeholders involved in the process.

302. A MIXED TREATMENT COMPARISON (MTC) TO COMPARE THE EFFICACY OF ANTI-THROMBOTIC AGENTS IN THE PREVENTION OF STROKE AND SYSTEMIC EMBOLISM (SE) IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION (NVAF)

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Background: This research was conducted during a review of the manufacturer's submission (MS) to the NICE Single Technology Appraisal programme for the oral direct factor Xa inhibitor, rivaroxaban.

Objectives: New anti-thrombotic drugs are available for prevention of stroke in patients with NVAF but evidence on their clinical effectiveness compared with existing treatments is limited. This research compared the clinical effectiveness of rivaroxaban, dabigatran etexilate (dabigatran), aspirin and adjusted standard dose warfarin (warfarin) in people with NVAF.

Methods: Randomised controlled trials (RCTs) for inclusion were identified using the MS for rivaroxaban, and 2 similar reports for dabigatran; inclusion was validated using published systematic reviews. RCTs were assessed for comparability based on patient population, disease severity, and treatments received. A Bayesian MTC was conducted, and fixed and random effects models were explored. Consistency was assessed via pair-wise meta-analysis for each treatment versus warfarin. Odds ratio (OR) was chosen as the summary statistic.

Results: The network of 8 RCTs formed a "radiating star". The fixed effects model was the best-fitting model. There was reasonable agreement between the number of unconstrained data points, residual deviance and pair-wise results, suggesting a coherent network. Statistically significant results compared with warfarin were: reduction in ischaemic stroke with dabigatran (OR 0.78; 95% Credible Interval [95%CrI]: 0.60–1.00); reduction in SE with rivaroxaban (OR 0.24; 95%CrI: 0.07–0.54); reduction in minor extracranial bleeds with dabigatran (OR 0.88; 95%CrI: 0.82–0.96) and aspirin (OR 0.57; 95%CrI: 0.33–0.91); reduction in intracranial bleeds with dabigatran (OR 0.41; 95%CrI: 0.27–0.60) and rivaroxaban (OR 0.66; 95%CrI: 0.46–0.92); increase in myocardial infarction with dabigatran (OR 1.43; 95%CrI: 1.02–1.97); and increase in discontinuations with dabigatran (OR 1.36; 95%CrI: 1.24–1.48).

Conclusions: This research suggests dabigatran and rivaroxaban may offer different clinical benefits and harms in patients with NVAF compared with warfarin.

306. METHODS FOR ANALYSING CROSS-OVER IN ONCOLOGY TRIALS: DO THEY INFLUENCE HTA REIMBURSEMENT DECISIONS?

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Background: Many oncology clinical trial designs allow patients in the placebo arm to cross-over to active treatment on progression. Whilst this is necessary from an ethical standpoint, the resulting data bias poses challenges for both pharmaceutical companies and payers in determining the overall survival (OS) benefit of treatment.

A number of extrapolation techniques have arisen to account for bias associated with participants switching from the placebo arm in a trial to the active substance once their disease has progressed.

Objectives: There is little evidence describing the relationship between extrapolation method used and the likelihood of approval by a HTA body. We therefore decided to analyse this with respect to PBAC (Australia) and NICE/SMC (UK) recommendations.

Methods: We focused only on those drugs indicated for renal cell carcinoma (RCC) which have been submitted to the aforementioned HTA bodies. Technology appraisals of everolimus, pazopanib, sorafenib and sunitinib were therefore analysed, paying particular attention to the modelling method used to extrapolate OS from progression free survival (PFS), specific details of the cross-over arm, and the reimbursement decision made.

Results and discussion: Two statistical methods were predominantly employed regarding all four drugs: Inverse Probability Censored Weighting (IPCW) and Rank Preserving Structural Failure-Time models (RPSFT). We identified 2 IPCW only submissions (0% approval), 3 IPCW and RPSFT submissions (33% approval; NICE), and 3 RPSFT only submissions (100% approval; NICE/SMC/PBAC). Based on decisions made by these three HTA bodies, the RPSFT method appears to be more acceptable to payers, supporting claims that RPSFT is the most consistent and least biased method.

Implications: When clinical trials allow cross-over to active treatment, using the RPSFT method to extrapolate OS from PFS data appears to be the most accurate and consistent method and is most likely to garner approval from reimbursement bodies.

311. POST-INTRODUCTION OBSERVATION OF NEW TECHNOLOGIES: PRIORITY SETTING IN SPAIN

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Background: Observation of health care technologies in real world settings is recognized a very valuable method for providing access to new technologies whilst resolving uncertainties. However, it is essential to prioritize which reimbursed technologies should be evaluated, taking into account the value of information. Since 2008 the Galician HTA agency (avalia-t) has been working on the development of a prioritization tool (PriTec Tools®) for decision making.

Objectives: This work aims to describe the results of the application of the PriTec Tools® in a real prioritization experience with key stakeholders involved in the approval and implementation of new technologies in the Galician Region.

Methods: The prioritization exercise was carried out by 15 key stakeholders: policy makers pertaining to the Advisory Commission that oversees the reimbursement of new technologies, hospital managers and head of medical departments. All technologies financed during 2008-2011 were assessed and decision support information sheets resembling mini-HTAs drawn up to aid scoring prioritization criteria. Priority scoring results were presented to the evaluators, exploring the degree of agreement with the results and potential use for direct decision making.

Results: The degree of concordance was high (ICC = 0.98) but evaluators were discrepant with the possibility of establishing a cut-off point for recommending observation. For some individual technologies, a great variability was observed in some of the domains and evaluators expressed the need for objective definitions as to how to translate specific results to a prioritization score.

Discussion and policy implications: The prioritization procedure was regarded as being a simple, useful and relevant. Even though the tool can require further improvements and adaptations, it is deemed relevant for helping make recommendations or starting discussions on the relevancy of conducting a post-introduction study.

354. EXPANDING THE APPLICABILITY OF HEALTH TECHNOLOGY ASSESSMENTS

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Objectives: The objective of the presentation is to expand the foundations of input into policy decision making relying on health technology assessments (HTA). HTAs are primarily based on systematic reviews (SR) and thereby mostly on randomized controlled trials (RCT). RCTs can be distinguished on a continuum between *explanatory* and *pragmatic* trials according to their level of control over variables in the study besides the examined technology. In explanatory trials emphasis are placed on internal validity in order to test the efficacy of a technology under ideal conditions while pragmatic trials emphasizes external validity and the effectiveness of a technology in normal daily practice. SR and HTAs favors internal valid trials and thereby proofs of possible cause-effect relationship between a technology and outcomes but at the expense of the wider perspectives of a technology. HTA have a policy-oriented perspective and aims at supporting health policy makers and therefore have to reflect policy applicable questions and answers. Simply relying on strictly controlled explanatory RCTs alone is too narrow to answer questions of relevance for policy making. It is suggested to supplement these highly controlled explanatory RCTs with the broader and more generalizable randomized pragmatic trials.

Implications: HTAs incorporating both explanatory and pragmatic RCTs will depict both clinically efficacy measures and outcome measures pertinent for the patients reflecting a wider spectrum of outcomes for the overall performance of a technology. They will also demonstrate the natural variations in implementation of the technology in different settings and contexts including variations between users of the technology and for the groups of real-life patients. In general, including both explanatory and pragmatic RCTs in HTA gives one the possibility of answering not only the question *Can it work?* but also the question *Does it work?*

375. COMPLEMENTARY AND ALTERNATIVE MEDICINE FOR PATIENTS WITH CANCER

Lene Kristine Juvet and Elisabeth Jeppesen

Norwegian Knowledge Centre for the Health Services. Norway.

Background: More than a third of all patients with cancer in Norway use some form of alternative or complementary therapy (CAM).

Objectives: In order to support The Norwegian Cancer Society's work with information we search for systematic reviews on the effectiveness and safety of complementary and alternative therapies for patients with cancer.

Methods: The following databases were searched in February 2010 for systematic reviews on cancer and CAM: The Cochrane Library, DARE, Science Citation Index, Medline, EMBASE, Pedro, Amed and PsycINFO. Two people independently read all abstracts, assessed the relevance and assess the methodological quality of the included systematic reviews.

Results: We included 39 systematic reviews of the following therapies: Vitamins and minerals, food supplements, different types of herbs, acupuncture, reflexology, massage, aromatherapy, hypnosis, homeopathy, traditional Chinese medicine and various body and mind techniques. Most of the included systematic reviews were based on included studies with low methodological quality. Many of these studies were small, and had mixed intervention or population. The interventions were different both in content, intensity, dosage and duration. The evidence was, with a few exceptions generally of low or very low quality when using the GRADE approach, and most results are uncertain.

Conclusions: There is a lack of evidence to draw convincing conclusions about efficacy and safety of most types of alternative therapies used by patients with cancer. Only within few interventions (acupuncture and cannabis) we can conclude about efficacy, most of the results are uncertain. For some of the alternative treatment methods there is evidence of adverse events.

Implications for the health system: To disseminating these uncertainties, we cover up for a major knowledge gap, which can use by health professionals when guiding patients.

384. TWO YEARS OF OPERATION OF THE PATIENT ACCESS SCHEMES LIAISON UNIT ASSESSING SCHEME (RISK SHARING) PROPOSALS FOR ENGLAND AND WALES

Andy Stainthorpe, Meindert Boysen, Emma Stewart, Tim Richardson and Carl Boswell

NICE. UK.

Background: In 2009, the National Institute for Health and Clinical Excellence (NICE) set up the Patient Access Scheme Liaison Unit to assess proposals for national Patient Access Schemes for inclusion in the appraisal of technologies for use in the NHS in England and Wales.

Objectives: Here we report the process used to assess scheme proposals, how this process has developed over two years of operation and the results of the assessments.

Methods: An overview of the process is and the results of two years of operation are presented.

Results and discussion: We also report how the effect the Unit has had on scheme proposals including the influence of the PASLU process, the type of proposals submitted and the approaches taken to maintain an effective dialogue with stakeholders and those putting forward applications. A review of the 12 or more applications submitted to PASLU per year will be discussed and identification of the key aspects of schemes which make scheme work in the NHS.

Implications for the health system/professionals/patients/society: Patient Access Schemes are a key mechanism by which manufacturers can allow access to new technologies without changing the list price. Their use in the context of health technology assessment is a key issue, particularly for technologies which might not have received a favourable review through technology appraisals.

389. METHODOLOGICAL GUIDELINE: HEALTH TECHNOLOGY ASSESSMENT (HTA) STUDIES FOR MEDICAL CARE EQUIPMENT (MCE)

Eduardo Coura Assis, Dayane Gabriele Alves Silveira, Flávia Tavares Silva Elias and Marcus Tolentino Silva

Brazilian Ministry of Health. Brazil.

Background: Medical care equipment management in Brazil faces a lack of methodologies and HTA studies. Due to this reasons the MCE management faces situations such as uncritical incorporation, unsatisfactory performance, high maintenance costs, elevated repair rates, inadequate use and a fast technological obsolescence.

Objective: To elaborate a methodological guideline to be adopted by the Brazilian Ministry of Health. Such guidelines will assist HTA studies during the diverse phases of medical devices useful life cycle - incorporation, use, and renovation or disinvestment.

Methods: Creation of a working group (WG) in order to identify the main methodological differences of HTA in MCE which differ from other health technologies. Validation of the guidelines by Methods working group of the Brazilian Network for Health Technology Assessment (REBRATS).

Results: The guidelines are undergoing review by specialists and will contribute to improve HTA studies for MCE. It deals with technical-scientific characteristics, admissibility criteria, operational aspects and dimensions of the economic and industrial health complex, thus providing improved management in the Brazilian Public Health system (SUS) sphere.

Discussion: This guideline will complement gaps in Brazilian HTA guide.

Implications for the health system/professionals/patients/society: It is hoped that the scientific community can use this instrument as an element of support for the elaboration of HTA studies with MCE.

395. "MINI-EVIDENCE ASSESSMENTS": WHAT IS THEIR PURPOSE AND WHAT ATTRIBUTES DO THEY INCLUDE?

Gillian Barnett[a], Kathy Cargill[b] and Liesl Birinyi-Strachan[c]

[a]Gillian Barnett and Associates. Ireland. [b]Medtronic International. Switzerland. [c]Medtronic. Australia.

Objective: To investigate the purpose and attributes (time to completion, what type of evidence was considered) of "mini-evidence assessments" (MEAs) including early/pre/rapid assessments, horizon scans, brief technical reports, hotline responses, rapid reviews/responses, rapid health technology assessments, or new product alerts specific to medical devices.

Methods: A systematic search (up to 2011) of medical and HTA agency databases was conducted to identify all published full and MEA reports that evaluated medical devices in selected therapy areas. Searches, study selection and data extraction were performed according to a predefined protocol.

Results: Information on 38 MEAs was extracted for review (29% cardiac rhythm disease management, 21% CV, 29% neurological, 8% spine, 13% diabetes). These assessments were developed for Argentina (29%), Canada (18%), UK (16%), Sweden (11%) and Australia/NewZealand (8%). The primary reasons for their development were to assess available evidence (50%), assess an emerging technology (24%), update an existing assessment (13%), rapidly review the available evidence (10%) and to determine the need for a full HTA (3%). While all assessments included reviews of clinical data, 82% excluded economic data. An estimate of the mean length of time taken to develop an assessment was possible in 53% only, showing an average of 4.3 months to completion, while 18% were completed within 1-year

of device approval. Among those assessing new/emerging technologies, the majority were completed within 1-year of device approval (56%) and a minority were completed before product approval (22%).

Conclusions: While the reasons for carrying out a MEAs are broad, the main purpose was to assess available evidence. In the majority of reports, the assessment of economic data was excluded and insufficient numbers provided start and completion dates to allow determination of how long these abbreviated reports take to complete.

410. BEYOND DIAGNOSTIC ACCURACY – COST EFFECTIVENESS OF DIAGNOSTIC TESTS

Hanan Bell, Sarah Baggaley and Nick Crabb

NICE. UK.

The UK National Institute for Health and Clinical Excellence (NICE) has recently established the diagnostics assessment programme which applies methods developed specifically for assessing diagnostic technologies. In order to carry out cost-effectiveness analysis and develop recommendations for the best clinical use of diagnostics, decision-makers such as NICE need to consider more extensive evidence than is commonly provided by systematic reviews and meta-analysis of diagnostic accuracy data. The challenges of assessing diagnostic test accuracy and methods for systematic review and meta-analysis are well known and frequently discussed. Using examples from NICE's early diagnostics guidance, this presentation will cover a number of other technical issues encountered by the programme in producing guidance that is applicable in the real-world setting of the national health service. These include: 1. What costs and benefits are included in the analysis? Most benefits from diagnostic tests come from downstream treatments. This means the entire care pathway usually needs to be included. However, this can make for a complex problem where the cost-effectiveness of a diagnostic may change when the cost of a treatment changes. 2. How do we deal with equipment or tests which are subject to frequent upgrades and modifications, particularly where evidence applies to earlier versions of the test? 3. How is the situation handled where there is no "gold standard", or where the new test may be more accurate than existing tests?4. How should the value to the patient of the information supplied by the test be included in the evaluation? This includes the value of prognostic information as well as the anxiety (or relief) created by test results. NICE will use its experience of applying these questions to live topics to further enhance its evaluation methods.

418. USER NEEDS IN KIDNEY DISEASE MONITORING – A USER ORIENTED APPROACH TO HEALTH TECHNOLOGY ASSESSMENT

Janine van Til, Maarten IJzerman and Ron Kusters

University of Twente. Netherlands.

Introduction: The perspective of the end-user is often overlooked in the evaluation of a technology, especially in the development phase. We aim to extent on an existing model to include the needs & wants of actual users into health technology assessment.

Methods: The novel application of the Medimate Multireader® is focused on the monitoring of electrolytes in the blood and is targeted especially at patients at risk of kidney disease. The application should be used by the patient itself. We conducted literature analysis, clinician and patient interviews, and questionnaires to estimate the impact of this technology on the patient, and their willingness and ability to perform self-monitoring tests.

Results: First, we identified that patients with diabetes mellitus were the largest and easiest identifiable target group for the device. Second, the clinical needs of the patient group were identified through literature review, practice guideline analysis and interviews with general practitioners and patients. It was concluded that the clinical benefit of this technology to the patient is limited, but there is a desire among patients to have more frequent checks of kidney function. Third, different "use" cases were developed based on the qualitative data collected. In the fourth phase of this study, which is currently ongoing, we use a conjoint analysis methodology to place values on the different aspects of the technology implementation, to determine which factors are most crucial for future development and ultimately implementation.

Discussion: The model enables active gearing of the technology towards user needs. As implementation of the technology is crucially dependent on user related factors such as acceptance and actual use, this is paramount. With the addition of quantitative data gathering in the last phase, value judgments are made explicit and further development decisions can be based on data that is easy to interpret for the developer.

437. MAPPING THE IDENTIFICATION PROCESS AND COLLABORATION BETWEEN EARLY AWARENESS AND ALERT SYSTEMS

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Background: EuroScan International Network is a collaborative network of member agencies carrying out early awareness and alert (EAA) activities. Previous surveys amongst EuroScan's members showed differences in the way they approach the basic steps to achieve their goals, and similarities among the main source of data used. A better understanding of the identification process of each member could help in the discovery of existing tools, the development of appropriate new tools and the improvement of collaboration between members.

Objectives: This study aims to map the identification process of new and emerging technologies and explore the support for and practicalities of developing a more collaborative approach within EAA activities worldwide.

Methods: A survey was carried out amongst INAHTA's members to identify agencies (other than EuroScan members) developing EAA activities and amongst EuroScan members to identify collaborative work.

Results: The response rate of INAHTA members (excluding EuroScan members) was 26%. The survey revealed nine Non-EuroScan agencies undertaking EAA activities and three who were thinking of starting activities. Four EuroScan members reported collaboration with other agencies related to identification, prioritisation and assessment of new and emerging health technologies. The main reasons reported for the absence of collaboration were: lack of financial or human resources and lack of opportunity. The identification process and existing collaborations between agencies will be explored by means of an interview to investigate further how collaboration can be promoted or assisted.

Conclusions: International collaboration between agencies is important to reduce duplication and use of resources and increase coverage and efficiency. However, our study indicates that despite being part of a collaborative network, collaboration between individual agencies is uncommon.

471. A SYSTEMATIC APPROACH FOR IDENTIFYING CURRENT PRACTICES OF DOING HTAS ACROSS INTERNATIONAL HTA AGENCIES

Dimitra Panteli, Julia Kreis and Reinhard Busse

Berlin University of Technology (Technische Universität Berlin). Germany.

Background: When researching specific methodological issues related to HTA production, an overview of established practices is a prerequisite for facilitating knowledge transfer, analyzing best practice and potentially formulating new methodological recommendations.

Objectives: For the purpose of investigating approaches regarding unpublished data and equity issues in HTA, we aimed to systematically identify agency practices regarding HTA methodology in the international context, both on the basis of official methodology guides and on the basis of actual HTA reports.

Methods: We used a systematic, iterative approach to pinpoint agencies, their method guides and HTA reports. We combined the membership lists of EUnetHTA, HTAi and INAHTA and completed the agency pool using comparative publications of the two latest available years of IJTAHC. Between February and May 2011, we used both online resources and direct (email) contact to obtain methodological guides and specific reports from each agency and filtered these based on specific exclusion criteria. We subsequently analyzed both methodological handbooks and reports from the same agency.

Results: Of the 101 agencies identified, 19 were deemed eligible for the analysis of methodological guidelines and HTA reports. Reasons for exclusion included limited access to information (language and confidentiality), no active HTA report production and no methodological guidance universally applied to reports by the agency.

Discussion: Identifying a representative sample that is at the same time feasible to work with proved to be a more challenging task than expected. The exclusive utilization of online resources is a potential limitation to the completeness of the sample. However, the combination of international networking platforms and recent comparative peer-reviewed publications is a reasonable starting point for exploring contemporary practices across HTA agencies.

Implications: The introduced approach can be used for investigating different methodological issues across HTA agencies and therefore enhance knowledge transfer with the aim of advancing HTA methods.

483. USING A NOVEL FRAMEWORK FOR TEST EVALUATION TO INFORM THE DESIGN OF DECISION MODELS IN TEST HTAS

Chris Hyde[a] and Lavinia Ferrante di Ruffano[b]

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Background: HTAs of tests remain a major challenge. There is a desire to make decisions about market access or reimbursement of new tests on the basis of evidence about the effect these tests will have on patient outcome. But achieving this with existing evidence and HTA methods is a challenge. Possibly one of the most promising approaches is the "linked evidence" approach using modelling to bring together evidence on test accuracy and treatment effectiveness. Experience of this, such as by NICE's Diagnostic Assessment Committee is that defining the question to be addressed is critical to the ultimate success of model. We have recently developed an evaluation framework for tests (BMJ in press). This project explores whether such a tool might facilitate question definition in decision modelling for test HTAs.

Methods: We will conduct structured interviews with the modellers responsible for the design of the models used to inform NICE's Diagnostic Assessment Committee decisions so far.

Results: Interviews will be completed during May 2012.

Conclusions: We believe the framework we have developed, by encouraging investigators to be explicit about the mechanisms by which they expect a new test to impact on patient outcome and offering a typology of means by which this could be achieved, will be of assistance in model development.

504. THE INFLUENCE OF CURRENT ACCOUNT BALANCE ON THE DECISIONS OF HTAS REGARDING SELECTED MEDICAL DEVICES

Gillian Barnett[a] and Andrew Eggleston[b]

[a]Gillian Barnett and Associates. Ireland. [b]Medtronic Australia. Australia.

Objective: To investigate trends in the decisions of national and within-country regional HTAs performed on selected medical device therapies according to economic indicator (primarily current account balance as a % of gross domestic product [CAB%GDP]).

Methods: A systematic search (up to 2010) of medical and HTA agency databases was conducted to identify full published HTA reports that evaluated medical devices in selected therapy areas. Searches, study selection and data extraction were performed according to a predefined protocol. Only HTAs carried out from the perspective of publically funded HC systems were included. The ratio of the odds of a favorable decision (FD) by HTAs occurring in countries with a current account surplus to the odds of a favorable decision by HTAs occurring in countries with a deficit was calculated (odds ratio [OR]). The CAB%GDP was extracted for the year of HTA publication.

Results: 85 full HTAs were included for review (28% cardiac rhythm disease management, 28% CV, 20% neurological, 15% spine, 8% diabetes). Of these, 76% were carried out in Canada (22%), UK (14%), France (14%), Australia (13%) and Spain (13%).The decisions of 74% of these HTAs were favorable (22/36 in countries in surplus, 41/49 in countries in deficit). Therefore, the odds of a FD in surplus countries is 1.57 and the odds of a FD in deficit countries is 5.12, an OR of 0.306. Examination of trends in decisions by HC expenditure provided no additional information.

Conclusions: A FD by a HTA agency is less likely to occur in a country with a current account surplus as a % of GDP. In an era of increasing spend on HC as a% of GDP and overall, there appears to be little influence of CAB%GDP status on agency decisions. However, confounding variables have not been accounted for in this analysis.

551. BENEFIT-RISK ANALYSIS IN ABSENCE OF CLINICAL EVIDENCE: DECIDING FOR TREATMENT OF SKULL DEFORMITY IN BABIES AGED 5 MONTHS

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[a]University of Twente. Netherlands. [b]Radboud Universiteit Nijmegen. Netherlands.

Introduction: Skull Deformaty (SD) is a flattening of the head as a result of pressure on the malleable skull in infants in the first months of life. Presently, a RCT is conducted to compare the effect of an orthotic helmet to the natural recovery of skull shape in the first three years of life. Burden of treatment is considerable; the helmet has to be worn 23 hours a day for at least 6 months. Possible harms include acceptation problems, pressure wounds and severe skin rash or eczema. The harms of treatment are perceived as an important reason for low adherence to and parental refusal of helmet treatment. The

objective of this study is to estimate the risk-benefit trade-off in SD management in pediatric physiotherapists.

Methods: A discrete choice experiment was performed with the most important attributes of SD management. A total of 267 pediatric physiotherapists stated their preference for treatment of a 5 month old child with SD. A three scenario design was chosen Each scenario was characterized by its effect, its burden and the harms of treatment. Logistical regression analysis was performed to analyze the results of the discrete choice experiment.

Results: Not surprisingly, child physiotherapists' ideal treatment has a high probability of timely success with low burden and minimal harms. At present, most attributes indicate a strong preference for awaiting natural recovery. Risk benefit assessment favoring the helmet will only be attained if the helmet can show highly significant clinical benefit.

Conclusions: This study shows that risk benefit analysis can give early indications on the potential of a treatment, by estimating the effectiveness at which the treatment becomes more favorable than its comparator. Whether the risk-benefit analysis will be in favor of helmet treatment in the case of SD, is questionable, as earlier studies have not demonstrated superiority of the helmet.

557. VALIDATING A MULTI-CRITERIA DECISION ANALYSIS (MCDA) FRAMEWORK FOR HEALTH CARE DECISION MAKING

Janine van Til[a], Marijke Lieferink[a], James Dolan[b] and Mireille Goetghebeur[c]

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Introduction: When evaluating healthcare interventions, decision-makers are increasingly asked to consider multiple criteria to support their decision. The MCDA-based EVIDEM framework was developed to support this process. It includes a simple weight elicitation technique, designed to be easily applicable by a broad range of users. The objective of this study was to compare the EVIDEM technique with more traditional techniques.

Methods: An online questionnaire was developed comparing the EVIDEM technique with four alternative techniques including AHP, best/worst scaling, ranking and point-allocation. A convenience sample of 60 Dutch and Canadian students were asked to fill out the questionnaires as if they were sitting in an advisory committee for reimbursement/prioritization of healthcare interventions. They were asked to provide weights for 14 criteria using two techniques, and to provide feedback on ease of use and clarity of concepts of the different techniques.

Results: Results based on the first 30 responses show that EVIDEM is easy to understand and takes little time to complete, three minutes on average. Criteria weights derived using the EVIDEM technique and best/worst scaling are divergent. Comparing the rank order of criteria respondents gave using these two techniques; there is more resemblance in rank order of criteria weighted with the EVIDEM technique. Compared to AHP/ranking/point-allocation, EVIDEM takes less time to complete but is only preferred by 33% of decision-makers. AHP/ranking and point allocation were often described as clearer and more reflective of the respondents' opinion. CONCLUSIONS: The simple technique is proposed as a starting point for users wishing to adapt the EVIDEM framework to their own context. Other techniques may be preferred and their impact on the MCDA value estimate generated by applying the framework is being explored. This project is part of a large collaborative work that includes developing and validating this framework to facilitate sound and efficient MCDA-applications.

561. MEDICAL TECHNOLOGY EVALUATION II: CATALYSING THE DEVELOPMENT OF PRIMARY CLINICAL EVIDENCE FOR PROMISING TECHNOLOGIES

Chris Pomfrett, Bruce Campbell, Phil Pugh, Mark Campbell and Mirella Marlow

NICE. UK.

Health technology assessment (HTA) of medical technologies has the potential to improve both patient care and the efficiency of health services, by promoting adoption of devices and diagnostics with demonstrable advantages over current practice. Established HTA methods may not be readily applicable, because of the large number of new technologies, their typically sparse evidence base, the need for timely guidance (especially for products with a short market life) and the inexperience of many manufacturers with the requirements and principles of HTA. In the UK, the National Institute for Health and Clinical Excellence (NICE) has developed a novel methodology for generating further high-quality clinical and proof of concept evidence where gaps in the literature prevent its independent advisory committee from making confident recommendations about the use of apparently promising technologies. NICE has developed an indirect model of evidence generation, to ensure that it remains independent of study design and findings. When recommendations for further research are made in published guidance, NICE asks external assessment centres to assess the feasibility of research and to generate protocols for testing one or more scientific hypotheses which address the identified evidence gaps. To date, research recommendations have been made for four technologies (of a total of 11 guidance topics). We will present research protocols for studies on the first technologies handled in this way. Feedback from manufacturers, clinical researchers and academics has, so far, been positive. This independent model also encourages funding from manufacturers with an assurance of independence and the avoidance of potential bias in the research. The aim of this novel approach is to drive an increase in the quality and quantity of primary clinical evidence which can support recommendations for adoption of medical technologies.

565. HTA: LEADING OR FOLLOWING CLINICAL RESEARCH?

Moni Choudhury, Sarah Garner and Tarang Sharma

National Institute for Health and Clinical Excellence (NICE). UK.

An inevitable output of systematic reviews/HTA is that more research is needed due to uncertainties in the identified evidence base. It is often important that this research is undertaken to inform subsequent revisions of guidance and resolve clinical questions. In many countries, like the UK, the resources for primary research are separately administered from HTA so co-ordination is necessary. This has been difficult to date. *Recommending research through active prioritisation?* In 2010, with a view to supporting the development of the evidence base, NICE reviewed the processes and methods related to clinical research recommendations. This led to an improvement in the quality and clarity of research recommendations and supporting information. The changes have also reduced the time taken for research recommendations to be referred to research funders.

Mirroring the UK model? There are a number of initiatives that aim to improve the mapping of uncertainties. Further co-ordination is required. In the UK this will be facilitated through the UK's Database of Uncertainties about the Effects of Treatments (UK DUETs). A cancer-specific database has also been created with the aim of streamlining the communication and prioritisation of uncertainties identified by EU guideline development agencies.

Proposal? Systematic reviews and health technology assessments create a comprehensive map of the current research knowledge. As a

result they are well placed to identify important gaps in knowledge, particularly when they are done in the context of clinical guidelines. Co-ordination with other initiatives and funding could facilitate prioritisation across a disease area. Given most HTA agencies use prioritisation methodology to select topics it would suggest that the arising research uncertainties would be of priority. Yet in most countries there is little transfer of the outputs of HTA into the research agenda and there is much duplication of effort.

591. REVIEWING THE EVIDENCE TO INFORM THE CONCEPTUALISATION AND POPULATION OF COST-EFFECTIVENESS MODELS WITHIN HEALTH TECHNOLOGY ASSESSMENTS

Eva Kaltenthaler, Paul Tappenden and Suzy Paisley

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Background: Health technology assessments usually require the development of a cost-effectiveness model which in addition to clinical effectiveness evidence will require other information to populate parameters. These information requirements can provide researchers with considerable difficulties depending on the size, timing and number of review requirements. The reviewing activity associated with the model development needs to be both timely and systematic and there is a tension in terms of the need to ensure that the process is transparent and reproducible. Methodological standards for reviewing the broad range of relevant evidence in the context of model development do not currently exist.

Objectives: The purpose of this research was to provide guidance and advice on what might constitute a systematic and transparent approach where there is not a requirement to use conventional systematic review methods but where little procedural guidance exists.

Methods: A series of focus groups were held with HTA experts in the UK including systematic reviewers, information specialists and cost effectiveness modellers and framework analysis was used to analyse the qualitative data generated by the focus groups.

Results: Recommendations include the use of rapid reviewing methods and established hierarchies of evidence sources. Transparency in the reporting of review methods was emphasised. It was suggested that additional attention should be given to the reporting of parameters deemed to be more important to the model or where the choice of evidence was not clear.

Discussion: These recommendations will help to ensure a more systematic, transparent and reproducible process for the review of model parameters within HTA. These recommendations form part of a Technical Support Document commissioned by the National Institute for Health and Clinical Excellence in the UK.

597. A QUALITATIVE STUDY TO EXPLORE THE IDENTIFICATION AND REVIEWING OF EVIDENCE USED IN COST-EFFECTIVENESS MODELS IN HEALTH TECHNOLOGY ASSESSMENTS

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Background: The development of a cost effectiveness model within health technology assessments always requires additional information beyond costs and clinical efficacy. A systematic consideration of possible data sources is required and there is a need for a systematic transparent and justifiable approach. Although the issues have been highlighted in detail there appears to be very little guidance in this area with regard to best practice.

Objectives: This aim of this research was to use qualitative methods to explore issues around the identification and review of evidence and to suggest options for their resolution.

Methods: A series of focus groups were held with UK HTA experts including systematic reviewers, information specialists and cost effectiveness modellers. Framework analysis was used to analyse the themes generated in the focus group transcripts.

Results: Seven themes were generated from the analysis of the focus group transcripts. These included (1) time constraints and how this impacts on the chosen approach; (2) the need for expertise within the team developing the model; (3) the importance of judgments with regard to the appropriateness and relevance of data choices; (4) the need for transparency to ensure reproducibility and to enable the justification of choices made; (5) the importance of communication within the team; (6) the need for appropriate searching methods to ensure the retrieval of relevant evidence and (7) issues around model parameters including robustness, the use of existing evidence and expert elicitation.

Discussion: This research highlights numerous issues in the process of identifying, selecting and using evidence to inform models and some possible solutions. Further guidance is required to ensure that such research activity is transparent, timely and rigorous.

650. ABIRATERONE ACETATE FOR METASTATIC CASTRATE-RESISTANT PROSTATE CANCER (MCRPC): MODELLING OVERALL SURVIVAL FOR THE NATIONAL INSTITUTE OF HEALTH AND CLINICAL EXCELLENCE?

Martin Connock[a], Deepson Shyangdan[a], Amy Grove[a], Ewen Cummins[b], Beth Hall[a] and Aileen Clarke[a]

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Background: Abiraterone acetate (AA) is used in conjunction with prednisolone and licensed as a second line treatment of mCRPC. An RCT demonstrated superior overall survival for AA+prednisolone (AAP) versus placebo plus prednisolone (PP). The cost effectiveness of AAP versus PP was recently assessed by NICE as part of its STA programme. An important element of the appraisal concerned the modelling of overall survival.

Objectives: To critique modelling of overall survival.

Method: The submission to NICE used a 10 year time horizon and analysis was for 174 three week cycles. Unusual features in survival modelling were the use of raw Kaplan-Meier data until a cut-off at 10% of patients at risk, and extrapolation beyond cut off using a constant hazard (i.e. an exponential extrapolation). We examined some underlying assumptions in this approach.

Results: The constant hazard used for extrapolation depended on the observed survival at a single arbitrary cut-off point. With alternative cut-offs, hazard values varied as did mean survival estimates (557 to 761 days for AAP arm). Parametric distributions delivered stable estimates of mean survival (e.g. 534 to 567 days for AAP arm). In contrast to parametric fits, the different cut-offs used in the constant hazard model resulted in variable estimates of survival gain from AAP over PP.

Discussion: The original submission to NICE gave an estimation of overall survival gain from AAP which was arbitrary and sensitive to the cut-off used. Well fitting parametric distributions fitted to the observed data provided more stable estimates.

Implications for the health system/professionals/patients/society: The NICE Appraisal Consultation Document considered that survival modelling in the AAP submission resulted in an overestimate of cost effectiveness.

654. QUALITY APPRAISAL OF GUIDELINES FOR BREAST, COLORECTAL AND CERVICAL CANCER SCREENING

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Background: Oncologic **s**creening programs are evidence-based interventions recommended by most Governmental Agencies and Scientific Societies guidelines. Nevertheless international and national guidelines on their organisation and implementation differ in their main characteristics.

Objective: The aim of the study is to assess guidelines on screening programs, using the AGREE instrument. As a secondary objective the applicability of the AGREE tool to preventive guidelines is also evaluated.

Methods: A literature search was carried out through the main databases in order to identify the most recent guidelines (since 2000) on population screening programs for breast, cervical and colorectal cancers. In particular general websites on health care, some specific websites for guidelines as well as webpage of several scientific societies of interest have been explored. Only documents written in Italian and English were included. Selected guidelines were then independently assessed by two investigators using the instrument developed by the AGREE Collaboration.

Results: Through the literature search relevant documents for cervical (33), breast (32) and colorectal cancer screening (18) have been identified. Only few documents (19, 12 and 13 for cervical, breast and colorectal cancer screening, respectively) could have been evaluated with AGREE. Items included in the domain "scope and purpose" obtained the highest scores, followed by "clarity of presentation" domain, while "the applicability", "patient involvement" and "conflict of interests disclosure" domains obtained the lowest scores. Some items were not easily applicable to guidelines on prevention.

Discussion: Many recommendations about screening are usually presented in government Acts not structured as evidence based guidelines. The quality of documents could be improved addressing barriers to applicability and disclosing conflicts of interest.

Implications for the health system/professionals/patients/society: Some modification to the AGREE tool may improve its ability to assess guidelines on preventive intervention.

656. ALTERNATIVE INTERVENTIONS TO DECREASE SECLUSION AND RESTRAINT IN HOSPITALIZED PATIENTS: AN HTA REPORT ON BARRIERS AND FACILITATORS ASSOCIATED WITH THEIR IMPLEMENTATION AND USE

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Background: Despite clear recommendations of the Quebec health authorities to decrease seclusion and restraint in hospitalized patients, use remains high in some healthcare settings. However, little is known about factors that may facilitate or limit implementation and use of alternative interventions (AIs).

Objectives: To document use of AIs in targeted healthcare settings and identify the barriers and facilitators associated with their implementation and use.

Methods: A multicenter, multidisciplinary, workgroup was involved in identifying AIs and preoccupations associated with their use in different healthcare settings [long-term geriatric (LTG), short-term psychiatric (STP), short-term medical (STM), readaptation (R)]. To identify key issues related to the use of AIs, a triangulation method was carried out, including a standardized questionnaire sent out to 39 care settings and 10 focus groups composed of multidisciplinary stakeholders (n = 66).

Results: A variety of AIs were identified across settings. Surveillance devices were the most frequently reported in LTG (63%), STM (100%) and R (67%), but were not used in STP. Behavioral approaches were most frequently reported in STP (89%) and R (67%) but were not used in STM. According to the majority of respondents (74%), AIs are available but are not always used consistently. Major preoccupations across all settings regarded efficacy, safety and costs of patient surveillance methods. Lack of financial and human resources, staff and family resistance, lack of training and follow-up, and specific infection-control recommendations were the most frequently mentioned barriers. Support from organization and care teams, staff motivation, convictions and leadership were among the most valued facilitators.

Discussion: Factors related to staff, organizational culture, and families appear to be essential to ensure effective and sustained use of AIs. This study has yielded important information to support best clinical practices and plan future cost-effectiveness investigations.

660. NEW AND EMERGING TESTS FOR DIAGNOSIS AND SCREENING - RESULTS OF HORIZON SCANNING REVIEWS IN 2010-2011

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Background: In 2009, the National Horizon Scanning Centre in England developed a new product that focuses on a specific technology group/clinical field and identifies all related developments on the horizon. This "technology specific" review was developed to inform commissioning and planning. Between 2010 and 2011, 3 such reviews have been requested that focus on new and emerging technologies for diagnosis or population screening: point of care tests for influenza, tests for human papilloma virus (HPV), and biochemical tests for screening for colorectal cancer.

Objectives: To report on the results of the three "technology specific" reviews and provide an insight into the challenges of horizon scanning for diagnostic and screening technologies.

Methods: Each review involved the identification of companies active in the development of the technology of interest through internet searches and contact with trade associations and experts; contacting the identified companies to obtain information on the technology; and application of exclusion criteria to select those technologies of relevance to the review.

Results: Over two hundred potentially active companies were identified for the three reviews (56 influenza, 48 HPV & 98 colorectal cancer review). Of these, between 52-61% companies responded to a request for information. In total for the three reviews, 306 diagnostic/screening tests were identified as being potentially relevant (58 influenza, 106 HPV and 142 colorectal cancer). After exclusion criteria were applied this number reduced to 204 technologies.

Conclusions: Identification of new and emerging IVD tests is resource intensive due to the number of companies involved in the development of such technologies and the even greater number of technologies being developed. Obtaining early information about the technologies is challenging due to the lack of publicly available information and the unwillingness to provide information by some companies.

679. IS INDEXING OF DTA STUDIES IMPROVING?

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Background: Efficient searching and screening for diagnostic test accuracy (DTA) studies is problematic due to poor reporting and suboptimal indexing. Using search terms relating to condition and diagnostic tests only may provide high sensitivity but generate an impractical number of records to screen. EMBASE has recently introduced the check tag "*Diagnostic Test Accuracy Study*" to improve the retrieval of DTA studies.

Objectives: To investigate the ability of current indexing, including the new check tag, to assist retrieval of DTA studies.

Methods: Two DTA reviews are in progress**.** The search strategies included terms relating only to disease and diagnostic tests and potential DTA studies were identified by title/abstract screening by two researchers. DTA-related MeSH and EMTREE were identified from the database thesauri. Retrieval performance will be assessed against records selected as potential DTA studies and those confirmed as such by full text assessment. Only studies published in 2011 will be included to permit evaluation of the new check tag.

Results: 13 MeSH and 15 Emtree were identified as potentially DTA-relevant. Preliminary results for one review show that performance of individual terms was variable. The terms that achieved the best balance between precision and sensitivity were *Sensitivity & specificity* (44%, 33% respectively) for MEDLINE and *Diagnostic test accuracy study* (47%, 35% respectively) for EMBASE. Restricting the subject search by any of the indexed terms retrieved 83% of potentially relevant MEDLINE records and 91% of EMBASE records (98% articles; 84% conference abstracts) with an accompanying reduction in number screened by 32% and 36% respectively.

Discussion: The new check tag achieved highest balanced performance. Including all terms would have substantially reduced the records to be screened with minimal loss in potentially relevant articles for EMBASE. Analysis using confirmed DTA studies will inform to what extent the loss was confined to non-DTA studies.

680. SULTHIAME IN THE USE OF CHILDREN WITH REFRACTORY EPILEPSY IN THE CEARÁ, BRAZIL: A HEALTH TECHNOLOGY ASSESSMENT

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Background: The Sulthiame (STM), Ospolot® is a sulfonamide, anhydrase inhibitor used as a anticonvulsant, was established as second line drugs for treatment of partial epilepsy. In Brazil there is no record of the STM in the National Agency of Sanitary Surveillance (ANVISA).

Objective: To present the HTA on the use of STM in children with refractory epilepsy in the state of Ceará, Brazil.

Methods: Elaboration of HTA. The inclusion criteria were studies of Systematic Review (RS) of randomized controlled trials (RCT), RCT or HTA. The HTA's question was based on available evidence which related to the used of STM in refractory epilepsy in children. For the search of the scientific evidence, the terms used was "sulthiame" [Suplementary concept] OR "sulthiame" [Text Word] AND Systematic [sb] in databases Tripdatabase, Pubmed, HTA international Vortal, Virtual Health Library, Cochrane Library and Centre for Reviews Disseminations.

Results: One SR with 14 RCTs was selected. But just one was about of the therapy of infantile spasms with sulthiame. However, the outcome was a cessation of infantile spasms in 30% of treated group. In addition to the SR, two others RCTs were selected. The outcomes were related to a transitory normalization to the electroencephalogram (EEC) in patients with benign centrotemporal seizures (BECTS) and to efficacy and safety of STM in preventing seizures in BECTS.

Implications for the health system/professionals/patients/ society: The ATS described that there are insufficient evidences for the use of STM in children with refractory epilepsy. As regards the law, the STM is not registered in ANVISA, Brazil. Therefore, the ATS did not favour the incorporation of the technology due to lack of methodological and legal conditions in Brazil.

688. THE USE OF DISCRETE EVENT SIMULATION IN HEALTH ECONOMICS

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Background: Discrete Event Simulation (DES) is a modelling technique based on individual simulations following the natural concept of time. It is a more flexible way of modelling clinical realities and allows the inclusion of interaction among individuals (that occurs, for example, when health resources are not available at given time generating queues). Its use is well established in operational research but still controversial in the field of health economics. Some authors discussed that DES models can add complexity without justify in terms of better decisions. Others stated that DES provides more accurate estimates without being computationally prohibitive. **Objectives:** To present the key characteristics of the DES technique and how it can be implemented using the software Matlab; and discuss how a carefully searching for a better model can add valuable information for decision purposes.

Methods: This work shows a practical example to present the main characteristics of the DES technique. The example compares two interventions for a coronary disease. Interventions are performed at a daily basis. When the number of daily interventions is limited the patients need to wait in queues. This situation is modelled using DES. The simulations were performed using the Matlab software and some insight of this software will be given. A brief comparison of results from the DES model and from a simple Decision Tree model (for the case where the daily number of interventions is not limited) is presented.

Conclusions: DES models can incorporate patient interaction naturally and the Matlab software can implement these characteristics without computational costs. When limited resources are available its incorporation through a DES model has decision impacts.

700. ENDOVASCULAR TREATMENT OF RUPTURED CEREBRAL ANEURYSM COMPARED TO CONVENTIONAL SURGICAL TREATMENT: THE SEARCH FOR EVIDENCE

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Background: The cerebral aneurysm is an abnormal dilation of an artery that can lead to rupture, and it is main cause of aneurysmal

subarachnoid hemorrhage (ASH). The treatment may be surgical (gold standard) or by endovascular therapy. The choice depends on the clinical condition of the patient and the characteristics of the aneurysm. Objectives: Identify the scientific evidence of safety and effectiveness of endovascular treatment, compared to conventional surgical treatment.

Methods: Searches in databases: Medline (by Pubmed), Tripdatabase, The Cochrane Library (by Regional Library of Medicine), Google Advanced. We selected 7 studies, where it was considered the data from International Subarachnoid Aneurysm Trial held in 2002, updated in 2005, countersigned/referenced in the other selected studies whose patients included were eligible for both treatments, with similar outcomes.

Results: The endovascular treatment produces better survival without sequelae for patients with subarachnoid hemorrhage in good clinical condition.

Discussion: The ASH represents less than 5% of all Strokes (AVC) with an incidence of 6-10 per 100,000 inhabitants in most western countries. Approximately 40 to 50% results in death (30% in the first 24 hours and, if not treated, 25% to 30% within four weeks of rebleeding, vasospasm or hydrocephalus. Approximately 10 to 20% will survive with serious sequelae. Only 40% recover their physical condition without disabilities. Implications for the health system/professionals/patients/society: Considering the type and location of the aneurysm, the hospital infrastructure and the expertise of the professionals, the endovascular treatment compared to surgical treatment proved greater effectiveness and safety because it is less invasive, reducing the hospitalization time and postoperative complications representing an important option for the Public Health System.

710. OPERATIONALISING MULTIPLE CRITERIA DECISION ANALYSIS FOR HEALTH TECHNOLOGY ASSESSMENT

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Objectives: This paper will discuss the different methods of multi criteria decision analysis (MCDA) that could be used in health technology assessment (HTA) and their relative merits.

Description: The current practice of health technology appraisals is based on the incremental cost-effectiveness ratio (ICER) i.e. the incremental cost per quality adjusted life year (QALY) gained by recipients of treatment. Even though other factors (e.g. severity, life saving, etc) are considered along with ICERs, there is concern that its approach may fail to capture other important sources of value. MCDA is aimed at supporting decision makers faced with evaluating alternatives taking into account multiple, and often conflictive, criteria in an explicit manner.

Methods: An overview of MCDA is provided and is compared against the current health technology appraisal processes. A number of important questions are addressed to identify the most appropriate MCDA method that might be used to support decision making. For example, what criteria should be incorporated? Whose weights should be used and how to elicit them? How to incorporate uncertainty into the MCDA process? How do we consider the value of displaced technologies? What should the 'basic' cost-effectiveness threshold be? How do we estimate it? This paper will discuss these questions, outline and assess methodological issues that would be raised by the use of MCDA in health technology assessment (HTA).

Results: MCDA does not just stop at simple weighting and scoring; more flexible approaches are available that appear to be more relevant to health technology appraisal and value based pricing (VBP). A potential MCDA approach for HTA is to calculate "weighted" QALYs from the QALY weights which reflect the broader value of the product's benefits and compare against the updated "basic threshold" value.

Conclusions: There are general practical issues that might arise from using this MCDA approach in the HTA process and further research needs to be performed to address the issues identified in order to ensure the success of this MCDA technique in the appraisal process.

753. CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY (CCSVI) AND MULTIPLE SCLEROSIS (MS): SUPPORTING DECISION-MAKING IN THE CONTEXT OF LITTLE EVIDENCE AND MUCH PATIENT CONCERNS

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Background: Dr. Zamboni's work on MS has led to the hypothesis that CCSVI causes the disease. Faced with public pressure to access proposed treatments (venous angioplasty and stenting), Quebec's health ministry asked INESSS to update the scientific evidence on CCSVI diagnosis and treatment.

Objectives: To illustrate how INESSS tackled the challenges of carrying out a health technology assessment (HTA) in the context of mainly exploratory research and much social and political pressure, fueled by patients through social media.

Results: We first adopted a classical HTA by completing a systematic literature review on CCSVI diagnosis/treatment. Heterogeneity of studies precluded meta-analysis. The evidence base was insufficient to support coverage of proposed CCSVI treatments. The disconnect between scanty evidence and the legitimate desire of patients to access a potential treatment for an incurable disease pointed to the need to adjust our methodology. We performed a daily horizon scanning of both the scientific literature and the media throughout the project. The grey literature was also thoroughly and prospectively searched for the social context (e.g. treatment outcomes from medical tourism), for expert statements and for examples of social pressure and political responses within and outside of Quebec. This approach implied continuously updating the evidence in the report, but allowed consideration of the global perspective of the issues at hand. The results of the daily scanning were sent to the minister in a timely fashion to inform on developments throughout the project and allow for intervention, if necessary, before the publication of the complete report.

Conclusions: The results of an HTA are based as much as possible on scientific evidence. In such a highly mediated circumstance incorporating non-scientific sources is essential to take the patient's perspective into account.

767. DIRECT COMPARISONS VERSUS INDIRECT COMPARISONS: EVALUATION OF A CASE IN RHEUMATOID ARTHRITIS

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Background: The indirect comparison is a methodology for comparing two treatments that have not been compared head to head. For example, if a randomized controlled trial (RCT) compared treatment

A to treatment B (A vs B), and another study compared treatment B to C, it is possible to compare indirectly treatment A vs C.

Objectives: To determine the differences in results between a direct comparison (head to head trial) and an indirect comparison.

Methods: Three appropriate RCTs were identified. One of them compared abatacept + methotrexate vs methotrexate + infliximab in patients with rheumatoid arthritis (Schiff 2008). The other two studies compared abatacept + methotrexate versus placebo + methotrexate (Kremer 2006) and infliximab + methotrexate versus placebo + methotrexate (Westhovens 2006). Relative risks (RR) and confidence intervals of 95% (95%) for ACR20/50/70 as efficacy outcomes were reported.

Results: The direct comparison between abatacept versus infliximab for ACR20/50/70 after 6 months of treatment were (RR 95%): 1.12 [0.95-1.33], 1.09 [0.83-1.44] and 0.81 [0.48-1.37], respectively. Indirect comparison resulted in 0.74 [0.57 to 0.97], 0.70 [0.43-1.14] and 1.09 [0.47-2.50].

Discussion: The results showed a discrepancy in all variables, finding a significant difference in ACR20. This result may be because one of the studies (Westhovens 2006) included patients with milder disease compared to other studies.

Implications for the health system: The results of this methodology significantly depend on the comparability of the populations of the included studies. Although in some situations such comparisons are the best tool available, the results should be interpreted with caution for decision-making in health.

796. USING MULTI-CRITERIA DECISION ANALYSIS TO PRIORITIZE THE USE OF A MEDICAL ISOTOPE

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Background: Technetium-99m (^{99m}Tc) is used in a variety of diagnostic imaging procedures. Following shortages in its supply, the Canadian Agency for Drugs and Technologies in Health (CADTH) was asked to develop national guidance on its optimal use in times of supply disruption. A Multi-Criteria Decision Analysis (MCDA) approach was implemented to develop a priority ranking of clinical uses of ^{99m}Tc. MCDA was selected because of the complexity of the project - access to alternative imaging modalities varies across Canada and ^{99m}Tc is used across a number of clinical areas. It also allowed for consistency when comparing the clinical uses.

Objective: To provide national guidance on the priority use of the medical isotope ^{99m}Tc in times of supply disruption.

Methods: CADTH, in partnership with the multidisciplinary Medical Isotopes and Imaging Modalities Committee (MIIMAC): identified the 24 clinical uses accounting for a large portion of all ^{99m}Tc-based imaging procedures performed in most diagnostic imaging centres; selected 11 criteria with which to evaluate the ^{99m}Tc-based test and its alternative(s), for each of the clinical uses; established the relative importance (weight) of each criterion; incorporated information supporting each criterion into a single research report for each clinical use.

Results: MIIMAC scored the 24 clinical uses to generate a priority ranking. The priority ranking identifies which clinical use(s) ^{99m}Tc should be allocated to first, in the event of a shortage.

Discussion: The guidance will also become the foundation for a flexible, web-based tool that can be customized for local use. Use of MCDA allows the incorporation of multiple relevant perspectives into healthcare decision making.

Implications for the health system/professionals/patients/society: The resultant national guidance will offer clinicians an evidence-informed, priority ranking of the clinical uses for ^{99m}Tc during a supply disruption.

839. EVOLUTION OF A RAPID REVIEW PROGRAM

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Background: For over two years the Knowledge Synthesis Group of Ottawa has explored the methods, execution, and teaching of rapid reviews.

Objective: To share the evolution of our rapid review program and delineate ongoing rapid review projects.

Methods: An 8-step rapid review process was developed iteratively based on the needs of knowledge users, Cochrane principles, and a review timeline of 4-6 weeks. Decision makers requiring evidence summaries were either solicited based on expected need or approached our team independently. Workshops outlining the rapid review approach, our experience with using it, and findings of pertinent reviews were developed for key stakeholders.

Results: From November 2009 to December 2011 we produced 18 rapid reviews on a variety of questions related to health interventions, health systems and health services. We also delivered 3 workshops on rapid review methodology for a diverse range of stakeholders (e.g., methodologists, policy analysts) across Canada. Ongoing work focuses on 3 distinct but interrelated areas: 1) methodological development; 2) review execution; 3) knowledge translation.

Conclusions: Rapid reviews are a plausible tool for addressing the evidentiary needs of stakeholders. Opportunities for expanding and refining the rapid review program continue to be explored.

884. HOSPITAL CARE PROFILE OF POLICE OFFICERS IN THE RIO DE JANEIRO STATE, BRAZIL

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Background: The expected increasing of 48.1% of police officers in the State, will demand the expansion of their Central Hospital. In order to plan this expansion, it is essential to know the group needs of health care, however this information is not available. This study aimed to evaluate the hospital care profile of this group in order to improve the estimation of their needs.

Methods: Data was collected from the records of 950 police officers hospitalizations in the year of 2010, by means of a bespoken form. After an analysis of consistence, 125 forms were excluded.

Results: The descriptive analysis of 130 forms, which included 124 patients, revealed that 61.5% of the admissions were done by the emergence unit and 38.5% of the hospitalizations were done in the surgery clinic and 36.2% in the medical clinic and the average length of stay was 6.8 days. Surgery was recorded in 46.1% of the hospitalizations. Circulatory diseases (17.7%) and digestive problems (16.9%) were the causes of hospitalization and injuries by firearms were reported in 4.6%. Among the patients was observed that 92.7% were male with an average age of 39.7 years, being 5.6% smokers and 9.7% alcohol consumers. The main comorbidities were hypertension (23.4%), drug allergies (8.9%) and diabetes (6.5%).

Discussion: These findings seem to corroborate with other few similar studies in the literature. Besides, it also revealed that the admission at emergency is not related to traumatic causes. This may suggests the need of a better organization and access to primary care facilities in order to improve the health care of police-officers.

914. HEALTH TECHNOLOGY ASSESSMENT, A TOOL FOR DECISION MAKING IN RARE DISEASES: FABRY DISEASE (FD) CARDIOMIOPATHY, AS AN EXAMPLE

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Background: Fabry disease (FD) is a lysosomal disease, caused by deficiency of the enzyme alfaGAL-A. Its incidence is estimated as 1:40.000-100.000 of male newborns. Cardiac manifestation are common, it has been recognized that hypertrophic cardiomyopathy (HCM) represents a major complication in this population, with high morbi-mortality associated. Two enzymes are licensed for enzyme replacement therapy (ERT) for FD: agalsidase alfa and beta. Initial findings suggest that ERT in patients with mild LVH, could benefit them. The annual cost of treating a person with FD with ERT is $115,000.

Objectives: Evaluate in patients with FD at initial stages of LVH, 'treated' or 'not' with ERT, the development of HCM and death.

Methods: A review of the literature was performed estimating: ERT effects in LVH, progression to HCM and risk of death (constant risk rates were assumed). The follow up time was 12y. The number of events in those 'using' or 'not' ERT were estimated and compared.

Results: Considering 100 cases of FD with initial LVH in each arm (ERT/no ERT), followed by 12y, we estimated: In the 'ERT arm', 57 cases of HCM and 6 deaths. In the 'no ERT arm' the numbers were 84 cases of HCM and 9 deaths.

Discussion: According to the model, after 12y, almost all the patients with 'no ERT' developed HCM, a 30% increase compared to those treated. The number deaths also was 50% higher in those 'not treated' compared to those 'treated'. But the model had limitations, mostly because the scarce data about FD cardiopathy and ERT effects.

Implications for health system/professionals/patients/society: The use of these models help to identify/quantify the possible benefits of ERT. Allowing prescribers and patients to have a clear understanding of the gains of the treatment. Also, could contribute to better use of health system resources.

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938. WORKING TOGETHER WITH LOCAL ENTERPRISES. SUPPORTING HEALTH TECHNOLOGY INNOVATION PROCESSES THROUGH PRIVATE-PUBLIC PARTNERSHIP

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Objective: To design and co-develop projects of new products and services for the public healthcare use. To demonstrate their cost-effectiveness in the Basque health system.

Methods: Regular contact with companies (mainly local) from the health care sector offering them a platform from which they can identify all its new products and inform, in a structured and predefined way, the health system on their characteristics. The information feeds a database that include relevant information on safety, efficacy, cost-effectiveness, etc. The platform implemented provides the necessary means (monitoring system), using our health network, to inform about the identified health technologies.

Results: In addition to sporadic contacts with companies we have organized two mass meetings where the structure of the process was explained. Currently, there is a coordinated strategy with Biobasque, the Ministry of Industry established entity that supports the promotion and dissemination of biotechnological industry, to identify health technologies. Also we organise regular meetings with the responsibles of technological innovation of the Basque Technology parks and the Spin-off incubators that are funded by the Departments of Industry of the Basque Provinces. In addition, we act in harmony with the Research and Innovation Foundation to define criteria to be assessed in public-private partnership health technology demonstration or coverage with evidence studies.

Discussion: Data requirements to support product assessments are increasing and evolving, heightening the need for early dialogue with payers to ascertain what evidence they are looking for in the decision-making process. In addressing cost-effectiveness assessment, manufacturers will need to question whether the company is investing in the right place; whether the critical component of comparative effectiveness is integrated into the development plan; and where the new product fits into the current treatment paradigm. Public-private partnership is crucial for successful implementation of these strategies.

233. ENHANCING THE UTILISATION OF GENERIC CLOPIDOGREL: IMPLICATIONS FOR FUTURE EFFICIENCY SAVINGS

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Background: Countries must learn from each other to maximise efficiency from generics. However, savings reduced if originators challenge entry and use. Clopidogrel provides a good case history as initial generics a different salt with fewer indications and high expenditure ($10bn globally in 2010 prior to patent loss).

Objectives: (a) Appraise activities of authorities to licencing, reimbursing and encouraging utilisation of generic clopidogrel; (b) Compare countries to provide future guidance.

Methods: Feedback from payers across Europe, Middle East and Australia. Period from 2006 (when first generic clopidogrel preparations available) to 2011.

Results: Considerable variation: (a) Generic clopidogrel reimbursed for all indications in Croatia with reference pricing (molecule); (b) Abu Dhabi – compulsory INN prescribing including clopidogrel (similar in Lithuania); (c) Austria - authorities stated no efficacy or safety problems with different salts and indications; prescribing restrictions eased for generic clopidogrel; (d) Initial confusion in France – with some advocating prescribing originator whilst others INN; now resolved with substitution target of 75%; (e) Portugal - first generic clopidogrel approved in April 2009, reimbursed from December 2009; however some formulations challenged by originator leading to withdrawals; (f) Scotland - generic prescribing endorsed as perceived limited risks; (g) Spain - activities ongoing in regions to address prescribing of originator including scientific publications and presentations; (h) Sweden - mandatory substitution agreed prior to generics. In contrast, originator challenged generics in Norway and Slovenia, e.g. in Slovenia, generic available from June 2006-June 2008. Subsequently, removed as patent problems but reimbursed from May 2010. Considerable differences already exist in reimbursed prices.

Conclusions: Considerable variation in availability, utilisation and pricing of generic clopidogrel across countries. Activities thwarted by physicians and/or originator in some countries limiting savings. Countries already learning from each other to enhance future efficiency including measures to further lower generic prices and accelerate disinvestment.

408. HEALTH TECHNOLOGY ASSESSMENT ON SURGICAL OR NON-SURGICAL TREATMENT OF DEGENERATIVE SHOULDER DISORDERS

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Background: During the last decade a significant growth and variation in the surgical activity in patients suffering from shoulder disorders has been observed across the Danish regions. Moreover, it is uncertain whether or not surgical interventions can be proven more effective than non-surgical interventions, such as medical care or treatment by a physiotherapist. Furthermore, an overview of the total costs of treatments is lacking.

Objectives: The primary aim was to document clinical and economic effects of the use of surgical treatment compared with non-surgical treatment for patients with degenerative shoulder disorders.

Methods: Overall, the report analyzes was based on national/international systematic reviews and primary studies. Register data from the National Patient Register was summarized, and an economy analysis was conducted.

Results: No difference in efficacy of surgical treatment and the effect of eg physiotherapy or exercise program was found in patients suffering from impingement syndrome (moderate evidence). Patients suffering from rotator-cuff rupture may benefit more from surgical treatment than non-surgical treatment (limited evidence). The health economic analysis concluded that surgical treatment is not cost-effective compared with non-surgical treatment in patients suffering from impingement syndrome, while surgical treatment is cost-effective for patients with rotator-cuff rupture compared with non-surgical treatment.

Discussion: There is a need for a standardized approach in treating patients with degenerative shoulder disorders and use of standard measuring tools and methods for documentation. Developing clinical guidelines to support the decisions making is recommended.

Implications for the health system: Non-surgical approach is recommended in conditions which are not emergency surgery demanding. There is no basis for an increase in surgical activity - rather the opposite. Treating patients with degenerative shoulder disorders is not particularly well-founded, and well-designed research projects showing the right way is required.

559. EXPERT CONSENSUS AS A STRATEGY TO IDENTIFY LOW VALUE OR POTENTIALLY OBSOLETE PRACTICES IN HEALTHCARE

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Introduction: Appropriate use of resources and the abandon of practices of little value for the process of care increase health systems quality. In Catalonia, the ESSENCIAL Project aims to promote and implement these processes. Diagnostic Imaging Procedures (DIP) is one of the priority areas. Among the strategies to identify low value practices is the opinion of experts when scientific evidence is scarce.

Objectives: To identify low value DIP for non-traumatic shoulder and neck pain in frequent primary care clinical situations.

Methods: Delphi method to achieve consensus on appropriateness of use for 5 DIP (conventional X-Ray, magnetic resonance imaging, scintingraphy, computer tomography (CT) and echography) in 6 most frequent clinical scenarios for each, shoulder and neck pain. Two groups of clinical experts (radiologists, rheumatologists, orthopedists, rehabilitators and primary care physicians) were established: 44 and 41 participants for shoulder and neck pain, respectively. Use was rated from 0 (not appropriate) to 9 (very appropriate). The appropriateness for each DIP was obtained by two parameters: the median score that defines the adequacy of DIP and, the distribution of scores that defines the agreement.

Results: Response rates were 77.6% and 68.0% in shoulder and neck pain groups, respectively. The median range score (MRS) for CT ranged from 0 to 1 and the rate of agreement (RA) in the interval 0-3 ranged from 71.1% to 100.0%. Results for scintigraphy show an MRS of 0 and a RA range from 67.9% to 100.0%.

Conclusions: CT and scintigraphy were inappropriate in practically all analyzed primary care clinical scenarios. These statements were included in the ESSENTIAL Project, and specific communication strategy for each of the identified low value practices will be designed and implemented, including scientific societies implication, training materials and use of Web2.0. Impact on daily clinical practice will be evaluated using quantitative and qualitative methods.

562. IDENTIFICATION AND CONTEXTUALISATION OF LOW-ADDED VALUE OPHTHALMOLOGY TECHNOLOGIES USING THE EUROSCAN DATABASE

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Background: The identification of low-added value technologies is a new field whose goal is to improve the management of patient's healthcare. A recent study noted that new-technology databases may help with this identification process.

Objectives: To identify low-added value ophthalmology-related technologies using the information contained in the EuroScan database.

Methods: Selection of substitutive ophthalmological technologies identified prior to May 2008 was made. Questionnaires were designed a) to determine whether the current technologies they were replacing are being used in the Basque Country and b) to know whether any of the current technologies have been substituted by the new one. These questionnaires were sent to local clinicians and the results collected and analysed.

Results: A total of 11 new ophthalmological technologies (six devices, a diagnostic test, three drugs and a procedure) were identified. Four of the questionnaires prepared compared one current technology with the new one, whereas seven compared it to various current technologies. Seven questionnaires showed that one or more of the current mentioned technologies are being used in the public health system in the Basque Country (two only in research studies). Likewise, six questionnaires showed that one or more of the mentioned current technologies are of low-added value. The need to draft an assessment report was only found for three cases. In conclusion, a total of 14 low-added value technologies, such as betaxolol to treat chronic open-angle glaucoma and photodynamic

therapy (Visudyne) for age-related wet macular degeneration, have been identified.

Discussion: EuroScan database can be used to identify low-added value technologies, although what happens with the other substitutive technologies identified in this database should also be studied. Clinical experience is vital when it comes to contextualising such technologies. Furthermore, mechanisms to evaluate their impact and to analyse whether they should be eliminated need to be developed.

685. OPPORTUNITIES FOR DISINVESTMENT OF UNNECESSARY PRACTICES USED DURING NORMAL CHILDBIRTH CARE IN SPANISH NATIONAL HEALTH SYSTEM (NHS)

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Background: The Clinical Practice Guideline (CPG) for normal childbirth in the Spanish National NHS (developed by 21 multidisciplinary professionals together with three female charity representatives) makes various recommendations as regards to eliminating clinical procedures that are unsafe or of little usefulness and others that promote effective health-care practices.

Objectives: To identify opportunities for disinvestment of unnecessary practices used during normal childbirth care in Spanish hospitals.

Methods: We developed a survey consisting of 33 questions classified into six areas (hospital admission, first, second and third stage, analgesia and monitoring) related to the main recommendations of the CPG for normal childbirth in the Spanish NHS. This survey was submitted anonymously to 1,107 professionals in July 2011 via the Spanish Associations of Midwives and Gynaecologists. The cumulative responses were collected in October 2011. Herein we describe the degree of compliance with the recommendations of the CPG regarding the elimination of useless and unsafe practices during normal childbirth care -'Do not do'-.

Results: 629 (57%) hospital professionals answered the survey, however only 388 (35%) provided information regarding the type of institution (public and private) in which they work. On the basis of all responses (n = 629), this study shows a low degree of adherence (< 60%) as to the recommendations to eliminate unnecessary practices such as cardiotocography, fundal pressure, amniotomy, and administration of oxytocin on admission. When comparing by hospital type (n = 388), a significantly lower use of unnecessary practices such as enema, shaving, amniotomy, episiotomy and use of oxytocin was observed in public hospitals.

Implications: This study of the degree of compliance with evidence-based recommendations has effectively identified areas for disinvestment. In Spanish hospitals, particularly in private institutions, it has identified several opportunities for improving the quality of childbirth care by eliminating unnecessary and unsafe interventions for both mothers and babies.

838. SWITZERLAND'S OFFICIAL LIST OF REIMBURSABLE LABORATORY ANALYSES: A CASE OF DISINVESTMENT

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In Switzerland, an official tariff system applies for the reimbursement of laboratory analyses for out-patients, stipulated by the law on health insurance. This list of reimbursable laboratory analyses is periodically reviewed by the authority in charge in order to ensure that it meets the criteria of effectiveness, appropriateness and efficiency, as the law specifies for all medical services. During its recent revision, it was decided to actively disinvest on analyses that were obsolete and of which clinical benefit or cost-effectiveness have been superseded by other available alternatives in laboratory medicine. The following mechanism was chosen to identify these analyses: 1) 3 Experts of laboratory medicine selected all analyses that fulfilled the predetermined criteria of disinvestment. Their list was exhaustive and contained all five domains of laboratory medicine. 2) The five Swiss societies of laboratory medicine examined the selected analyses of their respective domain. In case they recommended to maintain an analysis in the reimbursement list, they had to apply to the Federal Office of Public Health (FOPH), supporting their recommendation by scientific literature. 3) The FOPH reviewed the supportive literature and, in a two step procedure, proposed a final consensual list of analyses to undergo disinvestment. 4) As a result of this consensus work, the Federal Minister of Home Affairs removed all proposed analyses from the official list of reimbursable laboratory analyses. 122 out of a total of 1660 analyses were withdrawn from reimbursement according to this mechanism. As all players in the field of laboratory medicine had been involved in the process, the political acceptance of this disinvestment procedure was high.

840. RATIONALIZING HUMAN ALBUMIN USE IN A TURKISH HOSPITAL: A DISINVESTMENT DECISION USING HTA

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Background: Ankara Numune Training and Research Hospital (ANEAH) is a teaching hospital in Turkey, covering 38 clinical specialties. Its budget for 2012 is 100 million Euros. The hospital has been the first hospital in the country to adopt HTA, being its first application for disinvestment purposes. In 2011, the hospital pharmacy noticed that the use of human albumin (HA) rose from 1561 boxes in 2006, to 6165 in 2008, and to 8406 by 2010. The rapid increase in the use has not been explained by any change in the type of services provided, neither by changes in the profile of patients. The chief of medical staff asked to investigate whether this raise match the current scientific knowledge about clinical indications of HA.

Methods: Review of current use of HA in hospital by clinical services at ANEAH. Cost analysis on HA consumption over time. Literature search and review on HA use. Development of an evidence-based guideline inappropriate use of HA. Guideline dissemination to users of HA. Impact analysis through clinical record review.

Results: The literature review identified a list of indications for the appropriate use of HA. After 6 months of implementing the guideline, a 48% decrease in the use of HA was observed, which lead to a savings of 120,000 Euros in a year.

Policy implications: After this study the hospital management has promoted the use and extension of HTA activities in the hospital.

78. THE WHOLE IS GREATER THAN THE SUM OF ITS PARTS: AN NHSSCOTLAND INTEGRATED APPROACH TO THE CHALLENGES OF HEALTHCARE DELIVERY IN THE 21ST CENTURY

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A central tenet of the Scottish government's Healthcare Quality Strategy is that "The most appropriate treatments, interventions,

support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated". Four national healthcare bodies (Scottish Medicines (SMC) consortium, Scottish Intercollegiate Guidelines Network (SIGN), Scottish Health Technologies Group (SHTG), National Planning Forum (NPF)), have been developing their processes and links to ensure an integrated approach to meet this ambition. The actualisation of the coordinated approach can be seen in various clinical areas of which obesity provides a good example. Provision of weight management and bariatric surgery services has been a long-standing issue for NHSScotland. SIGN published an obesity guideline in February 2010 and this included a recommendation, that bariatric surgery could be considered for individuals with a BMI > 35, with one or more co-morbidities, for whom structured weight management programmes had failed. This was identified as having a very large impact for NHS Scotland. Around 40,000 patients were considered to meet these criteria but in recent years only several hundred bariatric procedures have been undertaken. SHTG therefore embarked upon an update of the clinical effectiveness review and examination of the cost effectiveness, affordability and levels of provision of the interventions in NHSScotland, in particular in relation to different co-morbidities. Concurrently the NPF set up a national expert group to advise them on the provision of treatment for severe and complex obesity in adults and used the SHTG and SIGN evidence products to help inform their deliberations. Having considered this evidence, alongside other factors, the NPF proposed the adoption of a phased increase in bariatric surgery, focusing on patient groups for whom the evidence of health gain is greatest and expanding the volume of surgery provided to match that undertaken in other public health systems within 3 years. A steering group including representation from the national bodies has now been put in place to develop patient pathways to take forward this recommendation and to ensure a consistent approach to the implementation across the regional planning groups within NHS Scotland.

127. ASSESSMENT OF MORBID OBESITY TREATMENT COST EFFICIENCY IN THE CZECH REPUBLIC

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Objectives: Recent epidemiological surveys show that the prevalence of morbid obesity reaches 2% in the adult population of the Czech Republic. Main aim of this assessment was to evaluate the cost efficiency of resources spent on conservative and surgical treatment of morbid obesity in the country.

Methods: The evaluation was performed by using standard tools of Health technology assessment. Clinical effects of both types of therapy for morbid obesity were determined by systematic meta-analysis of national and foreign clinical trials. The average annual cost of both types of therapy have been obtained by a panel of experts from a three Czech top centers under the Czech society for the study of obesity.

Results: Both types of compared surgical treatment (adjustable gastric banding and gastric sleeve) have much higher clinical effectiveness and cost-efficiency than conservative treatment despite their higher initial costs in the year of surgery. Also overall investments to bariatric surgery will return fully in 3-year term compared to conservative treatment and a subsequent savings in total direct medical costs reach from 86 to 90 million CZK (3,4 to 3,6 millions of euro) in 5-year term for 1200 patients which is average annual amount of patients operated by bariatric surgery in the Czech Republic.

Conclusions: The results of the assessment show that the initially more costly surgical treatment leads to significant savings in direct health care costs for morbidly obese patients.

177. LAUNCH PRICE FOR NEW PHARMACEUTICALS IN THE UNITED KINGDOM (UK): PATTERNS OF CHANGE BETWEEN 1981 AND 2010 IN FOUR THERAPEUTIC AREAS

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Background and objectives: The increasing price of newly launched pharmaceuticals is an important component of rising overall health costs. This increase has variously been explained as due to increasing regulatory and assessment requirements, research and development costs, attrition rates, production costs, the patent system, and marketing practices. We aim to examine the relative contribution of these explanatory factors through trends in launch prices between therapeutic areas subject to different levels and types of innovation.

Methods: Newly launched pharmaceuticals for colorectal cancer, rheumatoid disease, asthma and schizophrenia were identified by reviewing editions of the British National Formulary published from 1981-2010. Prices for usual doses administered over 28-days were calculated and adjusted to 2010/11 using GDP deflators for the UK. Trends were explored visually on scatter plots and best fitting regression models were estimated.

Results: Large increases in inflation-adjusted prices were observed for all four therapeutic areas; overall increases were greatest for colorectal cancer (6,637%), followed by asthma (5,284%), schizophrenia (1,469%), and rheumatoid disease (1,252%). For asthma, removal of a single outlier reduced the overall increase to 109%. Three distinct patterns were evident on the scatter plots. Prices of drugs for asthma and schizophrenia were widely scattered, and no regression model produced a close fit (adjusted R^2 for linear models = 0.20 and 0.34 respectively). Prices for colorectal cancer rose increasingly rapidly over time; an exponential model produced a good fit (adjusted R^2 = 0.80). Prices for rheumatoid disease demonstrated a single marked upward step, increasing by 2,379% in the period 1996-1999.

Discussion: There have been large increases in the inflation-adjusted launch price of new pharmaceuticals since 1981, but the size and patterns of the increase differs markedly between therapeutic areas. Further work is required to identify the nature of innovations associated with large price increases and better determine the drivers of rising prices.

211. USE OF VENTILATION SYSTEMS IN OPERATING ROOMS

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Background: The Danish health care system is investing in renovation and development of new hospitals. Therefore many new operating rooms will be built.

Objectives: The purpose of the report is to produce an overview of the effectiveness of two ventilation principles in preventing infection and the economics of these ventilation systems with the aim of contributing to the basis for making future investment decisions in Denmark's health care system.

Methods: The published health literature describing the use of these two ventilation principles and how effective they are in preventing infection was systematically reviewed. The review was limited to orthopaedic surgery procedures that pose a high risk of infection with the insertion of large foreign objects such as hip and

knee prostheses. Moreover the economical consequences are described. The quality of the evidence was assessed based on internationally recognized standards.

Results and discussion: Operating rooms with ventilation systems, where the air streams directly down onto the patient (laminar air flow) is not associated with fewer infections after surgery than so-called conservative operating rooms where the air has turbulent and diffuse streams. Operating rooms with laminar air flow are much more expensive in capital investment and maintenance than turbulent air flow systems. The marginal costs of laminar air flow systems versus turbulent air flow systems per operating room are estimated to be €200,000 in capital investment. The total annual marginal cost for laminar air flow systems is estimated to be €27,400 per operating room.

Implications for the health system/professionals/patients/society: The future prevention and monitoring of infection after implant surgery should focus on infection being an overall result of a varying number of potential causal factors. Such a focus will involve many other high-priority areas than the ability of ventilation systems to ensure ultraclean air.

212. ORGANISATION OF DIAGNOSTICS AND TREATMENT OF DIABETIC FOOT ULCERS

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Background: This health technology assessment should provide a basis for assessing whether the organisation of diagnosis and treatment needs to be changed and for preparing national clinical guidelines for this field.

Objectives: The aim is to explore strategies for diagnosis and treatment of diabetic foot ulcers and to analyse how the treatment can be organized in the best possible way.

Methods: Evidence on the effects of diagnosis and treatment of diabetic foot ulcers is reviewed. Based on literature reviews and interviews the now existing organisational models for these activities in Denmark are assessed and possible models for organisation of the diagnosis and treatment of diabetic foot ulcers are considered. The HTA also presents a study of patient related aspects and includes an economic analysis.

Results and discussion: The review reveals that the evidence regarding the diagnosis and treatment of diabetic foot ulcers is insufficient and insignificant. The organisational analysis shows that there is a great degree of cross-regional differences in the present organisation of diagnosis and treatment of diabetic foot ulcers and the criteria for referral of patients between sectors are vague and varying. Furthermore, the patients wish for security, consistency, communication and a holistic approach in the course of events. The economic analysis estimates the minimum socio-economic consequences of the diagnosis and treatment of diabetic foot ulcers to €106.630.000 each year.

Implications for the health system: The HTA outlines several options for appropriately organising the diagnosis and treatment of diabetic foot ulcers. National clinical guidelines could be completed as an appropriate linkage between the present knowledge and future organisation. The future changes should allow for better cross sector cooperation. Future developments should include an improved possibility to collect systematic evidence.

319. DEFINITIVE DIAGNOSIS OF ALZHEIMER'S IN THE GP SURGERY: A SEARCH FOR BIOMARKERS

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Background: Alzheimer's disease (AD) is a common and disabling condition whose diagnosis relies on clinical history, exclusion of other causes, and cognitive and mental state examination. There is unmet need for a validated, sensitive, non-invasive and inexpensive test to distinguish between pathological and age-related cognitive decline. Early diagnosis would enable prompt treatment and service planning.

Objectives: Horizon scanning review to identify emerging biomarker-based tests for the early diagnosis of AD for use in primary or generalist care in the near future.

Methods: We searched online sources to identify candidate biomarkers and tests. Tests were included if they used blood, saliva or urine samples; and there was some evidence of clinical trials in patients with AD. For tests licensed for use in clinical or research settings we requested information from the developer on the intended place of use and plans for availability in Europe.

Results: We identified 28 biomarker-based tests of which 5 (3 confirmed by developers) are available for research or clinical use. The closest to market were AclarusDX™ (ExonHit Therapeutics) a gene signature test in an observational study in French memory clinics; and INNO-BIA plasma Ab forms assay (Innogenetics N.V.) which may be CE marked for clinical use in 2015. Test accuracy data was almost non-existent and we found no evidence of clinical utility or cost.

Discussion: Proposed test need to have substantially more evidence of benefit before being recommended for use in specialist health care, never mind in primary care. At this stage there is no information available on the likely costs, which will play a significant part in acceptance for use in primary care.

Implications: Biomarker tests are nearing clinical availability and may have a future benefit as a referral decision tool for general practitioners, but they are not ready for trials of clinical utility.

325. BREAST CANCER DATA QUALITY AT THE POPULATION-BASED CANCER REGISTRY OF SÃO PAULO: IMPLICATIONS FOR PUBLIC HEALTH PLANNING

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Information based on populational data, such as Cancer Registries, are essential to endorse health planning and provision of cancer care services. This paper aims to present a data quality evaluation of breast cancer incidence data from the Population Based Cancer Registry of the Municipality of São Paulo, Brazil. The study included 46,305 new breast cancer cases recorded during a two five-year periods (1997-2001 and 2002-2006). Data analysis was focused on variables such as: date and age at diagnosis, method of diagnosis, clinical stage and topography. The study shows that some variables considered in the literature as essential to the validity and comparability of Registries, such as the diagnosis by histopathology exam and age of the patients, has good information, while than for

other relevant variables, such as clinical staging, there are problems of data completeness. Enhancements on data completeness for those variables can amplify the usability of population-based cancer registries.

396. THE DIFFERENCE IN BEHAVIORAL OUTCOMES BETWEEN THE FIRST-YEAR AND SECOND-YEAR PARTICIPANTS IN A COMMUNITY-BASED CANCER EDUCATION INTERVENTION

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Introduction: Colorectal cancer (CRC) is the third most prevalent cancer in China, and the fifth most lethal among all cancers. Community-based health education is helpful for health planners to promote cancer screening, yet relatively few studies tapped the temporal pattern of intervention effectiveness in a multiyear CRC education program. Using data from a two-year CRC community education, this study is aimed at exploring whether the health education intervention effectiveness differs between the first-year and the second-year participants.

Methods: A two-year health education intervention was carried out in four communities in Shanghai, China. The health education focuses on raising awareness about CRC, the principles of screening, the instruction of FOBT kit, etc. Local community health service centers conducted the lectures once a month. All adult residents were invited to attend these lectures. At the end of the first year and second year, structured in-person interviews were conducted for the residents who attended the lectures. There were 205 enrolees who completed the first-year interviews and 836 enrolees who completed the second-year interviews. Logistic regressions were used to compare the difference in attitudinal and behavioral outcomes of enrolees in Year 1 and those in Year 2.

Results: Of the 1041 respondents, 24.5% had received FOBT during the program period, while 12% had received colonoscopy check, both substantially higher than the background screening rate in Shanghai. Respondents in Year 2 were less willing to take FOBT than those in Year 1 (O.R. = 0.618, $p < 0.01$), but there was no significant difference between Year 1 and Year 2 in terms of willingness to take colonoscopy after we adjust for covariates in logistic regressions. Multiple logistic regressions also show that respondents in Year 2 were significantly less likely to take FOBT than those in Year 1 (O.R. = 0.263, $p < 0.01$) and less likely to take colonoscopy as those in Year 1 with borderline significance (O.R. = 0.600, $p = 0.074$).

Conclusions: The CRC screening rate after the health education compares favorably with the background screening rate, yet the decline in screening rate in Year 2 indicates that further study is needed to understand the determinants of intervention effectiveness.

417. SYSTEMATIC REVIEW AND QUALITATIVE STUDY FOR ASSESSMENT OF RESOURCES IN PALLIATIVE CARE SERVICES IN COMMUNITY OF MADRID, SPAIN

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Background: A structure questionnaire with 70 items was developed for palliative care services assessment of available resources.

Objectives: 1. Questionnaire items substantiation and support through a systematic review and qualitative research. 2. Descriptive study of palliative care services in the Community of Madrid (CM).

Methods: Systematic Review of published studies on palliative care resources in order to identify and validate a questionnaire previously developed. 1. Qualitative research for assessing professional opinions on palliative care resources in order to assess questionnaire content. 2. Survey with a resources questionnaire previously developed and validated in 2010. Areas: human and materials resources, patients and professionals.

Results: 1. 740 studies were identified; finally 9 studies were recruited: 2 systematic reviews with a qualitative study, 5 qualitative studies and 2 descriptive primary studies. 2. Two focus group with 8 palliative care professionals from ambulatory and hospital care. 3. In the Community of Madrid there are 41 teams of palliative care, the 27% are Home Care Teams and the 25% Hospital Teams. The nurses are the group with higher percentage of professionals (35%). The 70% of the patients are oncologic. Main Strength point from qualitative study: work in multidisciplinary team and patient integrated care.

Discussion: The results of this validation study and survey provides a source of information for identifying and designing health services available in palliative care and the healthcare flow in health setting.

619. NEWBORN SCREENING FOR LYSOSOMAL STORAGE DISORDERS USING TANDEM MASS SPECTROMETRY (MS/MS)

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Background: Lysosomal storage diseases (LSDs) are a heterogeneous group of inherited metabolic disorders which result from a deficient enzyme activity linked to the lysosomal system. LSDs may affect the central nervous system and show different severity. Currently, the screening strategy of hereditary metabolic disorders in Spain does not include these diseases.

Objectives: The aims of this study have been to assess the LSDs neonatal screening efficacy and the budget impact in the Spanish National Health Service (SNHS).

Methods: Systematic review of literature. A bibliography search was carried out to identify systematic reviews and health technology assessment reports on the CRD database, ECRI, the Cochrane Library and INHATA. To identify primary studies, a search was done on MEDLINE and EMBASE to May 2011, for efficacy studies, and to January 2012 for economic studies. Inclusion criteria: any type of study with data about LDSs neonatal screening using MS/MS.

Results: 20 studies have been included, 17 assay validation studies and 3 pilot studies. No economic studies were identified. The analytical studies showed different enzyme activity assays to optimize the screening test. All the assays were able to distinguish between healthy and affected newborn. The inter-assay and intra-assay coefficients of variability were generally acceptable. Cutoff values were not standardized. A neonatal screening program based on MS/MS involves an important budget impact in the SNHS.

Discussion: LSDs neonatal screening efficacy remains to be determined. The assays must be validated in large screening studies to determine the sensitivity, specificity and clinical utility. Efficacy of the current therapies and the unclear correlation between genotype and phenotype are issues under debate and must be taken into consideration for screening program extension.

Implications for the health system/professionals/patients/society: Neonatal screening for lysosomal disorders is feasible but their potential benefits remain unclear.

645. CHARACTERIZATION OF A NON-USER POPULATION OF AN OUTPATIENT PHARMACY AT A PUBLIC UNIVERSITY HOSPITAL IN SÃO PAULO

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Background: The dispensing of medications is an important issue when it comes to patient care and health spending. Therefore, understanding the dynamics that led the patient to take his medicines from a public service or buy them elsewhere can influence directly on service and health systems planning.

Objectives: The objective of this study is to characterize the population that does not obtain their medication from an outpatient pharmacy at a public university hospital in São Paulo.

Methods: Because the prescriptions were mostly manual during the study period, the method used to recognize the non-user population consisted in identifying at databases medical consults that did not result in medicine dispensing at the hospital´s pharmacy. Then, a telephone survey was done with a random sample of 343 patients who underwent medical consultation in April 2011. They were questioned about the prescribed medications, reasons for not using the hospital pharmacy, places of acquisition and interest in receiving medication at home. Difficulty in locating patients and the correct description of prescribed medications are among the study's limitations.

Results: From the 343 telephone calls made, 29.2% provided valid information to the study. It was observed that 55.0% of consultations have resulted in a prescription. The most cited acquisition places were conventional pharmacies (41.9%), by out of pocket payment, and Community Health Centers (30.6%), with no charge. No patient was left without his medication. The most cited reasons for not using the hospital pharmacy were waiting time (41.8%) and the fact that some medicines are not dispensed in this service (18.2%). 67.0% of the sample expressed interest in receiving medication at home. Finally, it was observed that the sample had a considerably lower prescription value (US$ 10.62) than the average prescription dispensed at the hospital pharmacy (US$ 77.87).

Discussion and implications: The study demonstrated that non-user population obtained their drugs in other health facilities. In fact, financial value, lack of some items, convenience and comfort are involved in the decision to purchase or obtain elsewhere.

674. CONSENSUS OF PERFORMANCE INDICATORS OF OPERATING ROOMS FOR THE BENCHMARKING OF HOSPITALS

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Background and objectives: In the Spanish context, no publication was identified comparing the efficiency of operating rooms (OR) of different hospitals. The aim of this study was to develop a set of performance indicators and adjustment variables for the benchmarking of OR in the Spanish Health System.

Methods: An exhaustive review of the literature was carried out in the main biomedical bibliometric and HTA databases. Unpublished initiatives were reviewed contacting key informants. A conceptual model was defined based on domains emerging during the content analysis of included documents. Indicators and determinants were classified following the conceptual model. An initial priorization was defined based on the most frequent indicators identified. Consensus meetings with 25 experts were carried out. Indicators and adjustment variables were finally sent by e-mail to experts who assessed their importance, feasibility (score range: 1-10) and degree of consensus (totally agree, agree with modification, eliminate).

Results: Seventy-eight documents were included and a total of 142 indicators, the majority measured the process of healthcare (77%). Most process indicators measured the time consumed and 17 indicators included the overall performance of OR. Six indicators and 6 variables for adjustment for comparative studies were finally proposed. The mean values of importance and feasibility were above 8.0, and experts' that totally agreed or agreed with modifications (of the formula or justification of indicators) ranged from 88.0 to 96.0%.

Discussion: This is, to our knowledge, the first initiative that reviews publications on performance of OR and formal consensus of stakeholders. A feasible number of indicators were proposed with adequate content validity. Initial feasibility and validity of indicators was confirmed, with the moderate to high degree of consensus of experts, the identification of similar indicators in the literature and because they are being used routinely for the planning of agendas and resource allocation in hospitals.

758. PROFILE DETERMINATION OF ADMISSIONS IN A HOSPITAL INPATIENT UNIT LINKED TO THE EMERGENCY DEPARTMENT OF A UNIVERSITY HOSPITAL IN SÃO PAULO

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Background: The Emergency Departments overcrowding have been shown to be critical for organization of health services. Thus, it is essential that hospital beds available to the emergency department can provide resolutive care and withstand the demand with quality and efficiency.

Objectives: The objective of this study is to determine the profile of admissions to an inpatient unit linked to the Emergency department of an university hospital in São Paulo.

Methods: A sample of 184 patients admitted in the Emergency department has been selected, in the specialties of Internal Medicine, Surgery, Neurology and Neurosurgery, from day 03 to 11 of October 2011. Researchers recorded gender, age, address, admission reason, average length of stay, number of admissions in the emergency department and outpatient treatment in the last twelve months.

Results: The population was predominantly female (53.2%), older age groups (43% above 60 years) and originated in São Paulo (74%). Rates of hospitalization were motivated by carrying out treatments such as antibiotics (13.8%) and clinical stabilization (10.8%), by performing procedures such as dialysis (7.9%) and surgery (3.6%) and wait for internal (6.9%) and external (9.3%) transfers. In addition, a significant percentage of patients was eligible for palliative care (5.5%). The average length of stay was 4.1 days. However, 18.8% of visits generated admissions for a period exceeding 10 days. The mean duration of each category was: 3.9 days to perform treatments, 8.3 days for procedures and to 5.8 days for transfers. The waiting time for transfer to intensive care units (2.3 days) was considerably lower than that for the ward (6.4) and external transfers (7.6). Finally, we determined the average number of admissions in the Emergency department (2.2) and outpatient visits by admission diagnosis (78) in the last 12 months.

Discussion and implications: There is a need for greater encouragement to the outpatient care, especially for those on dialysis

and palliative care. The importance of greater dynamism in the internal and external transfers to ensure efficiency and turnover of beds was also identified.

779. INCORPORATION AND EXCLUSION OF TECHNOLOGIES IN THE BRAZILIAN PUBLIC HEALTH SYSTEM IN 2011

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Background: In Brazil, the Public Health System (SUS) has been based on the principles of universality, comprehensiveness, and equity, based on the guidelines of prioritization, decentralization and community participation, with the aim of enabling according to the needs of prevention, promotion, diagnosis, treatment and rehabilitation of health, best practices available and applied to the various realities of the country. In order to do this, it is necessary for the incorporation of technologies, which, since 2006 up to 12/21/2011, was managed by the Committee for the Incorporation of Technologies (CITEC) of the Brazilian Ministry of Health.

Objectives: Analyze the demands by incorporation and exclusion of health technology evaluated by CITEC in 2011.

Methods: A retrospective, descriptive study. The data were obtained in the database of CITEC. The demands were classified according to the type of technology, the area of health for which it was requested; the demandant is the result of the evaluation.

Results: In the year 2011, CITEC evaluated 62 technologies within a universe of extensive areas of health, such as: rheumatology, oncology, cardiology, endocrinology and others. Of that total, 36 (58%) were not incorporated; 32% (20) were incorporated; 2 were excluded; and 4 were not excluded. 50% Of the claimants of technologies for evaluation include the pharmaceutical laboratories, 40% the Ministry of Health and 10% the medical associations and hospitals.

Implications for the health system/professionals/patients/society: The careful work of CITEC on the evaluation of technologies for inclusion or exclusion in SUS, based on scientific evidence of effectiveness, accuracy, effectiveness, safety and cost-effectiveness, makes the process of management of the resources of the health care system more efficient and safe, favoring the Brazilian population.

828. SAFE SURGERY: DEPLOYMENT IN A PUBLIC HOSPITAL OF BRAZIL

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The University City Hospital of "São Bernardo do Campo", city of Saint Paul State, Brazil, began in October 2010 a pilot project for the deployment of Secure Surgery Protocol recommended by the Ministry of Health of Brazil. In 2011 the Safe Surgery Program, with your check list and involvement of health professionals as the anaesthetist doctor, surgeon doctor and nursing staff was deployed and is being monitored on a monthly basis the implementation of the programme in Surgical Center and at the end of the year of 2011 started in Birth Center at the end of the year of 2011 with the values show in the table. Still find difficulty in achieving the goal of 100% implementation of the Protocol because of the urgent surgeries, deliveries of urgency, the accession of the whole team in the program due periods with scarce human resources. The introduction of this patient safety program denotes the new health care management and the application of the concept of medicine safely.

Surgical Center		Birth Center	
90.2%	Jan	0	Jan
66.9%	Feb	0	Feb
69.7%	Mar	0	Mar
71.4%	Apr	0	Apr
74.6%	May	0	May
71.2%	June	0	June
88.6%	July	0	July
0%	Aug	0	Aug
79.3%	Sept	74.50%	Sept
68.2%	Oct	77.70%	Oct
53%	Nov	74.50%	Nov
64.50%	Dec	77.70%	Dec

834. SWOT ANALYSIS: A TOOL TECHNOLOGY IN HEALTH PLANNING

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Objectives: We tried to analyze in this study the visibility of the planning process developed at the Health Department of the State of Bahia (SESAB), Brazil, in 2007/2009 time frame by using the SWOT matrix (Strengths, Weaknesses, Opportunities, Threats) and reflect on the use of this tool as a diagnostic technique strategic. Method: A qualitative study critical and reflective; the used techniques of data collection were systematic observation and document analysis. First, based on documentary analysis, we identified the progress and difficulties found during the process of health planning. Therefore, we proceeded to the application of the SWOT matrix in order to discriminate these advances and difficulties in internal and external environments of the institution. For this, we created an analytical model based on elements from the discussion of power proposed by Testa (1992) to better characterize the findings. This way, political, technical and administrative aspects are dimensions of the analysis.

Results and discussion: Results showed a progressive legitimisation of a given process and institutional growth, despite the limitations identified, and revealed the importance of using analytical tools to guide strategic planning processes and evaluation in government health systems. Final thoughts: The matrix used for the SWOT analysis was not considered as a rigid instrument. Rather allowed successive adaptations to account for the specificities of reality. It is suggested the incorporation of this technology as a tool for group discussion, that will enable a greater understanding between the technical team and so planning takes into account the "different approaches". Finally, we highlight the importance of using SWOT analysis to be rethought institutional strategies regarding the planning and also for the assessment of planning processes.

859. ASSESSMENT OF THE APPLICATION OF RESOURCES FOR PROCUREMENT OF ESSENTIAL DRUGS IN CITIES IN SOUTHERN BRAZIL

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Background: The constitution of 1988 and the Health Law of 1990 universalized access to health care, grants all Brazilian citizens the

right to procure free health assistance. Unified the public health system and decentralized the management and organization of health services from the federal to the states and especially at administration cities level. The access to essential medicines is co financed by federal, states and cities. The administration of cities is responsible to buy and dispense to patients the primary care medicines. All Health Centers should stock the drugs recommended for ambulatory care on Brazil's national list of essential drugs, in agreement to federal legislation.

Objectives: The aim of this work was monitor the application of resources for essential medicines for public health service.

Methods: A cross-sectional study was conducted based on administrative data system of MHM (Management Health Surveillance). We analyzed the financial management reports for the year 2010 with the type of expenditure and the amount of funds invested in the cities of Rio Grande do Sul, a state in southern Brazil.

Results and discussion: Analyses of 491 cities, based on database MHM showed that the local government expends 72% of resources available for acquisition of medicines in primary health care. Cities until 15,000 habitants (75.2% of the cities and 18% of population) expend 74.3% resources. Cities between 15,000 and 200,000 habitants (22.8% of the cities and 45.6% of population) expends 66.6% resources. Cities over than 200,000 habitants, expends around 47% and represent 37% of the total population of the state. In addition, all cities provide medicines out of the national list of essential medicines, causing a significant increase in public spending.

Implications for the health system/professionals/patients/society: Promote individual and community access to essential drugs. Utilization of a national list of essential medicines as a tool to help governments to rationalize the application of resources and qualify the health care.

890. COST OF TREATING HYPERTENSION IN MEXICO

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Background: Hypertension is one of the most prevalent chronic diseases in Mexico. In the last two decades, a substantial increase in the prevalence of HT was observed in Mexico from 25% in 1993 to 43.2% in 2006 in adult population (≥20 years old).

Objectives: To assess the medical care costs of hypertension and their impact on the health care expenditures of Mexican Social Security System.

Methods: The cost per care episode and per hypertensive patient was calculated by adjusting the unitary cost (2011) as a function of standard and extreme utilization of IMSS health services. The resulting amount was then projected to the total population of hypertensive patients receiving their medical care from Mexican Social Security Institutions and compared to the annual health care expenditures of it. (Exchange rate: 12.4 mexican pesos per 1USD)

Results: The expected annual cost per patient with hypertension was USD$570 and considering a population of 14.6 millions of patients in the social security system represents more than $8,300 millions of dollars just for medical attention and clinical analysis.

Conclusions: The costs of hypertension medical care account for a good portion of healthcare resources of Mexican Social Security Institutions. It is necessary to assess strategies to reduce the economic burden of this illness.

159. MORBIDITY PERCEIVED BY RESIDENTS OF BAÑADO SUR PREVIOUS TO THE IMPLEMENTATION OF THE COMMUNITY SURVEILLANCE FOR ACUTE FEBRILE SYNDROME, USING INFORMATION AND COMMUNICATION TECHNOLOGIES (ICTS)

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The Ministry of Public Health and Social Welfare in conjunction with National University of Asuncion, under the technical support of the University of the Basque Country of Spain, have developed a system of community surveillance for acute febrile syndrome called BONIS, established as a pilot project in the area known as *Bañado Sur* in Asuncion, Paraguay. The system was designed to promote community involvement in syndromic surveillance. In order to establish a baseline on the health aspects of the population; previous to the implementation of the system, a telephone survey was conducted from 18 to 28 February 2010. Phone numbers were provided by the community agents. A total of 366 householders were surveyed, of which 76.2% were female. In 246 households (70%), at least one person with a disease was reported, yielding a total of 438 people with a disease. In this group, hypertension was the most frequent condition reported (36.3%), followed by allergies (13.5%), metabolic syndrome (12.8%), heart disease (10%), asthma (7.8%), diabetes (6.8%) and acute respiratory syndrome (5.9%). Few people reported symptoms consistent with dengue fever or other syndromic fevers. The pathologies that affect the residents of this community are basically similar to the rest of the country with a high frequency of chronic conditions. Limitations of this study may include recall bias inherent to surveys and the possible subjectivity of self-reported morbidities. We highlight the need to strengthen community programs addressed to the identification and report of suspected cases of dengue. The community shows good attitude to collaborate in solving their own health problems, which facilitates the implementation of community surveillance based on ICTs.

166. EVALUATION OF TELEMEDICINE IN OBESITOLOGY USING INDUSTRIAL ENGINEERING METHODS

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Introduction: In order to support a decision making process various management and so called industrial engineering (IE) methods were established. Appling those methods within a Healthcare sector already point out for significant benefits as better organization, planning, cost savings and increasing the effectiveness. A high potential can be seen especially when apply IE methods as an appropriate tool for HTA analysis. The current situation in Czech health care is dealing with cost increasing problem due to high elderly population growth, lifestyle diseases and other aspects. This development requires new approaches to providing health care. At

this point innovative technologies e.g. Telemedicine play an essential role and need further assessment in case of future adaption.

Objectives: Our objective was to explore circumstances of novel medical approach using Telemedicine in obesitology. We designed a case study comparing patients assigned to receive conventional care with patients assigned to receive home Telemonitoring support. The main aim of the research is to observe both clinical and economical aspects. For this purpose we suggest implementation of IE methods such as Time-motion study or ABC (Activity Based Costing) supplemented with CBA (Cost Benefit Analysis). The research focus on evaluation of current system of provided health care for obese patients and its challenges for application of novel medical technique, exploration of new opportunities and definition of the impact of Telemedicine especially in the term of quality, efficiency and costs. The results of a five month long study will be presented.

Conclusions: This paper represents IE methods as valuable support for the purpose of HTA. As an example was given their implementation in the field of Telemedicine in obesitology, were further investigation such as legislative and reimbursement issues are desired.

213. POP DB, THE EUNETHTA PLANNED AND ONGOING PROJECTS DATABASE - DEVELOPMENT AND FUNCTIONALITIES

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Background: The EUnetHTA Planned and ongoing Projects (POP) database was developed to facilitate the exchange of information on (planned and ongoing) HTA projects before publication and the identification of potential collaboration. A first pilot period (using a spreadsheet stored on a shared online folder) allowed to set up the database characteristics (fields, MeSH indexation), the workflow (provision of information by a contact person at each participating agency) and the monitoring procedure (quality check and quarterly reminders).

Objectives: To present the development of the online POP database as part of the EUnetHTA Information Management System, and results after one year of activity.

Methods: Specifications and functionalities for the online database were identified based on the experience gained by the team during the 18 months' pilot, and by surveying information providers. The database was developed using JAVA, prioritisation resulted in a two step approach.

Results: A first release of the online POP database was delivered in September 2011. Contact persons at agencies may create and edit (update, unpublish) descriptions of their agency's projects. Users of the POP may identify interesting projects in various ways (search, browse, automatic list of potential collaborations based on MeSH indexation). Access to the database makes use of the EUnetHTA ID, a single login for all EUnetHTA tools.

Discussion: POP database helped to start collaborations between agencies at an early stage or actual cooperation/joint assessments took place. Current online version, and planned ameliorations like automatic email notification (POP db release 2, 2012) will further facilitate the early identification of potential collaboration. Impact of the POP db on collaboration will then need a regular monitoring.

Implications for health system: To reduce duplication of HTA-work and therefore increase efficiency will have impact on standardisation of methodology, increased output of bi-lingual assessments and eventually on an increase of HTA-productivity.

225. EPIDEMIOLOGIC STUDY OF ORAL HEALTH OF CHILDREN FROM 3 TO 5 YEARS OF AGE TO RURAL COMMUNITIES HUARAZ DISTRICT WITH THE USE OF MOBILE DEVICES IN A WEB

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In Peru in rural areas, mostly working with the paper support on the establishment of epidemiological studies. The incursion of computerization in this case is the establishment of a new method to secure information collected through ICT, in particular of PDAs with a web system, in regard to the management and generation new epidemiological reports, considering the digital environment as the means most optimal dental management today. The aim of the research was to design and implement a web to mobile devices, for the epidemiological study of oral health of children from 3 to 5 years of age in rural communities in the district of Huaraz. At the end of this research study was reached the following conclusions: be able to automate and implement the epidemiological indicators in a system web, mobile devices to provide higher quality information; The results determined that there is a significant impact with respect to CPOD in communities where the study was determined. The town of Coyllur presented the highest number of cases; Regarding the IHO indicate in the study communities, it was determined that the same way that the CPOD index shows a significant difference. As I could determine that the community has the highest percentage Coyllur; The developed system will do the monitoring, evaluation and control, for better decision making in epidemiological studies of communities in our country.

243. EXPLORING THE IMPLEMENTATION OF E-HEALTH PRACTICES IN A LOW INCOME COUNTRY

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Background: In low income countries like Paraguay, broad segments of the population have only limited access to health services and lack sufficient human and financial resources as well as infrastructure for an appropriate health service delivery. At the same time, access to information and communication technologies (ICTs) varies across countries and population groups. The Research Group of the Department of Biomedical Engineering and Imaging of the Research Institute for Health Sciences (IICS-UNA) seeks to improve access to and quality of health services through the use of ICTs. Among other things, these ICTs are expected to increase efficiency in the use of time and resources and improve input for complex decision-making, including epidemiological surveillance, patient diagnosis and treatment. The new ICTs tools and its wide territorial spread in the country offer important possibilities to improve patient diagnosis and epidemiological surveillance. In this sense the Research Group has developed and promoted, among others, the use of Tele-Ultrasonography (tele-Health) in primary care, which under the right education and training of human resources, offers the possibility to improve ultrasound diagnosis services for abdominal and gynaeco-obstetric pathologies in remote populations in the country without the need of a traditional face to face consultation. Technology: the Tele-ultrasound consists of an architectural software that stands alone to catch images from the ultrasound device. The computer integrates ActiveX controls to handle the video capture card and

subsequent digital image processing. A technique called "store & forward" transmits these images through the Web to a remote specialist for further diagnosis, medical report delivery/patient; diagnosis/treatment physician. The Tele-Epidemiological Surveillance System (m-Health) is a community surveillance system which uses web technologies and databases for patient records and appropriate follow-ups by the health personnel. It has the ability to record, classify, and prioritize automatically through the IVR (Interactive Voice Response) suspected cases of syndromic fever.

Objective: To explore implementation of information and communication technologies (ICTs) that improve access to a quality health services.

314. CHRONIC ELDERLY PATIENTS' AND PRIMARY HEALTHCARE PROFESSIONALS' COMPLIANCE WITH A HOME TELEMONITORING SYSTEM (THE TELBIL STUDY)

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Background: The issues of follow-up and compliance with emerging telemonitoring systems, although critical for the adoption of these technologies, have not been thoroughly evaluated.

Objectives: To evaluate the compliance of patients and healthcare professionals with a novel primary care-based telemonitoring system after 12-month follow-up.

Methods: In-home patients with heart failure and/or chronic lung disease aged 81.0 ± 7.5 years were enrolled at 23 primary healthcare centres and randomised to either usual care (n = 30) or a home telemonitoring intervention (n = 28), which consisted of daily transmissions of self-measured respiratory/heart-rate, blood-pressure, oxygen-saturation, weight, temperature, and a brief clinical questionnaire. The telemonitoring system comprised personalised alerts set for each patient, triggered when measurements were out of the established limits. Final telemonitoring compliance outcomes were evaluated at 12-month follow-up. Compliance variations over time were analysed.

Results: Patients' compliance with the telemonitoring system was high. During a cumulative monitoring period of 8,828 days, there were 6,882 data transfer sessions, a mean of 245.8 (SD 119.6) per patient. 71.5% of the patients conducted the pre-established daily data transmission. There were 6,741 accesses to the telemonitoring Web-platform by healthcare professionals. General practitioners accessed the platform more frequently than nurses, 55.7% over 44.3%, respectively. An average of 153.5 alerts was generated per patient. The alerts were mainly triggered by high blood-pressure (24.7%), increased respiratory-rate (21.3%) and low oxygen-saturation (21.2%). The total number of alerts decreased from 1,406 during the first trimester to 794 during the fourth trimester of follow-up.

Discussion: Compliance with telemonitoring was high and well documented both for patients and healthcare professionals. Our results indicate that the use of information and communication technologies for healthcare applications is feasible for elderly patients with limited computer literacy. Despite the compliance of nurses has been fairly high, strategies should be put in place to enhance the roll of nurses in future telemonitoring interventions.

316. EVALUATION OF AN E-HEALTH INTERVENTION FOR CANCER PATIENTS' SUPPORT

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Background: Incorporating information and communication technologies into the field of medical oncology may bring about new forms of healthcare provision, including remote monitoring of chemotherapy-associated toxicity.

Objectives: To evaluate the feasibility, safety, usefulness and clinical impact of a novel tele-oncology intervention.

Methods: A one-year randomised single-centre pilot study will be conducted. Male and female patients with breast or colorectal cancer, aged over 15 years and starting a new chemotherapy regime with Capecitabine or CAPOX (Capecitabine + Oxaliplatin) will be randomised to either usual care (n = 20) or a tele-oncology intervention (n = 20). The intervention consists of the use of an e-health system (Oncomed) for completing a 7-item Web-based chemotherapy-associated toxicity questionnaire twice a day. The e-health system will then assess the severity and progression of the symptoms reported, and, if necessary, alerts will be triggered. Patients in the intervention group will additionally receive usual care. The follow-up period will be of 6 chemotherapy cycles.

Results: Preliminary results will be shortly available. The primary study outcome measure is the feasibility of Oncomed as a support tool for cancer patients receiving oral chemotherapy. Secondary outcome measures evaluate the effect of the use of Oncomed on quality of life (QoL), toxicity-control and health service utilization. Oncomed-related safety issues will be evaluated. Additionally, a cost analysis will be conducted. Patients' and healthcare professionals' experiences with the e-health system will also be explored.

Discussion: Cancer patients could benefit from this novel e-health intervention aimed at improving the monitoring of chemotherapy-associated toxicity. Enhanced toxicity control may, in turn, result in a reduction of hospital admissions and emergency department visits. We postulate that the use of tele-oncology is not only feasible, but also beneficial for the support of cancer patients. Tele-oncology may thus improve the QoL of these patients and benefit all involved parties: patients, family-caregivers and healthcare professionals.

353. INFORMATION AND COMMUNICATION TECHNOLOGY (ICTS): AN ENABLING TOOL TO MONITOR NEW TECHNOLOGIES AFTER THEIR INTRODUCTION INTO CLINICAL PRACTICE

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Introduction: Monitoring of new technologies in the health care system is a fundamental process to assess their effectiveness, safety and resource use in a real context. At present, advances in information and communications technology (ICTs) make it possible to create applications that can be used on line and that allow dynamic tracking of procedures as they are implemented in clinical practice. The aim is to facilitate the introduction of data, observation and evaluation of the new technology by the physician, and to optimize those aspects that may be susceptible of improvement.

Methods: *Web application: development and description:* staff at the Galician Health Technology Assessment Agency (avalia-t), in collaboration with information technology technicians, developed a database in web format to monitor new technologies called *Observatec*. The procedure selected for the design of the web application was laser treatment of benign prostatic hyperplasia. The most representative variables required for the monitoring of this technology were gathered from a systematic review of the literature; afterwards they were discussed by a group of experts till a consensus was reached. The result was an efficient and safe web application that allows users to access the system and entry data from any geographic location. Data entry is simple, versatile and systematic, and is automatically linked to Excel spreadsheets which allow exporting it to statistical programs such as SPSS and others.

Conclusions: The database developed by avalia-t for case recording through the web is an innovative tool. It can be adapted to any new technology simply by changing the variables as required for each specific procedure.

Implication of health professionals is essential in its development for a successful implementation of this monitoring system and for the achievement of its goals.

At this stage the application is being used by professionals in the Galician Health System and it is expected to become a useful tool also at a national level.

357. SYSTEMATIC REVIEW OF ALTERNATIVES TO IN-PATIENT TREATMENT OF PATIENTS WITH EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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Odense University Hospital. Denmark.

Background: Admission with exacerbations of chronic obstructive pulmonary disease (ECOPD) is the single most common cause for admissions to medical wards and a significant part of health care costs of COPD is related to hospital care.

Objectives: To assess the clinical and economical consequences of alternatives to inpatient hospital treatment of patients with COPD, including early discharge at Odense University Hospital with a telemedicine COPD-briefcase.

Methods: A systematic literature review of the evidence for early discharge and hospital at home interventions (ED/HH) for COPD patients from 1999 to March 2010. Meta-analysis was performed regarding inpatient days at the index admission.

Results: Primary and secondary literature suggests that health outcomes are unchanged. In other words, compared to in-patient treatment the interventions are clinically as safe for the patients, concerning mortality rate and readmission days. Most primary and secondary studies suggest that the patients favour ED/HH-interventions; few studies however, find a statistically significant difference. Primary and secondary literature reports predominantly of cost savings in ED/HH interventions, in the range of 16 to 50 percent reduction in total costs per patient, but most results are statistically insignificant. However, the evidence is not based on a sound methodological foundation.

Discussion: For selected patients, avoiding admission through provision of ED/HH interventions yielded similar outcomes to inpatient care, at a similar or lower cost. However the above results are based on evidence of mixed quality regarding the internal and external validity of the studies.

Implications for the health system/professionals/patients/society: The project team recommends: Develop guidelines for a better identification of the patient group in order to ease the selection of patients eligible for treatment by an ED/HH intervention. Provide knowledge about the economical consequences, especially based on an analysis of the economics aspects in mature interventions in a large scale set-up.

510. COMPLEX TELEHEALTH INTERVENTION FOR POST-DISCHARGE FOLLOW-UP OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) PATIENTS: A RANDOMIZED CLINICAL TRIAL (RENEWING HEALTH PROJECT IN CATALONIA)

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Background: RENEWING HEALTH is a large scale project carried out in 9 European regions from 2010-2013 targeted at patients with chronic conditions. Aims to confirm whether innovative integrated care services (ICS) with support of information and communication technologies improve quality of life and user satisfaction, enable patient empowerment and have potential for cost containment by reducing healthcare services use. The current report presents the study in Catalonia, Spain.

Objectives: To assess the effects of a complex telehealth intervention as part of an ICS for COPD patients after hospital discharge because of an acute exacerbation.

Methods: Randomized controlled parallel-group unblinded trial. Eligible patients are assessed at discharge and classified in tree groups of clinical complexity (high, low, very low). 380 patients are randomized in 1: 1 ratio to intervention or usual care group. Intervention is tailored according to patient's clinical complexity and includes: real-time video-teleconsultations, daily remote monitoring with sensors, access to call center and patient personal health folder. Primary outcome: number of hospital readmissions. Secondary outcomes include: SF-36v2; Hospital Anxiety and Depression scale (HADS); lung condition (FEV1); COPD Assessment Test (CAT); mortality; Service User Technology Acceptability Questionnaire (SUTAQ) and health services use rates. Assessment is performed at baseline and after 3 months follow-up. Economical and organizational impacts of the service are also evaluated. Design, analysis and reporting are based on the Model for Assessment of Telemedicine applications (MAST).

Results and discussion: Preliminary results will be reported, together with insight on encountered challenges and lessons learned. Technical issues related to interoperability, need for training and user acceptance, together with organizational issues related to changes in care continuum are elements of complex interventions that influence study quality and results and thus, shall be carefully considered a priori. Conclusions could be of use for similar studies and to improve research in telehealth field.

552. PATIENT OPINION OF AN ICT INTERVENTION: A EUROPEAN EXPERIENCE

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Objective: The main objective of epSOS (Smart Open Services for European Patients) is to develop a practical Health framework and ICT

infrastructure that will enable secure access to patient health information regarding Patient Summary (PS) and ePrescription (eP) services when travelling in Europe. One of the objectives of the project is to assess not only the technical and implementation aspects, but also the usability, the interactions with legal and regulatory frameworks and user's acceptance (patient, health professional, pharmacist and provider).

Methods: An online questionnaire to be answered by the physician and a paper-based questionnaire for the patient were developed to collect the opinion regarding usability, data safety, acceptance and quality of life aspects. The questionnaires were developed by epSOS experts using focus group methods. Both questionnaires will be filled in immediately after the visit at the Point of Care.

Results: The infrastructure involved in the PS service includes a total of 103 points of care, from 7 different European countries. The development process will end up in one year pilot phase, in which the functionality of the framework and the services (PS/eP) will be tested in practice. The pilot phase for the PS will start in March 2012.

Conclusions: For the first time, patients in Europe will have the opportunity to use cross-border ehealth services when seeking healthcare in participating epSOS pilot countries whether as tourists, business travelers, commuters or exchange students. The opinion and experience of end users will be helpful to improve the healthcare services throughout Europe.

The epSOS project is partially funded under the ICT Policy Support Programme (ICT PSP) as part of the Competitiveness and Framework Program by the European Community.

572. SPANISH AND CATALAN VERSIONS OF THE SERVICE USER TECHNOLOGY ACCEPTABILITY QUESTIONNAIRE (SUTAQ): TRANSLATION AND CROSS-CULTURAL ADAPTATION

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Background: There are few instruments exploring patient perceptions and satisfaction with technologies or equipments used for remote healthcare. SUTAQ is a 22-item self-administered generic instrument especially designed for telehealth and telecare users. During the Whole System Demonstrators programme in UK it was used in nearly 3000 patients. As part of the RENEWING HEALTH project, SUTAQ is translated to 10 European languages.

Objective: Our aim is 1) to describe the cross-cultural adaptation and testing of Spanish and Catalan versions of SUTAQ and, 2) present the final versions of the instrument.

Methods: Forward and backward translations were performed independently by 2 professional translators for each language. Final versions were agreed during a common consensus meeting. Emphasis was put on language used by the layman. To assess comprehensibility of the translated versions 46 subjects (19 potential users and 8 health professionals per language) were consulted through an online survey. Appropriateness and understanding of terminology, wording, response options and format were evaluated. Opinion was asked if important aspects were omitted.

Results: There were no major linguistic or cultural problems identified during the translation. Testing response rates were 63% and 100% for users and professionals, respectively. Almost all respondents (96%) felt comfortable with questionnaire's format and only 5 of the items were found being ambiguous. A 39% of the respondents encountered some unclear expressions, which led to inclusion of brief explanations and/or examples in the final versions of the instrument. Response scale was declared problematic for 35% of the participants and after consultation with the authors, numbering was added to the original 6-point Likert scale.

Conclusions: Linguistically valid and culturally adapted Spanish and Catalan versions of SUTAQ are developed. Both versions proved to be comprehensible and well accepted by the users. Further analysis of psychometric properties will be done during the RENEWING HEALTH Project.

72. COMPARATIVE ANALYSIS OF HTA STRUCTURES AND HEALTH PRIORITY SETTING PROCESSES IN FIVE LATIN AMERICAN COUNTRIES: BRAZIL, CHILE, COLOMBIA, MEXICO AND URUGUAY

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Introduction: HTA and economic considerations to prioritize healthcare resource allocation decisions are increasingly being accepted in Latin America (LA).

Objectives: To review current processes for making health technology funding decisions in five LA countries, as part of an Inter-American Development Bank (IDB) sponsored project for the Ministry of Public Health of Colombia (MoH).

Methods: NICE, IDB and the MoH jointly developed a template to characterize the main attributes of the decision making process and the institutions involved in priority setting decisions by country. The template included 60 questions/topics divided into six macro dimensions: 1) Contextual: regulation and research; 2) Legal support and role of judiciary; 3) Financing of entities; 4) Technical: methods for HTA; 5) Human resources; 6) Future policy initiatives. IECS was in charge of data gathering based on published papers, public sources and the local experts selected in each country.

Results: The nature of the institutional structures dedicated to HTA, the methods used and the types of decisions involved varied widely. HTA has influenced different aspects of the health system from coverage or pricing decisions of individual technologies to the definition of benefits packages. Some features may be identified as cases of "success": 1) the institutionalization of the structures involved in the HTA, with explicit roles in making decisions (not simply "providers" of reports); 2) technical personnel properly trained; 3) Funding to carry out or commission HTA; 4) continuity and stability of HTA health policy, since the greatest gains were observed after several years of implementing these initiatives.

Conclusions: All countries studied have HTA entities adapted to its own systems and values for setting priorities. Despite the many examples of application of HTA to specific decisions or processes in the region, there is in general a lack of institutionalization of HTA structures and processes.

76. EVIDENCE-BASED ADVICE IN A NUTSHELL: PROVIDING ADVICE STATEMENTS FOR NHSSCOTLAND DECISION MAKERS

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Despite the often very limited good quality evidence available to assess the clinical effectiveness of many non-medicine health technologies, let alone their cost effectiveness, health planners and

policy makers still have to make decisions on their provision. The Scottish Health Technologies Group (SHTG) was set up in 2007 to provide evidence-based information and advice to NHSScotland to assist with decision making on the adoption, utilisation and withdrawal of non-medicine health technologies. Since its formation, SHTG has provided rapid reviews of the evidence on health technologies. However, feedback from decision makers within NHSScotland revealed that what was most wanted from SHTG were succinct (several sentences only) summaries of the evidence with a view from the group on whether the technology should be used within NHSScotland. SHTG has responded to this request by providing brief summary statements, known as Advice Statements, to accompany the evidence review products. The Advice Statements aim to outline in a consistent manner the view of the SHTG on the clinical and cost effectiveness evidence for the technology in question in the context of NHSScotland. Devising a process for creating these Advice Statements and attempting to create standard wording has been challenging and there has been a continual learning process for those involved in their production. Discussion of some examples of Advice Statements which have been produced to date, including TAVI, radical prostatectomy and gastric electrical stimulation, illustrate the approach followed and some of the difficulties encountered. Qualitative interviews with key stakeholders indicated a favourable response towards the Advice statements. With rising healthcare costs, diminishing budgets, and ever greater patient and clinician expectations of healthcare, making available such advice to decision makers on the effective and efficient use of health technologies becomes increasingly important.

79. COST-UTILITY ANALYSIS IN ADJUVANT TREATMENT OF COLON CANCER STAGE III (DUKES C)

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Background: Colon cancer is one of the most prevalent kinds of cancer around the world. In stage III its treatment consist of surgery followed by adjuvant therapy that can be based on one of many existing protocols. There are no studies considering Brazilian costs to help decision makers to choose which protocol standardizes in public hospitals.

Objective: To evaluate cost-utility relation among capecitabine, fluorouracil/leucovorin (5fu/lv, *Mayo Clinic Regimen*) and fluorouracil/leucovorin/oxaliplatin (flox) as adjuvant treatment therapy in colon cancer stage iii under the perspective of a large public and academic hospital.

Methods: Considering data already published related to clinical outcomes and accessing costs under the perspective of a public and academic hospital, the cost-utility was evaluated among capecitabine vs. 5fu/lv, flox vs. 5fu/lv and, indirectly, capecitabine vs. flox in a markov model constituted of 10 cycles of 6 months each. It was defined four health states: antineoplasic therapy, disease free, recidive and death. Discounting of 5% was considered and applied for costs and outcomes. Costs were showed in us dollar (u$) in values of 2011 and the outcomes in quality adjusted life month (qalm). Sensitivity analysis was carried out in one-way analysis.

Results: The comparison between capecitabine and 5fu/lv showed an incremental cost-effectiveness ratio (icer) of u$ u$ 7,304.11, while flox vs. 5fu/lv showed an icer of u$ 541.89/qalm. Capecitabine vs. flox revealed flox as dominant strategy. Sensitivity analysis suggests that the results are robust.

Discussion: Capecitabine is not a viable strategy due to its acquisition cost when compared to 5fu/lv and flox. Flox promotes 1.75 and 1.42 qalm more than 5fu/lv and capecitabine respectively, and its incremental cost is covered by government financial support. The results suggest that flox is the best strategy to be standardized as adjuvant therapy to colon cancer dukes c in the hospital, providing treatment in a sustainable manner.

117. LIMITATIONS OF ANALYZES OF TARIFFS AND DELIBERATION OF TECHNOLOGIES OF CITEC DURING THE YEAR 2010

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Background: The Committee for Incorporation of Technologies (CITEC) is an advisory body of the Ministry of Health in Brazil, which has the function evaluating requests for incorporation, inclusion or exclusion of technologies in the context of the Brazilian Public Health System (SUS), according to the guidelines of the National Policy for the Management of Technologies in Health in Brazil.

Objectives: Show the limitations of analysis of tariffs and deliberation of technologies of CITEC during the year 2010.

Methods: If you look at all the technologies based on official meetings of CITEC during the year 2010, the following variables were considered: the total number of meetings, full of technology based, total of deliberations completed and not completed, number of meetings in which the technology has been guided and origin of the demand.

Results: There were 15 meetings of CITEC and guided a total of 86 technologies during the year 2010. Two were the average of meetings in which a technology was based. 62.8% (54/86) technologies had deliberations completed; these 57.4% (31/54), 24.1% (13/54) and 18.5% (10/54) of the decisions were taken at 1, 2 and 3 and 4 more meetings respectively. This last group, the 54.8% (17/31), 76.9% (10/13) and 50% (5/10) were arriving by internal demand in the Ministry of Health.

Discussion: The average of meetings in which a technology has been characterized in CITEC is considered acceptable. Only 57.4% of the deliberations concluded were decided in a single meeting and 54.8% of them are from internal demands of the Ministry of Health which may be attributed to a better quality of information. The high number of meetings a technology shows the great complexity of analysis. The implementation of the law n° 12,401 and the decree 7,646 will help to solve these limitations.

135. REGENERATIVE MEDICINE IN CARDIOVASCULAR DISEASE (CVD): HORIZON SCANNING REVIEW

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Background: Regenerative medicine, in particular cellular therapy, is a rapidly developing field under consideration for the restoration of function in many areas including CVD. There are conflicting results on its potential effectiveness in improving ventricular function.

Objectives: To identify emerging applications of regenerative medicine (cell or factor-based therapy) which have the potential to benefit patients with CVD, and to investigate their stage of development.

Methods: We identified networks, organisations, experts, contacts and companies active in the field and undertook a scoping search to identify appropriate organisations in the UK. We conducted online

searches of: Medline, Embase and the Cochrane research database; regulatory authorities; UK research councils; EU framework programme research consortia; global trial registries; and UK regenerative medicine organisations and networks. Once identified, we searched clinical trial databases to identify the developers of specific technologies in trials closer to licensing and launch. For technologies in phase II or III trials additional information about complete or ongoing trials was collected.

Results: We identified 38 emerging technologies in development for CVDs including heart failure, stroke and coronary artery disease. 5 are in phase III; 13 in phase II/III and 16 in phase II trials. 14 technologies are in industry-led trials and 24 in academic-led trials. 3 of the products (all industry-led development) use allogeneic cells, the remainder use autologous cells. Techniques include factor-based therapy and/or the delivery of new cells including mesenchymal or bone marrow-derived stem or progenitor cells, myoblast stem cells, and adult stem cells expressing CD34+, CD133+ or ALDH.

Discussion and conclusion: Early clinical trials of regenerative medicine demonstrate some encouraging results however, translation into clinical practice may be some way off. There is, as yet, no agreement on the standard methods for cell harvest, preparation and isolation or the optimal method, timing or site for delivery of cellular therapy.

162. MAPPING OF HEALTH TECHNOLOGY ASSESSMENT – DEVELOPMENT AND TESTING OF AN EVALUATION MATRIX IN SELECTED COUNTRIES

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Background: Review of the literature shows little systematic evaluation of the level and trends in development of HTA.

Objective: To develop and test an evaluation matrix to map the level of HTA utilization in decision making at country level. We focused on selected middle-income countries (Argentina, Brazil, India, Indonesia, Malaysia, Mexico and Russia) as well as countries well-known for their comprehensive HTA programs as reference countries (Australia, Canada and United Kingdom).

Methods: Desk research was performed to develop the matrix which was then reviewed by selected HTAi members. We systematically collected and reviewed relevant information to map the level of HTA in the selected countries. The country profiles were supplemented by information from a structured survey among relevant experts in the field of HTA in the selected countries (response rate: 65/385).

Results: The results show that mapping of HTA in a country can be done by focusing on the level of institutionalisation and the process of HTA: identification, priority setting, assessment, appraisal, reporting, dissemination and implementation of HTA in policy and practice. Although HTA is most advanced in industrialised countries, there is a vibrant and growing community in middle-income countries that are interested in developing and using HTA. For example, Brazil is rapidly developing effective HTA practices and programs. India and Russia are still at the very beginning of introducing HTA. The other countries show intermediate levels of development in HTA compared to the reference countries.

Discussion and implications: This study presents a set of indicators for documenting the current level and trends in HTA at country level. The data can be used as a baseline measurement for future evaluation. Regular monitoring is necessary. The approach is comprehensive and can help different actors to assess the development of HTA at country level, help inform HTA strategies, and justify expenditure for HTA.

173. THE STEPS TO EVIDENCE BASED DECISION MAKING IN SLOVENIA- NON PHARMACEUTICAL TECHNOLOGIES

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In Slovenia, health technology assessments (HTAs) as a way of informing the decisions is developing slowly. With the increasing pressure of cost containment, the Ministry of Health (MoH) has recognized the importance of transparent and evidence based decision making. With regard to this, amendments to the Rules of the Health Council and the amendment of the Protocol for the introduction of new, non- pharmaceutical medical technologies were adopted. This revised document stresses the importance of evidence-based programs, clearly defined number of patients, the role of professionals responsible for the doctrine and introduces elements of cost-effectiveness evaluation. To support the latter, a separate commission with the Health Council (HC) was formed to appraise the assessments provided by the applicants. Due to the new procedure of introducing non-pharmaceutical technologies into the health system, the HC in 2010 approved new health technologies in the amount of 15 mio € and rejected technologies in worth 38 mio € due to insufficient evidence, especially undemonstrated cost-effectiveness. There is still lack of knowledge in preparing applications that are sufficient and transparent in providing evidence of cost effectiveness of new health technologies. Therefore, MoH is planning to create an official HTA network in accordance to Directive. Also, as it is evident that cost effectiveness of new technologies in some cases cannot be proved due to it being innovative (organizational forms, genetic tests...) the MoH recognizes the need of financing such projects from the budget to enable conditional coverage. Such projects will need to prove their ethical and safety component as well as potential of being implemented to national level from clinical and organizational point and have potential of being cost effective.

235. HELPING WITH CLINICAL DECISION: PSYCHOSOCIAL INTERVENTIONS IN THE MANAGEMENT OF DEMENTIA

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Background and objective: People suffering from dementia are highly vulnerable to stress, both physically and psychologically. Evolution of dementia depends not only on the underlying pathology and early diagnosis, but also on the availability of effective treatments for a number of symptoms that interfere with patients' quality of life. The objective of this study is the development of a new software tool to support clinical decision when treating dementia, which summarizes all existing evidence about the efficacy of psychosocial interventions. Additionally, a pilot study was conducted in order to test its feasibility.

Methods: Data derived from a systematic review of randomized controlled studies of psychosocial interventions in people affected with non-vascular dementia have been synthesized in an algorithm which has allowed to design a web-based application that facilitates

the decision-making process. A pilot test in two centers of different healthcare level has been performed. A 12-item questionnaire about the feasibility of this tool has been designed and sent to therapists involved in the pilot test.

Results: Our web-based decision-support system consists of different steps. Once the dementia level (*mild, moderate or severe,* according to the Mini-Mental State Examination Index) has been chosen, disorders such as anxiety, depression, aggressiveness, aphasia, orientation or autonomy and cognitive impairment, can be selected. Different possible interventions together with their evidence level are shown. Therapists choose the most suitable one according to the patients' characteristics. A total of 120 patients have been analyzed retrospectively. In all cases, the web-based tool was successful in suggesting the best evidence intervention to be tailored to each patient. Therapists agreed about the tool feasibility and suggested some improvements in order to optimize it.

Conclusion: Despite the lack of high quality trials about psychosocial interventions in people suffering from dementia, it has been possible to summarize the best available evidence. Our Decision-Support System based on clinical evidence in the managing of psychotherapies is a new useful tool that allows translation of existing evidence into clinical practice.

251. CONSTRUCTION AND IMPLEMENTATION OF AN INFORMATION SYSTEM FOR PRIMARY HEALTH CARE IN BOTUCATU CITY/SP, BRAZIL

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Background: Management of out-patient health care depends on information systems which meet the needs of professionals, managers of Units and the Health System Evaluation Center. Few studies on systems with these characteristics have been found in the literature. From 1994 on, a system to achieve these objectives was designed and implemented in Botucatu city/SP.

Objectives: To describe the current conditions of the Municipal Health Information System in Botucatu/SP (SiMIS) in 2008.

Methods: The characteristics of the system were described based on a PhD dissertation on the evaluation of this information system at the local level in the Unified Health System- SUS (2003), and the SiMIS Descriptive Data Sheet from 1994 to 2008.

Results: SiMIS was designed, implemented and developed by a technical team which defined the structure and software needed for computerization of the current procedures in primary health care. The characteristics of the system were as follows: Structured in integrated modules, the system reaches all the programs and main health care actions; variables and categories are standardized; it generates consolidated reports for administration, assessment and management; it was permanently suitable to the needs pointed out and therefore, meeting the requirements from professionals involved; it provides on-line and real-time integration of all out-patient units in a centralized processing. Data input, consultation and operational report generation are performed directly by the system users (health professionals) following the flow of assistance and managerial processes.

Discussion: The elements which guided the creation, implementation and development of SiMIS led to a suitable management system in primary health care, which is currently imperative in the Local Health System.

Implications for the health system: SiMIS has been important to improve management and quality in primary health care.

272. RAPID TECHNOLOGY ASSESSMENT ON IMMUNOGLOBULIN THERAPY FOR ASSISTED REPRODUCTION

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MOH. HTA Branch. Singapore.

Background and objectives: MOH HTA branch, Singapore conducted a rapid technology assessment on the use of intravenous immunoglobulin therapy (IVIG) for assisted reproduction to inform hospital services development policy.

Methods: A search through MEDLINE, EMBASE, NHS CRD databases and the Cochrane Library was conducted for systematic reviews, HTA reports, randomised controlled trials, clinical trials and clinical practice guidelines using the terms "immunoglobulins", "in vitro fertilisation", "recurrent miscarriages" and "unexplained pregnancy loss" and their variations.

Results: 4 systematic reviews, 1 editorial review, 8 RCTs published from 1988 to 2010 were included. In addition, 4 clinical practice guidelines and 3 insurance coverage policies from 2000 to 2010 were also included. The systematic reviews found that IVIG did not show significant differences between treatment and control groups in terms of subsequent live birth in women with unexplained recurrent miscarriage. Seven RCTs show insufficient evidence that IVIG treatment increases the live birth rate for patients with either primary recurrent miscarriage or secondary recurrent miscarriage. One RCT showed that IVIG increased live birth rates in patients with recurrent miscarriage. Two CPGs recommended that recommended that IVIG is not appropriate for recurrent pregnancy loss and two CPGs recommended that IVIG for recurrent pregnancy use should be used in an experimental or clinical trial setting. All three insurers reviewed do not cover the use of IVIG for recurrent spontaneous miscarriage (primary and secondary) as there is limited or insufficient clinical evidence.

Discussion and conclusion: In general, there is insufficient evidence to prove that IVIG significantly increases the live birth rate for patients with either primary recurrent miscarriage or secondary recurrent miscarriage. More evidence is required and IVIG for recurrent pregnancy loss should be used in an experimental or clinical trial setting.

275. THE BRAZILIAN MINISTRY OF HEALTH'S DECISION-MAKING PROCESS IN THE HTA APPROACH TO SOCIAL APPLICABILITY

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Introduction: The impact of Health Technology Assessment (HTA) on the decision-making process regarding the incorporation of health technologies into the Brazilian Public Health System (SUS) has been discussed in many work groups conducted by the MoH. Since 2006, the HTA Unit at the Brazilian MoH supports the Commission on Health Technology Incorporation of the MoH (CITEC) in decision-making regarding health technology reimbursement. CITEC is a permanent commission that analyzes requests for incorporating new technologies into the SUS in line with social health needs. Therefore, many technologies are frequently produced, as requested by different MoH internal petitioners. The MoH's HTA Unit produces HTA Rapid Response Reports and HTA Rapid Reviews for various areas at the Brazilian MoH in order to support local health-care policy-making.

Objectives: To identify the origin of solicitations and the number of Rapid Response Reports and Rapid Reviews produced in 2011, favoring a policy research approach, ideally providing an objective assessment to support health care and policy-making.

Results: In 2011, the MoH's HTA Unit elaborated a total of 55 Rapid Response Reports and 15 HTA Rapid Reviews for the following: CITEC, The Technical and Multidisciplinary Commission to Update the Brazilian List of Essential Medicines, The Technical and Multidisciplinary Commission to Elaborate and Update the Brazilian List of Medicinal Plants and Herbal Medicines, Legal Units and other areas. The majority of the request assessments (52%) regarding Rapid Reviews came from The Technical and Multidisciplinary Commission to Update the Brazilian List of Essential Medicines.

Conclusions: These numbers regarding HTA public decisions made in Brazil show that the HTA Unit at the Department of Science and Technology of the Brazilian Ministry of Health is increasing its capacity to respond to demands and to elevate the number of studies used to support the decision-making process.

277. PROOF OF VALUE DECISIONS FROM PROOF OF CONCEPT DATA: A REVIEW OF CANADIAN FORMULARY REVIEW RECOMMENDATIONS FROM 2004-2010

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Background: Regulatory approval of drugs is often based on trials designed to demonstrate proof of concept. However, such studies are not typically designed to simultaneously demonstrate proof of value in a formulary recommendations setting.

Objectives: To enumerate types of inadequate information in drug submissions which received a "do not list" recommendation from the Canadian Expert Drug Advisory Committee (CEDAC).

Methods: CEDAC "do not list" recommendations from 2004-2010 were reviewed. We identified recommendations where cited reasons for recommendation involved some form of inadequate information, and recorded this data; multiple forms of inadequacy for each submission were captured if present. A summary of these reasons was compiled.

Results: Of 84 "do not list" recommendations resulting from expert review of a total of 171 submissions, 81 (96.4%) were associated with one or more forms of inadequacy of information. Amongst them, 40/81 (49.4%) were associated with inadequate evidence of a clinically meaningful benefit compared to either placebo or an active comparator; 23/81 (28.4%) were associated with a lack of trials versus any active comparator or a particular active comparator of interest; 12/81 (14.8%) failed to report data for a key outcome measure; 18/81 (22.4%) used a surrogate outcome or other outcome considered to be of limited value; 5/81 (6.1%) were associated with inconsistencies of findings across studies or outcomes; and 4/81 (5%) were associated with limited generalizability of study population or sought listing in a population different than those seen in related studies.

Conclusions: Proof of concept studies doesn't always provide sufficient information to show proof of value, and represent a challenge for recommendation panels. In such situations, value judgments play an important role due to uncertainties regarding the information available. Carefully planned trial designs involving relevant comparators, evaluating outcomes relevant to the interests of regulators, physicians and patients, will increase the likelihood of a recommendation for formulary listing.

278. DO VALUE JUDGMENTS PLAY A ROLE IN EVIDENCE-BASED RECOMMENDATIONS WHEN INFORMATION IS BASED ON PROOF OF CONCEPT? A REVIEW OF CANADIAN DATA FROM 2004-2010

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Background: The Canadian Expert Drug Advisory Committee (CEDAC) delivers evidence-informed formulary recommendations for drug reimbursement based on data from clinical systematic reviews and critiques of health economic information. Past work suggests value judgments play a role in evidence interpretation and recommendations.

Objectives: To explore the role of value judgments in CEDAC recommendations.

Methods: CEDAC recommendations from 2004-2010 were reviewed. Recommendations were evaluated which had (1) a partial or full listing, where evidence consisted of only placebo controlled trials; and (2) a do not list recommendation, where evidence consisted of only active comparator trials. Information was gathered on factors potentially influencing the recommendation, such as: drug novelty (i.e. first drug for indication or first in drug class); indication risk/rarity; insufficiency of evidence; study quality; economic considerations; and harms concerns.

Results: 27 partial or full listing recommendations were identified based on only placebo controlled trials, and 24 "do not list" recommendations based only on active comparator trials were identified. Of the 27 "list" recommendations, potential for cost savings (23/27) and therapeutic need (5/27) were influential factors for full listing, while data limitations were important for "list with criteria" recommendations. Reasons underlying the 24 "do not list" recommendations related to insufficiency of evidence versus comparators (22/24; lack of studies versus key comparators, lack of meaningful improvements over other active therapies, missing a key outcome, inconsistency of findings across studies, use of outcomes of limited clinical interpretation), cost/cost-effectiveness (21/24; increased cost or uncertainty surrounding cost-effectiveness) and study quality (11/24; blinding or withdrawals/missing data, appropriateness of non-inferiority margin, other design issues). For the "do not list" category, recommendations were often made in consideration of ≥2 criteria (23/24 = 96%).

Conclusions: The absence of active comparator trials may not be the determinant of a recommendation as value judgments related to the reliability of clinical trial data, therapeutic need, and other factors also play an important role.

279. DEPTH OF CANADIAN FORMULARY RECOMMENDATIONS FROM 2004-2010: APPRAISING EXPERT PANEL DECISIONS

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Background: The Canadian Expert Drug Advisory Committee (CEDAC) delivers evidence-informed formulary recommendations for drug reimbursement in Canada. Reviewing the nature and extent of factors influencing such decisions is of interest.

Objective: To review CEDAC recommendations to identify both the nature and quantity of factors are that typically involved in the determination of a "list", "do not list", or "list with criteria" decision.

Methods: CEDAC recommendations from 2004-2010 were reviewed. We extracted information from the cited reasons for

recommendation regarding the types of evidence and interpretations that played a role in the decision, and counted the number of factors having a role in order to assess how multi-faceted these decisions are. Categories of information considered were cost/cost-effectiveness, evidence inadequacy, study quality, harms concerns, and therapeutic need.

Results: 171 recommendations were reviewed: 84 (49.1%) were for full listing or listing with criteria for the drug, while 87 (50.9%) were against listing. Overall, the median number of criteria cited as influencing the recommendation was 3 (IQR 2-4), and the most commonly cited factors influencing the recommendation were as follows: adequacy or inadequacy of the evidence for meaningful clinical benefit (92.4%), cost/cost-effectiveness (87.1%%), concerns regarding harms data (30.4%), study quality concerns (14%), and therapeutic need (7%). In "list" and "do not list" recommendations, the median (IQR) numbers of criteria were 3 (2-3) and 3 (3-4), respectively. Cost/cost-effectiveness and adequacy of the evidence of meaningful benefit were cited jointly in 72/87 (82.8%) of "do not list" recommendations. Overall, 8/171 (4.7%) recommendations were based on only a single criteria (2 therapeutic need, 1 inadequate evidence of meaningful benefit, 1 study quality concerns, 4 cost/cost-effectiveness).

Conclusions: Both "list" and "do not list" recommendations were generally found to be based upon > 1 criteria. Various aspects of the evidence impact this work.

312. JUDICIARY BRANCH IN BRAZIL: AN ANALYSIS OF JUDICIAL DECISIONS INVOLVING ETANERCEPT, INFLIXIMAB AND ADALIMUMAB

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Background: Worldwide the judiciary branch has been an active player in public health policies, especially regarding drugs. In Brazil, this is a huge concern. This abstract presents an evaluation of the judicial response to cases regarding three biological drugs: etanercept (enbrel), infliximab (remicade) and adalimumab (humira), all TNF inhibitor agents for the treatment of patients with autoimmune diseases.

Objective: To identify the prevalence of scientifically grounded judicial decisions and the knowledge of Brazilian judges regarding clinical protocols, evidence-based medicine and health technology assessment.

Methods: Electronic databases of the Supreme Court (STF), the Superior Court of Justice (STJ) and all Federal Regional Courts (TRFs) were searched using the keywords "etanercept" (enbrel), "infliximab" (remicade) and "adalimumab" (humira).

Results: 102 judicial decisions were found: 6 collegial judgments (6%) and 96 monocratic decisions (94%). Of these, 29 were excluded due to procedural reasons (28%) and 73 met the eligibility criteria (72%). Of those 73, 69 decisions (95%) determined that government have to supply the medications. Only 2 decisions (2.5%) considered it improper to supply the drug due to a lack of evidence regarding its effectiveness. Additionally, 2 decisions (2.5%) determined the need for forensic expertise. Out of the 73 decisions examined, 65 did not rely on scientific evidence. Another 2 referred to evidence-based medicine, without, however, taking it as a plea for the decision-making process. Only 2 decisions considered evidence as a basis for decision-making. On the other hand, just 4 decisions referred to expert medical opinions.

Conclusions: The judiciary branch does not rely on scientific evidence or health technology assessment as a tool to the decision-making process. In order to preserve the right to health and the public health system's sustainability, it is necessary to employ medical evidence methods in judicial decisions.

324. EFFICACY AND SAFETY OF TOCILIZUMAB IN RHEUMATOID ARTHRITIS: A RAPID REVIEW FOR CLINICAL GUIDELINES

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Background: Rheumatoid Arthritis (RA) threatens quality of life and impacts individuals and society economically. In Brazil, the prevalence represents almost one million people. Due to the high costs for the State and pressure for incorporation into the Brazilian Public Health System, technical studies are needed to evaluate new technologies, like tocilizumab, for rational incorporation.

Objectives: To evaluate the efficacy and safety of tocilizumab in treating RA in patients with an inadequate response to methotrexate (MTX) and disease modifying antirheumatic drugs (DMARDs), comparing it to other biological agents and verifying relevant outcomes, such as ACR50, quality of life, adverse events and infections.

Methods: The Cochrane Library, The Centre for Reviews and Dissemination, and Medline were searched. Five high quality evidence studies that compared tocilizumab with other treatment options were selected: 4 systematic reviews and 1 health technology assessment drawn from randomized clinical trials.

Results: Tocilizumab was effective in achieving ACR50 and improving quality of life as a monotherapy or compared to MTX/DMARD and especially when combined with MTX/DMARD. There was no difference between tocilizumab and anti-TNF. Regarding the safety profile, tocilizumab groups are more likely to experience adverse events, infections and dyslipidemia. The correlation between tocilizumab and severe outcomes, such as lymphoma, could not be determined.

Discussion: It is not possible to conclude that tocilizumab should be the first option in biologicals after failure with MTX/DMARD. The use of tocilizumab should be reserved for cases in which patients did not respond to previous treatment with an MTX or another DMARD, with combined DMARDs and with other biological agents.

Implications for the health system: To aid the process of updating the Brazilian clinical guideline regarding RA treatment and to serve as a source of evidence for incorporation, allowing for an optimization of resources and a supply of safe products to society.

327. AN ANALYSIS OF EQUITY IN THE DISTRIBUTION OF CT AND MRI IN CHINA

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Background: CT and MRI are two of the most accepted high-technology medical equipment in China. While they have been increasingly used by Chinese patients in the past 20 years, there have been no published studies examining equity in the distribution of CT and MRI across Chinese regions and over time.

Objectives: To measure equity of the distribution of CT and MRI scanners in China in 2006 and 2009, and to provide evidence for management of high-techchnology medical equipment in the context of health reform.

Methods: Four provincial-level regions were selected as the sample. Shanghai was selected to represent the highest level of

medical technology in China while Zhejiang, Hunan and Shaanxi were selected to indicate the east, middle and west part of China. Data of CT and MRI distribution in the study sites were collected. We analyzed the equity of CT and MRI distribution using Lorenz curves and Gini Coefficients.

Results: The number of CTs and MRIs per million population for the entire sample was 7.4 and 2.1 in 2009, an increase of 45.3 percent and 55.7 percent from 2006. The Gini coefficient of CTs and MRIs per million people for the entire sample dropped from 0.09 in 2006 to 0.08 in 2009 and 0.19 in 2006 to 0.17 in 2009. The number of CTs and MRIs per million population both were significantly correlated with GDP per capita at city level both in both years, but the correlation coefficient decreased in 2009.

Conclusions: The equity status of the distribution of both CT and MRI got improved from 2006 to 2009 in China. Equity status of CT was better than that of MRI.

Implications for the health system/professionals: Given China's economic growth, the numbers of CTs and MRIs are expected to continue to increase, and policymakers and researchers need to monitor the equity status of CT and MRI distribution in the coming years. Future studies also need to examine decision to purchase CTs and MRIs by local hospitals, and the effectiveness of CT and MRI use by providers.

358. DIAGNOSTIC ACCURACY OF ECHOCARDIOGRAPHY FOR CO-EXISTING PATHOLOGIES IN ATRIAL FIBRILLATION PATIENTS: SYSTEMATIC REVIEW

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Background: Atrial fibrillation (AF)is the most common sustained cardiac arrhythmia. It may or may not present with symptoms. If left untreated, AF is a significant risk factor for stroke and other morbidities. Transthoracic echocardiography (TTE) is a procedure that allows imaging of the heart to identify structural and functional cardiac abnormalities. Currently, TTE is not routinely recommended in all patients with AF. By undergoing echocardiography, significant cardiac pathologies can be diagnosed earlier than would be anticipated in current practice.

Objectives: The review investigated the clinical effectiveness of diagnostic accuracy of TTE for clinically relevant pathologies in AF patients and the prevalence of these pathologies within the AF population.

Methods: Evidence about the diagnostic accuracy of TTE for pathologies in AF, and the prevalence of these pathologies in AF was systematically reviewed. Bibliographic and supplementary searches were conducted between March and August 2010. Diagnostic accuracy and prevalence data were extracted from published studies. Results were tabulated and discussed in a narrative synthesis.

Results: Forty-four diagnostic accuracy studies, five prognostic studies and sixteen prevalence studies were included in the review. Diagnostic accuracy data showed high specificities (≥ 0.8) and sensitivities (≥ 0.6) for a majority of selected pathologies. Reported specificity was lower for aortic dissection and pulmonary disease while sensitivity was also lower for atrial thrombi, atrial septal defect and pulmonary embolism. Prognostic studies provided mixed evidence regarding the increased risks of thromboembolism, stroke or mortality associated with co-existing pathologies. Prevalence data indicated a high prevalence (around 25-30%) of ischaemic heart disease, valvular heart disease and heart failure in AF patients. The review demonstrated that routine TTE in newly diagnosed AF patients would identify co-existing pathologies in many patients. However, the impact of this approach on subsequent management of AF patients is uncertain.

387. BEVACIZUMAB FOR NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

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Background: Age-Related Macular Degeneration (AMD) is a common cause of irreversible blindness among the elderly worldwide. Vision loss results from the abnormal growth and leakage of blood vessels in the macula. Without this macular vision, patients become legally blind. Vascular endothelial growth factor (VEGF), the cytokine primarily responsible for blood-vessel growth, is inhibited when anti-VEGF drugs are injected repeatedly into the eye, and blindness is prevented in the majority patients. Because of the significant difference in cost compared to ranibizumab, bevacizumab is used off-label to treat AMD.

Objective: To evaluate the best scientific evidence currently available regarding the efficacy and safety of bevacizumab for the treatment of neovascular AMD.

Methods: In order to identify systematic reviews and randomized clinical trials (RCT) published in English, Portuguese, and Spanish, a wide search in the following databases was performed: MEDLINE (Pubmed), Cochrane Library, Tripdatabase, and CRD.

Results: Three RCT studies were selected, demonstrating equivalence with functional and structural improvements between bevacizumab and ranibizumab. In the CATT Research Group's study (2011), after 1 year, both had equivalent effects on visual acuity when administered according to identical schedules. The proportion of patients who experienced serious systemic adverse events was higher with bevacizumab than with ranibizumab. However, the study does not have sufficient statistical power to correlate the events to the drug.

Discussion and implications: Based on the results of the CATT study and global experience, the New England Journal of Medicine published an editorial supporting the use of ranibizumab and/or bevacizumab to treat AMD. In addition, the National Health Surveillance Agency (ANVISA) published a technical report concluding that both can be used as equal alternatives in terms of efficacy. Safety aspects may arise from the handling of bottles for bevacizumab use and can be resolved through the regulation of pharmacy networks. The use of bevacizumab is necessary for access to treatment to be provided; clinical guidelines and a Pharmacovigilance Programme should be adopted. Bioethical issues should be discussed bearing in mind the market strategy of the industry.

390. RAPID REVIEW OF DRUG-ELUTING VERSUS BARE-METAL STENTS IN PATIENTS WITH CORONARY ARTERY DISEASE AND WITH DIABETES MELLITUS

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Background: Records from a private hospital in Brazil indicates that off-label usage corresponds to approximately 80% of Drug-Eluting Stents (DES) implanted. These patients have increased the risk of both restenosis and late in-stent thrombosis. A systematic review conducted in Brazil describes that clinical benefits of DES have not been highlighted compared to Bare-Metal Stents (BMS) in the Coronary Artery Disease (CAD) treatment.

Objectives: This rapid review evaluates the scientific evidence currently available regarding efficacy and safety of DES *versus* BMS in patients with CAD and with Diabetes Mellitus (DM).

Methods: To find the best evidence currently available a wide search was performed in databases such as Medline, The Cochrane Library, Centre for Reviews and Dissemination aiming to find systematic reviews (SR) or, in the absence of this, randomized clinical trials (RCT). Economic assessments, cost-effectiveness and cost-utility studies, case reports, protocols and narratives studies haven´t been selected in this search. Also, only published studies in English, Portuguese or Spanish were selected.

Results: The role of DES is limited to the hypothesis that must be confirmed by RCT of DES dedicated to patients with DAC and DM, containing participation statistically relevant.

Discussion: The scientific evidence showed that the DES, when compared to BMS, was associated with reduction of revascularization, but this did not implicated in reduction of clinically relevant outcomes such as mortality, myocardial infarction (MI), target lesion revascularization (TVR) and major adverse cardiac and cerebrovascular event (MACCE). The studies also showed no statistically significant reduction in the rates of in-stent thrombosis compared to BMS.

Implications for the health system and society: Compared to individuals without diabetes, people with DM have a higher prevalence of CAD, a greater rates of coronary ischemia and are more likely to have a MI and silent myocardial ischemia.

416. PARTICIPATION OF THE DEPARTMENT OF SCIENCE AND TECHNOLOGY OF THE BRAZILIAN MINISTRY OF HEALTH IN ELABORATING THE BRAZILIAN LIST OF MEDICINAL PLANTS AND HERBAL MEDICINES

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In 2010, the Technical and Multidisciplinary Commission for the Elaboration and Update of the Brazilian List of Medicinal Plants and Herbal Medicines (COMAFITO) was created, coordinated by the Pharmaceutical Assistance and Strategic Inputs Department (DAF) of the Secretariat of Science, Technology and Strategic Inputs (SCTIE) of Brazilian Ministry of Health (MoH). COMAFITO's main objective was to create a list of strategic herbal medicines to be recommended for use within the Brazilian Public Health System (SUS). The Commission was composed of fourteen members. One of them was the Department of Science and Technology (DECIT/SCTIE/MoH). Each member was responsible for evaluating various herbal medicines for specific indications. This evaluation followed a standard methodology that consisted of searching scientific literature in renowned databases (e.g. Medline, Cochrane, CRD); selecting and appraising the best scientific evidence available; interpreting and synthesizing the results; and making a recommendation regarding inclusion or not on the list. The evaluations were presented to all members during the Commission's monthly meetings. When the majority of members voted in favor, the herbal medicine was thus included on the list. In 2011, DECIT elaborated 10 appraisals: *Glycine max* for menopausal vasomotor symptoms, osteoporosis, hyperlipidemia and hypertension; *Harpagophytum procumbens* for osteoarthritis and lower back pain; *Zingiber officinale* for osteoarthritis and for nausea and vomiting in post-operatory reactions, during pregnancy and when induced by chemotherapy. DECIT's recommendation was in favor of inclusion for *H. procumbens* for lower back pain; *Zingiber officinale* for nausea and vomiting in post-operatory reactions, during pregnancy and when induced by chemotherapy. The Commission's final decision regarding the 10 appraisals was in accordance with DECIT's recommendations. The Commission's work is highly innovative because herbal medicines are generally used in Brazil based on popular knowledge alone. Additionally, this list may contribute to a rational use of herbal medicines in the SUS.

423. HEALTH TECHNOLOGY ASSESSMENT FOR A PATIENT DECISION AID IN PROSTATE CANCER

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Background: In Spanish clinical context, prostate cancer patients and health professionals must face diagnostic and treatment decisions. For this reason, initiatives have been developed in this area to provide assistance in patient decision-making, establishing support efforts amongst patients and the clinical team.

Objectives: To develop a Patient Decision Aids (PDA) for prostate cancer with health technology assessment (HTA) tools. Our final aim is to improve the quality of decisions for therapeutic options and to promote shared decision-making.

Methods: A systematic review (SR) of Decision Aids in prostate cancer was performed. Search includes main databases as well as websites of institutions working with PDAs. Additionally, qualitative research (QR) techniques were conducted: in-depth interviews and a focus group with stakeholders (patients, family members and health professionals). Through this SR and QR, we have developed a PDA for prostate cancer.

Results: The SR shows that PDAs in prostate cancer increase patient knowledge on the illness and generates more realistic expectations. There is a clear correlation between patient choice and patient values. PDAs also reduce passivity in the decision-making process to find the option that best suits their medical and personal preferences. Analysis of QR reflects that both patients diagnosed with prostate cancer and health professionals agree that type of surgical treatment and side effects are the most important decisions to face. Patients' subjective experience of the illness is directly related to patient anxiety in the decision making process. After this HTA process a software format PDA was developed.

Conclusions: Information retrieved from SR and patient view from QR guide the PDA content and format. PDA for prostate cancer allows patients to access information and to share the decisions with the clinical team. It also provides patients and health professionals the opportunity to acquire knowledge and to exchange experiences.

428. CLASSIFICATION OF OECD COUNTRIES' REIMBURSEMENT SYSTEMS AT THE POLICY IMPLEMENTATION LEVEL (PART 1)

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Objective: To apply a published analytical framework for describing and classifying pharmaceutical reimbursement decision-making systems using Health Technology Assessment (HTA) and to identify the similarities and differences between fourth hurdle systems at the policy implementation level.

Methods: OECD countries with universal health care and institutionalised HTA were included. Systems were classified in four categories: establishment of the system, objectives of the system,

implementation of the decision and accountability of the reimbursement system. The reimbursement institution(s) responsible for decision-making was identified and their websites searched for data on each element of the framework. When data were unavailable from the institution's websites, published and grey literature were searched and contact was made with the institution to identify missing data.

Results: The sample included 24 OECD countries' reimbursement systems. Systems varied with respect to the institutions, their relationship with the Ministry of Health and the final reimbursement decision. The systems principle objective was categorised as affordability, access or cost-effective use of medicines and there was a degree of overlap and conflict between each objective, especially where multiple institutions were present. Systems implemented decisions through a sickness fund, Ministry of Health scheme, regional scheme or other schemes. Few detailed documents were identified with respect to the accountability of the reimbursement institutions. Where information was available this tended to be considered with respect to intermediate outcomes such as number of guidance rather than impact on final health outcomes. The ability of various stakeholders to appeal and processes of appeal varied widely across countries.

Conclusions: Reimbursement systems are diverse with respect to their objectives, purpose and remit. This may explain differences in reimbursement decisions across countries and the use and influence of HTA on decision-making. Public information was sparse in some countries for elements of the policy implementation level and this limited comparison.

431. CLASSIFICATION OF OECD COUNTRIES' REIMBURSEMENT SYSTEMS AT THE INDIVIDUAL TECHNOLOGY DECISION LEVEL (PART 2)

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Objective: To apply a published framework for describing and classifying pharmaceutical reimbursement decision-making systems using Health Technology Assessment (HTA) and to identify the similarities and differences between fourth hurdle systems at the individual technology decision level.

Methods: OECD countries with universal health care and institutionalised HTA were included in the sample. Systems were categorised at the individual technology decision level: assessment of evidence, the decision and the output and implementation. The reimbursement institution(s) responsible for decision-making was identified and the websites searched for data on each element of the framework. When data were unavailable from the institution's website, published and grey literature were searched and contact was made with the institution to identify missing data.

Results: The sample included 24 OECD countries' reimbursement systems. Variation was present in the assessment and appraisal of clinical evidence. A health economic analysis was mandatory in 17 of the OECD countries for some types of medicines but there was variation in the guidelines for the conduct of the analysis and the requirement for third party review. The appraisals were conducted by committees of varying size and composition. Forty-one stated decision-making factors were identified across countries and categorised into clinical evidence, economic evidence and non-evidence factors. Variation across countries was identified in the implicit/explicit use of cost-effectiveness thresholds and the interpretation of the threshold with respect to other factors. Final decision outcomes varied across countries with respect to the types of restrictions and the status of the decision.

Conclusions: The influence of evidence on decision-making has been studied in some countries but less attention has been given to the impact of the reimbursement process upon the use of evidence and the decision. Further comparative studies designed to control for process may help to address some of the unexplained variation in reimbursement decisions across countries.

433. USING INFORMATION GRAPHICS TO ILLUSTRATE HEALTH-ECONOMIC ANALYSES FOR NON-EXPERT DECISION-MAKERS: A REVIEW OF CURRENT PRACTICE

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Background: It is broadly accepted that, in order to produce evidence-based recommendations on services and care processes targeted at the multidimensional needs of a patient group, decision-makers have to consider the cost effectiveness of competing approaches as well as their relative clinical effectiveness. In the Clinical Guideline development process of the National Institute for Health and Clinical Excellence (NICE), recommendations are made by a Guideline Development Group (GDG) who are not experts in health economics. The cost-effectiveness evidence with which they are presented can be technically challenging. It is well known that the approach to visual display of data can be crucial in the context of learning and decision-making.

Methods: A systematic survey of the health economics presentations at NICE GDG meetings is presented to examine current practice in the use of information graphics in clinical guideline development. These visual displays are categorized based on type and content of information graphic; and analysed according to topic-specific characteristics (for example, type of analysis, type of healthcare intervention(s) under analysis and development centre). A taxonomy of the types and uses of information graphics encountered is developed.

Results: Information graphics are used extensively to illustrate the theory, development and outputs of health-economic analyses to non-expert decision-makers. There is an overwhelming reliance on Microsoft PowerPoint. Interactive and/or animated data visualisations are used occasionally. A detailed analysis of the type and content of information graphics and examples of their use will be presented.

Conclusions: Clinical guideline development makes extensive use of information graphics to illustrate health-economic analyses, but with little evidence of a systematic approach. The effectiveness of the various techniques remains uncertain. Research on the perceptions and understanding of decision-makers would be valuable.

452. HEALTH AND ECONOMICS – COMPARISON OF TREATMENT COST FOR ERECTILE DYSFUNCTION

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Background: The primary objective of Health and Economics, a periodic bulletin, is to improve the critical view of patients about the existence of different treatment cost between medicines with similar safety and efficacy levels

Objectives: The 7th edition of bulletin discuss the costs of drug treatments for the erectile dysfunction, defined as recurrent and persistent disability to get an penile erection in 50% of satisfactory intercourse attempts.

Methods: Between the therapeutic options available on Brazil, there are phosphodiesterase 5 inhibitors. In order to select the drugs to be compared, the evidence was searched on Medline and Cochrane Library electronic databases until December 2011. To determine the treatment costs, it was considered the maximum initial doses and the Brazilian maximum price to consumers including tax (18%).

Results: Because of the lack of high quality studies, it was not found evidence to support any therapeutic superiority among then. At January 2012, there are available on Brazil market: lodenafil (80 mg); sildenafil (25, 50, 100 mg), vardenafil (5, 10, 20 mg) and tadalafil (20 mg). The comparisons of treatment costs were made between the branded and generics drugs with the same substances. As a result, the differences in the treatment costs achieved 275%, between the lowest generic drug (sildenafil generic) and reference drug (Cialis, tadalafil reference drug). Morever, there were found differences of cost of treatment when it was compared the options for the same substance: 1) sildenafil: there were a difference of 56% between the most inexpensive generic drug and Viagra; 2) vardenafila: there were a difference of 65% between Levitra (reference drug) and Vivanza (most inexpensive similar drug).

Discussion: Finally, despite the same efficacy between phosphodiesterase 5 inhibitors to treat erectile dysfunction, there are large differences in terms of treatment costs when generic, similar and reference drugs are compared.

464. PERCUTANEOUS LEFT ATRIAL APPENDAGE OCCLUSION: A SYSTEMATIC REVIEW

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Objectives: The purpose of this study was to evaluate the strength of evidence that percutaneous left atrial appendage occlusion is an effective treatment of non-valvular atrial fibrillation.

Methods: A systematic literature review was used to evaluate the safety and effectiveness of percutaneous left atrial appendage occlusion. The literature review spanned from April 6, 2011 to May 15, 2011, and eight domestic databases including KoreaMed, foreign databases including Ovid-Medline, Embase and Cochrane Library were used. Key words, such as 'atrial fibrillation' and 'percutaneous left atrial appendage occlusion,' were used to search a total of 422 documents, but only a total of 4 studies regarding evaluation of diagnostics were included in the final evaluation. The SIGN (Scottish Intercollegiate Guidelines Network) tool was used by two evaluators to independently evaluate their quality.

Results: A total of 4 studies (1 randomized clinical trials, 1 cohort study, 1 case series, and 1 case study) were identified for the evaluation of percutaneous left atrial appendage occlusion. A total of 3 studies mentioned the complication such as serious pericardial effusion, bleeding, device embolism etc. However, the complication rate was higher or similar than warfarin therapy. A randomized controlled trials reported positive outcomes like ischeamic stroke, CV/unexplained death, hemorrhagic stroke etc. Although percutaneous left atrial appendage occlusion has high complication, it is an effective treatment for preventing ischemic stroke of non-valvular atrial fibrillation patients who can not use warfarin. The body of evidence as a whole is a level of strength of Grade B.

Conclusions: The percutaneous left atrial appendage occlusion is a safe and useful procedure in non-valvular atrial fibrillation with at least grade B evidence based on existent positive studies.

506. HEALTH TECHNOLOGY ASSESSMENT AS A 'RATIONALIZATION TOOL' FOR HIGH-COST TREATMENTS: NEPHROPATHY IN FABRY DISEASE (FD) AS AN EXAMPLE

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Background: Fabry disease (FD) is a lysosomal disease, caused by deficiency of the enzyme alfaGAL-A. Its incidence is estimated as 1:40.000-100.000 of male newborns. Renal failure is a leading cause of morbidity/mortality in this population. There are two licensed recombinant enzymes for enzyme replacement therapy (ERT) for FD: agalsidase alfa and beta. The effects of ERT in Fabry nephropathy are uncertain. The annual cost of treating a patient with FD with ERT in Brazil is $115,000.

Objectives: Evaluate the development of renal disease in FD, in those using or not ERT.

Methods: A Markov model estimating the likelihood of renal disease progression in male patients, with or without ERT was built and analysed.

Results: The probability of those who had only proteinuria to progress to more severe stages of renal dysfunction in those using ERT was 24% compared with a probability of 32% in those not using ERT. For patients that had already established advanced renal dysfunction (without dialysis) the likelihood of progression to dialysis was similar using or not ERT.

Discussion: Patients with initial renal dysfunction (proteinuria) when treated with ERT, had 25% of reduction in the likelihood of progressing to more advanced stages of renal dysfunction. This model was build using clinical outcomes, something uncommon on rare diseases.

Implications for health system/professionals/patients/society: The use of such models could help the identification of subgroups of patients with clinical benefit arising from ERT. This could help the professionals to evaluate the benefit-risk balance of ERT and to choose better who to treat. It would also help the patients to have an understanding of the possible gains of the treatment. These tools can rationalize and contribute to the sustainability of the health system itself. Similar approaches could help the development of public health strategies for rare diseases.

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507. INTERCONNECTION BETWEEN HTA, MULTI-CRITERIA ANALYSIS AND VALUE ENGINEERING AS A TOOL FOR HOSPITAL MEDICAL DEVICES INNOVATIONS

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Introduction: HTA should be and mostly is a part of decision-making concerning expensive medical equipment purchases. However, some steps – above all the way the benefits of health care are measured and valued – have a rather subjective dimension. Our evaluation system aims to make the whole process of medical equipment purchase more objective. The quality and efficiency are measured using methods of value engineering and multi-criteria decision-making, and results of such analyses become source data for a cost-benefit analysis and/or cost-effectiveness analysis.

Methods and conclusions: Within this methodology, determining the function importance value, evaluating costs for functions, and finally value analysis methods were used. All results were assessed using multi-criteria decision-making. As the next step, cost-

effectiveness analysis and/or cost-benefit analysis were employed. This methodological process was applied to three types of medical equipment: ventilation technology, vital function monitors, and hospital beds. This process can be beneficial in hospitals when purchasing medical equipment and/or in tenders. Hence, a decrease in medical equipment cost could appear within the particular health care facility. As concerns the decision process in hospital management, this process might become a significant supportive tool.

522. HEALTH TECHNOLOGY ASSESSMENT (HTA) AND MULTI-CRITERIA DECISION AID (MCDA) AS TOOLS TO SUPPORT HEALTH TECHNOLOGY INCORPORATION PROCESS

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Background: The Clinical Engineering through health technology management, in particular, Medical Equipment (ME) aims to insert parameters of quality at all the stages of the life cycle of technology. Thus, it develops methodology to incorporate technologies identifying the needs, constraints and factors to be considered in order to develop procedures that contribute to adequate planning for the incorporation of ME in Health Care Centers (HCC).

Objectives: To develop a methodology to support the ME incorporation process in HCC, considering the HTA and MCDA as tools to address multiple parameters.

Methods: Initially, some key aspects to be considered in the ME incorporation process were identified. These aspects involve parameters clinical, technical, operational and economic, which should be evaluated and synthesized. Therefore, the HTA and MCDA can be considered in the evaluation of the criteria and indicator generation, respectively. From these tools and the incorporation criteria identified, a methodology was developed to support decision making in ME incorporation.

Results: An example of application was made using the developed methodology; two non-competing ME were evaluated, as follows: robot-assisted and phototherapy equipment. To do so, clinical evidence and information available in the literature were recovered. Through the MCDA approach it was possible to perform the weighting of the criteria, strength of attractiveness between them and establishment of the performance of each option. Thus, a priority incorporation indicator of ME was obtained.

Discussion: The developed methodology can help the incorporation team to identify, predict and guide the implementation of measures to minimize adverse impacts. It still can maximize the benefits which were obtained through the ME incorporation process in the HCC.

Implications for the health system: This research may contribute to the delivery of health services in a safe and effective way as well as reduce the costs of the health system.

553. THROMBOPROPHYLACTIC TREATMENT WITH RIVAROXABAN OR DABIGATRAN VERSUS ENOXAPARIN IN PATIENTS UNDERGOING TOTAL HIP- OR KNEE REPLACEMENT

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Background: For years subcutaneous LMWHs like enoxaparin have been the primary choice for thrombosis prevention after major orthopaedic surgery. Recently, two new oral anticoagulants, rivaroxaban and dabigatran, have been suggested as possible alternative prophylactic treatments in Norway. However, the relative efficacy and cost-effectiveness of the two drugs remains unknown.

Objectives: The aim of this study was to assess the relative efficacy and cost-effectiveness of dabigatran and rivaroxaban compared with enoxaparin for the prevention of thromboembolism after total hip replacement (THR) and total knee replacement (TKR) surgery.

Methods: With respect to efficacy and safety, we conducted a systematic review of the literature and evaluated quality of documentation using GRADE. Cost-effectiveness was assessed by developing a probabilistic decision model. The model combined two modules; a decision tree for the short-term prophylaxis and a Markov model for the long-term complications.

Results: For rivaroxaban compared with enoxaparin we found statistically significant decreases in deep vein thrombosis, but also a trend towards increased risk of major bleeding. For mortality and pulmonary embolism there were no statistically significant differences between treatments. We did not find statistically significant differences between dabigatran and enoxaparin for the endpoints deep vein thrombosis, major bleeding, mortality or pulmonary embolism. Assuming a willingness to pay of EUR62,500 per QALY, rivaroxaban following THR had a probability of 38% and enoxaparin following TKR had a probability of 34% of being cost-effective. Efficacy data had the greatest impact on decision uncertainty.

Conclusion and policy implications: Dabigatran and rivaroxaban seem to be well tolerated antithrombotic medicines. Their efficacy and safety in hip and knee replacement surgery are comparable with enoxaparin. Our results showed that there is a great uncertainty regarding which strategy is the most cost-effective. More clinical research on the efficacy of rivaroxaban and dabigatran is therefore likely to change our results in the future.

610. SUBSTITUTIONS OR ADDITIONS: PREDICTORS OF PLACE IN THERAPY FOR NEWLY LICENSED PHARMACEUTICALS

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Background: New medicines may bring value to patients and health services, but their introduction incurs an opportunity cost. Typically, decision-makers determine a proposed place in therapy around the time of launch; substitutive therapies (which will be used in place of current therapy, either in preference or as an option) may allow disinvestment from current practices, while additive therapies (used alongside current therapy, typically following inadequate response) always incur additional costs. Predicting the place in therapy for drugs in development could aid decision-makers plan assessment strategies and manage introductions.

Methods: New indications licensed by the European Medicines Agency (EMA) from 2005-2010 (excluding generics and immunological products) available for use in the United Kingdom were identified from the EMA website and relevant editions of the British National Formulary. The expected place in therapy at time of launch was classified according to guidance issued by relevant National Health Service bodies for England, Scotland and Wales. Place in therapy was compared with pre-specified characteristics relating to the pharmaceutical (year of licensing, administration route, frequency,

treatment duration) and disease (population, severity, chronicity, ICD10 classification) by cross-tabulation.

Results and conclusions: NHS guidance was available for 114 out of 120 new indications. Of these, 55 (48%) were classified as 'substitutive', 29 (25%) as 'reserves' (used in place of current therapy only after inadequate response), and 30 (26%) as 'additions'. ICD10 classification, administration by the patient, and disease chronicity were all associated with place in therapy ($p \leq 0.05$, χ^2 test). Substitutive drugs were less likely to be indicated for chronic conditions or terminal malignancies; and more likely to be administered by the patient for diseases classified by ICD10 as endocrine, nutritional and metabolic, mental and behavioural, circulatory, and of the eye and adnexa. Further work is needed to identify the relative importance of each predictive factor through multivariate analyses.

617. HEALTH TECHNOLOGY ASSESSMENT ON DENOSUMAB IN THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS

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Background: Denosumab is the first fully human monoclonal antibody inhibiting the activity and the development of osteoclasts in the treatment of postmenopausal osteoporosis.

Objectives: The objective was to realize a HTA report on denosumab.

Methods: A HTA report was realized considering epidemiological, economic, organizational, social and ethical aspects. A scientific literature review was conducted through electronic databases to evaluate epidemiological context and risk factors for osteoporosis. For the economic evaluation, a cost-effectiveness and a budget impact analysis were performed. To evaluate ethical implications, clinical benefits and patient needs were considered.

Results: In Italy around 4.000.000 women are affected by osteoporosis, which is a social and economic priority due to the progressive aging of the population and to the non-optimal adherence to available treatments. Denosumab administered subcutaneously 60 mg every six months, is an effective treatment to reduce quickly, clinically relevant and consistent the incidence of vertebral, non-vertebral and hip fractures. Comparing with strontium ranelate, the Incremental Cost Effectiveness Ratio (ICER) was €69 per QALY and €18.047 per QALY in comparison with generic alendronate. The Budget Impact analysis has allowed us to estimate a reduction in costs for the National Health Service. Denosumab for administering property and safety, is indicated in outpatients treatment, involving General Practitioners. Ethical evaluation is on the whole positive, concerning efficacy, clinical benefits and patient needs.

Discussion: The introduction of innovative drugs, such as denosumab, could allow more effective management of the disease in presence of equity of access to the drug throughout the whole country.

Implications for health systems/professionals/patients/society: HTA application for denosumab represents an important instrument in health care decision making to produce a critical documentation about the real value of a product and its utilization in the Italian context.

634. ORGANIZATION OF AMBULATORY SURGERY AND QUALITY STRATEGIES. RESULTS OF THE DAY SAFE PROJECT IN CATALONIA (SPAIN)

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Background and Objectives: The DAY SAFE Project was defined to describe best practices and standards in ambulatory surgery (AS) in Europe. The aim of this study was to describe the organization and performance of AS in terms of quality of healthcare in Catalonia.

Methods: Twelve Catalan centers were selected by convenience with different volume of activity, healthcare regions and model of AS (hospital integrated facility, self-contained unit on hospital site or free-standing unit-FSU). A survey was sent to decision makers from the Catalan Health Service and in each centre to collect quantitative data on AS activity. Nine semi-structured interviews with hospital decision makers, and 2 focus groups including professionals from FSU were carried out. Information on strategies of AS, safety issues and monitoring of quality was collected. All interviews were recorded in audio and content analysis was carried out and descriptive analysis in the case of quantitative data.

Results: In Catalonia, 48% of AS procedures were carried out of the total planned surgical procedures (n = 211,938) during 2009. No specific barriers in the development of AS were identified, as hospitals resources were used in most centers. Outcome indicators are monitored periodically using information based systems and revised in quality commissions. The percentage of cancelled procedures ranged from 0.2% to 0.7%, anesthesiological complications from 0% to 14% and patient satisfaction from 87% to 99% between centers.

Discussion: Differently to some countries in Europe, few physical, human or financing barriers were mentioned when describing the development of AS in Catalonia. Hospitals and FSU have annual contracts with the Catalan Health Service for the reimbursement of procedures. The use of fully developed computer clinical records or monitoring of patient outcomes after discharge was some areas of improvement in Catalonia. Further research will be needed to define the best practice standards in AS in Europe.

638. COST UTILITY ANALYSIS OF ANKLE BRACHIAL INDEX COMPARED TO C-REACTIVE PROTEIN OR USUAL CARE IN RE-STRATIFICATION OF CARDIOVASCULAR INTERMEDIATE RISK PATIENTS

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Background: The state of art in primary prevention of cardiovascular events is to consider patient global risk score rather than focusing on specific factors. Although statin therapy is indicated for high risk patients and thought to be unnecessary to low risk ones, there remains uncertainty regarding patients at intermediate risk. Coronary calcium score, carotid ultrasound, C-reactive protein (CRP) and ankle brachial index (ABI) have been proposed for re-stratification of these patients (recommendation IIA of the ACCF/AHA guideline). CRP and ABI are less costly than the first two exams, and also require less training and technology.

Objective: We are constructing a Markov model to perform a cost-utility analysis of intermediate risk patients' re-stratification using either CRP or ABI, also compared to usual care.

Methods: The model will take into account the possible reduction in myocardial infarction, stroke and mortality provided by statin therapy, and consider the costs of physician appointments, subsidiary exams, and pharmacological therapy. Different cohorts starting screening at ages 40, 50 and 60 will be simulated, with time-horizon set as lifetime.

Results and discussion: We are currently collecting data and constructing the model. Although there is robust evidence regarding ABI use in risk stratification, with a recent meta-analysis pointing to re-classification of 18% of men and 36% of women when combining ABI to the Framingham Risk Score, there seems to be a general preference for using CRP, perhaps due to less use of office time. This study can evaluate this practice both from the clinical and from the economic perspective.

683. PERSPECTIVES, INTERSECTORAL EFFECTS AND COMPENSATION TESTS

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The impacts of public policies and policy interventions can be widespread and extend beyond the main focus of the policy/intervention, with costs and benefits falling on different areas of the economy, including Government, the private sector, and individuals. This paper considers the necessary characteristics of an economic evaluation that would inform decisions about the implementation of policies or interventions affecting multiple sectors. One form of economic evaluation, cost-effectiveness analysis, has been widely used to inform decisions about policies/interventions which affect only a single sector where there is a single agreed output (as in most evaluations of health care), however, its use for evaluating interventions with a wider impact is limited. Cost-benefit analysis (CBA), another form of economic evaluation, based on welfare economics, has been proposed as a method which allows the evaluation of policies/interventions where costs and benefits fall on several sectors, by simply aggregating costs and benefits into a given numeraire, normally consumption. However, a key weakness of CBA is that it fails to acknowledge the relevance of budget constraints faced by sectors. This despite the process by which budget constraints are set being viewed as having (democratic) legitimacy. We compare two analytical frameworks, first, where there is an explicit welfare function (either welfarist or extra-welfarist) and second, a societal decision-making which regards the values implied by the budget setting process as having (democratic) legitimacy. We show that trade-offs between different outcomes are inevitable and have to be made, but budget constraints cannot be ignored and differing opportunity costs of resources as a result of them must be taken into account. We also show how the use of an explicit welfare function can conflict with a legitimate budget-setting process. Finally we consider whether compensation payments to losers from a policy/intervention are appropriate.

689. THE METHOD OF ELICITATION AND ANALYSING REQUIREMENTS FOR MEDICAL EQUIPMENT

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Background: Poor management of medical technologies is the main reason of growth of financial losses in the global healthcare system (World Health Organization, 2010). Often unreasonable requirements are produced to medical equipment, that makes the prices increase for the functions that are will never be used in practice. Elicitation and objective analysis of the requirements may improve quality of the decisions at stage of purchase.

Objectives: The purpose of our work was to build a method for work with the requirements, which could been effective for medical equipment. Also, this method must have the ability to formalization, because it's a part of the software decision support system.

Methods: Requirements are often influenced by the wide range of stakeholders, including officials, regulators, doctors and patients. Usually, there is also a group of hidden stakeholders and their requirements and issues should be also taken into account. It makes future decision (device purchase) to be based on the concrete environmental conditions. The meaning of analysis according to requirements is process of ranking by importance. Soft Systems Methodology (SSM) was used as the conceptual basis for this method, because it was designed for systems with high human participation.

Results: The method was designed, described and implemented as a software component. Unified Modeling Language (UML) was used for visualization of the relationships between stakeholders. This method was integrated as a program module in concordance with the architecture of decision support system (DSS) framework for increasing the management quality by increasing the objectivity of decisions.

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697. COMPARISON OF SEMI-CLOSED AND OPEN CIRCUIT VENTILATION WITH HELIOX

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Introduction: This study compares semi-closed and open circuit ventilation with heliox. Ventilation with heliox is used primarily in patients with COPD, but its wider use is still being considered. Since the molecular weight of helium is lower than air, patients with respiratory problems find it easier to breathe. Ventilation using heliox open circuit is currently used. But the treatment is very expensive, mainly due to the cost of medicinal heliox gas. The clinical trials of semi-closed circuit are taking place at the moment with much lower cost of Heliox.

Methods and conclusions: Cost-effectiveness analysis and cost-benefit analysis were used for evaluation. The results of these analyzes establish whether the use of semi-closed circuit is beneficial despite worse clinical results. Functions in both types of ventilation with heliox, were compared using value engineering and multicriteria decision making. These values were then used in HTA. "The method of determining the cost of the function" was specified by semi-closed circuit parameters of the weakest function, in terms of cost and assessed possible changes in this area. The clinical trials of semi-closed and open circuit took place in Thomayer Hospital in Prague. Then evaluation of functions of ventilators was consulted with specialists at the Faculty of Biomedical Engineering and the Faculty Hospital in Motol.

735. THE BUDGET IMPACT ANALYSIS AS A TOOL FOR INCORPORATING HEALTH TECHNOLOGIES: FROM THEORY TO PRACTICE ON THE BEST RESOURCE ALLOCATION WITHIN THE BRAZILIAN PUBLIC HEALTH SYSTEM

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Background: The budget impact analysis is an essential instrument to make the best decisions on resource allocation in the public health

systems. Nevertheless, the investigation in this particular setting has an inherent struggle: the data sources for the appropriate analysis.

Objectives: To evaluate and discuss the worries about the suitable data for the budget impact analysis in the public health system.

Methods: We did a retrospective data analysis of the incorporation of sildenafil by the Ministry of Health (MoH), in Brazil, comparing its budget impact estimates with the real spending after its distribution.

Results: In 2010, the MoH included the sildenafil in the scope of available medicines to treat the Pulmonary Arterial Hypertension. At that time, the budget impact analysis, based on epidemiologic data obtained from the medical literature, estimated an annual minimum budget impact of US$ 24,323,940.89 (adjusted value to nowadays). Yet, in 2011, the Ministry of Health spent a total of US$ 9,746,785.14 with this specific providing, representing a difference of US$ 14,577,155.75 (59.93%) from the original estimates.

Discussion: The Brazilian public health system has been taking the budget impact analysis into account when deciding to incorporate or not a medicine. A problem with the assessment based on medical literature data is that the studies might be very scarce and barely developed on the same situation in analysis (population or health system structure). Centered on the sildenafil example, it seems clear that the simple analysis founded on extrapolating epidemiologic data is not an acceptable strategy for the budget impact estimation.

Implications: Alternative strategies, closer to the actual scenario, as the use of public health service's databases, should be also included in the budget impact analysis. These additional sources may help to solve challenges with unreliable considerations for the decision making process and its consequences.

743. USE OF IMIPRAMINE IN NEUROGENIC URINARY BLADDER (NUB)

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Background: *Neurogenic Urinary Bladder* (NUB) may be underactive or overactive. Imipramine is an antidepressant drug that has been used to treat overactive NUB for its antimuscarinic effects and blocking the reuptake of serotonin and norepinephrine.

Objective: To review the advantages and risks of the use of imipramine in the treatment of UNB.

Methods: A review of literature using Tripdatabase, Cochrane Library, PubMed/Medline, Lilacs and Scielo. The search terms were *Neurogenic Urinary Bladder* and *imipramine*.

Results: In the Cochrane Library was selected 1 of the 7 systematic reviews found. In Tripdatabase using filter *Guidelines*, 2 were selected from 18 references. In Pubmed/Medline, using the *Clinical Queries*, were found 2 Systematic Reviews, one being excluded because of lack of relationship with the object of research. In the category *Therapy*, 30 studies were found, 25 over twenty years publication were excluded, and only 1 showed a direct relationship with the subject investigated. The *National Guideline Clearinghouse* classifies imipramine level of evidence 3 and defines the degree of recommendation C. The *Canadian Urological Association Guideline* describes the efficacy of imipramine is only suggested in the treatment for specific conditions of overactive bladder. Cameron et al, 2009 concluded that the combination of drugs improved the clinical condition of NUB when compared with treatment with only one anticholinergic drug. According to Campbell *et al*, 2009, there is no evidence to suggest that imipramine is better or worse than anticholinergics on NUB therapy.

Implications for the health system/professionals/patients/society: There is no conclusive clinical evidence of the benefits of imipramine treatment of NUB. This is reinforced by publication of the Brazilian Society of Urology, 2006, concluding that non-pharmacological measures offer benefits similar or even higher to imipramine. More studies are needed to support the efficacy and safety of imipramine in the treatment of NUB.

754. INTRAVESICAL OXYBUTYNIN: EFFECTIVE OPTION FOR THE TREATMENT OF NEUROGENIC BLADDER?

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Background: Neurogenic bladder is the name given to a bladder dysfunction secondary to a nervous system involvement. This nervous impairment may be congenital or acquired. The main drug used orally in the treatment of neurogenic bladder is Oxybutynin hydrochloride due to the action of pharmacological blockade of cholinergic receptors or directly relaxation of the detrusor muscle, as well as a local analgesic effect in the bladder mucosa. It is important to explore alternative routes of drug administration to minimize the disadvantages of this orally.

Objective: Evaluate the results of scientific articles regarding the advantages and disadvantages presented to the group treated with intravesical oxybutynin, patient type, the total sample and outcomes.

Methods: A review of literature using Tripdatabase, Cochrane Library, PubMed/Medline, Lilacs and Scielo. These papers had to have complete outcomes, studies in humans, over the past 12 years, where an alternative treatment was intravesical oxybutynin. Scientific articles that were in duplicate or that do not meet this profile were excluded.

Results: Eight articles, being one review, were selected for meeting all required criteria, these three articles were in children, two in the elderly of both genders and one specifically for women. The other had a mixed sample. A total of 450 patients started studies, however, there were losses. The main advantage was highlighted by the articles to decrease the side effects common in patients who use oral oxybutynin, yet there was abandonment by no improvement of clinical, urinary tract infections, maintenance of side effects and difficulty as to the procedure intravesical.

Implications for the health system/professionals/patients/society: With the exception of review, articles present an insufficient sample, with low level of evidence, many possible biases and reports that do not support a statistically proven scientifically.

762. PRENATAL FETAL RHD GENOTYPING FROM MATERNAL BLOOD

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Background: The knowledge of fetal RHD status is of particular importance for the pregnancy monitoring of Rhesus – D negative women. The assessment of fetal *RHD* status has until recently only been possible through amniocentesis, a procedure associated with 1% risk of fetal loss and with increased risk of alloimmunization.

Objectives: The aim of this assessment was to establish the diagnostic accuracy and indications of the fetal *RHD* genotyping from maternal blood.

Methods: The assessment was based on the critical analysis of clinical data published between January 1995 and January 2010 and the statement of a multidisciplinary experts panel. Conclusions have been reviewed by a specialized committee of HAS.

Results: 31 studies including more than 10 pregnant women were selected. Real-time PCR has been the technique most frequently employed. Sensitivity and specificity were above 95% in the majority of studies. Those results were considered satisfactory, despite methodological shortcomings limiting their robustness. Published results of external quality controls carried out by a working group of the International Society of Blood Transfusion confirmed the accuracy established from published studies.

Discussion: Following this assessment HAS proposes that prenatal fetal *RHD* genotyping be covered by the National Health Insurance in two situations: -for prophylactic indications of anti-D immunoglobulin in RH: -1 pregnant women who are not immunized, -for the identification of immunized RH: -1 pregnant women who should benefit from specific specialized management.

Implication for the health system: Non invasive fetal *RHD* genotyping modifies the monitoring strategy of pregnant rhesus D negative women by identifying which pregnancies need anti-D immunoglobulin prophylaxis or antenatal intensive care.

768. TO MODEL OR NOT TO MODEL: PREDICTORS OF DE NOVO HEALTH ECONOMIC MODELLING IN THE DEVELOPMENT OF MULTIFACTORIAL CLINICAL GUIDELINES WITH NUMEROUS DECISION PROBLEMS

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Background: The National Institute for Health and Clinical Excellence (NICE) produces Clinical Guidelines for integrated care of patients across a spectrum of conditions and multidimensional settings. During Guideline development, Clinical Review Questions (CRQs) are created to focus on areas of clinical uncertainty. CRQs that are judged to represent high priority for health-economic analysis are identified and, where considered appropriate, developers produce de novo cost–utility models. Factors that predict the level and type of de novo health economic analysis that will be required for any individual CRQ are unknown.

Methods: Clinical Guidelines produced since the 4th edition of the NICE Guidelines Manual (2009) were evaluated to identify predictive factors of de novo economic evaluation. A descriptive analysis was produced. Multivariate logistic regression was conducted to explore a wide range of potential predictors including: question type (prognostic, diagnostic, intervention, patient/professional need, service delivery); inclusion of pharmaceuticals (branded and non-branded); and existence of previous NICE Technology Appraisals on comparators. Guideline-specific variables such as number of CRQs within the Guideline, publication year and development centre were also included.

Results: A preliminary analysis of Clinical Guidelines produced by NICE's Internal Clinical Guidelines team suggests that type of question and presence of branded pharmaceuticals are predictive of prioritisation for health economic analysis. Univariate analysis indicates that CRQs relating to interventions (OR = 7.86 [95%CI: 2.26, 27.36]; p = 0.001) and involving pharmaceuticals (OR = 21.88 [95%CI: 2.33, 205.78]; p = 0.007) had significantly greater odds of being modelled than other question types. Multivariate analysis of the full dataset including other variables will be presented.

Conclusions: Consideration of cost effectiveness is a crucial element of Clinical Guideline development at NICE. It is possible to identify factors within CRQs that will influence the requirement for de novo health economic modelling. These findings may assist in the prioritisation of health economist input.

770. THE HPV VACCINE AND CHALLENGES TO IMPROVING THE QUALITY OF SCREENING IN BRAZIL

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Background: In Brazil, the cervical cancer prevention program has an universal access and the technology used for the screening is the Papanicolau. It covers more than 70% of the population; above all, the disease still shows a high mortality rate due to the differences in coverage and screening quality throughout Brazil's regions.

Objectives: To find evidence on the efficacy, safety and budget impact of the vaccine against HPV, considering the Brazilian context for preventing cervical cancer, in order to support decision-making regarding incorporation.

Methods: For efficacy and safety, a systematized search was conducted by systematic reviews (SR) of randomized clinical trials with and without meta-analyses (MA). The Brazilian Cervical Cancer Prevention Policy and a Brazilian economic evaluation (EE) study were also employed as a basis for evaluating the cost-effectiveness and budget impact of the vaccine.

Results: Three MA were found that demonstrated efficacy and safety of the vaccines when compared to the placebo; the results were better when evaluated by protocol than by intention-to-treat analysis (ITT). The EE selected is a SR developed in several countries, including Brazil. The study's results demonstrated that the vaccine is cost-effectiveness when added to screening; however, uncertainties still exist regarding the Brazilian reality. The annual estimated budget impact was R$ 160 million.

Discussion: The efficacy results by ITT are closest to the Brazilian reality. Other aspects should be considered in addition to the cost-effectiveness of the vaccine in order to make incorporation decisions. The challenges to improve the screening quality are: the regional differences in coverage and the necessary resources for vaccine incorporating.

Implications: Regardless of the vaccine's incorporation, investments will be needed in order to improve the quality of screening, while focusing on the need for its continuity and its importance in preventing cervical cancer cases.

809. HTA FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION IN BRAZIL

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Background: In Brazil, there are about 3,000 patients with PAH being treated by some provinces or by means of legal actions; however there wasn't a clinical guideline for the treatment. The Committee for the Incorporation of Technologies (CITEC) at the request of the area responsible for health care at the Ministry of Health was held in 2011 to evaluate the available technologies in Brazil for the treatment of this rare disease.

Objectives: Analyze the process of evaluation and incorporation of technologies for the treatment of PAH in national level.

Methods: A retrospective, descriptive study. Data were obtained in the CITEC's database. Were analyzed the assessments of technologies performed and decision-making process on the incorporation

Results: In Brazil, are available two medicines for the refractory to first-line treatment for PAH: sildenafil, bosentan. It was developed a systematic review concluded that the two have similar efficacy, then it result in a cost-minimization analysis. The cost of monthly treatment for a patient with using sildenafil was about US$ 1,000.00 and with bosentan US$ 6,700.00, which became the first very cost-effective. CITEC, then decided that bosentan only would be incorporated if the price is reduced to a value that matches its cost of treatment to sildenafil. It was performed proposal to the laboratory about this value that was accepted. From then on, it was drawn up a clinical guideline for the treatment of PAH.

Implications for the health system/professionals/patients/society: The performance of CITEC in this case enabled that patients have access to two medicines for treating their disease. Health professionals also have two choices to be able to adjust the treatment to the specific needs of the patients. The Brazilian Public Health System (SUS) may offer the best treatment at a cost that is affordable to the health care system and for the society.

846. METHODOLOGICAL GUIDELINES FOR EVALUATION STUDIES OF INCORPORATION OF MEDICAL DEVICES

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Background: The healthcare technology, particularly medical equipment, contributes significantly to the constant growth of health costs, complexity and technology dependence. Thus, the decision making process to incorporate technology by the health managers, needs to become more systematic and rational as well as allow adequate planning for the medical equipment incorporation, in order to promote health care insurance, equitable and of high quality. Thus, it is necessary to identify tools and mechanisms to assist the medical equipment incorporation process, as the Health Technology Assessment (HTA).

Objectives: In this context, a methodological guideline to support the decision analysis to medical equipment incorporation by health managers is been developed by the Institute of Biomedical Engineering, Federal University of Santa Catarina (IEB-UFSC) in partnership with The Brazilian Ministry of Health and State University of Campinas (Unicamp).

Methods: The development of this methodological guideline is based on three components that are defined in the IEB-UFSC Healthcare Technology Management Model: infrastructure, human resources and technology. In addition, the HTA tool is used to support the decision making regarding medical equipment, according to the equipment life cycle, mainly in the incorporation phase. Through a comprehensive literature search, clinical, technical, acceptability, operational and economic aspects were identified as relevant to support the managers in the decision making process to medical equipment incorporation. Based on these aspects, relevant sources have been found in order to recover evidences and information aiming the formulation of recommendations for health managers.

Results: This methodological guideline provides a systematic process to medical equipment incorporation.

Implications: By considering multiple aspects, the methodological guideline is an effective contribution in order to increase the quality of life, the clinical procedures effectiveness, the balance of human resources, technologies and infrastructure that may provide improvements in the Unified Health System services.

883. HEALTH TECHNOLOGY ASSESSMENT FOR THE UPDATE OF THE UNIVERSAL HEALTH BENEFIT PLAN IN COLOMBIA

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Background: The Comisión de Regulación en Salud (CRES), a government agency under the Ministry of Health, commissioned eight research groups to evaluate the technologies to update the Universal Health Benefit Plan (POS).

Objective: To describe the experience of assessing the evidence regarding the effectiveness, safety, and cost-effectiveness of a group of technologies (drugs and medical devices), to support the update the POS.

Methods: We performed a systematic review using multiple databases (PubMed, Scielo, Cochrane, INHTA) and grey literature from abstracts and presentations of international and local scientific meetings to identify the evidence of each technology assessed. Based on the level of evidence, decision rules were developed to recommend the inclusion or not of new technologies in the POS. In addition, for those technologies selected to be included a financial impact analysis was performed.

Results: A total of 227 technologies in 120 different indications were evaluated. 147 new technologies were recommended and included in the POS. Technologies with indications for treatment of chronic diseases accounted for 86.7% (27% for cardiovascular disease and 13% for cancer). 48% of the assessments were inconclusive due to the limited evidence to support some of these technologies, particularly cost-effectiveness analysis.

Discussion and implications for society: Based on these assessments and recommendations, the Ministry of health of Colombia updated the Health Benefit Plan, starting January 2012, covering more than 96% of the population of the country.

904. RELATIVE MEDICAL VALUE INDEX (RMVI): A CORE STRATEGIC DRIVER OF R&D STRATEGY

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Background: The changing healthcare environment demands that health care solution organizations evaluate their approach to drug/device development to ensure that their products provide value to patients, providers and payers.

Objectives: Our objectives were to build upon/modify the EVIDEM Collaboration Framework to facilitate decision-making that supports the deliberative process, provides access to evidence, and enhances collaborative decisions within our organization.

Methods: Extensive analyses of the global literature, HTA/payer landscape and of the EVIDEM Collaboration were performed. The Relative Medical Value Index (RMVI) framework was developed to complement scientific translation assessments of internal development projects. RMVI Evidence Report generation and assessment by the trained Global Medical Affairs team produced medical value ratings for decision-making.

Results: A framework consisting of four categories (disease, target population, treatment and economic impact) via a multi-criteria decision analysis (MCDA) approach was developed to include eleven quantifiable metrics that are considered in population-based decision-making and are externally validated. A systematic approach to synthesize and assess the evidence accompanied the development of this framework. This approach positioned our R&D organization to

proactively address the value drivers for improved patient outcomes and innovation, focusing on unmet medical needs with potential to contain health care costs for the portfolio of development projects.

Discussion and implications: The RMVI framework is a systematic, transparent integrator of parameters that identifies key value differentiation to empower the development strategy of R&D projects. Further testing and validation is needed to refine the RMVI approach to ensure that it can be utilized across all therapeutic, geographic areas, as well as early and late phase development projects/products.

514. MAPPING HEALTH TECHNOLOGIES AGAINST BURDEN OF DISEASE - A BETTER WAY TO PLAN FOR HEALTH SYSTEMS

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Background: Queensland Health adopted a Health Technology Assessment Program in August 2009. The program is structured on a statewide advisory committee on new technology to oversee a New Technology Funding Evaluation Program. 5 Health Service District advisory committees were also established to provide advice at a local level.

Objectives: While the HTA Program has commenced the coordination of a process for introducing and evaluating new health technologies in Queensland, there is recognition that a more proactive approach needs to be adopted to map technologies according to the burden of disease (including current state of play and future directions). This is particularly important given the need to implement clinically effective and cost-effective technologies into the system.

Methods: The development of technology maps according to burden of disease will assist in health service planning, policy and clinical decision-making. Typically, a technology map will include technologies for screening, diagnosis, treatment (e.g. surgery, radiation therapy) and palliation. This process includes appraising the evidence and engaging with Queensland Health clinicians regarding the appropriateness, availability, accessibility and affordability of individual health technologies. This will seek to ensure the appropriate use/non-use of a technology. An audit is being undertaken on technologies that are currently used in Queensland Health, and technology briefs are being developed on those technologies that are early adopters and on the horizon. Maps will be updated as new technologies enter the Australian market.

Results: Development of technology briefs based on the available evidence. National collaboration under the Health Policy and Advisory Committee on Technology (HealthPACT) which has highlighted the need for better planning and working together across states.

Implications: This approach is a methodology for prioritising health technologies based on available evidence, while ensuring the patient journey through the public health system is captured.

515. HEALTH TECHNOLOGY ASSESSMENT AND ORGANISATIONAL FEASIBILITY: CHALLENGES FROM PHARMACY AUTOMATION

Kaye Hewson and Hong Ju

Queensland Health. Queensland Government Australia. Australia.

Background: A new model to introduce innovative health technologies into public healthcare system in Queensland Health (QH) through a Health Technology Assessment (HTA) program was commenced in 2009. Through the program, Pharmacy Automation, an automated picking/dispensing robot, was introduced into a public hospital in 2010.

Objectives: *Capital works:* Pharmacy Automation installation has required a significant change in electrical and data installation, platform construction, air-conditioning modifications and relocation, and installation of power outlets in both the main pharmacy and the wards where the solution is located, in a major hospital. *System compatibility:* This has been a major holdup for the implementation of the technology. At the time of adoption, the dispensing software on which pharmacies operate within QH did not support the interface with Pharmacy Automation. A major IT system upgrade has to be undertaken within QH in order to make it interfere fully with the Pharmacy Automation. *Increased cost:* Additional funds for service contract establishment (AU$70, 000) and solution re-establishment (AU$12, 000) with the vendor was allocated for the project due to the delayed functioning interface, totalling AU$82,000. In addition, funding for capital works in both the main pharmacy and wards has to be absorbed by the district/hospitals. *System capacity:* Handling packages prone to breakages, controlled medications, medications requiring cold storage and maximum package size all presented as issues needed to be considered. *Stakeholder engagement and support:* Due to the complex interface required for the dispensing software with Pharmacy Automation, the software company did not provide substantial support nor did it deliver the agreed outcome at the initial stage. A way forward was made possible only after all stakeholders were completely engaged.

Results: The organisational feasibility of adopting new technologies needs to be thoroughly assessed in order to ensure the smooth implementation and uptake of the technologies.

544. INEFFICIENCIES AND SOURCES OF UNSUSTAINABILITY IN HEALTH CARE SYSTEMS

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Background: Payers continually seek to increase and improve the outputs achieved by the health care system they fund. Where economic recession and fiscal reconstruction are the rule, the pressure to constrain costs grows, and with it the desire to increase health system efficiency.

Objectives: To identify and analyse: inefficiencies and bottlenecks that undermine health care systems' sustainability; and potential policy solutions to tackle them. We focused on Australia, Canada, France, Germany, Italy, Spain and UK.

Methods: The main sources of information were a review of the relevant literature and semi-structured interviews with expert, independent commentators on health care cost containment, health care reform and health care system efficiency. Most of our 16 commentators were interviewed twice. In total 29 interviews were conducted.

Results: We identified five key inefficiencies: (1) lack of primary/secondary care coordination; (2) inappropriate use of resources due to no or insufficient cost benefit analysis (broadly defined) to assess how to spend the health care budget; (3) inappropriate use of resources due to weak or perverse financial incentives to providers; (4) inconsistent implementation of HTA and/or clinical guidelines; (5) poor chronic disease management. In addition, poor or little use of health information technology was highlighted as an issue of high importance as it contributes to all five high priority areas. There was limited evidence quantifying the impact of addressing these inefficiencies at the system level.

Discussion: Our results confirm and reinforce some of the key inefficiencies that have been discussed in the literature. Some differences across countries emerge but there is considerable

consensus, with a major focus on better integrated care, especially for chronic diseases.

Implications: The findings imply a clear, high level health care policy agenda for tackling health system inefficiency.

635. ESSENCIAL PROJECT: INITIATIVE TO IDENTIFY LOW VALUE PRACTICES IN HEALTHCARE AND TO PROMOTE THEIR DISCONTINUATION IN CLINICAL PRACTICE

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Many clinical practices currently in use are of little value for the process of care because they are ineffective or lack scientific evidence support. Countries as Australia, Canada or UK introduced in the health policy agenda the concept of disinvestment: "the processes of (partially or completely) withdrawing health resources from existing healthcare practices, procedures, technologies, or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and thus do not represent efficient health resource allocation". These processes contribute to increase health systems quality. Our aim is to present and describe the ESSENCIAL Project intended to improve quality of healthcare by reducing low value practices use. Specifically: 1) Promotes disinvestment on procedures that are ineffective, inefficient or have poor risk-benefit profile; 2) Promotes professionals' participation in the identification of low value practices and their involvement in processes of change within the system; 3) Promotes avoiding waste at local level by creation of professional groups willing to re-design clinical pathways in their local environment. Identification of low value practices is based on systematic revision of scientific evidence (clinical practice guidelines, technology assessment reports and publications) and the consensus of health professionals. Recommendations on practices to be discontinued are compiled into a web-based open database and, after a prioritization process, actively disseminated to key stakeholders. Impact on the health system in terms of process and results will be evaluated applying quantitative and qualitative methodologies. Assessment involves three main areas: 1) The degree of knowledge of the recommendations among the key health professionals; 2) The direct impact on clinical practice, measured by the change in use rates of practices recommended as of "low value"; 3) The budgetary impact attributable to the integration of the recommendation. Initial experiences, results and lessons learned will be discussed.

652. SAVING PUBLIC HEALTHCARE COSTS WITH RHEUMATOID ARTHRITIS (RA) TREATMENT IN BRAZIL: RETROSPECTIVE ANALYSIS OF ADDING RITUXIMAB INTO MINISTRY OF HEALTH CLINICAL GUIDELINE

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Background: Rheumatoid arthritis (RA) is a systemic autoimmune disease which affects 0.5% of the population in developing countries. Rituximab is an anti-CD20 monoclonal antibody with demonstrated efficacy for patients with rheumatoid arthritis who had inadequate response to anti-TNF therapies (second line therapy). Currently, patients in the Brazilian public healthcare system (SUS) can only be treated with anti-TNF therapies (adalimumab, infliximab and etanercept) even after first inadequate response to treatment.

Objectives: To assess the budget impact of offering rituximab as an option for second line therapy of RA in SUS.

Methods: Real-world data on anti-TNF therapy switches from Jan/2011 to Sep/2011 were taken from DATASUS (Brazilian Ministry of Health database). We considered that 40% of all switches happened because of first failure to anti-TNF therapy and that 35% of patients would receive 2nd line treatment with rituximab if it was available on SUS. Only direct annual medical costs of biological drugs were considered and drugs dosages were: rituximab (2 g every 8 months), abatacept (750 mg at weeks 0, 2, 4 and then every 4 weeks), infliximab (4 mg/kg at weeks 0, 2, 6 and every 8 weeks), adalimumab (40 mg every other week) and etanercept (50 mg every week). Drug acquisition costs were taken from official public sources. Therapy costs were bring to present value.

Results: Annual therapy costs were: rituximab (BRL23,485.36), etanercept (BRL36,400.00), adalimumab (BRL36,374.00) and infliximab (BRL45,140.00). According to DATASUS, from Jan/2011 to Sep/2011, 3,535 patients had inadequate response to first anti-TNF therapy resulting in a total second line therapy cost of BRL123,424,774.30. Considering inclusion of rituximab, 1,237 patients would be treated with the drug and total costs of 2nd line therapy would drop to BRL114,717,703.94.

Discussion and implications for the health system: Including rituximab in Brazilian public healthcare treatment guideline would result in BRL15,983,489.16 of savings. With this savings, it would be possible to include approximately 681 more patients under rituximab treatment.

698. ROBOTICALLY-ASSISTED RADICAL PROSTATECTOMY – IS IT AN EMERGING TECHNOLOGY TO THE UNIFIED HEALTH SYSTEM IN BRAZIL?

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The Unified Health System (SUS in Portuguese) has an increased demand for the incorporation of robotically-assisted radical prostatectomy due to the alleged benefits in relation to conventional surgical techniques. Currently, the technology is available in few private hospitals. This survey aimed at obtaining the opinion regarding the use of this technology by three private hospitals with expertise in performing the procedure. A form was developed to address the following issues: technology description, performance indicators, potential benefits and risks, resources for deployment and hospital reasons for acquisition. The average response rate was 93.6%. The Da Vinci Surgical System IS-2000 was the device adopted by the three hospitals. The benefits reported were a decrease in blood loss, length of hospitalization, complication rates, post-operative pain, urinary incontinence and erectile dysfunction. The drawbacks reported were longer surgery time in early stage of surgeon's learning curve, need for changes in routine and workflow, adaptation of infrastructure and training to perform the procedure and the maintenance of the device. The costs for the device acquisition and maintenance were on average US $ 2,440,000.00 and US $ 89,000.00 per year plus US $ 2,500.00 per surgery for surgical supplies. The reasons for the device acquisition were clinician's and society demand, market pressure, research purpose and scientific evidence. The hospitals did not present any performance indicators or evidence of the alleged benefits, but the general opinion was favourable to the procedure. The literature corroborates with the survey findings, since the former highlights the lack of robust evidence to prove the benefits, which are strongly influenced by the skill of the surgeon and professional experience of the team. Given the limitations of the available evidence and the

foreseen costs and organizational impact, there is a need for a full economic analysis before any decision about incorporation by SUS.

724. MANAGEMENT STRATEGIES IN THE QUEST FOR THE COMPREHENSIVE HEALTH CARE: THE EXPERIENCE OF THE SPECIALIZED PHARMACEUTICAL SERVICES COMPONENT

Roberto Eduardo Schneiders, Ivan Ricardo Zimmermann, Luana Regina Mendonça de Araujo, Rodrigo Fernandes Alexandre, José Miguel do Nascimento Junior and Carlos Augusto Grabois Gadelha

Brazilian Ministry of Health. Brazil.

Background: The Brazilian public health system ensures universal, equitable and comprehensive access to health technologies, including medicines. Outpatient medicines are divided into three components of its pharmaceutical services. The clinical conditions treated in the Specialized Pharmaceutical Services Component (SPSC) are defined in the Clinical Protocols and Therapeutic Guidelines (CPTD) in the form of lines of care.

Objectives: To describe the experience and results of the SPSC with its particular strategies in the quest for the comprehensive health care.

Methods: Focused on the SPSC's issues, we did a retrospective data analysis related to its management strategies for the pharmaceutical services in the public health system in the last two years.

Results: As a strategy to increase medicines access and optimization of resource allocation, the Ministry of Health (MoH) expanded the amount of centralized procurement medicines, from 13 to 46 products. This deed was focused on those medicines with a concentrated market. As a consequence, this action allowed average resource savings of 33% in two years, with 96% increase in the number of units distributed in the same period.

Discussion: The SPSC was designed in 2010 for the budgetary resources optimization and to expand access to medicines for diseases that require complex health services or high-cost medicines. Within this Component, the municipalities provide the first-line treatment and the states finance the medicines for refractory to first-line treatment. Further, the MoH finances the medicines with greatest global impact or to situations refractory to other treatments, by the centralized procurement or by financial transfers.

Implications: The purchasing power of the MoH, together with the appropriate selection of medicines, definition of lines of care, organization of services within the CPTD's recommendations are strategies that allowed expansion of access to medicines, with optimization of budgetary resources in the Brazilian public health system.

823. HOSPITAL ECONOMIC IMPACT OF THE RATIONALIZATION MEASURES OF PHARMACEUTICAL COSTS

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Background: The current economic crisis has forced many countries to take measures to reduce the public deficit. In our country, some of these measures have been aimed at the pharmaceutical costs through price review provisions that allow a reduction in the pharmaceutical bill, without taking other arrangements involving additional co-payments or a decrease of health services or loss of the universality health care.

Objectives: To analyze the economic impact of the price review measures adopted in May and June of 2010 by Spanish Ministry of Health, in the University Hospital of Canary Islands.

Methods: From the hospital registries, we studied the costs of drug consumption from January to June 2011 and we compared these to the same period of 2010. We calculated the costs per stay and outpatient costs for those patient groups that involve a greater expenditure (patients on antiretroviral, anti TNF, recombinant human erythropoietin, and growth stimulating factors colony of leukocytes therapies, among others).

Results: In spite of a significant increase in hospital activity (350 outpatients more were treated during this period) there was a cost reduction of drug consumption by 2.5%, there was also a decrease in the cost/stay of € 1.5 and a reduced outpatient cost of 3.7%. In this outpatient group the most costs saving have been detected in antiretroviral therapies (€ -124 patient per month), anti TNF therapies (€ -69 patient per month) and human erythropoietin therapies (€ -92 patient per month). As a result cost consumption of drugs has reduced € 517,620 in 6 months.

Conclusions: Measures adopted by the Spanish Ministry of Health of selective reduction of drug prices have broken the upward trend in pharmaceutical costs in previous years in our center. This is a positive impact on hospital costs. We believe that these measures can positively contribute to ensure the sustainability of the public health system.

45. ASSESSMENT OF ADVERSE EVENTS RELATED TO THE COMPUTED TOMOGRAPHY

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Objectives: The aim of this work was assess the adverse events (AE) related to the use of the computed tomography equipment informed in Brazilian and foreign notification system, to classify them accordingly to their causes following the Shepherd approaching model and to estimate its correspondence to the computed tomography equipments installed in Brazil.

Methods: The AE notifications were collected from the Brazilian National System of Adverse Events and Technical Complaints (NOTIVISA), from the Medical Device Reporting Database (MDR) and from the Manufacturer and User Facility Device Experience Database (MAUDE). The AE were classified based on Shepherd model (The Systems Risk Model - SRM). The AE estimate of occurrence in Brazil took place through the intersection of the data on the occurrence of AEs obtained in banks MDR and MAUDE with the records of the appliances sold in the country.

Results: There were collected 519 AE related to the tomography equipment, being 233 reports from MDR and 286 reports from MAUDE. None event was found from the Brazilian database. The study showed that 78.2% of AE were related to the medical device component being that 38.9% was related to the parts and circuits project sub-component. The study also showed that 64.5% of AE were ranked like malfunctioning. Our work classified the AE by flawed type, being the software error the most frequent one (20.7%). Verifying the correspondence of events found in the abroad notification database, comparing them to the similar equipments existing in Brazil, were found 356 events.

Discussion: In conclusion, we are able to affirm that Shepherd model is very useful to identify causes and assess the risks of AE surveyed. For future studies, it is proposed to use the model to evaluate the Shepherd AE related to the use of radiology equipment like conventional x-ray, ultrasound, MRI and mammography.

Implications for the health system/professionals/patients/society: There is a large number of reports of medical device-related AE compared to the other components (plant, operator, patient and environment), which may reflect a bias, because of the Shepherd model, that focuses medical devices to the detriment of other components.

46. TOWARDS A PATIENT CENTRED SYSTEM: A SYSTEMATIC REVIEW OF PATIENT ENGAGEMENT STRATEGIES TO IMPROVE QUALITY CARE

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Objective: To explore optimal strategies to engage patients and the effects of these engagement strategies on patients and quality care.

Methods: Systematic review and qualitative content analysis of international published medical, nursing, business and administration literature, published in English between 1990 and December 2010.

Results: Thirty studies were identified that described 40 engagement strategies. A range of facilitators and barriers to patient engagement were identified, particularly with respect to the design, sampling, recruitment and operational aspects. The outcomes ranged from educational or tool development, improved care or service delivery and informing policy or planning initiatives, which largely derived from consultative to co-design strategies. Interestingly, only a minority of studies (n = 10; 33%) formally evaluated patients' experiences with the engagement activities. While most experiences were positive - being linked to regaining control, having a voice, feeling empowered or independent - some patients questioned their role and felt that their involvement was important but tokenistic, at times.

Conclusions: There are numerous insights on how to optimally engage patients. Patient engagement can result in informed education, care, and policy. Yet it remains unclear how these initiatives effect patients and whether these improvements translate into quality care.

136. ATRIAL FIBRILLATION IN CLINICAL PRACTICE IN SPAIN. COMPARISON OF THE MANAGEMENT AMONG GENERAL PRACTITIONERS IN THE CANARY ISLANDS AND THE NORTH OF SPAIN

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Background: Atrial fibrillation (AF) is the most common sustained arrhythmia. Its growing prevalence requires a coordinated approach of patients by Cardiologists and General Practitioners (GP) to optimize clinical assistance.

Objective: To compare clinical management of AF between GP from the Canary Islands (CI) and the North of Spain (NS) (Navarra, Euskadi and Cantabria).

Methods: A 22-item survey was used. Nine questions assessed clinical management through the following issues: referral to Cardiology, anticoagulant treatment usage; and the role of GP in treatment, ECG usage and patient follow-up. Chi-squared test was performed to compare management among GP from CI and NS.

Results: A random sample of 84 (CI) and 244 (NS) GP completed the survey. Clinical practice was consistent ($p > 0.05$) for 6 of the 9 issues assessed. The number of GP deciding to intervene in patient management and the number of those directly referring to a cardiologist were similar in both regions (33% and 67% vs 37% and 61%). Criteria for urgent referrals were also consistent 51% vs 45% for patients with prior heart disease, 93% vs 85% for patients with heart failure and 15 vs 17% for all patients in CI and NS respectively. Furthermore, in both regions GP were reluctant to prescribe anticoagulants (54% vs 47%), and treatments for ventricular response or heart rhythm control were rarely prescribed (4% and 15% vs 3% and 8% in CI and NS respectively).

However, less GP from CI ($p = 0.018$) considered follow-up of stable patients a primary care responsibility (58% vs 69%) and 38% of GP in CI versus 16% in NS ($p < 0.001$) considered treatment and ECG usage ought to be decided by a cardiologist.

Discussion: Clinical management of AF was similar in both regions; nevertheless, GP from the NS seemed more willing to assume the management of AF patients than those from CI.

138. ASPECTS OF PATIENT-CENTERED CARE IN SCHIZOPHRENIA: THE ROLE OF ADHERENCE AS PERCEIVED BY CARERS, NURSES AND PSYCHIATRISTS IN EUROPE

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Background: Prescribed antipsychotic medications, provided patients are adherent, have been shown to be effective in the treatment of schizophrenia.[1-3] Non/partial-adherence to medication is associated with an excess annual cost of > £5,000 per patient for total service use.[4] Schizophrenia remains a deeply distressing and highly stigmatized condition for service users and carers.[5]

Objective: To get better understanding of the size of the problem of non-adherence in schizophrenia, three surveys were conducted investigating carers', nurses' and psychiatrists' perspectives on non/partial-adherence among patients with schizophrenia in Europe.

Methods: Psychiatrists (January-March 2010) and nurses (January-April 2011) were given surveys, pre-paid envelope and letter explaining the aims. Carers were asked (January-April 2011) to complete an online-survey via EUFAMI website (www.eufami.org). Independent research agency analyzed completed surveys using summary statistics.

Results: Surveys of 3538 psychiatrists, 4009 nurses and 138 carers were analyzed. Psychiatrists and nurses estimated that 53% of their patients are non/partial-adherent; Carers (66%) experience treatment adherence to be a burden for the patient and over 39% were affected daily. Carers often carry the burden of non-adherence associated care. Psychiatrists cited lack of insight (37%) and irregular daily routine (34%) as main reasons for non-adherence. Psychiatrists (60%), nurses (93%), and carers (50%) felt that ensuring continuous medication with a long-acting injectable (LAI) has long-term benefits for patients. Carers (72%) believed that the illness itself contributes to non-adherence, however, potency of antipsychotic medication (92%) and low side-effects (90%) were considered very important factors to supporting adherence. Carers (67%) expressed some negative views on schizophrenia treatments, which was higher than stated by psychiatrists (4%).

Conclusion: About 4.7 million schizophrenia patients in Europe are potentially non/partial-adherent, possibly leading to deterioration

in a third of patients. Adherence issues tend to be a major aspect of overall caregivers' burden. LAIs appear to be the preferred choice for improving management of patient adherence.

144. HEALTH SURVEILLANCE IN REMOTE AREAS THROUGH A COMMUNITY CENTERED SYSTEM

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The Bonis system based on telephone (fixed and mobile) notification has been developed to support the National Epidemiological Surveillance System in Paraguay by promoting community involvement in syndromic surveillance. This community surveillance system uses web technologies and databases for patient records and appropriate follow-ups by the health personnel. It has the ability to record, classify, and prioritize automatically through the IVR (Interactive Voice Response) suspected cases of syndromic fever. It has been implemented in a primary health care unit in an area of marginalized citizens on the banks of the Paraguay River in Asuncion and it is monitored by the National Centre for Health Surveillance (DGVS/MSPBS). Geographically isolated communities from the Paraguayan Chaco may be integrated into the National Surveillance System through the use of the Bonis System. In order to evaluate the usefulness of the system in a rural area we have selected a district with difficult access named Tte Irala Fernandez from the Paraguayan Chaco. In this area, chronic infectious diseases such as tuberculosis and acute diseases such as hanta virus are more frequent as compared to the rest of the country. Therefore, the system will be adjusted to this new scenario. Moreover a health advising service which will be added to the system in order for a health worker or community leader conduct a telephone consultation to professional staff on acute processes (fever, diarrhea, vomiting, stings, minor accidental injuries, etc.) to assist a patient or in cases of serious health problems to derive the patient to the nearest health reference center. Considering the variables of this new (population, distance, availability of mobile cellular) this application will give a better picture of the possibilities that the Bonis system may have in areas of high exclusion in health.

198. TELECONTINUITY CARE. TELEPHONE FOLLOW-UP OF FRAIL PATIENTS

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In the last years, our community is undergoing a series of changes similar to other industrialized countries that have a direct impact on their overall health, their needs and their pattern of use of health services. There is an aging population, with a consequent increase of people needing care by increasing chronic diseases, disability and dependence. The Andalusian Public Health System (SSPA) sets off a series of measures to adapt its operation to the new social context in response to the demands and expectations of users. In 2005 were created the application for *"Telephone follow-up to hospital discharge of frail patients on weekends, public holidays and eve."* Patients could be included in the telephone follow-up are valued and include, according to frailty criteria established, by the nurse responsible for discharge with the consent of the patient or their relatives. In the application are include clinical data needed for subsequent telephone follow-up for *Salud Responde* and primary care nurses. The nurse in charge will dump all the data in the web environment so that they are so readily available. Within a short period of time (few hours), *Salud Responde* nurse will make an initial call to the patient, including a brief telephone interview. After this first contact, and according to the patient's clinical condition, will evaluate the implementation of a second call based on criteria established in a standardized way.

From the data obtained in the interviews and collected in the assessment, the nurse will carry out the necessary interventions through protocols and decision trees by assigning a risk level of the patient, which will establish the priority attention from Primary care. When the patient's condition requires, suggest home visits by the primary care team within 24 hours after the second phone call made by *Salud Responde.* After the weekend or holiday, Nursing Coordinators in the health centers be able to view patient data in their area, to prioritize the home visit by the nurses.

200. FRAIL PATIENT MONITORING AT HIGH TEMPERATURES

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In recent years, our community is undergoing a series of changes similar to other industrialized countries that have a direct impact on their overall health, their needs and their pattern of use of health services. There is an aging population, with a consequent increase of people needing care by increasing chronic diseases, disability and dependence. Therefore, the Andalusian Public Health System (SSPA) sets off a series of measures to adapt its operation to the new social context in response to the demands and expectations of users. In 2005 were created new tools in the field of TeleContinuity care including the application for the "Prevention and Intervention Plan to extreme temperatures". This application is intended to effectively address the health problems that may arise from the high temperatures reached in summer in our community, about the most vulnerable people of the SSPA. Each year, from the month of May the nursing case manager and primary care nurses begin the assessment and collection of people at risk to high temperatures for subsequent monitoring at home and for inclusion in the monitoring plan *Salud Responde* by telephone. Recruits in previous years are automatically displayed in the application and just need to confirm their inclusion in the plan. Recruits in this plan are classified into three risk levels according to established criteria including chronic diseases, type of medication they take, social and liveability of their homes. This Plan will be active from June 1 until September 30. Forecast is received daily temperatures for the next 5 days by the Meteorological Agency, so that if the forecast temperature exceeds thresholds established for each area, an alert is generated (with three levels of alarm) and makes a Telephone follow-up to people who may be affected. This plan is supplemented by intensification of home visits by nurses in primary care, training workshops for caregivers, distributing brochures, advice on radio, television, press, etc.

221. HEMODIALYSIS TREATMENT COST REDUCTION THROUGH A PROCESS ORIENTED METHODOLOGY

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Hemodialysis has an enormous cost impact in health delivery systems in general, which is most important in middle-income

countries. The use of a process-oriented methodology is necessary in a clinical network system in order to reduce costs. Our premise is to reduce the patient's treatment costs from an average of 40 to 20 thousand USD dollars per year. Goals: (a) reduction of operational costs, (b) reduction in the use of medications (EPO, chelating agents, anti-hypertensive medications, etc), (c) reduction of the treatment's dose selection variability, and (c) reduction of negative treatment outcomes. The business process management (BP-M) technique was used to design and apply a continuous health improvement process. Transdialytic exercise and hemodiafiltration (HDF) were used in the treatment process silo. An on-line physiological monitor measuring energy expenditure and heart rate variability were used in the quality control process silo to assure the patient's hemodynamic stability. General costs were reduced by at least 1/3 in a pilot study of 15 patients since medication was usually not necessary. The probability of negative events was reduced from 35% to 8%. The on-line monitoring results show evidence of the benefits resulting from the combined use of HDF and the transdialytic exercise. The methodology assures the reproducibility of the system through the use of previously defined processes. It has proved to be very useful to replicate and to continuously improve the treatment's quality. These preliminary results showed that the original premise is validated. The yearly treatment costs can be reduced further if the BP-M can be scaled in a network of hemodialysis clinics. More research is needed in order to define a new well- documented operating standard, with a global solution beyond medical guidelines or norms that need not be cost-reduction oriented. The hemodialysis treatment costs must be reduced in any health system. This is not only a medical issue but is a complex problem, which can be approached from a process- oriented point of view. If these issues are not addressed only a very small proportion of patients will continue to have access to these treatments.

260. DEVELOPMENT OF A MODEL PREDICTING THE IMPACT OF TELEMONITORING FOR PATIENTS WITH CHRONIC HEART FAILURE IN FRANCE

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Background and objective: Chronic Heart Failure (CHF) is a serious condition associated with frequent hospitalisations. Telemonitoring (TM) can improve CHF management and reduce all-cause mortality and CHF-related hospitalisations. A model was developed to predict the effect of telemonitoring on CHF-hospitalisations and survival in CHF patients in France.

Methods: A Markov modelling approach was used to simulate the CHF progression, with telemonitoring compared to usual care, over 5 years. The number of hospitalisations was considered as an indicator of disease progression. The model assumes that telemonitoring alerts can prevent transitions to health states with increased risk of decompensation. Input data were obtained from the literature and French hospital statistics. The effectiveness of telemonitoring in preventing CHF-hospitalisations and all-cause mortality was based on published meta-analyses. Deterministic and probabilistic sensitivity analyses were performed to assess uncertainty around results.

Results: The model predicted that patients would survive on average for 2.28, 1.97 and 1.85 years after 1st, 2nd or 3rd hospitalisations respectively, with 6.15, 6.76 and 6.93 hospitalisations over lifetime. Telemonitoring would increase life-expectancy by 3.47, 2.92 and 2.65 months for patients starting after 1st, 2nd or 3rd hospitalisation, and would save 0.54, 0.40 and 0.37 hospitalisations per patient over 5 years. The number of hospitalisations per life-year would decrease by 0.51 (95% credibility interval: 0.34-0.66), 0.56 (0.37-0.72) and 0.58 (0.38-0.74), respectively. Providing telemonitoring to 1000 new patients per year, after 1st hospitalisation, would avoid approximately 2,530 hospitalisations over 5 years.

Conclusions: The predicted numbers of CHF-hospitalisations avoided and improvements of life-expectancy support further investigations aiming to develop telemonitoring for CHF patients. Our results suggest that telemonitoring should start following 1st hospitalisation rather than at later stages. The model predictions appear consistent with data from the literature, but we recommend updating it using information collected through a telemonitoring programme when implemented in clinical practice.

296. LONG-TERM RESIDENTIAL CARE HOMES OF THE FUTURE

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A rapidly aging society presents important challenges to long-term residential care (nursing and care-only homes). Faced with increasingly elderly residents and progressively more complex clinical and social care needs, the care homes of the future will have to address a number of issues. These include: how to maintain residents' quality of life as well as quality of care; how to integrate health and social care provision; how best to manage their interface with hospitals in order to prevent avoidable hospitalizations and facilitate early discharges; and how to utilise new technology in a cost-effective manner. Evidence will be presented from 3 major research projects to demonstrate how care homes can evolve to meet these challenges, with particular discussion of the future role of integrated nursing and social care working and the role of new technologies. Interest in new models of care is growing due to the pressure of an ageing population and an increasing awareness of the need to ensure resources are used cost-effectively. In order to be cost-effective, the nursing and care-only homes of the future will need to safeguard outcomes, including quality of care, while containing costs. Meeting this twin challenge will require change and innovation. Better partnership working between nursing, social care and medical professionals will be required in order to map out a pathway for future change. The presentation will examine evidence on enhanced training of social care staff in clinical skills and improved ways of working within care homes. Externally, hospitals and other healthcare providers will also need to work collaboratively with care homes in order to identify joint-strategies to prevent unnecessary hospitalizations and to reduce delayed discharges. The need for leadership in the development of such collaborative models and new ways of working will be discussed.

305. ESTIMATING THE EFFECTIVENESS OF THE CERVICAL CANCER SCREENING ACTIONS THROUGH WOMAN CENTERED INDICATORS

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The Cervical Cancer Information System (SISCOLO in Portuguese) was established in 1999 to monitor the performance of the National

Screening Programme of Cervical Cancer. However the programme effectiveness is unknown, since the current indicators are not focused on the woman enrolled in the programme. This study aims at estimating the effectiveness of the screening actions in the Rio de Janeiro State, Brazil, from July 2006 to June 2009. The effectiveness was measured by number of detected atypical lesions per total number of estimated atypical lesions. Probabilistic record linkage techniques were applied to the SISCOLO database, consisting of two files with production data on the cytopathology and histopathology exams, in the period analysed. This approach allowed to link the records associated with the same woman. Among the 2,030,074 records in the cytopathology file, 1,477,147 women were identified and 74.4% of them had a single examination in the period, with an annual coverage indicator of 11.6%. Of the 638,324 women identified in the first twelve months, 3.7% (23,498) were eligible to repeat the exam in 6 months; however 36.3% (8,524) of these patients were not identified with a subsequent examination record. This same loss of follow-up was observed for 35.9% (1,864) of eligible women for immediate colposcopy. These two groups were monitored until the third exam and 6,397 atypical lesions at high risk for cancer were detected and followed up. On the other hand, it was estimated that 12,730 atypical lesions were lost to follow up, leading to an effectiveness of 33.4%, considering the women covered by the program. The study revealed the potential of the applied approach to create new indicators to better estimate the program effectiveness and the need of extending this analysis to a national level with a large and updated dataset.

355. EVOLUTION OF EPIDEMIOLOGICAL SITUATION OF ISCHEMIC HEART DISEASE AND CARDIOVASCULAR RISK FACTORS IN MADRID

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Background: Ischemic heart disease (IHD) is a significant public health challenge due to its high burden of morbi-mortality and associated social and health care costs. According to the WHO, in 2004 IHD was the leading cause of death in the world being the responsible for 12.2% of mortality. Although control of cardiovascular risk factors (CRF) has been associated with the highest attributable impact on reduction of IHD mortality, the control degree of control of is still very low.

Objectives: To assess the evolution (2006-2010) of the IHD prevalence and CRF in the population attending primary care (PC).

Methods: Longitudinal study. The database contains information from 227,984 patients over 24 years, who visited their PC center at least one time in 2006. This cohort has been followed through information collected in their electronic medical records through 2010. The prevalence of IHD and CRF was calculated by sex, age and income. Percentages are shown at the beginning and the end of the period.

Results: Overall, during the period of 5 years analyzed, there has been an increased in the prevalence of heart problems (arrhythmias (4.7% vs 8.6%), IHD (3.1% vs 4.2%), stroke (1.6% vs 2.6%), valvular heart disease (1.2% vs 1.8%), heart failure (0.9% vs 1.9%), peripheral atherosclerosis (0.01% vs 0.03%)) as well as of CRF (hypertension (25.9% vs 32.9%), lipid disorder (20.3% vs 31.3%), obesity (10.0% vs 14.8%), diabetes (8.0% vs 10.8%), smoking (3.9% vs 6.6%), alcohol (1% vs 1.5%)). All differences were statistically significant ($p < 0.001$). Cardiovascular diseases were more prevalent in women (except ischemic heart disease and stroke) over 65 years and in higher income levels.

Discussion: IHD still represents a major public health problem. This population based longitudinal analysis indicates an increased prevalence both of cardiac conditions and of CRF.

359. INTEGRATED CARE OF WOUNDS IN THE PATIENT'S OWN HOME – CLINICAL AND ECONOMIC CONSEQUENCES

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Background: Odense University Hospital (OUH) in the Region of Southern Denmark has organised a wound centre for outpatient treatment of problematic wounds. However, for fragile patients long transportation is not optimal.

Objectives: To assess the clinical and economical consequences of pressure wound treatment by an outgoing specialised hospital nurse in the patients' home – in comparison with traditional outpatient visits at the hospital.

Methods: A randomised controlled trial was conducted and clinical and economic data were collected at baseline and each following month until wound healing.

Clinical parameters were analysed by means of statistical methods including multiple regression analysis. Cost comparisons were performed including costs related to: staff, wound materials and transportation costs.

Results: A total of 76 patients were included. The primary clinical outcomes were wound healing, wound development and pain. The study found no statistically significant differences on these parameters. The mean costs were € 100 lower in the intervention group but the difference was not statistically significant. Sensitivity analysis showed that the cost reduction could be € 266 lower when treatment is implemented in daily practice.

Discussion: Treatment of pressure wounds in the patient's own home by a wound nurse from the hospital has the same clinical impact on wound healing as treatment in the outpatient clinic. The economic analysis did not show a statistically significant difference in costs between the two groups, but sensitivity analysis shows that the cost savings were considerably underestimated.

Implications for the health system/professionals/patients/society: The research group recommends: Establish an option of outgoing treatment of problematic wounds at larger hospitals. The target group should be patients: -Unable or unwilling to transport themselves to the outpatient clinic. -Where treatment and prevention do not function in everyday life and where an improved relationship between hospital and municipality is needed.

377. NURSING IN CHRONIC PATIENT CARE: DEVELOPING NEW NURSING ROLES

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Background: As part of the Strategy for Tackling the Challenge of Chronicity in the Basque Country promoted by the Basque Department of Health and Consumer Affairs the Strategic Project No. 8: "Defining and implementing advanced nursing skills", was launched, which, aims to develop and deploy in practice, new nursing roles focused on

chronic care. These figures seek to improve health outcomes and quality of life in people with chronic and complex conditions, and their caregivers.

Objectives: a) Identify develop and implement new nursing skills for the Basque Health Service; b) Evaluate the effectiveness of the figures to establish organizational and structural recommendations.

Methods: 1. Design and implementation of eigth pilot experiences to cover different possible scenarios: Nurse Case Manager for Hospital Liaison (EGEH), Nurse Case Manager for Continuum of Care (EGC) and Nurse Case Manager with Advanced Competencies (EGCA). 2. Creation of a collaborative Web as a communication and information between project managers and experience. 3. For evaluation of the effectiveness of the nursing figures activity have been used: Quality of Life questionnaire (SF12), satisfaction questionnaire for patients and caregivers (SATISFAD), Osakidetza professional satisfaction questionnaire, rate of hospital re-admission.

Results: Recruited patients data during their experience in the project was gathered, including readmissions, quality of life and satisfaction (final data analysis still pending).

Discussion: From the results obtained can be underlined: EGEH encourages coordination between levels of care, mobilizing resources, managing cases to ensuring continuity of care; EGC facilitates patient transition between levels of care, establishing direct communication with the team regarding the patient; EGCA develops required health care activity for each patient assessing, planning, implementing, coordinating and evaluating health needs.

Implications for the health system: The implementation of the new nursing roles will be a change in the organization of teams and assumption of new responsibilities.

382. HTA TO GUIDE TELEMONITORING DEPLOYMENT IN VENETO REGION: THE EUROPEAN PROJECT RENEWING HEALTH

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Background: In Veneto Region several initiatives have been carried out in order to develop telemonitoring solutions for chronic diseases management, but the lack of evidence about their real life impact has hindered their larger use so far. The European Project RENEWING HEALTH represents an important occasion to transform telemonitoring from pilot applications into large-scale services.

Objectives: In 9 European regions RENEWING HEALTH aims to validate, in real life settings with a common HTA methodology (MAST), the use of telemonitoring applications addressed to patients with diabetes, cardiovascular diseases and COPD.

Methods: In Veneto Region a unique technological platform has been developed for delivery of both telecare and telemonitoring services to chronic patients who are equipped with portable devices for 24/7 real time detection of emergencies at home and clinical data measure. Data are transmitted and managed by an eHealth centre that is the point of connection between patient and clinician. The integration of social and healthcare services guarantees the complete remote management of these patients, facilitating the continuity of care outside hospital settings. This service is delivered by 9 Local Health Authorities and evaluated with MAST methodology (Model for ASsessment of Telemedicine), based on the EUnetHTA Core Model, but especially designed for telemedicine assessment.

Results: The study will determine the benefits of telemonitoring compared to usual care in terms of improved clinical outcomes and health-related quality of life, of economic and organizational impact, and of acceptability by patients and health professionals.

Discussion: The evaluation of large scale pilots through HTA will allow to provide strong multidisciplinary evidence on telemonitoring impact, that be the basis for decision making for regional policy makers who have to decide the future strategies for healthcare innovation.

Implications for the health system/professionals/patients/society: Positive evidence on telemonitoring could result into a large deployment of these applications, involvement of more patients and professionals, potential savings for the health system.

385. EVALUATION OF THE HEALING ENVIRONMENT FOR THE DESIGN OF A NEW PAEDIATRIC ONCOLOGY UNIT

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Background: Implementation of an optimal healing environment is an opportunity to improve overall healthcare services and provide substantial benefits to patients, family and staff. Objectives: This study evaluates physical settings of a healing environment in order to integrate them into the design of the paediatric oncology unit at the "Centre hospitalier universitaire de Sherbrooke" (CHUS).

Methods: As a first approach, we conducted a review to determine settings negatively perceived by patients, staff and family in paediatric units. We also searched for evaluations and recommendations aiming to create an optimal healing environment. Lastly, to assess specific needs, we collected data from the paediatric oncology unit at the CHUS.

Results: Excessive noise was a major problem which could be associated with disruption of sleep and stress among patients: installation of sound absorbing tiles in the unit and a sound barrier at the nursing station are the principal recommendations for the reduction of excessive noise. Since there is data suggesting that sunlight exposure can have direct effects on patients by reducing stress, pain and need for medication, we advise using the bright side of the hospital for treatment rooms. In designing the new unit, natural scenes could be included, because studies have shown that views on nature can have a restorative effect and reduce stress. Colors were also investigated: data collected show that blue is preferred by children and is associated with positive emotions. Based on qualitative studies, healthcare environment should meet the needs of two distinct patients (adolescents and children) and this duality should be reflected by the design. In addition, to increase confidentiality and reduce noise in inappropriate places, specific consultation rooms should be created. Finally, because benefits of social support between patients are part of the healing process, shared space should be integrated in the care environment.

Discussion: With the goal of creating an optimal paediatric oncology care-unit, the implementation of a healing environment provides an opportunity to rethink the design of the hospital.

Implications: The improvement of health care facilities in this direction could deeply benefit patients and professionals.

407. VENETO ESCAPE PROJECT: ORGANIZATIONAL AND TECHNOLOGICAL REVOLUTION IN LHAS OF VENETO REGION

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Background: Veneto ESCAPE is the project for national Reuse of ESCAPE solution (developed by LHA n.9 Treviso in 2001) promoted

and co-funded by Government Ministry of Public Administration and Veneto Region to deploy for the first time the entire clinical documents lifecycle digitalization. The project will complete its implementation in 2012 providing medical reports to the 4.9 million citizens of Veneto Region.

Objectives: The main aim is introducing digital life cycle management of electronic documents and preparing the necessary infrastructure for regional patients' Electronic Health Record. This means managing the dematerialization steps (digital signature, transmission systems, access, distribution and electronic storage of medical data) to guarantee data protection, interoperability and scalability using international e-Health standards.

Methods: Assessments on organizational, economic and social impacts generated by dematerialization processes are based on HTA, declining ad hoc EuneHTA Model. The study focuses on the recontextualization of the preliminary analysis of Bocconi University for the national development of Reuse project and of the indicators addressed by Government Ministry of Public Administration.

Results: Veneto-ESCAPE benefits will be compared to process effectiveness (-96.5% of lead time in report production) and efficiency, allowing an annual saving of € 72 million for citizens and of € 8 million for LHAs in 4 years. Additional effects are a greater privacy protection, thanks to fewer professionals having access to digitally signed records (-50%), and by decreased CO2 production (-7 million kg/year).

Discussion: The project aims to standardize the introduction and management of whole digital documents' lifecycle, creating an easily exportable solution to start the health digital revolution for citizens and public administration.

Implications for the health system/professionals/patients/society: A secured availability of clinical reports on platforms allows patients to access their record avoiding travels, reducing waiting times and decreasing LHAs' costs. The new approach to clinical documents' lifecycle will improve clinical workflows, representing a shared good for the community.

441. CLINICAL EFFECTIVENESS CENTERS OF INTEGRATED CARE FOR QUALITY IMPROVEMENT AND COST REDUCTION: A PUBLIC HEALTH STRATEGY IN A BRAZILIAN STATE

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The Hospital de Clínicas de Porto Alegre in partnership with the Rio Grande do Sul State Health Secretariat started in 2003 the implementation of Clinical Effectiveness Centers of Integrated Care (CECIC). This assistance model performs the diagnosis, treatment, drug dispensing, vial sharing and/or drugs requests evaluation, aiming at patients' comprehensive care and promotion of rational drugs use trough the effective implementation of the Brazilian Clinical Guidelines. These guidelines establish the diagnosis and treatment criteria for diseases that involve high cost drugs and suggest the implementation of CECIC to monitoring and orientation of these patients. In order to receive the treatment it is necessary a formal request, that is evaluated by medical experts and, if the need of this drug is proved, it will be provided free of charge. Nine centers which accomplished patients' monitoring were created for the following diseases: Gaucher´s Disease, Dystonias, Spasticity, Rheumatoid Arthritis, Crohn´s Disease, Multiple Myeloma, Sickle Cell Disease, Phenylketonuria and Chronic Pain. In addition, five centers perform the drug request evaluation for the treatment of Glaucoma, Alzheimer´s Disease, Multiple Sclerosis, Dyslipidemia and Uveitis. In 2011 1095 patients were periodically accompanied and 8100 drug requests were evaluated. The applications of the drugs imiglucerase, botulinun toxin and infliximab were performed in 300 patients in a schedule basis in the center, allowing vials sharing, avoiding possible wastes, and promoting a saving of more than US$ 150.000,00 to the public health system. In addition to this direct economy, it should be emphasized that this management model qualifies and systematizes patients' assistance, allowing the registration of clinical and pharmacoepidemiology data and conducting researches focused on Brazilian Public Health Systems interests. This strategy allows to perform clinical effectiveness studies, to improve quality of assistance and to reduce wasting of resources and costs. It might be useful for other countries.

490. EVALUATION OF THE CARE CONTINUITY PROCESS FOR PATIENTS WITH SEVERE MENTAL DISORDER IN THE REGION OF MURCIA (SPAIN)

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Many of the sickest patients served by the mental health network will require attention in various mental health resources (emergency hospital psychiatric inpatient unit, mental health centers, drug addiction centers, rehabilitation units, day centers, medium-stay psychiatric units...). Patients with Severe Mental Disorder (SMD) will use the various facilities throughout his illness, giving the possibility of losing contact with their reference center, to the detriment of the therapeutic process. The care continuity process was developed with all the centers and services heads. Its purpose is to get patients with SMD and/or severe substance abuse problems, with little or no social and family support, do not leave treatment prematurely passing between centers and services. As a general principle, the patient referred to another service or unit is the responsibility of the referring center - until they confirm that the patient has reached its destination. After implementing the process in several health areas, we present the results of the evaluation of key indicators. We discuss some lines to improve the process as a consequence of the results.

494. IMPLEMENTING COMMUNITY BASED SUPPORT FOR PEOPLE WITH SEVERE MENTAL ILLNESS – EXPERIENCES FROM DENMARK

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Background: Community based mental health is diverse, and beside professionally led services increasingly also encompasses activities by volunteers. One example of such a service is the so-called 'community families', who offer people with severe mental health problems regular contact with private individuals/families. The initiative originated from the US in the 1960s, but since has spread to other countries including Denmark.

Objectives: The present paper analyses experiences with a country-wide pilot project in Denmark, which introduced 'community

families' in seven local authorities between 2006 and 2011. The analysis draws on a research project, which investigates the qualitative/quantitative effects of the pilot project, and which encompasses several sub-projects. The present paper focuses on organisational issues and examines the implementation of the pilot project, especially the specific factors enabling or constraining this process.

Methods: The analysis draws on qualitative interviews with the professional staff responsible for the day-to-day running of the pilot project together with the member of staff who has overall management responsibility. Interview data was collected both at the beginning and at the end of the pilot project. The interviews were complemented by participant observations at meetings for the professional staff from across the different provider organisations.

Results: Drawing on organisation studies and especially theories of alignment/organisational design the analysis identifies four set of factors affecting implementation: factors at the level of the environment, the organisation, the workforce and the individual.

Discussion: The analysis raises questions about the relative importance of individual factors as well as the interplay among them. There is also evidence that additional factors, including geographical characteristics and the nature of the service field, play a role.

Implications: Thus, the study has interesting implications for the lessons to be learned for similar initiatives in the future.

530. THE MIRRINJINI DISPENSING KIOSK: IMPROVING PATIENT SAFETY AND MEDICATION COMPLIANCE IN INDIGENOUS AUSTRALIAN COMMUNITIES IN FAR NORTH QUEENSLAND, AUSTRALIA

Kaye Hewson and Hong Ju

Queensland Health. Queensland Government Australia. Australia.

Background: The average lifespan of Indigenous Australians living in remote areas of Queensland is reduced to only 56 years due to the prevalence of chronic diseases such as diabetes. Funding was provided for the implementation of Mirrijini Dispensing Kiosks in 12 remote indigenous Cape York communities, covering an area of 200,000 km^2, which are often isolated in the "wet season". Medication is one mechanism employed to combat chronic disease, however, poor literacy and patient compliance limit the effect of this approach. Prior to the introduction of the Kiosk system all Cape York health care facilities used a paper based dispensing and stock control system.

Objective: To replace existing hand written/manual pharmacy systems with easy to use touch screen computer kiosks, with the broader objective of increasing time spent by clinicians in providing patient education, improving compliance to medication and self management of chronic disease.

Methods: Staff were surveyed pre and post introduction of the kiosk to ascertain patient ease of reading and understanding of labels. Staff measured how long it took to supply hand written labels compared to printed labels.

Results: Patient compliance data are not yet available, however, early results from the piloting of the Kiosks include: between 260 and 475 working days saved per year due to the increased efficiency; improved control of pharmacy stock across a difficult to reach and vast area; improved patient experience due to a clearer understanding of how and when medication should be taken; and improved legal requirement with drug labelling regulations.

Conclusions: The technology has improved the quality and legibility of medication labels, resulting in increased staff and patient satisfaction. Furthermore, it has helped to lift Cape York Health Service District out of the 'developing country' category (according to the International Pharmaceutical Federation categorisation system) into the developed world.

545. DESIGNING AN ELECTRONIC VALIDATION MANAGEMENT TOOL

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Introduction: Computerized clinical decision support systems, tools to enhance the quality provided in health institutions, have proven to be useful when used to improve the application of preventive practices in the field of primary health care. The development of prescription systems and electronic prescriptions must be accompanied by tools that facilitate the clinical decision making of all professionals/patients involved (prescribers, dispensers, validation inspectors, managers, patients/caregivers), and promote the correct use of medication, thereby increasing efficiency and safety of pharmacological treatments for the patient.

Objectives: To implement a system to ensure the proper management of certain drugs, dietetic products or medical devices that require special conditions of prescription, dispensing and/or funding, through the electronic validation management tool.

Methods: Designing an electronic validation management tool from a Corporate Vademecum, which includes decision making modules for both the prescriber and the validation inspector. This tool is built into the electronic prescription system, with the prescription, dispensing and vademecum modules, and improves and/or solves problems in medication management of patients, having all a shared communication channel.

Conclusions: The tool promotes a safer and more efficient use of medication, providing all the agents involved in the pharmaceutical provision with enough information for a rational use, additionally avoiding at all levels unnecessary red tape.

Implications for the health system/professionals/patients: The patient and their caregivers become the focus of the health system, with a model of shared decision making process based on a relationship between patients and health professionals, facilitating the work of the health professional and medication self-management by the patient.

585. AFTER THE FALL: ORGANISATIONAL DIFFICULTIES OF SETTING UP A RCT IN EMERGENCY CARE

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Background: The Support and Assessment for Fall Emergency Referrals (SAFER) 1 trial evaluated the effectiveness of Computerised Clinical Decision Support (CCDS) which assists ambulance crews to assess and triage older people to appropriate care following a fall. The trial was conducted in two UK ambulance services, in collaboration with NHS and voluntary sector community based falls services, private sector hardware and software providers and academics from

three universities. Trial funding was provided by several Government agencies.

Objectives: To describe challenges in conducting a randomised controlled trial (RCT) of CCDS for emergency ambulance paramedics to assess and plan care for older people who fall; and to discuss how to overcome these challenges.

Methods: Descriptive analysis of trial event data was used to give a summary of the events. A comparative analysis of reports to the funders, researchers' meeting minutes, action logs, management action logs and the data collection pilot report was undertaken to identify recurrent themes.

Results: SAFER 1 has had to seek two funding extensions, delays related to: Reorganisation of ambulance services in England; Implementation of new electronic patient records in most services; Internal restructuring of partner services; Performance pressures; Complexities of inter and intra--organisational collaboration.

Recommendations: Our analysis leads us to believe that the processes involved can be improved by continued development of research capacity within ambulance services and aligning research activity with strategic priorities and service objectives. Before starting a multifaceted trial of this nature, the implementation team should undertake an early and thorough analysis of the project management and organisational context in which the trial will take place.

601. SURVIVAL ANALYSIS OF A COHORT OF PATIENTS WITH HEART FAILURE IN MADRID, SPAIN

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Background: Heart failure (HF) represents a major public health problem. In Spain, in 2009 HF represented the fourth leading cause of mortality (4.6% of total deaths) and was also the fourth most frequent cause of hospitalizations. The prognosis of this condition is not very favorable, although there is evidence that Primary Care based interventions could have a positive impact on the survival of patients with HF.

Objectives: To assess the factors associated with survival in a cohort of patients with HF.

Methods: Retrospective longitudinal study of a cohort of patients 24 year and older with at least a visit to a Primary Care center in 2006 in one area of the Region of Madrid followed through 2011. Information was extracted from electronic medical records. A proportional hazards Cox regression model was conducted to obtain hazards ratios to estimate the adjusted effect of a series of clinical and socio-demographic variables on survival.

Results: 3.061 patients with HF were identified. Mean age was 76 year (SD: 10.6). Overall mortality was 17%, being higher in men than women (0.72). Patients with ischemic heart disease or diabetes had a higher mortality (1.44 and 1.39). A series of factors showed a protective effect: annual flu vaccination (0.01), treatment with lipid reduction drugs, beta-blockers and ACEI (0.72, 0.78, 0.80), and having X-rays, ECG and blood tests indicated in Primary Care (0.81, 0.90, 0.97). Being referred to a cardiologist did not show any significant effect.

Discussion: Those results reflect the elevated risk of mortality of patients with HF but also the existence of a series of clinical factors that are associated with better outcomes of these patients. Given the protective factors identified in this work it could be suggested that patients with a higher degree of Primary Care implication in their care have better outcomes.

613. IS DEPTH-IN INTERVIEWING AN IMPORTANT STEP IN THE ADAPTATION PROCESS OF A QUESTIONNAIRE? OUR EXPERIENCE IN THE DEVELOPMENT OF AN OPINION SURVEY ABOUT INTEGRATED CARE EXPERIENCES IN OSAKIDETZA/BASQUE HEALTH SERVICE

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Background: Integrated care is an important building block within the strategic plan for improving the health and wellbeing of the population of The Basque Country. Organisations are involved in experiences trying to improve the coordination between primary and secondary care. These can be evaluated measuring staff satisfaction through opinion surveys. The adaptation process of questionnaires includes forward translation, expert panel, back-translation and cognitive interviewing. Depth-in interviewing is a good way to pretest the instrument on the target population as it detects comprehension problems and expressions unacceptable or offensive.

Objective: To present the main results of depth-in interviews during the adaptation process of an opinion survey for health staff after integrated care experiences.

Methods: We included individuals representative of those who will be administered the questionnaire. Before the interview, the participants had already completed the survey. Interviews (45-60 minutes) were conducted by an experienced interviewer. He focused on what they thought the question was asking, whether they could repeat the question in their own words, what came to their mind when they heard a particular phrase or term, ask them to explain how they choose their answer, etc. When two consecutive interviews did not give new information we finished the recruitment process.

Results: 23 interviews were conducted (16 females, 35-60 years) in 4 health Organisations. Most of them were physicians and nurses. We found that "Organisation", and important concept that appears along the questionnaire, was interpreted in the wrong way.

Discussion: Depth-in interviewing was an effective method to detect comprehension problems in target population not found in previous steps (expert panels).

Implications: Personal interviewing increases the content validity of the adapted surveys.

649. COST REDUCTION TO THE BRAZILIAN MINISTRY OF HEALTH: THE STRATEGY OF A CLINICAL EFFECTIVENESS CENTER OF INTEGRATED CARE FOR CROHN´S DISEASE - CECIC-CD - FROM A PUBLIC HOSPITAL

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Background: Crohn´s Disease (CD) is an inflammatory bowel disease which affects in a high incidence young adults between 15-30 years. A Brazilian study showed that prevalence of CD is 5.65 cases/100,000 inhabitants. Its treatment in severe cases can be done with infliximab every eight weeks, usually for a long period of time. This drug is distributed by the Brazilian Ministry of Health (BMH). In

order to promote a better assistance to these patients and a rational use of drugs, in 2007, we created the CECIC-CD at Hospital de Clínicas de Porto Alegre.

Objective: To estimate, based on the savings obtained in a single center, the savings that would be possible in state and national levels, through the expansion of this project.

Methods: Based on the study of prevalence we estimate 10,800 people with CD, from these about 10% are severe cases (indication of infliximab).

Results: Considering the number of infusions (740) and the vials of infliximab saved (261) in 36 months, the CECIC-CD produced savings of approximately US$215,000.00. CECIC-CD concentrates half of the patients (61) who use infliximab in our State, the savings could be doubled. Considering 1,080 patients have the indication of use of infliximab the saving to the BMH in 36 months could be superior than US$3,800,000.00 if this model had been applied in the whole country.

Discussion: The creation of this center generated an important saving to the public health system. The expansion of this project would generate a saving almost 18 times bigger, optimizing costs expending with drugs as well as allowing other investments in the health sector.

Implications for the health system/professionals/patients/society: This model systematizes patients' assistance and the saving generated by the better resource management might return to the public health system, thus to the society. It might be useful for other countries.

682. MODEL OF PARTICIPATION IN THE DESIGN OF A CLINICAL TRIAL ABOUT TYPE 2 DIABETES MELLITUS IN THE CANARY ISLANDS, SPAIN. THE CLINICAL TRIAL INDICA

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Background: This study is the result of the concern about the high prevalence of T2DM in the Canary Islands and the conviction of public institutions, researchers, endocrinology services, patients and Universities of the need of interventions about effective practice and organisation of care for improving the health in patients with T2DM.

Objectives: To include all the agents involved in the tertiary prevention of T2DM to design the clinical trial aimed to identify the best interventions according to available evidence and experience of patients and professionals.

Methods: A work team of endocrine specialists, primary care physicians and nurses, multiprofessionals researchers, health educators, health services manager and patient associations was created. We performed ten literature reviews and the opinion of professionals and patients were collected by qualitative methods.

Results: The result is a community randomized control trial with three arms of multicomponent intervention with one control group. The first arm consists in an educative intervention targeting patients and their relatives for promoting the self-management of their disease supported by information and communication technologies. The second arm consists in an intervention aimed at primary care professionals with an educative component and with the support of a tool integrated in the electronic clinical history for taking clinical decisions. The tertiary arm of the study combines both arms. The objective of INDICA is to modify the behaviours which favour a better tertiary prevention in T2DM.

Discussion and implications: We must include in the design of clinical trials about effective practice and organization care the viewpoint of every agent implicated in the different dimensions of one problem. To involve patients and professionals since the first stage of a study design is a key point to achieve their acceptance. This is the basis to transfer the interventions assessed as effective from the research to the daily clinical practice**.**

732. CLINICAL EFFECTIVENESS CENTER FOR INTEGRATED CARE OF CHRONIC PAIN: AN INTEGRATED PATIENT CENTER TO IMPROVE DRUG MANAGEMENT AND QUALITY OF THE CARE

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Background: Chronic pain (CP) is one of the most common reason for patients to seek medical care, often lead to health care overutilization, and substantial direct and indirect costs. The treatment of CP patients requires efficient drug management and integrated patient assistance. The Clinical Effectiveness Center for Integrated Care of Chronic Pain (CECIC-CP) was created in partnership with the Hospital de Clínicas de Porto Alegre (HCPA) and the Rio Grande do Sul State Health Secretariat to allow fast request evaluation and dispensing of methadone and morphine to patients who fulfill the National Clinical Guideline criteria (malignant and non-malignant CP).

Objective: To describe the patient's sample assisted at the HCPA CECIC-CP.

Methods: The registers of the whole HCPA CECIC-CP that receive morphine and methadone in year 2011 were evaluated.

Results: A total of 558 patients compose this sample, being 281 (50.4%) male, with a mean age of 58 ± 14.6 years. From these, 79 (14.0%) have non-oncologic pain and 479 (86.0%) oncologic pain. The total sample follow-up median time was 122 days (3-2,437). One hundred sixty-nine patients died in this period, from these, 6 (3.5%) were non-oncology patients with median follow-up time of 472 days (13-1,464) and 163 (96.4%) were oncology patients, with 101 days (3-1,699) of median follow-up time.

Discussion: Considering the significant number of CP patients and the short period of time from treatment to death, a specialized center seems to promote fast solution for these patients. This model can improve the quality of care, treatment's adhesion, control the dispensing of these drugs and the register of the clinical and epidemiological data.

Implications for the health system/professionals/patients/society: This strategy allows to improve quality of assistance and to reduce wasting of resources and costs. This public health strategy is certainly useful for other countries.

734. COST-EFFECTIVENESS OF COMPUTERISED CLINICAL DECISION SUPPORT FOR EMERGENCY AMBULANCE PERSONNEL: RESULTS FROM THE SAFER 1 TRIAL

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Background: The Support and Assessment for Fall Emergency Referrals (SAFER 1) trial assessed the costs and benefits of a new healthcare technology - hand-held computers with Computerised

Clinical Decision Support (CCDS) software - to help paramedics decide who needs hospital attendance, and who can be safely left at home with referral to community falls services.

Methods: Eligible patients were aged 65 or over and categorised by the emergency call-taker as a fall without priority symptoms. Outcomes were collected 30 days after the initial 999 call for emergency department and in-patient admissions and from questionnaires on care, fear of falling, perceived quality of care and health-related quality of life.

Results: The intervention did not reduce emergency health care use, or improve health related quality of life, within 30 days among patients randomised to the intervention group (436) relative to those in the control group (343) who received usual care. However it did double the rate of referrals to the community falls service (from 5%-10%) at a cost of only £154 per intervention patient.

Discussion: At first sight the findings show that it is highly unlikely that the intervention is cost-effective relative to current practice. However limiting follow-up to 30 days effectively prevented us from studying the medium- or long-term effects of the intervention. One of the main pathways by which CCDS achieves benefits is by referrals to falls services, which take up to six weeks to respond, and even longer to yield benefits for those referred.

Implications: Results, coupled with the known effectiveness of community falls services, suggests that the SAFER 1 intervention has the potential to yield value for money. However, more research is needed to evaluate this technology, especially over a longer period to permit internal study of the putative benefits of the CCDS on quality of life and the cost-effectiveness of the care pathway through falls services.

740. UNPLANNED HOSPITAL READMISSIONS IN CATALONIA

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Objectives: To study the risk factors and the likelihood of unexpected hospital readmissions in Catalonia during 2007.

Methods: This is a retrospective cohort study in population over 14 years of age admitted to hospitals of the public hospital network (PHN). The dependent variable was the emergency readmission at 6 months. First emergency admission or index admission was considered all emergency admissions occurred between 01/01/07 and 31/12/07; and emergency readmission were all readmissions occurred in the 6 months following index admission. The independent variables were: sociodemographic (gender, age and health region), morbidity (number of concurrent diagnoses, diabetes, ischemic heart disease, chronic obstructive pulmonary disease (COPD), asthma, emphysema, bronchiectasis, and heart failure) and use of hospital services during two years before index admission (emergency and programmed admissions, and programmed emergency and scheduled stay). Logistic regression models were adjusted to study factors associated with readmission.

Results: Of the 195,729 persons urgently admitted in 2007, 19.5% was readmitted during the next 6 months. Factors associated with readmission were being a male, having ≥65, having ≥5 concurrent diagnoses, heart failure, COPD, diabetes and ≥2 emergency admissions in 2006 or 2005. The factors with strongest association were having ≥5 concurrent diagnoses (OR = 4.37, 95% CI = 4.23 to 4.52), having heart failure (2.89, 2.78 to 3.01) and COPD (2.76, 2.63 to 2.90). The area under the Receiver Operating Characteristic curve (ROC) was 0.74.

Conclusions: The predictive model allows the identification of patients at risk of hospital readmission and may represent an annual reduction of 27,302 (3%) hospital discharge. The inclusion of a classification of morbidity groups, combination of administrative and individual data, and social determinants of health could improve these models.

744. RANDOMISED TRIAL TO EVALUATE THE CLINICAL EFFECTIVENESS OF COMPUTERISED DECISION SUPPORT SOFTWARE FOR EMERGENCY AMBULANCE PARAMEDICS TO USE IN THE CARE OF OLDER PEOPLE WHO HAVE SUFFERED A FALL

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Background: Demand for immediate care through the emergency ambulance service has been increasing across the UK and internationally over recent years. This includes older people who have fallen. Although health policy in the UK encourages emergency ambulance services to offer alternative services to such callers, there is little evidence about the safety and effectiveness of these new models of care.

Objectives: To evaluate the clinical effectiveness of computerised decision support software (CCDS), in two UK emergency ambulance services, for paramedics to use in the face-to-face assessment and care of older people who fall.

Methods: Paramedics were randomly allocated to intervention (CCDS) or control group (standard care). The principal outcomes for the trial were: onward pathway of care (referral to falls service; Emergency Department avoidance); and interval to the first subsequent emergency contact after the index call or death within 30 days.

Results: Forty two paramedics volunteered to participate in the trial; 779 patients were included in analysis. We found no differences between intervention and control groups in subsequent emergency healthcare contacts or death related to a fall. The proportion of patients referred to falls services was significantly higher in the intervention group than in the control group [adjusted proportions: 31/436 (7%) versus 13/343 (4%); relative risk 2.04 with 95% CI from 1.12 to 3.72].

Discussion: The CCDS did have an effect on decision making and pathways of care. Though infrequently used this affected the care of patients.

Implications: Findings highlight the potential for improving patient health outcomes if uptake can be improved. Findings provide evidence to support the further development of CCDS in an integrated and user friendly format for further evaluation in services that are committed to completion of a fully powered trial.

771. THE ADHESION TO THE BRAZILIAN CLINICAL GUIDELINE FOR CROHN´S DISEASE PATIENTS TREATED WITH INFLIXIMAB IN A CLINICAL EFFECTIVENESS CENTER OF INTEGRATED CARE - CECIC - IN SOUTH OF BRAZIL

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Background: Crohn's disease (CD) is a chronic inflammatory bowel disease affecting any part of the digestive tract, having its diagnosis and treatment guided by the Brazilian Clinical Guideline (BCG). The

main drugs provided by Brazilian government for its treatment are aminosalicylates, corticosteroids, immunosuppressants and monoclonal antibodies.

Objective: To evaluate the adhesion to the BCG-CD and to describe pharmacotherapeutic, demographic and clinical profile of CD patients who were using infliximab assisted at the CECIC-CD at Hospital de Clínicas de Porto Alegre (HCPA) from March to September 2011.

Methods: We reported a cross-sectional study with 39 patients who were receiving infliximab as maintenance therapy at the CECIC-CD. Therapy adhesion was evaluated based on patients' attendances in medical visits and infusions.

Results: The adhesion to treatment and to BCG-DC was practically 100%. From this sample, 22 (56.4%) patients were male and the average age was 35 ± 14 years. The majority of them, 31 (79.5%), lived at metropolitan areas. Twenty-nine patients were in clinical remission (54.4%) and 23 (59%) didn't need surgical intervention to that date. The most used immunossuppressant drug was azatioprine (69.2%). Thirty (76.9%) patients have already used mesalazine. The average number of infusions was 10.1 ± 6.3; the infliximabe dose used was 379.7 ± 75.2mg with an interval between the infusions of 7.95 ± 1.4 weeks.

Discussion: The studied sample showed that the BCG has being strictly followed at the center. Pharmacological therapy was optimized in order to obtain prolonged response to infliximab. Multiple strategies adopted in CECIC for optimizing the treatment are welcome in this chronic disease.

Implications for the health system/professionals/patients/society: The adhesion to the BCG through CECIC promote the rational use of drugs, data management, clinical researches, cost savings and quality of assistance, thus benefiting society, patients, professionals and the health system. This strategy might be useful for other countries.

789. ASSESSMENT OF THE IMPACT OF A PATIENT CENTERED AND INTEGRAL DIABETIC FOOT UNIT IN A TERTIARY HOSPITAL AND ITS PRIMARY CARE SETTINGS

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Background: Diabetic foot ulcers prevalence among diabetics varies between 4% and 10%. Foot infections are the most frequent cause of hospitalization (25%), often long stay. Diabetes is the most common cause of non-traumatic amputation of the lower extremity in Europe and USA. The amputation rate ranges from 2.5 to 6 per 1,000 patients/year and the risk for diabetics is 8-15 times higher compared to non-diabetics.

Objectives: To assess the impact of an integrated and patient centered diabetic foot unit (DFU) in terms of professionals satisfaction and reduction of the number of admissions in emergency departments, number of amputations, average stay and cost-effectiveness.

Methods: The impact was assessed using electronic clinical records (admissions, amputations and average stay) and cost-effectiveness modeling. Utility was obtained from quality of life questionnaires. Professionals satisfaction was assessed using questionnaires and integration of care analyzing professionals' compliance.

Results: The core unit comprises Endocrinology, Rehabilitation, Vascular Surgery and Home Hospitalization professionals in coordination with Primary Care, Emergency Department, Microbiology and Infectious Diseases Unit. The DFU has defined its processes based on quality clinical practice guidelines (according to AGREE II). In the studied period 64 patients were admitted, and 99 admissions were recorded. 54% of the admissions were observed at the emergency department. Main reasons were: 36 (68%) grade IV ischemia and 17 (32%) infection. Average hospital stay was 14.3 days. Major amputations were 8. The mean value in the EuroQol-5D was 4.7. In the DFU 64 patients were referred from primary care and emergency department without hospital admission, with an average of 2.18 visits (range 1-12).

Discussion: The unit has shown effectiveness and cost-effectiveness in the detection of complications and chronic management at the three levels of care (primary, hospital and home). The unit has generated synergies and aligned efforts by proposing a coordinated and patient centered care**.**

793. ANALYSIS OF SATISFACTION OF RURAL RESIDENTS TOWARDS INTEGRATED HEALTH MANAGEMENT OF COUNTY, TOWNSHIP AND VILLAGE IN HAINAN PROVINCE

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Background: Medical prevention and health care network at three levels in the rural area of China is a holistic system, while the formation of organization system of health institution structures of county, township and village and the implementation of their function would be reflected in the coordination and management schemes among the network. This Integrated Health Management Model reinforce communication between provincial and local governments, enhance their supervision of medical institutions of township and village, improve efficiency through decreasing administrative hierarchy, combining the characteristics of Hainan Province.

Objectives: To analyze the effects of the integrated health management of Hainan Province and propose policy recommendations.

Methods: Random cluster sampling were adopted in a survey for rural residents in 7 County Hospitals, 26 Township Health Centers and 24 Village Health Clinics; and expert consultations with 43 Senior Health Administrators were conducted in Hainan.

Results: 464 village residents were investigated, overall satisfaction with the health service of the Health Centers of township and village was above 80%; perception of medical facilities and environment was overall fair and good; trust of doctor was around 60%; 66%-78% of them perceived the village clinics were basically sufficient to cover their common needs.

Discussion: County Hospitals act as a driving force to provide professional guidance and support for institutions of township and village, improve their diagnosis and treatment level and ensure the prevention and health care function of "bottom of the net" of village clinic.

Implications: Support from higher level hospitals for health institutions at the lower levels and enhancement of continuous education for medical professionals and their benefits are needed to reinforce, in order to improve the capacity of medical staff at grass root level, stabilizing medical teams, and eventually improve the degree of satisfaction and trust of the rural residents.

795. CLINICAL EFFECTIVENESS CENTER OF INTEGRATED CARE - CECIC - FOR MULTIPLE SCLEROSIS AND IMPLEMENTATION OF A NATIONAL CLINICAL GUIDELINE: A PATIENT-CENTERED HEALTH POLICY FOR BETTER DRUG THERAPY MANAGEMENT IN RIO GRANDE DO SUL, BRAZIL

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Background: The CECIC for Multiple Sclerosis (MS) was created in 2006 to implement the Brazilian Clinical Guideline (BCG) for MS and also to qualify the care in our State. The main drugs for MS are supplied by the Brazilian Government. At the CECIC-MS a multiprofessional team evaluates and performs treatment's follow-up aiming to improve treatment´s adhesion, doctor's adhesion to BCG, dose optimization and cost reduction. The Center evaluates all MS drugs' requests in Rio Grande do Sul (RS) State besides to assist all the outpatients at our university hospital.

Objectives: To describe the proportion and the costs of the prescribed drugs to all patients in our State.

Methods: We developed a cross-sectional study to review all MS treatment's request in RS. The data were collected from the RS Health Secretariat formal applications and drug management system.

Results: The center evaluates monthly an average of 100 drugs requests, of which, 10 to 15 are new ones. Currently, are 1,007 patients in treatment for MS in RS, 71% of them were female and the average age was 43.6 ± 13 years. The most prescribed drugs were: betainterferon-1a 22 mcg (32%), glatiramer 20 mg (23%), betainterferon-1a 30mcg (21%), betainterferon-1b 300 mcg (14%), betainterferon-1a 44 mcg (7%), azathioprine (1.4%) and natalizumab (1.1%). In 2011 the cost to RS for MS treatment was US$17,648,857.00.

Discussion: Actually 12,761 patients are in treatment for MS in Brazil and the RS State is responsible for 12% of the direct annual cost. Due to the lack of published information of patients on treatment for this disease elsewhere it is difficult to compare the treatment rates in Brazil with other countries. Implications for the health system/professionals/patients/society: The registry and follow-up of this chronic disease are essential to reduce costs, measure guideline's adhesion, and to improve treatment's effectiveness. This public health strategy might be useful for other countries.

808. PRENATAL INTEGRATION SERVICES IN SÃO PAULO CITY

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São Paulo is the most populous city in Brazil. It is the sixth largest city in the world and its metropolitan area, with 19,223,897 citizens, is the fourth largest urban agglomeration in the world. Women need assistance to perform prenatal care in order to avoid problems during the pregnancy and childbirth and provide better treatments. Some problems may arise during pregnancy such as abortion, anemia, Rh incompatibility, problems with the placenta, preeclampsia, etc. A program of the Public Health of São Paulo, called "Mãe Paulistana" aims to assist women during the gestational cycle, from prenatal consultations, childbirth, and the postpartum period until the first year of baby's life. The assistance to pregnant are a set of services for monitoring of prenatal consultations, performing all necessary examinations to monitor the pregnancy, visit the hospital where the child will be born, free public transport to the consultations and examinations during the pregnancy and the first year of child, and finally a basic set of clothes for the baby. In five years of the program, 592,731 mothers have signed up. From March 2006 to September 2011 were made 593,432 births - an investment of R$ 45.5 million on clothes and R$ 12.3 million for transportation. In relation to prenatal care, were held 3,508,470 consultations, 4,350,158 examinations and 642,138 obstetric ultrasound. All monitoring events of pregnancy are registered in an integrated management system called SIGA-SAÚDE, which supports the Public Health Management. The Public Transport Service is automated and guarantees free public transport for those women. Integrate poor mothers into the public assistance providing medical care for pregnant and childbirth, and the integration of free public transport services, significantly improves the quality of life in big cities like São Paulo.

815. EVALUATION OF BIOLOGICAL AGENTS EXCHANGES ON RHEUMATIC DISEASES (RD) TREATMENT IN A CLINICAL EFFECTIVENESS CENTER OF INTEGRATED CARE (CECIC) IN A UNIVERSITY HOSPITAL IN SOUTH OF BRAZIL

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Background: Biological agents (BA) for RD proved to be effective in conventional disease-modifying anti-rheumatic drugs non-responders patients. The Brazilian Public Health System provides for RD treatment adalimumabe, etanercept and infliximab. However, 20-30% of the patients don't respond to the treatment, due to inefficacy or adverse events (AEs). Patients who are non-responders to first BA can be treated with a second one with success expectations.

Objectives: To describe the patients sample in treatment with BA assisted at the CECIC-RD at Hospital de Clínicas de Porto Alegre.

Methods: All the CECIC-RD patients from January/2007 to December/2011 were included in this study.

Results: Ninety-one patients were evaluated: 84.6% were female and the average age was 51 ± 12 years. From these 89.0% have rheumatoid arthritis, 4.4% psoriatic arthritis and 6.6% ankylosing spondylitis. The follow-up median time was 19 (1-54) months. The first BA was: adalimumab (37%), infliximab (36%) and etanercept (26%) for a median time of 13 (1-54) months. Among them, 49.5% discontinued the first biologic and the main causes were: primary failure (17.8%), secondary failure (62.2%) and AEs (11.1%). From the patients who had the treatment suspended, 84.4% started to use a second agent (31.6% etanercept, 21.1% rituximab, 18.4% adalimumab, 15.8% abatacept, 13.1% others). The median time of second agent use was 9 (1-24) months. Ten patients initiate a third agent (60%-rituximab).

Discussion: The rate of patients who discontinued treatment due to failure or toxicity is consistent with literature. Those patients who discontinued the second agent, the reasons for discontinuation were recurrent. Therefore, treatment monitoring in specialized centers is important to improve treatment's adhesion and to enable clinical and epidemiological data registration.

Implications for the health-system/professionals/patients/society: Such information is important once treatment safety is not well established and due to high cost of these drugs which have a substantial impact on the public budget.

820. PHARMACOVIGILANCE AND TECHNOVIGILANCE DEVELOPMENT IN URUGUAY

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Background: Integrated National Health System of Uruguay, created in 2007, introduced new policies to promote rational and safe use of health technologies and resources. To ensure safety and effectiveness of these products was necessary to structure a monitoring system for medical devices and drugs. According to new requirements, all health services should set up patient safety and hospital infection committees. Pharmacovigilance Unit (FVG) of Health Ministry was stated in 2006 with an advisory committee and a peripheral node network for reporting adverse drug's events according to World Health Organization (WHO) recommendations. At the same time, Technovigilance Unit (TVG) started processing international alerts and recalls of medical devices. Medical products acquisition of public health services is in charge of a centralized purchasing unit without reliable data on the performance of products in the market.

Methods: A project to improve the baseline is in implementation: -Monitoring units of health products are being created. -Developing computer notification service, centralized in Health Ministry. -Strengthening links between Public Centralized Purchasing Unit. -Strengthening contact with surveillance agencies of regional countries. The strategy is based on: Identification of stakeholders and managers TVG-FVG, development of procedure manuals for TVG-FVG, training activities and development of computerized reporting system.

Results: Manuals have been elaborated. Reporting system has been developed in the first stage. During 2011, FVG 604 notifications were received, 78% adverse drug events and 12% medication errors. In TVG, 46 incidents and 15 recalls. Guidelines have been established between the regional countries for reporting adverse events in the context of MERCOSUR health coordination.

Conclusions: A program of continuing medical education in this subject might be established involving stakeholders and systematic actions might be done to expand the network to the whole country, taking into account patient safety and hospital infection committees.

832. MULTIDISCIPLINARY TEAM ASSISTING SICKLE CELL ANEMIA PATIENTS USING HYDROXYUREA IN A PUBLIC HOSPITAL IN THE SOUTH OF BRAZIL

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Background: Sickle cell anemia (SCA) is a blood disorder characterized by pain crises, acute clinical events and early mortality. Hydroxyurea (HU) has been shown to improve laboratory parameters and ameliorate clinical complications of SCA. Its use should be made with strict monitoring because of its high incidence of adverse events. The patients should be accompanied throughout their lives. In September/2011 a Clinical Effectiveness Center of Integrated Care for SCA (CECIC-SCA) was established at Hospital de Clínicas de Porto Alegre, funded by the Brazilian Ministry of Health.

Objectives: To describe the general profile of SCA patients treated with HU at the CECIC-SCD.

Methods: The patients were interviewed by a social assistant, nurse and pharmacist, and submitted to routine medical examination. Semi-structured interviews were conducted with questions about age, gender, race, place of residence, social-class, medications, hospitalizations in the previous year, comorbidities.

Results: Fifty-nine patients were interviewed from September to December/2011 being 61% female with a mean age of 24y. Forty-six patients were from metropolitan areas of the Rio Grande do Sul State. Seventy-three percent were African descents. Regarding social class, 42% of the patients belong to class C1 (family income: US$800.00/month). Interviewed patients use approximately 4 ± 2 other drugs. The median number of hospital admissions in the previous year was 1 (0-6). Forty-six percent of the patients had at least one comorbidity.

Discussion: The data found is consistent with literature. The center is in expansion in way to assist all 180 patients who already have medical care at this hospital.

Implications for the health-system/professionals/patients/society: The intervention made by a multi-professional team is extremely relevant in the assistance of chronic patients, especially in SCD. Early discovery of signs of the disease's severity, proper handling of crises and practicing preventative measures are essential and bring benefits to all stakeholders: patients, health professionals and society.

845. CLINICAL EFFECTIVENESS CENTER OF INTEGRATED CARE FOR MULTIPLE MYELOMA: A PUBLIC POLICY STRATEGY IN THE BRAZILIAN PUBLIC HEALTH SYSTEM

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Multiple Myeloma (MM) is a plasma cells' neoplasia which corresponds to approximately 10% of all hematological cancers. The drug thalidomide is one of the treatment options provided by the Brazilian Government for the treatment of MM. Its use is regulated by a National Clinical Guideline, which defines therapeutic regimens, monitoring mechanisms and assessment results to ensure their safe and effective prescription. In 2010, the Hospital de Clínicas de Porto Alegre (HCPA) in partnership with the Rio Grande do Sul (RS) State Health Secretariat implemented a Clinical Effectiveness Center of Integrated Care for MM (CECIC-MM) for the patients on use of thalidomide. The CECIC-MM is composed by a multidisciplinary team that performs drug dispensing to the on-site service patients, provides orientation's use and performs systematic monitoring of adverse events. The RS State has approximately 190 patients with MM that use thalidomide, of those 30 (16%) patients are treated at HCPA CECIC-MM. The total number of thalidomide tablets´ dispensed per month for MM in RS is 8,670 (47 tablets/patient/month) and from these total, 1,215 tablets are dispensed in the CECIC-MM (41 tablets/patient/month). The mean number of tablets dispensed in the center is 13% lower than in the rest of the State. This difference may be related to structure multidisciplinary monitoring of these patients. A cost-utility study is in progress to evaluate this service, to measure the treatment adhesion and quality of care besides the treatment costs. The rational and controlled use of thalidomide in specialized centers is essential for the treatment efficiency and patient safety, since its use is associated with significant adverse effects, highlighting teratogenicity and peripheral neuropathy. These data are useful for public health planning and policy making.

861. CLINICAL AND ORGANIZATIONAL IMPACT OF THE IMPLEMENTATION OF THE OSNA (ONE STEP NUCLEIC ACID AMPLIFICATION) SYSTEM FOR THE ASSESSMENT OF THE SENTINEL LYMPH NODE (SLN) STATUS IN BREAST CARCINOMA

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Background: The SLN is the first node into which the breast tumor drains and therefore a metastasis is most likely to occur in this node. If a metastasis is found, all lymph nodes of the axilla are removed. In our laboratory, SLN has been usually examined entirely by frozen sections (FS) at the same time of breast surgery. In the last years, a more rapid method for the SLN status assessment has been introduced. This system, called OSNA, is based on the quantification of the copy number of cytokeratin 19 mRNA, which is supposed to be expressed in almost all breast carcinomas and so, in their metastasis.

Objectives: To compare the conventional method (FS) with the OSNA system and to evaluate the clinical and organizational impact of the introduction of the new method.

Methods: Two similar periods of time of about four months each were compared: the first one in which only the conventional method was used, and the second one, in which only the OSNA method was applied. For each of these periods, the turnaround time (TAT) for surgical pathology reports, the number of patients, the number of breast surgery operating sessions and the waiting time from the cancer diagnosis to the surgical operation were evaluated.

Results: With the introduction of the OSNA system we had a reduction of the TAT from 80 to 47 minutes. This yielded to a reduction of the time of surgery, an increased number of patients that underwent surgical intervention in each operating session (from 1.7 to 3), a reduction of the waiting time before breast surgery (from 67.9 to 39.2 days).

Discussion: These early data show that OSNA system is a very effective method because it reduces the surgical waiting lists and can improve the health-care worker productivity.

865. PREDICTIVE RISK STRATIFICATION MODEL: A TRIAL IN CHRONIC CONDITIONS MANAGEMENT (PRISMATIC)

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Introduction: An ageing demography and increase in the prevalence of chronic conditions is placing an unprecedented demand on health and social care services. In response, predictive risk models have been developed in the USA, Germany and UK using routinely collected patient data to identify those most at risk of unplanned hospitalisation, who may benefit from early intervention. In Wales, UK the Predictive Risk Stratification Model (Prism) derives a score (0-100) based on the risk of emergency hospital admission in the following year. Although Prism, like other models, has been shown to be effective at predicting admissions, questions remain about how the model is adopted and what impact adoption will have on patient care. This study aims to describe the process of introducing a predictive risk stratification model (Prism) in primary care and to assess the effects on the delivery of care to patients living with or at risk of developing a chronic condition, and to those with no perceived risk.

Methods: Using a randomised multiple interrupted time-series study design, invited general practices will begin as controls - becoming intervention practices on receipt of Prism at randomly determined points over 20 months. 77 practices in one Welsh health board area will be invited to participate, with each receiving Prism and access to integrated community-based health and social care resource teams. Validated patient questionnaires (n = 800), routinely collected medical data and Prism risk scores will be collected at baseline, 10 and 20 months, to support analysis of patient satisfaction, quality of care, service usage, and risk. With qualitative investigation of health practitioners' experience, the data will permit assessments of the cost and clinical effectiveness of Prism implementation.

Conclusions: The use of risk stratification models is recognised as a major area of interest for the health and social care community. Yet there remains a deficit of evidence about the effects of implementation in primary care. Findings from this study will inform chronic conditions management policy and practice internationally.

909. A STAKEHOLDER DRIVEN, INTEGRATED, PATIENT CENTRIC APPROACH TO THE DEVELOPMENT OF AN EVIDENCE-BASED DIABETES PATIENT SUPPORT PROGRAM IN THE US

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Background: Diabetes is associated with significant morbidity and premature death. Despite efficacious medications, lowering blood glucose to guideline thresholds requires a holistic approach that extends beyond pharmacotherapy. Research demonstrates that optimal patient support is multi-dimension a rigorous assessment of unmet diabetes care needs must be conducted and this includes patient, physician and payer participants. This in turn leads to identification of gaps in care and definition of integrated solutions that supports the patient –centered care.

Objectives: To design an evidence-based patient support program and evaluate its effectiveness in the real-world.

Methods: An on-going US diabetes patient support program research initiative is comprised of the following: Stage I: Identification of Unmet Need: Conduct an analysis of a patient web survey linked to a claims database analysis; Physician interviews to compare with patient perception of care gaps; Payer interviews to delineate necessary elements of an effective diabetes patient -support program; Database analyses of diabetes patterns of care and outcomes. Stage II: Patient Support Program Design. Stage I results will be used to inform the specific aspects of diabetes patient support program design such as patient stratification and including patient self monitoring device, physician care coordination aspects, payer monitoring and other interventions as needed. Stage III: Prospective longitudinal study. In general, the study should provide real-world evidence related to physician and patient satisfaction along with effectiveness of, the patient support program that is meaningful to patients, physicians and payers alike. Key considerations include the need for a broad range of demographically and clinically diverse patients, a sufficient sample size, a usual care control group, naturalistic assessments, relevant patient –reported outcome variables and measures, and appropriate study period.

Discussion and implications: Effective interventions that optimize care and increase patient adherence to pharmacotherapy through integrated solutions are warranted. A step-wise, scientifically rigorous approach to the design and evaluation of a diabetes patient support program can optimize the potential impact on patient outcomes.

912. DEVELOPMENT OF A MODEL PREDICTING THE IMPACT OF TELEMONITORING FOR PATIENTS WITH CHRONIC HEART FAILURE IN FRANCE

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Background and objective: Chronic Heart Failure (CHF) is a serious condition associated with frequent hospitalisations. Telemonitoring (TM) can improve CHF management and reduce all-cause mortality and CHF-related hospitalisations. A model was developed to predict the effect of telemonitoring on CHF-hospitalisations and survival in CHF patients in France.

Methods: A Markov modelling approach was used to simulate the CHF progression, with telemonitoring compared to usual care, over 5 years. The number of hospitalisations was considered as an indicator of disease progression. The model assumes that telemonitoring alerts can prevent transitions to health states with increased risk of decompensation. Input data were obtained from the literature and French hospital statistics. The effectiveness of telemonitoring in preventing CHF-hospitalisations and all-cause mortality was based on published meta-analyses. Deterministic and probabilistic sensitivity analyses were performed to assess uncertainty around results.

Results: The model predicted that patients would survive on average for 2.28, 1.97 and 1.85 years after 1st, 2nd or 3rd hospitalisations respectively, with 6.15, 6.76 and 6.93 hospitalisations over lifetime. Telemonitoring would increase life-expectancy by 3.47, 2.92 and 2.65 months for patients starting after 1st, 2nd or 3rd hospitalisation, and would save 0.54, 0.40 and 0.37 hospitalisations per patient over 5 years. The number of hospitalisations per life-year would decrease by 0.51 (95% credibility interval: 0.34-0.66), 0.56 (0.37-0.72) and 0.58 (0.38-0.74), respectively. Providing telemonitoring to 1000 new patients per year, after 1st hospitalisation, would avoid approximately 2,530 hospitalisations over 5 years.

Discussion and implications: The predicted numbers of CHF-hospitalisations avoided and improvements of life-expectancy support further investigations aiming to develop telemonitoring for CHF patients. Our results suggest that telemonitoring should start following 1st hospitalisation rather than at later stages. The model predictions appear consistent with data from the literature, but we recommend updating it using information collected through a telemonitoring programme when implemented in clinical practice.

934. DISEASE MANAGEMENT MODEL FOR DELAYING INSTITUTIONALIZATION OF DEMENTIA PATIENTS: A SYSTEMATIC REVIEW OF THE LITERATURE

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The issue of dementia is assuming a growing relevance in terms of public health. In Italy, it is estimated that there are about 1,000,000 cases of dementia and 3,000,000 members of their families involved in their assistance. The evidence from international literature is highlighting the positive effects on heath, policy and costs of an integrated management of different professional skills. This systematic review aims at determining the effectiveness of a disease management model for patients with dementia and their primary caregivers in delaying time to nursing home placement. Starting from 1264 hits found in biomedical databases, only nine studies showed a quality level in order to be evaluated in the systematic review. All studies compared outcomes for a group of patients submitted to an intervention aimed at disease management for Alzheimer disease and their primary caregiver, with a control group. Patients who received the intervention experienced a variable reduction in the rate of nursing home placement compared with usual care controls. Caregivers involved in the interventional group generally showed a relief in their subjective and objective burden. Although there is evidence that disease management is effective for dementia, the degree of this effect is mild and it is still not clear which type of intervention is the most useful for the caregivers and at which stage of the disease.

940. PHOTOVOICE: THE USE OF PHOTOGRAPHY IN PARTICIPATORY HEALTH RESEARCH (PHR)

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Background: Photovoice is a method in which patients take photographs that best represent their views, perspectives, and challenges of living with a health condition. Although photovoice has been extensively used in participatory action research projects, especially for engaging ethnic minorities and other underserved populations, its use in PHR is novel.

Objectives: The objective of this review was to identify the applications of photography in PHR, integrated care and for reaching out to underserved populations.

Methods: Systematic review of the MEDLINE, EMBASE, and PsyInfo databases.

Results: The search of the peer-reviewed literature identified three ways in which photovoice is used in PHR: 1) Photo elicitation, a method where patients take photographs that represent their health experience, and healthcare professionals use this information to educate medical students and to design clinical research studies. 2) Participatory action research, a method in which patients photograph health hazards in a hospital setting or their environment, and healthcare professionals use this information to improve healthcare quality. 3) Photographic memory aid, a method where healthcare professionals program a smart phone for an Alzheimer patient to automatically take photos, which then serve the patient as a memory aid.

Discussion: Photovoice can be used to elicit the patient perspective in medical education and healthcare research, in identifying safety concerns or health risks, and as memory aid for Alzheimer patients in integrated care. The use of photography could give a voice to patients who have difficulties expressing themselves verbally. Additional research is needed to determine the validity of the elicited information and the impact on research and healthcare quality.

Implications for the health system/professionals/patients/society: The use of photovoice could improve medical education, the design of clinical studies and increase the quality of healthcare delivery and integrated care.

39. PROGRAM INTEGRATION TO ACHIEVE DISEASE ELIMINATION

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Background: The timely delivery of effective health interventions to communities in developing countries is one of the greatest challenges in global health. While governments have invested in the development of the primary health care infrastructure, it is still insufficient for tackling some of the major communicable diseases present in the world's poorest regions. In response, numerous public health programs focused on single-disease interventions, such as the

International Trachoma Initiative (ITI), have been developed and implemented in countries around the world. With the tremendous growth in the reach and effectiveness of these single-disease programs, however, has come a significantly increased workload for health personnel and volunteers.

Objectives: The potential for integration of single-disease control programs as an efficient and sustainable solution to disease control in the developing world.

Methods: In the summer of 2008, the ITI began a research study to examine other single-disease programs and to evaluate their suitability as partners for integration. Lymphatic filariasis was found to be a good partner for integration with trachoma-control programs, IT! began implementing integration among these programs by facilitating a meeting between program managers and policy-makers involved in trachoma and lymphatic filariasis in Uganda and Tanzania, countries selected due to the fact that both have the high prevalence of the diseases, strong national leadership of the disease-control programs, and a well-established record of community-based activities.

Results: Areas in which the lymphatic filariasis and trachoma control programs in Uganda and Tanzania will collaborate include the training of health workers, the establishment of multi-disease task forces, water and sanitation initiatives, drug distribution, the development of joint data collection methods, and integrated health promotion messages.

Conclusions: The integration of trachoma and lymphatic filariasis programs in Tanzania and Uganda offers an innovative approach to communicable disease control that will result in more sustainable and efficient programs that will be mutually beneficial to both initiatives.

68. ASSESSMENT OF TRANSCATHETER AORTIC VALVE IMPLANTATION

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Background: In 2008, the French National Authority for Health (HAS) supported innovation and recommended for reimbursement the transcatheter aortic valve implantation (TAVI) to rapidly provide this technique despite limited clinical data. However, the HAS has required to reevaluate this technique after three years with data from randomized controlled trials and from a French registry on all patients implanted.

Objectives: To assess effectiveness and safety of TAVI (Sapien and CoreValve devices) to support reimbursement decision by the French National Insurance Funds (FNIF).

Methods: Systematic literature review was performed. The ensuing report was discussed by a multidisciplinary working group, then submitted to the relevant HAS Committees for validation.

Results: At 1 year, TAVI significantly reduced the rates of death compared to standard therapy in patients with severe aortic stenosis who were contraindicated for surgical aortic-valve replacement (SAVR). In high-risk patients, TAVI and SAVR were associated with similar rates of death. However, these two techniques had their own complications: more bleeding with surgery and more strokes and vascular complications with TAVI. Pacemaker implantation rates were higher with CoreValve compared to Sapien. Results from the French registry were concordant with literature data. Study investigating efficiency, comparing TAVI with SAVR, was not available. The cost study, carried out on the French registry data, showed that the ratio of the refund paid to the hospital by the FNIF and the average cost of the hospital stay was appropriate.

Conclusions: After a temporary period of reimbursement, HAS recommends limiting TAVI to patients with symptomatic severe aortic stenosis contraindicated for surgery for medical or anatomical reasons. The aortic valve replacement and the contraindication to SAVR should be considered by a heart team with the involvement of a geriatrician. HAS also defines eligibility criteria of centres which could use TAVI (cardiology and cardiac surgery departments in the same building).

104. THE ECONOMICS OF RARE DISEASES: THEORY, EVIDENCE AND PUBLIC POLICIES

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The objective of this paper is to review the economics of rare diseases and orphan drugs trying to analyze their implications. It search to respond how are defined the rare diseases, why they are considered a public health problem and what are the implications of this for the formulation of public policies. Rare disease is a illness that presents a low prevalence in a given population. They are a public health problem because affects millions of people around the world. They are usually degenerative, chronically debilitating and require long-term treatment, affecting the physical, mental, sensory and behavioral patient. Orphan drugs are medicines used for diagnosis, prevention and treatment of rare diseases. The rarity of cases implies difficulties to proof the clinical efficacy of these medicines. Are presented the regulatory systems for rare diseases in the United States and the European Union, as well as the key economic considerations related and how are the influence of these mechanisms on the development of orphan drugs. It was concluded that the regulatory mechanisms are able to stimulate the development of new kind of drugs to treat of rare diseases. These incentives provided for development policy of orphan drugs represent a kind of pro-market regulation. Such mechanisms are able to encourage companies to develop drugs that would not be produced under normal conditions, which can be proved by the increasing availability of treatments based on the implementation of these regulations. From the analysis of the evolution of the number of orphan drugs available on the European and USA after the adoption of legal frameworks, it was concluded that the policy is effective. However, It is necessary to intensify the debate on rare diseases in Brazil, since there isn´t a public policy to facing this problem in this country.

126. ASSESSMENT OF EXTERNAL PROSTHESES IN UPPER LIMB AMPUTEES BY FRENCH NATIONAL AUTHORITY FOR HEALTH (HAS)

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Background: Upper limb prostheses have been reimbursed by French National Health Insurance Fund for many years. Prostheses which can be reimbursed are included on the List of products and services qualifying for reimbursement. They are defined through generic descriptions of different prostheses types inherited from the past and have no more clinical relevance.

Objective: To up-date the technical characteristics, indications and prescription conditions of upper limb prostheses qualifying for reimbursement.

Methods: We performed a literature review and obtained the opinion of a multidisciplinary working group of healthcare professionals. The ensuing report was validated by the relevant HAS Committee.

Results: Few clinical publications were available and their methodological quality was low. Therefore, this assessment mainly relies on the clinical experience of the working group. HAS has confirmed the actual benefit of upper limb prostheses and recommends a classification based on the actuation mode of the prosthesis terminal device: inert, passive, mechanically active and electrically active prostheses. As these prostheses offer different functions corresponding to various prehension activities, they all have to be available for reimbursement. In order to design the best matching prostheses, the multidisciplinary team taking care of an amputee must assess his/her needs and projects related to daily life prehension activities. These needs relate either to esthetical and/or functional aspects. In this view, HAS has recommended that custom-made cosmetic covers, not funded yet, should be reimbursed.

Conclusions: This new modular classification for upper limb prostheses, completely adapted to prosthetics practice, will i) link reimbursement conditions and currently available prostheses ; ii) be a prescription guide for prostheses matching better each amputee's needs and life goals.

143. KIDNEY TRANSPLANTS - AN APPROACH FROM THE AGENCY THEORY APPLIED TO BRAZIL

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Background: Brazil has the most public of transplants and occupies the second place (behind only the United States) in number (absolute) of surgeries of this size, with emphasis on the kidney transplant.

Objectives: This paper aims to check and analyse the institutional mechanisms and incentives offered to hospitals that perform the abstraction of organs (especially rim) for transplants in Brazil.

Methods: The theoretical approach to be used is the Principal-agent model under asymmetric information context (that is, when one side of the contract knows more on the other side). This theory is well suited to analyze this type of problem, because the main welfare (SUS) depends on the efforts of hospitals (agent) to capture the organs for transplants. SUS (principal) is responsible to prepare and propose a contract (developed from Brazilian legislation of transplants) hospitals (agent) to perform actions related to funding of organs for transplant.

Results and discussion: It is noteworthy that the level of effort made by the hospital depends on some measures which this does to improve uptake in organs and tissues, which are: training of transplant coordinators, acquiring knowledge of the clinical phases, bureaucratic and logistical donation process; regional meetings with intensivistas; courses on organ donation and transplantation to all professionals who work in hospitals; regular meetings with journalists, communication experts and opinion formers; lectures and debates about organ donation.

Implications: It was found that the SUS has adopted various measures incentives for hospitals that perform the abstraction of organs, such as: creating a specific fund for financing of transplants; uniform payment to hospitals and universities; expansion of the types of hospital procedures to be paid by SUS; frequent adjustment of the remuneration paid by procedure of hospital information system Procedures of the single health system and courses and/or meetings with health professionals who work in the process of donation-transplantation.

Conclusions: Concluded on the basis of evidence that, if such hospitals Brazilian pickups receive compensation, the fundraising process and transplantation will be performed more efficiently and, consequently, the imbalance between the need and the demand for organs can be minimized in Brazil.

161. A BRAZILIAN EXPERIMENT USING THE REGULATORY IMPACT ANALYSIS IN THE PRIVATE HEALTH PLANS MARKET

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Background: Listening to the providers and patient's groups, the Brazilian Authority observed that in many occasions when the patient (Health Plan's User) tried to be admitted in a higher level of accommodation in the case of unavailability of beds at the lower level of accommodation (in accordance with the terms of his contract) in the hospitals licensed by the health plans, neither the health plan nor the provider wished to pay for the patient admission extra fee. Thus, a new approach to responsive regulation was necessary in order to extend the regulator's oversight over regulated organizations, taking into account the visions of all stakeholders.

Objectives: The regulatory intervention aimed to enforce the provisions of Article 33 from Brazilian Law 9656/1998 to ensure the patient the rights to a higher level of accommodation in the case of unavailability of beds at the lower level of accommodation (in accordance with the terms of his contract), with no additional burden to the patient. The purpose of the new rule was to clarify the obligation of the health plans to pay for the patient admission additional fee, because Brazilian Legislation did not indicate that clearly.

Methods: To cope with this problem, Brazilian Regulators used the Regulatory Impact Analysis (RIA) in the new rule creation process. RIA is a mechanism for obtaining useful information for the decision makers concerning the regulatory policy. Co-opting other stakeholders to the purposes of regulation, the transparency was strengthened.

Results: Once the Market Failure (Information Asymmetry) was detected, a regulatory response was required in order to make information clear and available to all the stakeholders. RIA helped to implement a compliance model with a view to providing higher quality health services.

185. PROCESS OF INCORPORATION OF TECHNOLOGY IN HEALTH IN BRAZIL: REVIEW OF THE YEARS 2006 TO 2011

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Ministry of Health. Brazil.

Background: The Ministry of Health (MS) of Brazil has published ordinance, in 2006, creating the Committee for the Incorporation of Technologies of MS - CITEC for dealing with the case of incorporation of technologies whereas social needs in health and management of the Brazilian Health System (SUS). CITEC completes its work when the federal law no 12,401/2011 has established new rules for the incorporation of technologies and new composition for the Committee, now known as National Committee for the Incorporation of Technology in SUS-CONITEC.

Objectives: To know the results of the incorporation of health technologies (HT) adopted in Brazil between the years 2006 and 2011.

Methods: Retrospective, descriptive study, in which the collection of data was performed in the database of CITEC (period from 2006 to 2011). Classified to the demands of the incorporation of HT, by type of technology and for completion of the process: filed the application by the applicant or by having record health canceled, not assessed and evaluated. Among the evaluated, it was classified as HT incorporated and not incorporated, and is generated exclusion of any other technology.

Results: The 340 demands for incorporation of technology, 69% (n = 227) it was medication. Were filed 2.3% of the demands and 44% were not evaluated. Among the 182 demands evaluated (53.7%), and 57% were incorporated, 37% is not incorporated and 6% of HT already incorporated were excluded from the list of SUS.

Discussion: The lack of a state policy for the incorporation of HT in the Brazilian Health System may be the reason why many technologies were not assessed, because they were prioritized the internal demands of MS, and the physical structure and human resources were reduced. Meanwhile, the population did not fail to be benefited, as the demands of MS are generally dealt with HT to predominant diseases in Brazil.

Implications for the health system/professionals/patients/society: The new law brings as a differential equality for evaluation of the demands, when all should be evaluated, with time and rules predetermined.

287. HEALTH TECHNOLOGY ASSESSMENT PROCESS: ANALYZING BRAZILIAN PROCESS

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Background: The Brazilian health technology assessment (HTA) process has been recently established. The aim of this study was to describe, analyze and compare the opinions of healthcare system leaders about HTA process currently used in Brazil.

Methods: Study design: observational study. A structured questionnaire was e-mailed to 597 leaders from the public and private healthcare systems. These leaders represented different healthcare interested parties. The questionnaire contained inquiries regarding the Brazilian laws concerning the currently HTA process and also the process itself. Descriptive statistics was used. Qui-squared test was used in order to compare groups.

Results: 200 participants (35%) answered the questionnaire. Most respondents were between the ages of 41 and 50 years (37%) and were acting as managers of the healthcare system (36%). 50.7% is inserted in the public healthcare system while 49.3% acts in private system. Most of them considered that the timeframes for submission of new technology process are inadequate (85%) and that the analysis timeframes should be clearly defined (90%). Almost 85% affirmed that the total time for the request to be analyzed once being filed should be up to 12 months. 77% mentioned that should be distinguished processes for different types of technologies. 88% stated that academia and experts (representatives of the associations, boards, professional societies, patients, health insurances and health plan operators) are important groups who also should be involved in the process.

Conclusions: In spite of being a recently developed and well-thought process, healthcare system leaders feel that the actual process can be improved to allow it to reach the expected goals. Additional surveys are needed to track the HTA process and its application in Brazil.

589. EVALUATION OF A MEASURE TO PROMOTE THE RATIONAL USE OF MEDICATIONS IN CHRONIC PATHOLOGIES: CHANGE TO PRESCRIPTION BY ACTIVE INGREDIENT OF ATORVASTATINE, CLOPIDOGREL, LOSARTAN+ HYDROCHLOROTHIAZIDE AND RISEDRONIC ACID

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Introduction: In the current economic crisis, the control and proper management of the pharmaceutical provision service is of paramount importance. The situation requires additional measures in the implementation, follow-up and evaluation of new control measures of the pharmaceutical expenditures to meet the budgetary targets. The Pharmaceutics Directorate promoted in June 2010 the automatic replacement of brand based prescriptions by those based on the active ingredient, through the electronic prescription system of the following drugs: Atorvastatine, Clopidogrel, Losartan+ Hydrochlorothiazide and Risedronic acid.

Objectives: Assessment of the economic impact of the automatic replacement in the electronic prescription system of brand based prescription for active ingredient based prescription in the selected drugs.

Methods: Retrospective study of the use of selected drugs in the prescriptions issued between May and December 2010. Data of expenditures of active ingredient based prescriptions of Atorvastatine, Clopidogrel, Losartan+ Hydrochlorothiazide and Risedronic acid has been extracted from the database of the Pharmaceutics Directorate in the Health and Consumer Department of the Basque Government. Consumption data is recorded as number of cartons delivered. The economic impact is based on the average prices per carton of brand and generic drugs.

Results: In May 2010 the percentages of active ingredient based prescriptions were 3.22%, 10.6%, 14.42% and 1.78% for Clopidogrel, Losartan+ Hydrochlorothiazide, Atorvastatine and Risedronic acid respectively, which increased to 64.34%, 86.78%, 82.87% and 64.08% in December 2010. Consumption of generic drugs from May to December increased 1,400%, 713%, 407% and 3.600% for Clopidogrel, Losartan+ Hydrochlorothiazide, Atorvastatine and Risedronic acid, respectively. This amounts to a saving of 8.1 million euro.

Conclusions: The change to the active ingredient based prescription has resulted in savings of 8.1 million euro for the Pharmaceutics Directorate. Active ingredient based prescriptions and use of generic drugs have been thus promoted.

Implications for the health system/professionals/patients: Efficient management in the expenditure of the pharmaceutical provision service.

598. ENDPOINTS OF ADVANCED AND METASTATIC BREAST CANCER TRIALS; MARKETING APPROVAL FOR NEW ANTI-CANCER DRUGS BY THE EUROPEAN MEDICINES AGENCY OVER THE LAST 10 YEARS

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Background: The choice of endpoints to be used in clinical trials is a critical issue in drug development. Given its objectivity and the

unquestionable benefit for patients, overall survival (OS) has been historically considered the most important endpoint in advanced breast cancer. In recent years, the number of anticancer drugs launched after the completion of clinical trials in which the efficacy and safety are evaluated based on surrogate endpoints has increased. A surrogate endpoint is defined as an outcome that is used in place of a clinical outcome. The replacement is usually made because the surrogate endpoint is available in a shorter period of time, at a lower cost or with less variability than the clinical endpoint.

Objectives: To evaluate efficacy endpoints in randomized clinical trials used by the European Medicines Agency (EMA) to approve new anticancer drugs for treatment of advanced and metastatic breast cancer over the last 10 years.

Methods: Given the key role played by the choice of endpoints for clinical trials and for drug approval, the National Comprehensive Cancer Network guidelines were reviewed with the specific aim of detecting the drugs used in advanced and metastatic breast cancer. The drugs that were marketed from 2000 to 2010 were selected based on the information available on the EMA website. Information about empirical evidence supporting the approval of each anticancer drug (pivotal trials) was retrieved from the European Public Assessment Report (EPAR).

Results: The primary endpoints most frequently used were time to progression (TTP) (50%), and response rate (RR) (33.3%), followed by progression free survival (PFS) (16.7%). In all cases, OS was assessed as a secondary endpoint.

Implications for health system/professionals/patients: In conclusion, new anticancer drugs for advanced and metastatic breast cancer are often approved on the basis of surrogate endpoints such as RR, TTP or PFS.

629. THE PERIOD OF TIME BETWEEN THE NEW DRUGS LICENSE IN BRAZILIAN HEALTH SURVEILLANCE AGENCY (ANVISA) AND THE INCORPORATION REQUEST TO THE MINISTRY OF HEALTH

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Introduction: The new drugs registration is done by ANVISA that evaluates mainly the criteria of safety and efficacy for the issue of the registration. In 2011 April the Law 12,401 established criteria for health technology incorporation in the Brazilian Health System (SUS) and it creates a new National Commission for the Incorporation of Technologies–CONITEC.

Objectives: To analyze the period of time between the license and the request for incorporation to monitoring of new health technologies.

Methods: The ANVISA database was used to analyze the registration publication date. The Ministry of Health database of technologies requested for incorporation was used to analyze the incorporation request date, for the years 2010 and 2011.

Results: The total of requests for 2011 was 14. For this year two drugs were registered for more than 10 years, 5 from 2008 to 2010 and 6 in the same year of request. The total of requests for 2010 was 18. For this year three drugs were registered for more than 8 years, 6 from 2006 to 2009, 5 in the same year and 3 in the following year of request.

Discussion: In 2011, 80% of drugs had their license in the last 4 years, and of these, 43% had the license on the same year of the request. In 2010, 61% of drugs had their license in the last 4 years, and of these, 28% had the license on the same year of the request. For this year it was observed that 17% of requested drugs were only registered on the following year. However, with the new law this couldn't be accepted, because all of drugs need the previous registration at ANVISA. It is observed that there is reduction on the period of time between the ANVISA registration and the incorporation request into the SUS.

748. PRODUCT DEVELOPMENT PARTNERSHIPS (PDPS) IN THE BRAZILIAN PUBLIC HEALTH SYSTEM AS A STRATEGY FOR EXPANDING ACCESS: EXAMPLES OF ATYPICAL ANTIPSYCHOTICS

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Background: To ensure the universal and comprehensive access to health care, as guaranteed in the Brazilian public health system, health became a priority of national development policy, combining the enlargement of access with potential innovation, especially for medicines. The establishment of Product Development Partnerships (PDPs) is a strategy for this purpose.

Objectives: To describe the strengthening of the Brazilian health industrial complex through the PDPs and how this can promote the improvement of medicines access in the context of the national public health system.

Methods: We did a descriptive analysis of the results of ongoing PDPs in Brazil, designed by the Ministry of Health (MoH), focused on the medicines used to treat schizophrenia.

Results: In Brazil, 30 PDPs have been established to answer strategic MoH programs, as mental illness, immunization, chronic diseases, AIDS and tuberculosis. Particularly for the treatment of schizophrenia, there are the PDPs of the atypical antipsychotics clozapine and quetiapine. In this setting, the MoH provided a 30.3% increase in access, in terms of units of medication, with an average reduction of 5% of unit value, which means a savings of approximately US$ 32 million for the health system.

Discussion: The Clinical Protocol and Therapeutic Guidelines (CPTG) for the management of schizophrenia, in Brazil, ensures universal and comprehensive access to treatment with typical and atypical antipsychotics. The savings with the PDPs that reduce the treatment costs enables the quantitative increase in medicines distribution, therefore, a successful strategy for ensuring the access to such technologies. In addition, clear results are obtained in the process of technological development, innovation and supply of those products.

Implications: The PDPs are strategies for the strengthening of the Brazilian industrial complex with direct consequences on the provision of universal and comprehensive access to medicines.

756. ADDITIONAL BENEFIT OF NEW DRUGS OVER STANDARD CARE AS BASIS OF REIMBURSEMENT IN GERMANY – A SYSTEMATIC ANALYSIS OF MAGNITUDE OF ADDITIONAL BENEFIT

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Federal Joint Committee. Germany.

Background: A new law for early drug evaluation (AMNOG) came into force in Germany. It aims to regulate reimbursement price on the basis of additional benefit (AB) to standard care. Impact on market access in Germany and on drug reference prices in Europe is expected to be considerable, even comparable to a fourth hurdle.

Objectives: For the assessment process of AB, the German Institute for Quality and Efficiency in Health Care proposed a classification scheme based on magnitude of relative risks (RR) and respective 95%-C.Is in relation to outcomes relevant for patients. We aimed to identify drugs that could be categorized into the highest category of AB (= large).

Methods: A systematic literature search was performed in MEDLINE/EMBASE from 2006 to 2010 for RCTs. During abstract screening, RCTs were included if drugs were tested against placebo or an active comparator and if the upper boundary of 95%-C.I. of effect measures was ≤ 0.85 for mortality or ≤ 0.75 for morbidity outcomes. In a second step, further factors such as indication, type of outcomes, comparator or type of data analysis were extracted.

Results: 5661 publications were identified, screening resulted in 112 published RCTs with at least one large effect were included in the final analysis. Most studies were found for cardiovascular diseases (27%) followed by cancer (21%). 52% of drugs were compared versus an active control. In 60% of the RCTs, the major effect was reported for the primary endpoint (12% for mortality) with additional large effects for secondary endpoints in 13% of those RCTs. However, 19% of the major effects were only derived from composite endpoints (16%), subgroup- (6%) or post-hoc analysis (6%).

Discussion: Reimbursement decisions on pharmaceuticals vary between decision bodies. Due to a lack of "common" thresholds for additional benefit we systematically identified a surprisingly high number of RCTs reporting drug effects of great magnitude. However, those large effects must be evaluated carefully since reporting is still prone to potential bias in the trials or emphasizes often on composite endpoints, subgroup- or post-hoc analyses.

769. ISSUES AND CONCERNS RELATED WHIT THE ENTRY OF GENERIC ANTIVRETROVIRAL MEDICATIONS IN PHARMACEUTICAL MARKET OF HIGH-INCOME COUNTRIES

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Italian Medicine Agency. Italy.

Background: Over the next years, patents of some antiretroviral (ARV) medicines will expiry in the EU.

Objectives: To quantify the expenditure for ARV treatment in Italy, and to estimate the potential impact of the introduction of generic ARV in the Italian pharmaceutical market.

Methods: Using a data-set of pharmaceutical expenditure in Italy, the total expenses for ARVs were analyzed at national level. We then calculated the potential cost-saving for the following generic ARV that will be soon available in Italy: zidovudine (AZT), lamivudine (3TC), nevirapine (NVP) and efavirenz (EFV). We modeled different scenarios with price reduction between 20%-60% of the originators prices.

Results: In 2010, the expenditure for ARV therapies was €500.689.927: the most relevant proportion was attributable to fixed-dose combination (FDC), accounting for €238.826.599 (47.7% of total costs). The percentage of ARV costs related to the use of AZT, 3TC, NVP and EFV was 7.33% (€36.713.056). Assuming the prescriptions of these drugs to be constant in next years, different scenarios of price reduction (from 20% to 60%) for generic drugs showed an estimated cost-saving ranging from 1.5% to 4.4% of total costs. In a sensitivity analysis, assuming that FDC could be partially substituted by single components with generic medicines, cost-saving rises to 5.36-16.08% of total expenses (€26.832.726-80.498.178).

Discussion: The availability of some ARV generics could be an option for safely and effectively cost-saving. In our study, the greater reduction of costs has been estimated by FDC substitution, with the potential for increasing regimen complexity. Further studies have to evaluate safety/efficacy of FDC substitution with generics incorporating both treatment adherence and pharmacoeconomic outcomes.

Implications for the health system/professionals/patients/society: The introduction of generic antiretrovirals represents an opportunity to involve different stakeholders (policy makers/Medicines Agencies/physicians/patients/pharmaceutical industry) in a great effort to combine a patient-centered medicine with the constrained resources for health care.

773. AN EXPLORATORY STUDY TO DEFINE A HIGH-COST DRUG PRODUCTS

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Background: In Uruguay, funding of high cost drugs for general population is provided universally through the National Resources Fund (NRF). The NRF is who largely financed the high-cost drug products, but so far there is no definition of such products in terms of the economic cutoff point, so the decision if NRF should fund a new drug may be controversial. There is very limited information regarding methods to set the price cutoff point for high-cost drug products.

Objectives: To develop an indicator and estimate a value that allows deciding when a drug product is of high-cost in Uruguay.

Methods: The indicator selected was the annual cost per patient or cost per patient for treatment durations < 1 year, considering only the cost of the drug product. Costs were determined for a selected sample of drug products included in the Health System.

Results: The average costs per patient per year or per treatment resulted in 9,168 U.S.dollars (95% [2,064-16,273]) and 22,654 (95% [12,179-33,128]) for the Integrated Providers and NRF, respectively.

Discussion: It is estimated that a reasonable cutoff point can be in the middle point between these parameters calculated: 15,911 U.S. dollars. This amount represents approximately 1.3 GDP per capita (2010 GDP per capita = 11,996 U.S.dollars) so this could be the reference cutoff point. However, it should be noted that the per capita GDP of Uruguay in 2011 could increase significantly (approximately U.S.dollars 15,000), which would alter the cutoff point in absolute values. While GDP per capita can be an interesting indicator, this is not directly related to the price of drugs or health spending so it should be taken into account until a better parameter is identified.

Implications for the health system: More research is needed to develop new indicators that relate more directly with drug products and health costs.

780. ORPHAN DRUGS IN THE EUROPEAN PHARMACEUTICAL POLICY. A FOCUS ON THE EXPENDITURE AND THE UTILIZATION OF ORPHAN DRUGS IN 5 EUROPEAN UNION COUNTRIES

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Background: One of the most challenging problems for pharmaceutical policy is how to pay for very expensive new drugs for rare diseases, known as "Orphan drugs" (ODs).

Objectives: Aims of this work were to compare the expenditure and utilization of ODs among five European Union Countries (France, Germany, Italy, Spain, UK) and identify the ATC group with the major impact on Italian ODs expenditure and utilization.

Methods: European database from IMS and the AIFA internal database were consulted for the period 2009-2010 according to the ODs approved by European Medicines Agency.

Results: In all 5EU both utilization and expenditure increased in the year 2010 compared to 2009 ranging respectively around 13%-28% for the expenditure and around 7%-17% for the utilization. Italy is third after Germany (917 Ml€) and France (828 Ml€) for the expenditure and second after Germany (22 Ml standard units) for utilization. 80% of the ODs authorised by EMA is available in Italy, the remaining 20% is not accessible (marketing reasons). During 2010 Italian expenditure for ODs amounted to 5,5 Ml€, with an increase of 19% comparing to 2009. For the utilization, the value of ODs amounted to 20 Ml standard units, with an increase of 15% compared to 2009. "L" ATC code (antineoplastic) represents the highest expenditure (63% of total ODs) and utilization (60% of total ODs). Within "L" ATC group, Imatinib is the most used molecule (146 Ml € and 8,5 Ml standard units) with an average cost/patient/year of 38,500€ (assuming weight 70kg) ranging from 5,700€ (Anagrelide) and 44,500€ (Nilotinib).

Discussion: Results suggest that ODs expenditure and utilization is rapidly growing up, particularly for some ATC groups.

Implication for the health system/patients: The increase of ODs' utilization is a great challenge for Health Technology Assessment in order to guarantee a balance between patient access and System sustainability.

782. AN HTA APPROACH FOR PRICING & REIMBURSEMENT DECISIONS: THE ITALIAN EXPERIENCE WITH MANAGED ENTRY AGREEMENTS

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Background: To support reimbursement & pricing decisions and to ensure rapid access to new potentially beneficial medicines, payers are adopting innovative HTA-oriented approaches called Managed Entry Agreement (MEAs). AIFA has pioneered in the design and implementation of MEAs for the last two decades.

Objectives: The objective is to describe and quantify AIFA's MEAs used to support decision-making in situations of uncertainty.

Methods: Data on MEAs were retrieved from the AIFA monitoring registries and databases, and analyzed between August 1st 2011 and December 15th 2011.

Results: The management of uncertainty of new medicines/ therapeutic indications (TI) is performed through arrangements based on access with evidence development i.e. "AIFA monitoring registries" which can be associated with outcome based schemes: "Payment by Results (PbR)" or "Risk-Sharing (RS)". To manage utilization, AIFA set "Restricting Notes for Prescription" (RNP), a tool to restrict NHS reimbursability of medicines for a particular condition/disease, and the "Therapeutic Plans" (TP), which guarantee reimbursement only under specialist monitoring. To achieve management of budget impact, financial-oriented schemes are in place: The "Volume-based Agreements" (VbA), a negotiation of volume of sales between AIFA and manufacturers, and the Cost-sharing (CS), a discount on the initial therapy cycle(s) for all eligible patients. The AIFA Registries include 78 TI: 44 refer to oncology, 15 to rare diseases, 7 to diabetes and the remaining to other therapeutic areas. Among 78 TI, 14 were PbR, 12 CS and 2 RS. For the remaining 50 indications, no scheme for reimbursement was applied, but registries were used to monitor post-marketing safety and effectiveness. Furthermore AIFA implemented 32 RNP and a total of 85 VbA and TP for more than 350 medicines.

Discussion: Unlike other European authorities which base reimbursement decisions on thresholds, AIFA implemented an extensive range of HTA-oriented tools to allow healthcare access and budget sustainability.

Implications for the health system/professionals/patients/ society: These strategies ensure proper utilization of standard therapies and guarantee access to most recent innovative medicines.

791. THE BIOTECHNOLOGY MARKET FOR HUMAN HEALTH: ACCESS TO CANCER MEDICATION IN BRAZIL

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The oncology medicine sector (antineoplastic drugs and cytostatic hormone therapies) has been strongly influenced by modern biotechnology, which was initially mainly driven by dedicated biotechnology companies (DBCs). The commercial success of bio-pharmaceuticals has led Big Pharmas to purchase those DBCs that sell biological leaders and/or have important product portfolios in the pipeline. Many of these products are anti-cancer MABs (Monoclonal antibodies) whose high cost makes them less accessible, particularly for populations from poor and developing countries. The high cost of MABs, which is a consequence of market concentration, has posed a crucial question for national health systems, including the Brazilian public health system, known as the Unitary Health System (*Sistema Único de Saúde*: SUS): how can they be incorporated to ensure the treatment of people with cancer without causing inequity, which could lead to the reduction of resources for other health activities, including cancer prevention? This paper seeks to help answer this question and aims to analyse the MAB market and discuss its possible effects on equity within the Brazilian health system. Results demonstrate that SUS only provides one anti-cancer MAB. However, society has demanded that these medicines be available through judicial demands and these in turn have prevented the Ministry of Health from using the government's purchasing power to negotiate lower prices. *Per capita* spending on the purchase of these technologies was US$ 23,000 and US$ 15,000 in 2009 and 2010 respectively. In a country in which the 2008 *per capita* expenditure on health was R$ 559 (US$ 304.7), the State's judicial obligation to supply high cost drugs has serious implications for equity.

837. CONVERSION FROM ORIGINAL TO A GENERIC IMMUNOSUPRESSIVE DRUGS IN TRANSPLANT RECIPIENTS. AN IMPACT ON HEALTH CARE SYSTEM

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Background: Immunosuppressive drugs are great advantage in the care of patients receiving organ transplants. Improved therapeutic strategies have been associated with better patient and graft survival rates. Most of them are expensive drugs and generic alternatives may offer cost advantages. However, generic alternatives must be shown to provide equivalent clinical efficacy and savings for health care system.

Objectives: The aim of the study was to answer the question what are clinical and economical aspects of switching from original to generic drugs in group of patients after kidney and heart transplantation. We also tried to find other impacts on health care system when making decision about such conversion.

Methods: We made systematic review of immunosuppressive drugs in transplant recipients in accordance with Polish guidelines for HTA. We also sent questionnaire about conversion to 47 Polish transplantation centers. We decided to made IDI (Individual In-Depth Interviews) with clinicians who had the biggest experience in area of immunosuppressive switch.

Results: Eleven completed trials involving 545 patients were included in our review. From 47 Polish centers only 6 reported that they have experience with conversion. The key conclusion from both

sources was that decision about switch needs additional visits and rigor monitoring, especially laboratory tests of safety parameters. We calculated total costs of conversion of all Polish patients for National Health Fund as 3.5 million Euro.

Discussion: We concluded that while deciding about conversion of all Polish patients from original to generic immunosuppressive drugs decision maker should take into consideration not only clinical data but also direct costs of switch, possible problems with access to transplantation specialists and ethical issue.

Implications for the health system/professionals/patients/society: Actually in Poland there is a reform of drugs reimbursement system. The conclusions of this study is one of voice in a discussion about immunosupressive drugs financing.

898. MEDICAL TECHNOLOGY IN THE BRAZILIAN SUPPLEMENTARY HEALTH SYSTEM IN 2010-2011

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This work analyzes the supplementary healthcare policies adopted by Brazilian Health System in 2010-2011. Among the actions performed by Agência Nacional de Saúde Suplementar - ANS is the periodical revision of a list of procedures that constitute the minimum obligatory coverage. Data were collected through system applied in the website of ANS for 2 months. In the latest revision (2010-2011) 60 new procedures have been included, 40 considered as true new technology items and 20 already established procedures, added in consonance with national health policies. The main topics investigated were: the definition of clinical protocols, the solution of disputes regarding the indication and coverage of procedures, incorporation of materials and medicines, and the setup of a technical group with representatives of HMOs, beneficiaries and the scientific community, for discussion of health technology issues. The use of health technology assessment tools is of the foremost importance for all these actions, which are detailed in the conclusion by this work. We conclude that the HTA based on on health care system in Brazil is still growing with regard to the quality of health services offered to the beneficiaries.

910. EVALUATION OF DRUGS WITHOUT REGISTRATION AT ANVISA REQUESTED BY JUDICIAL ORDER IN CEARÁ

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Background: The sanitary registration of drugs is the activity for which the health authority evaluates the results of studies of active substance and publishes the specifications established for its use and marketing. This activity is therefore a mechanism of rationalization and qualification of the pharmaceutical market of a country. However, in Brazil is becoming increasingly common to use the judicial order for obtaining the access to drugs without registration, which is opposed to the current health law.

Objectives: Evaluate the drugs without registration at ANVISA requested by judicial order to the State Health Secretariat of Ceará (SESA-CE) in the period 2004 to 2010.

Methods: This is a descriptive, retrospective study. Information was collected from the database of the Pharmaceutical Assistance Coordination SESA-CE.The drugs were evaluated in respect to the year of the request, status of registration, an indication for which it was requested and spent.

Results: In the study period were requested 34 drugs, of which 18 are still unregistered. Of the total of drugs requested 35% were indicated for treatment of rare diseases, especially genetic diseases: mucopolysaccharidosis, Gaucher Disease and Cystic Fibrosis.Spending on the acquisition of imported drugs ranged from R$ 93,043.60 in 2004 to R$ 3,529,887.04 in 2010.

Implications for the health system/professionals/patients/society: The judicial orders of drugs without registration at ANVISA cause a distortion in the National Drug Policy, is opposed to the current health law and contribute to the irrational use of drugs, since it implies the existence of a safe and effective products, registered and marketed after evaluation of the national sanitary authority.

539. COST-EFFECTIVENESS OF DENOSUMAB VERSUS ZOLEDRONIC ACID (ZA) FOR THE PREVENTION OF SKELETAL-RELATED EVENTS (SRE) IN PATIENTS WITH BONE METASTASES FROM BREAST CANCER IN SWEDEN, SWITZERLAND AND PORTUGAL

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Background: The prevention of painful, debilitating and costly skeletal consequences of BM remains an important goal of therapy.

Objectives: Assess cost-effectiveness of denosumab (120 mg Q4W) versus ZA (4 mg Q4W) in the prevention of SREs in women with breast cancer and BM in Sweden, Switzerland and Portugal based on results from a phase III, head-to-head, randomised, double-blind clinical trial (clinicaltrials.gov: NCT00321464).

Methods: A three-state Markov model was developed. In the absence of real-world SRE rates, ZA SRE rate was estimated from the clinical trial and used together with the trial-based treatment effect (1st and subsequent SRE rate ratio) for densoumab versus ZA to estimate the denosumab SRE rate. Overall survival was similar between treatment arms and was assumed equal in the models. For extrapolation beyond the trial duration, overall survival was estimated using generalised gamma parametric distribution. Analyses were based on a lifetime horizon. SRE-related utility decrements were derived from a time-trade-off study. Treatment costs, SRE-related costs and administration costs were based on local data. Costs and outcomes were discounted at 3%.

Results: Denosumab was dominant versus ZA, due to fewer SREs, higher QALYs and lower total costs. Incremental QALY gains of 0.044 were predicted and total cost savings per patient were €4,705, €12,484, and €1,333 in Sweden (9.1 SEK/€), Switzerland (1.20 CHF/€) and Portugal, respectively. Extensive deterministic and probabilistic sensitivity analyses confirmed the robustness of results. Probabilistic analyses indicate that denosumab offers overall cost-savings with a probability of 1.0 in Sweden and Switzerland and 0.98 in Portugal.

Discussion: Denosumab is dominant versus ZA, offering superior efficacy with fewer SREs, improved QALYs and lower total cost. The results are based on the use of trial-based SRE rates, potentially underestimating the annualised SRE rates and value of densoumab.

Implications for the health system/professionals/patients/society: Denosumab represents good value for money in the prevention of SREs in breast cancer patients with bone metastases.

346. USE OF INFORMATION AND COMMUNICATION TECHNOLOGY ICTS IN A CONTEXT OF DISABILITY IN ORDER TO AVOID SOCIAL EXCLUSION

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Poverty levels in which human needs considered basic (physical health and autonomy) can not be satisfied for a long period in time or unintentionally, which affects risk groups. Among them are people with disability and family environment, which suffer from social exclusion process. This situation is an ideal area for the use of information and communication technology ICTs in an atmosphere of exclusion in health. Our objective is underlying the prevalence of disability and the characterization of people with disabilities in the city of Atyra, Paraguay. Methodology: The application area was 61 km from the capital city of Asuncion in City Atyra to take a survey of 102 household with their consent, were determined the sex, age, educational level, type of disability and needs if a family member had it. Visits were made to 102 heads of households with a total of 482 members, 12%was the prevalence of disability, 13% in women, the distribution by age group was 4.2% (0-9 years) 3.2% (10-19 a), 9.1% (20-29 y), 6.6% (30-39 y), 17.4% (40-49 y), 28.6% (50-59 y), 47% (60-69 y) and 37% (70-89 y). The areas affected were: general health14.3%, 12.3% impaired vision and hearing damage. Level of education, 3.4% have university level, 25% work activity. For them, ICTs not only serve to enhance their capabilities, but also to mitigate and compensate for potential limitations, it can solve most accessibility issues, especially for the poor and the disabled population.

944. VIRTUAL SERIOUS GAME TO ASSESS THEORY OF MIND IN CHILDREN: E-MOTION1.0

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Introduction: Virtual reality has emerged as a potentially effective way to provide health care services, and appears poised to enter mainstream psychotherapy delivery. Given the interactive media characteristics and intrinsically motivating appeal, virtual serious games are often praised for their potential in assessment and treatment. Aim: to validate a virtual serious game (eMotion1.0) lead to evaluate emotional facial expression recognition and social skills, components of theory of mind. Emotion 1.0 has two sections: 1) emotional recognition tasks which includes different static and dynamic faces with basic emotions: surprise, anger, fear, happiness, sadness, disgust and neutral; 2) empathy and social skills task contains virtual scenes in which each participant has to answer to different questions related to interpersonal relationships.

Methods: The total sample was composed by 1.014 children classified by age (8-12 years old), gender (male = 505; female = 509) and educational level (3º-6º Primary level). Ten schools from Basque Country and twenty trained evaluators participated in this study.

Results: There are differences in eMotion1.0 scores between groups of children depending on age ($p < 0.01$) and gender ($p < 0.05$). Moreover, there is a moderate significant correlation ($p < 0.05$) between emotional recognition scores of eMotion1.0 and Feel facial recognition test (Kessler, 2002) and Mehrabian´s empathy questionnaire scores (Spanish adaptation, Garaigordobil, 2000).

Conclusion: These results indicate that eMotion1.0 shows concurrent validity with instruments which assess emotional recognition and empathy. Results support the adequacy of eMotion1.0 in assessing components of theory of mind in children.

Acknowledgments: Emotion1.0 has been created in collaboration with VirtualWare. We extend our appreciation to schools, children and evaluators who participated in this study.

158. SCREENING FOR ABDOMINAL AORTIC ANEURYSM (AAA) – QUALITY OF LIFE AMONG PARTICIPANTS

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Background: AAA is an outpouching on the main artery in the abdominal cavity. While mainly without symptoms the major complication of AAA is rupture, which is life-threatening. AAA might be detected by screening and the patient either followed over time or offered an operation, depending on size of the AAA. An HTA on screening for AAA was conducted in 2008, including a review on quality of life. This review will be updated this spring and the results presented at the conference.

Objectives: The objective of the study is to examine how quality of life is affected for participants in a screening program for AAA.

Methods: The work builds on a systematic literature review. A model was developed illustrating the points in time, where it was found relevant to measure quality of life and a review was structured around the model.

Results: Some important results: Screening participation does not seem to have any substantial effect on quality of life. Participants diagnosed with AAA seem to have a poor quality of life before screening participation. Most changes in quality of life are registered within the relatively large group of participants who are diagnosed with a minor AAA (4.3% of all participants and 88% of all diagnosed with an AAA). Some of these minor AAA will never rupture.

Discussion: Participants who are diagnosed with a minor AAA can be caught in a difficult situation. In worse case scenario they will find themselves, participating in a control screening program until they die of another condition. The participants themselves can't do much to improve the condition connected to the AAA.

Implications for the health system: Special attention must be given to the participants diagnosed with a minor AAA if a screening program is implemented.

947. UNBIASED SURVIVAL INFERENCE WITH CROSSOVER DESIGNS IN METASTATIC RENAL CELL CARCINOMA (MRCC) TRIALS

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Background: Cost-utility analysis requires statistically significant survival effect estimates that are unbiased. Trials of progression-free survival (PFS) of targeted agents in mRCC lack such estimates because crossover is permitted upon progression which, in turn, biases survival estimates assumed, but not proven, to be toward the null.

Existing proposals to adjust for crossover in the analysis have not been validated.

Objectives: The aim is to model, using past trials, PFS as surrogate and overall survival (OS) as outcome, and determine the PFS difference ('surrogate threshold effect' STE) needed in a new trial to infer, rather than measure, overall survival.

Methods: A systematic search was made of mRCC trials reporting by-arm median PFS and OS; errors-in-variables regression models were fitted. The intersection of the lower 95% prediction band and horizontal axis is the STE.

Results: The targeted-trial model (9 trials, reliability 0.8) showed an STE of 3.14 months (p = 0.004; R2 = 0.714). The all-trial model failed to demonstrate any STE.

Discussion: Interpreting a new trial as demonstrating an OS benefit requires both that trial PFS difference exceed 3.14 months and that crossover confer a survival benefit. It is possible that late initiation (at progression) of a new agent may not confer benefit if patients are too debilitated and the new agent adds toxicity. One way to ensure that crossover does confer a benefit is to design a 'trial-within-a-trial' second randomization of control arm progressors, crossover versus no crossover. If the trial then shows the needed PFS difference and a survival benefit due to crossover, together these imply an OS benefit. This approach enables unbiased inference of OS.

Implications: The availability of an unbiased OS benefit will enable cost-utility analysis and reduce uncertainty in health technology assessments based on mRCC clinical data. A similar approach may be applicable for trials of other solid tumors.

164. REGISTRIES FOR EVIDENCE GENERATION FOR RARE DISEASES

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In making the right treatments available to the right patients while developing and maintaining a sustainable healthcare delivery system, decision-makers look to make evaluations based on good evidence. Yet the quality of evidence can vary depending on the data available and the methodologies used. Rare diseases, with very small patient populations, often globally distributed, can present a challenge to obtaining sufficient data to generate good evidence. Within a single rare disease cohort, large variations in disease severity and progression, age at diagnosis and national and regional treatment and support service access make generating sufficient evidence difficult. Registries, focusing on a disease, a treatment or a regional population are viewed as crucial for increasing our knowledge of rare diseases and their treatments. This review will look at the strengths and weaknesses of evidence generated from registry data and provide real world examples. Are these data resources appropriate and sufficient for analyzing treatment outcomes, comparative effectiveness, cost-effectiveness? What biases, inherent in this type of observational data, should decision-makers be alerted to when assessing the quality of studies based on registry data for rare diseases? If single data sources, such as a national registry, are too limited, what is the feasibility of combining data sources and what issues arise by doing so? Can registry data expand our knowledge of personalized medicine for patients with rare diseases - that is, needs of specific sub-populations patient groups or patients in specific locations? Good quality evidence is essential to supporting a fair and sustainable healthcare system. The pros and cons, strengths and weaknesses of registry data and methodologies to analyze the data will be described to give decision-makers a framework for assessing the quality of registry data and analyses for rare diseases.

943. ENDOSCOPIC STENTING VERSUS COLOSTOMY FOR THE MANAGEMENT OF MALIGNANT COLONIC OBSTRUCTION (MCO): COMPARISON OF CLINICAL OUTCOMES AND HOSPITAL COSTS

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Objective: Although stenting is increasingly performed, colostomy is considered the gold standard for emergent relief of MCO. The aim of this study was to compare clinical outcomes and hospital costs between colostomy and stenting for management of MCO.

Methods: A retrospective claims analysis of the Medicare (MedPAR) database was conducted to identify inpatient hospitalizations for colostomy or stenting for colon cancer (2006-2008). Outcomes evaluated using MEDPAR were to compare total length of hospital stay (LOS) and costs between cohorts. As MEDPAR is a claims database that does not provide outcomes at a patient level, a single institution retrospective case control study was conducted where each stenting patient was matched with 2 colostomy patients. Outcome measures (institutional data) were to compare rates of technical and treatment success, post-procedure LOS and re-interventions between cohorts.

Results: The MEDPAR data evaluated 778 stenting and 5,868 colostomy hospitalizations. There was no difference in gender, age distribution or comorbidity between groups. Compared to colostomy, median LOS (8 vs. 12 days; $p < 0.0001$) and median cost ($15,071 vs. $24,695; $p < 0.0001$) per claim were significantly less for stenting. Stenting was more commonly performed at urban vs. rural hospitals (84% vs. 16%; $p < 0.0001$), teaching vs. non-teaching hospitals (56% vs. 44%; $p = 0.0058$) and larger institutions (mean bed strength, 331 vs. 227; $p < 0.0001$). The institutional data included 12 stenting and 24 colostomy patients. While both modalities were technically successful, compared to colostomy, the median postprocedure LOS (2.17 vs. 10.58 days; $p = 0.004$) and re-admission rate for complications (0% vs. 25%; $p = 0.01$) were significantly less for stenting.

Discussion: While technical and clinical outcomes of colostomy and stenting appear comparable, stent placement is less costly and associated with shorter LOS. Dissemination of stenting beyond large, teaching hospitals located in urban areas as treatment for MCO is important given implications on patient care and resource use.

616. A SYSTEMATIC REVIEW OF CLINICAL PRACTICE GUIDELINES ON THE TREATMENT OF ALZHEIMER'S DISEASE

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Background: While there is no cure for Alzheimer's disease (AD), several treatments are available for the management of cognitive, psychological and behavioural symptoms. While clinical practice guidelines (CPGs) have become an important resource in clinical decision making, choosing the best recommendations is difficult, since it is not possible to be certain of the guidelines quality. To our knowledge, there are no published systematic reviews of CPGs comparing recommendations on Alzheimer's treatment.

Objectives: To identify CPGs addressing the issue of pharmacological treatment for AD, and carry out a quality assessment using AGREE II in order to provide a summary of the recommendations.

Methods: A systematic search was conducted using PubMED, National Guideline Clearinghouse, TripDatabase, NICE UK and GuíaSalud to identify CPGs for treatment of AD published between

2006 and 2011. Publications addressed to health professionals and using a system for grading recommendations were retrieved an assessed by three independent reviewers using the AGREE II instrument. Recommendations were extracted and compared between guidelines.

Results: Sixty out of 66 documents were excluded for not meeting the eligibility criteria. Five guidelines were appraised as high quality and thus included in the review. Strong evidence supports the use Donepezil, Galantamine, Rivastigmine and Memantine for the treatment of cognitive symptoms. Similarly, there is agreement regarding non-effective treatments. Consensus also exists to recommend a conservative use of antidepressants and antipsychotics.

Discussion: Taken together, this five good quality CPGs from different countries suggest similar recommendations on the pharmacological management of AD. Although it is out of the scope of this review, non-pharmacological treatments play an important role in Alzheimer's treatment and should also be taken into account.

Implications for the health system: Proving health professionals with a synthesis of "do"/ "do not do" recommendations not only facilitates and simplifies clinicians´ work, but also reduces inequalities in patient care.

556. ANALYSIS OF THE ORGANIZING MODEL FOR RESTORATION: EVALUATION OF THE IMPACT THROUGH HEALTH TECHNOLOGY ASSESSMENT IN THE AZIENDA OSPEDALIERO-UNIVERSITARIA OF UDINE

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Background: The present study applies the HTA method in analyzing the hospital food service, comparing the "cart" and the "tray" services. To date, no data are available in the Literature on which of the two methods is preferable.

Aims: To identify tools for a rationalization and improvement of restoration process.

Methods: We reviewed the Literature on HTA data-banks and on the organization of restoration in the hospital setting. We conducted the analysis on prevalence (time/work of catering process) and compared the "cart" and "tray" models on the HTA dimension. We evaluated the perceived service quality in the patients of our Institution and in a regional hospital.

Results: The "tray" system ensures a spare of time in delivering food to the patients, but requires greater resources and is perceived as of "average to low" quality. In the ethical-social and safety analysis, some caring and managing activities era not ensured as time and employment are required to maintain the higher standards of care.

Discussion: The comparison of different HTA dimensions supports the choices of appropriate resources' use. The switch from the "cart" to "tray" food model does not cause a loss of competence, but ensures a spare of time, to be employed in the care and safety of the patients.

Implications for the health system and patients: There is a need to define the level of reinvestment of the time regained from the "lost care" in assisting patients, particularly in managing and monitoring depending patients' alimentation. To maintain high standards of food safety requires attention and time from operators. The time the caregivers spend in patient's care and support has a social cost that deserves to be considered in the health system.