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HEIRES questionnaire: ensuring equality in health research

Cristina Rius[a,b,c,d], Rut Lucas-Domínguez[a,b,e,*]

[a] Department of History of Science and Information Science, University of Valencia, Valencia, Spain
[b] UISYS Joint Research Unit, University of Valencia; Associated Unit Research Institute for Higher Education and Science (INAECU) UC3M-UAM, Valencia, Spain
[c] Spanish National Centre for Cardiovascular Research (CNIC), Madrid, Spain
[d] CIBER de Enfermedades Cardiovasculares (CIBERCV), Spain
[e] CIBER de Cáncer (CIBERONC), Spain

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ABSTRACT

Objective: The inadequate collection, analysis, presentation and dissemination of sex and/or gender disaggregated data leads to persistent gender bias in biomedical research, clinical trials, publications and health information systems which have a negative impact on medical practice. In addition, gender gap persists in many scientific institutions and among researchers, despite various initiatives to promote equality among all professionals involved in research teams. The aim of this study is to create a tool to assess the inclusion of a gender perspective in biomedical research.
Method: Relevant scientific publications on gender inclusion and biomedical studies indexed in the Web of Science were analysed, and guidelines and recommendations developed by leading governmental institutions, funding agencies and academic organisations were also reviewed. A panel of experts then used the Delphi method to identify useful variables for designing a questionnaire on gender inclusion in health sciences research.
Results: For the first time, the questionnaire HEIRES assesses the integration of a gender perspective in a transversal way at all stages of biomedical research, from team composition to study development and dissemination. The final result is an immediate and objective score that allows professionals, institutions and policy-makers to identify strengths and potential areas for improvement in the integration of gender perspective in their research and/or within their organisations.
Conclusions: Identifying gaps in the biomedical research process improves the quality of research centres, teams and studies and bring them closer to a fairer, more inclusive and equitable scenario towards personalised health.

Cuestionario HEIRES: igualdad en la investigación sanitaria

Palabras clave:
Cuestionario
Perspectiva de género
Investigación biomédica
Igualdad de género
Sesgo de género
Asistencia sanitaria

RESUMEN

Objetivo: La recolección, el análisis, la presentación y la difusión de datos de manera inadecuada por falta de desagregación de las variables por sexo o género conducen a la persistencia de sesgos en la investigación biomédica, los ensayos clínicos, las publicaciones y los sistemas de información sanitaria, lo que repercute negativamente en la práctica médica. Además, la brecha de género persiste en muchas instituciones científicas y equipos investigadores, a pesar de las diversas iniciativas para promover la igualdad entre todas las personas que participan en la investigación. El objetivo de este estudio es crear una herramienta para evaluar la inclusión de la perspectiva de género en las investigaciones biomédicas.
Método: Se analizaron las publicaciones científicas relevantes sobre inclusión de género y estudios biomédicos indexadas en Web of Science, así como las directrices y las recomendaciones elaboradas por destacadas instituciones gubernamentales, organismos de financiación y organizaciones académicas. A continuación, un grupo de personas expertas utilizó el método Delphi para identificar variables útiles para diseñar un cuestionario sobre la inclusión de la perspectiva de género en la investigación en ciencias de la salud.
Resultados: Por primera vez, el cuestionario HEIRES evalúa la integración de la perspectiva de género de forma transversal en todas las etapas de la investigación biomédica, desde la composición de los equipos hasta el desarrollo y la difusión de los estudios. El resultado final es una puntuación inmediata y objetiva que permite a profesionales, instituciones y responsables políticos identificar los puntos fuertes y las posibles áreas de mejora en la integración de la perspectiva de género en su investigación o dentro de sus organizaciones.

* Corresponding author.
E-mail address: Rut.Lucas@uv.es (R. Lucas-Domínguez).

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Conclusiones: La identificación de lagunas en el proceso de investigación biomédica mejora la calidad de los centros, los equipos y los estudios de investigación, y los acerca a una sociedad más justa y equitativa.

Introduction

Differences in incidence, mortality, and survival statistics between men and women make it imperative for researchers and health professionals to communicate scientific results disaggregated by sex and/or gender. The final purpose is to enable accurate interpretation and dissemination of the advances in the scientific-medical field, so that they can be extrapolated in an inclusive and safe way to the whole population.[1,2] In this context, the scientific literature has highlighted the importance of examining how science has historically been constructed from an androcentric perspective, that do not democratise the production of knowledge and do not include the voice and experience of all genders.[3] This has resulted in certain biases that have influenced research in biomedicine and health care, including the gender gap in scientific teams and the failure to integrate a gender approach at all stages of research, from design to communication.[4] At present, many clinical trials still lack a gender perspective, as they often do not include or analyse variables that capture the specific inequalities arising from the disadvantaged position of women. Therefore, gender bias in biomedical research persists due to the lack of disaggregated data collection and analysis, the fragmentation of health information systems, and the underrepresentation of women in clinical trials, all of which subsequently influence clinical practice.[2,5] As a result, important data gaps arise from potential sex and gender inequalities in infection rates, disease manifestation and progression, hospitalization, mortality, vaccination, and other related factors.[4] Most strikingly, these variables are often collected but not reported in a transparent or accessible manner, making difficult a meaningful analyses of the interaction between sex, gender, and health.[1] These problems are compounded by implicit constraints on research priorities and a lack of resources to conduct detailed studies that could address health inequities. One proposal to improve this situation would be for research projects to include a section on gender 'principles and values' in the research project.[6]

In this regard, clinically relevant differences in the functioning of the immune system, resistance to antibiotics, the effects of drugs, body composition, or the development of tumors have been identified, so that incorporating the gender perspective into the research process and health care activities would lead to significant advances in diagnostic and therapeutic approaches.[7] The goal is to achieve more personalised care, where health professionals develop clinical strategies, as well as health promotion and disease prevention measures, based on prior scientific activity that takes into account the sex and gender of each patient, including community LGBTQ + .[8] To promote the integration of a gender perspective in research, numerous strategic plans have been launched by governmental institutions, funding agencies and academic structures.[9] The growing awareness of biases related to sex and gender has led to the development of tools such as the Sex and Gender Equity in Research guidelines (SAGER)[1] and the Guidelines for Accurate and Transparent Health Estimates Reporting (GATHER).[10] The SAGER guidelines, published in 2016, are a widely accepted standard for reporting sex- and gender-disaggregated data in scientific research,[1] while the GATHER guidelines, adopted by the World Health Organization (WHO) in 2023, promote ensuring transparency in notifying estimates in global health. WHO adopted SAGER recommendations as GATHER guidelines to improve the collection, analysis and reporting of sex- and gender-disaggregated health data. The endorsement of this guideline by WHO as the global health authority, as well as by the EQUATOR network in 2022[11] and by the International Committee of Medical Journal Editors in January 2024[12] in its recommendations for the presentation of the main types of biomedical studies, constitutes a stimulus for academic publishers and scientific journals, which have included it among their requirements or standards, urging them to improve the quality of scientific publications and reports made with data disaggregated by sex and gender, promoting an update of health policies.[9] In the same vein, an increasing number of health journals are promoting the dissemination of knowledge from a gender perspective.[13]

Quality research requires not only the incorporation of a a gender approach in study design and content of research, but also effective gender equality within research teams. Among the main reasons are social responsibility and equity, scientific excellence and innovation, and the creation of better research teams.[9]

Healthcare, in particular, has historically been a male-dominated field, with women facing significant challenges in entering and advancing their careers. Although the situation has improved in recent decades and the percentage of female biomedical academics now exceeds that of men, it could be even better. The presence of women in scientific workforce has grown but their leadership positions, publications and funding could still improve,[14,15] which limits their ability to carry out large-scale, high-impact projects. In addition, there is a significant gap in publication output and citations, which negatively impacts the advancement of women in science. Moreover, studies show that gender inequality affects manuscript review times, with longer review and acceptance periods for papers authored by women in the first or last position. Increased awareness of this bias could help implement corrective measures.[16] Moving to the cardiovascular field, the paper by Blumer et al.[17] showed that while women's research participation is increasing, their representation in lead author and leadership roles remains limited. In turn, the lack of dedicated time for research is a major barrier for women who also have caregiving responsibilities. This issue is particularly relevant in the fields of oncology and cardiovascular health, where clinical demands can be particularly high.[18] Interestingly, the scientific literature shows that mixed-sex teams are better managed and more efficient than single-sex teams because they are more creative, have a greater diversity of viewpoints, and demonstrate higher quality decision making.[4] In this line, previous studies observed that the disaggregation of results by sex is more common when women are the first authors or when women make up the majority of the authorship.[19]

Many policy initiatives have been developed in recent years to minimise gender bias in science; however, despite progress, health research is still reluctant to fully adopt a gender perspective.[9] Often this is not due to a lack of will, but to a lack of knowledge and tools to analyze or evaluate this situation of inequality.[20] The aim of this study is to develop a questionnaire that will serve as a tool to evaluate and train the inclusion of a gender perspective in health and biomedical research studies, targeting both researchers and health professionals.

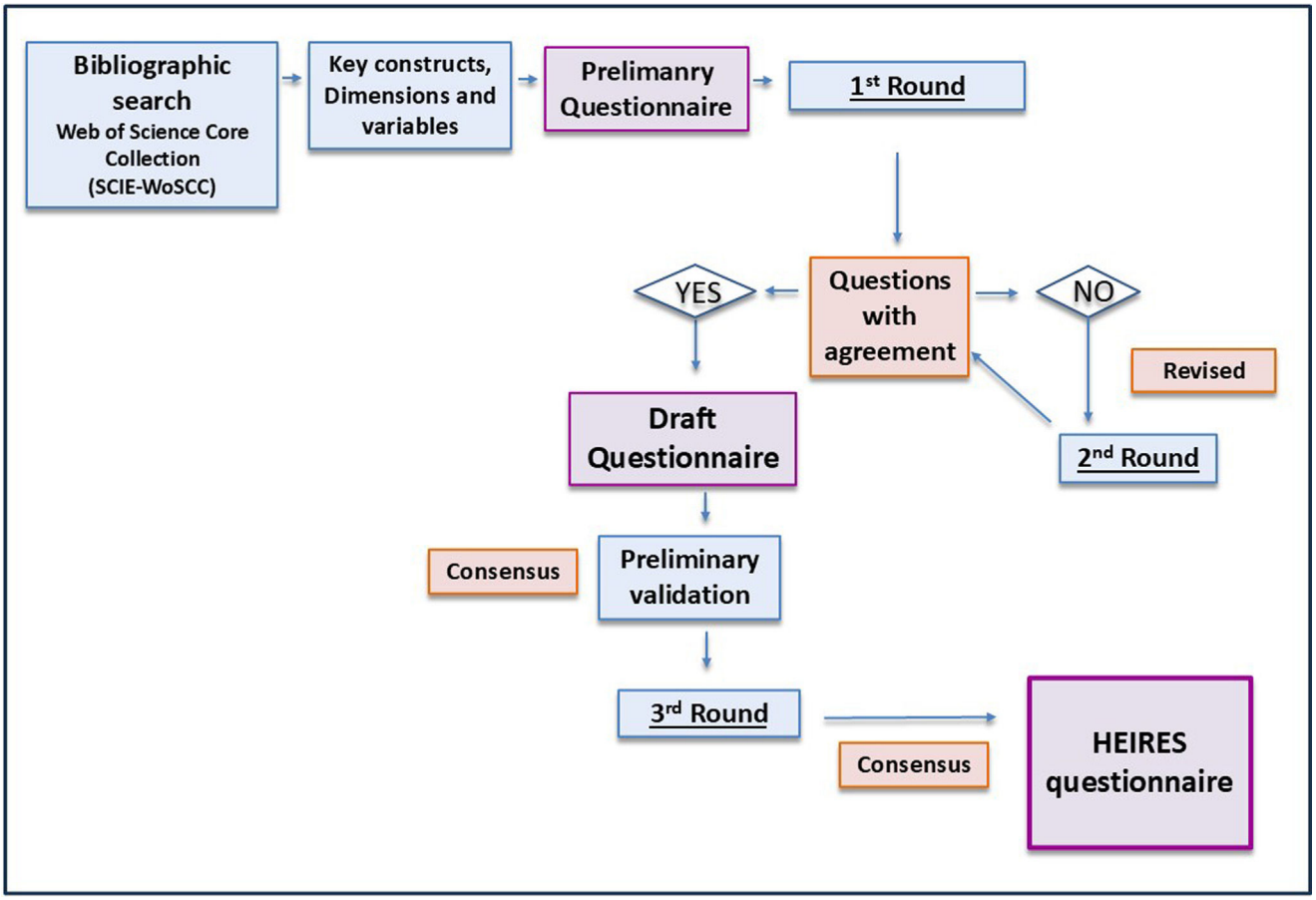

Figure 1. Methodology conducted for the development of the HEIRES questionnaire.

Method

In order to develop the HEIRES (HEalth Inclusive RESearch) questionnaire (Fig. 1), a literature review has been conducted followed by a simplified Delphi method.

Phase 1: bibliographic search

To identify the items to be included in the questionnaire, a bibliographic search was executed in the Science Citation Index-Expanded database of the Web of Science Core Collection (SCIE-WoSCC) on February 15, 2024, using the search equation: ((“gender perspective” OR “gender inclusion” OR “gender equity” (Topic)) and ((*medicine OR health (Topic)) AND ((survey* OR questionnaire* OR checklist* OR toolkit* OR guideline* (Title)). All 51 documents were retrieved and analyzed to extract variables relevant to the study. In addition, the guidelines, recommendations, directives and questionnaires developed by the organisations of the European Commission,[9] U.S.National Institutes of Health (NIH)[21] and WHO[10] were evaluated, as well as those created by the following institutions: Uppsala Universitet,[22] Stanford University (Gendered Innovations),[23] University of Saskatchewan,[24] Canadian Institutes of Health Research (CIHR),[25] Equal4Europe,[26] Gender-Based Analysis Plus (GBA+),[27] National LGBTQIA+health education center,[8] Warwick Interdisciplinary Research Centre for International Development,[28] and the guidelines promoted by the Equator Network[11] and the International Committee of Medical Journal Editors.[12]

Phase 2: simplified Delphi method

After consulting the scientific literature, key constructs were extracted, covering the gender perspective from various angles (equality, gender roles, discrimination, equal opportunities), then several key themes were identified: definition of related terms, researcher characteristics, type of research, research teams, institutional framework, study content, elaboration of scientific document, and dissemination. From this, the dimensions and variables were established (Table 1), on the basis of which a preliminary questionnaire was drafted and evaluated through a simplified Delphi process by a panel of 20 experts (60% women, 40% men) in gender equality, clinical care, biomedical research, psychology and information science (Fig. 1). Following the same procedure, a glossary of basic terms related to gender perspective was developed to ensure that research staff (scientists, academics, technicians, and other professionals responsible for conducting research) completing the questionnaire had adequate knowledge and understanding of the terms sex, gender, gender identity and sexual orientation, which were included as a preamble to the questionnaire.

Each question in the questionnaire that was not agreed upon in the first round (R1) of the Delphi process was revised; the revised questions were then sent to the Delphi panelists for approval in a second round (R2). Each expert took responsibility for making suggestions and recommendations. All recommendations were discussed and approved by all participants. Once the questions (draft questionnaire) were defined, a preliminary validation of the instru-

Table 1
Dimensions and variables extracted from recommendations, guidelines and publications related with gender perspective in scientific research.

Dimension	Researcher: Socio-demographic characteristics	Type of research: characteristics	Research team: characteristics	Institutional framework: committee selection criteria	Climate in the research team	Study content and development	Dissemination of the research, publication in a scientific journal	Preparation of the scientific document
Variables	Age	Field of research	Team: % women	Mixed composition	GP in developing activities	Research line with a gender focus	Gender balances editorial board and scientific committee	Title/Abstract: mentioning sex/gender
		Type of research	Leadership: % women	Gender mainstreaming training	GP in the type of contract	Analysis/justification of sex and/or gender variables	Double-blind peer review	Citation of inclusive literature
	Sex			Inclusion criteria	GP in the work schedule	Consultation of inclusive literature	Guidelines: sex/gender disaggregated data	Wording: sex and gender terminology and inclusive language
	Gender			Consideration of atypical career models	GP training	Representation of sample with gender-balanced (sex/gender 40-60%), social class, ethnicity, religion, functional diversity	Guidelines: Publication of authors' first names	Include and/or justify sex and/or gender variables in study design
	Ethnicity			Consideration of personal characteristics	Leadership with GP		Guidelines: inclusive language	Equal non-binary gender representation
	Type of institution				GP in promotion			In images and results: report sex and/or gender of sample (animals, cells, organ donors or humans)
	Country of origin							Clinical trial: data stratified by participant sex/gender

GP: gender perspective.

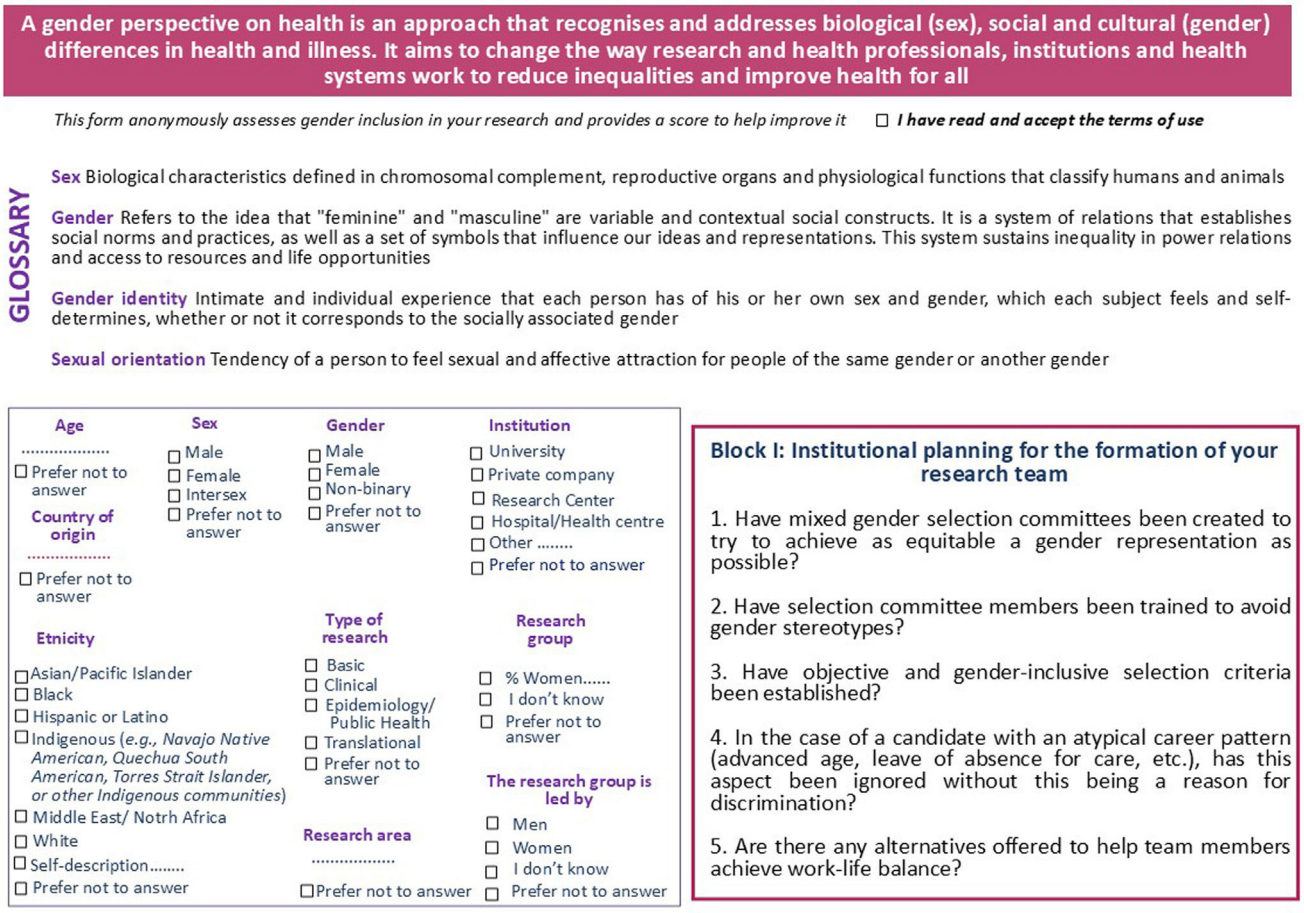

Figure 2. HEIRES questionnaire.

ment was carried out with a small sample to assess its effectiveness, in which 10 participants from the academic and/or research field of health sciences anonymously completed the questionnaire and provided valuable comments. The collected comments were presented to the panellists in a third round (R3) for final approval, resulting in the HEIRES questionnaire. Throughout the process, the leaders were responsible for collecting, reviewing and organising the comments according to their content, proposing changes to the questions where appropriate, removing questions if they were redundant or as suggested by the comments, or moving the questions to the next round.

In the rounds, the strength of consensus of the comments/recommendations was determined as "weak" or "strong", as follows: strong consensus if there is >95% agreement, consensus if there is >75% to 95% agreement, majority agreement if there is >50 to 75% agreement, no consensus if there is < 50% agreement.[29,30]

Results

HEIRES questionnaire creation

The HEIRES questionnaire developed consists of four general sections: A) purpose and glossary section, B) socio-demographic data section, C) thematic section and D) results and scoring.

The purpose and glossary section, located at the top of the questionnaire, refers to the request to complete the survey, describing the intended purpose, the responsible funding agency, and clear and precise instructions to guide respondants through the process. This section ensures that participants understand what they're being asked to do and can provide data suitable for statistical analysis. Information on confidentiality and the estimated time for completion is included. It also includes the glossary of terms with short of gender-related definitions (Fig. 2).

The socio-demographic section gathers information about participants' age, sex, gender, country of origin and ethnicity as well as professional variables (research field identification following the format of the WoSCC, type of institution, women in research team and leadership) (Fig. 2). The questions are primarily closed-ended, with a drop-down list of possible answers. In order to respect the issues raised, the respondent can always choose "I prefer not to answer" without affecting the outcome of the questionnaire. Exceptionally, age and geographical location are formulated as open questions.

The thematic section contains 41 items, related to gender inclussion as the cross-cutting topic, divided into five blocks which summarize the research process: institutional planning for the formation of the research group (block I) (Fig. 2); culture and climate of the research team (block II); content and process of the research (block III); and process for choosing the journal to publish in (block IV) (Fig. 3); and elaboration and writing the paper (block V) (Fig. 4). The questions generated have closed answers: "yes", "no" or "I don't know". In addition, if the respondent does not participate in any the whole research phases of journal selection and paper elaboration commited in the block IV and V, can be selected the option "I do not participate in this process" without affecting the final score. Furthermore, to ensure a more accurate response to the individual questions of block V, it is provided the option of "Not applicable to my research".

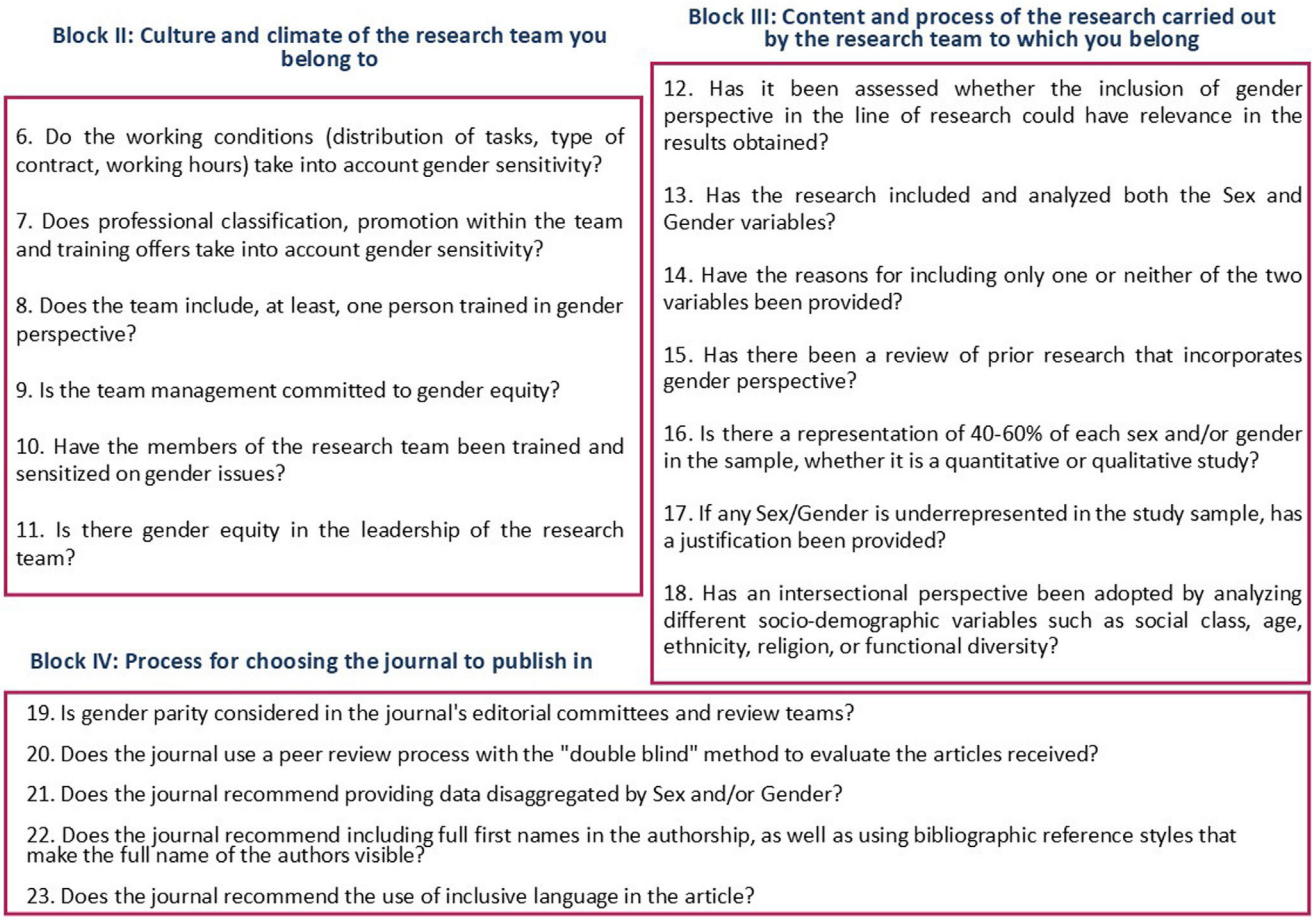

Figure 3. Questions on block II, block III and block IV.

The results section includes a development of a mathematical formula to objectively quantify gender inclusion as a result of the global questionnaire and by each block configuring the research (Fig. 5).

When completing the questionnaire, users will receive a numerical result that provides double feedback. First, an overview of gender integration across the entire scope of biomedical research; second, a detailed breakdown of results for each of the five blocks of the questionnaire.

HEIRES questionnaire dissemination

Questionnaire protection was performed through the official registration at the Intellectual Property Office of the Universitat de València (register number: UV-MET-202414R). An interactive web application freely accessible via the url https://healthinclusiveresearch.com was used to fill in the survey, implementing its availability in six languages (Chinese, English, French, Spanish, Portuguese and Brazilian Portuguese). An associated MySql database ensures that the information collected is stored and managed anonymously and confidentially.

Discussion

The HEIRES questionnaire represents a tool for assessing, raising awareness and identifying improvements in the integration of a gender perspective in each of the phases of biomedical research, from the establishment of the research team within its institutional framework, through the experimental design of the project itself, to the communication of results and the choice of dissemination methods. It has been designed and structured in five thematic blocks comprising a total of 41 questions. In addition, the respondent is asked to provide information on various socio-demographic variables.

The previous SAGER,[1] GATHER[10] and Uppsala Universitet[22] checklists include 12, 16 and 13 items, respectively, on the research data and information to be collected, detailed and reported to ensure transparent health science accessible to all populations, focusing on the description of objectives and funding, data acquisition and analysis, results and discussion. Likewise, the Gendered Innovations Division of Stanford University[23] provides a checklist to ensure that gender differences are recognised and addressed in research design in various scientific disciplines, which, in the field of health, specifies the choice and use of the measurement tool, the type of study, the protocol, analysis and dissemination, and specifies the application of the SAGER guidelines.[1] However, in none of the cases are indicated aspects related to the composition of research teams or journal committees.

Regarding team configuration, the University Warwick Toolkit[28] complements for other dimensions of research team composition which also are vaguely mentioned by the Equal4Europe[26] and Saskatchewan University.[24] At this respect, questionnaire HEIRES includes, in a concise and direct way, items relevant to the gender balance in the institution and in the research groups considering atypical careers and employment conditions for reconciling work and family life. Percentage of women researchers and leaderships are also assessed, helping to identify gaps and weaknesses in career development for each category of biomed-

Block V: Process for the elaboration and writing of your scientific paper

TITLE and ABSTRACT

24. If the study sample used only one Sex, or one Gender, is this fact specified in the Title and/or Abstract of the article?

INTRODUCTION

25. Does the Introduction include previous studies that show the presence or absence of Sex or Gender-related differences and/or similarities?

METHODOLOGY

26. Are the terms Sex and Gender used appropriately in the publication?
27. Are both Sex and Gender variables included in the study design? If applicable.
28. If only one of the two variables is used, are the reasons provided?
29. Does the study sample, if applicable, include representation of non-binary genders?
30. Has an attempt been made to make the representation as equitable as possible?
31. Do studies involving primary cultures or samples derived from humans or animals specify the gender of subjects or donors?
32. Has the sex of the cells been determined and indicated, applying the designations "mixed" or "unknown" only in cases where the sex cannot be determined by any method?

RESULTS

33. Are the data presented stratified by Sex/Gender?
34. Are the analysis results explained based on Sex/Gender, irrespective of whether the results are significant or non-significant?
35. In the case of clinical trials, are data on enrollment, participation, dropout, discontinuation, and loss to follow-up provided stratified by Sex and Gender?
36. In case images are included, is the sex of the animal or the Sex and/or Gender of the person indicated?

DISCUSSION

37. Are the implications that Sex and/or Gender may have on the interpretation of the results of the study analyzed and described?
38. If no analyses have been conducted based on Sex and/or Gender, is this mentioned as a limitation of the study?
39. Have other published works that consider the gender perspective been cited?
40. Has inclusive language been used?
41. To what extent do you think the inclusion of gender perspective in your research has increased over the past 5 years?

Figure 4. Questions on block V.

Percentage	Score = nº Yes × 100 / (nº Yes + nº No)
0-30%	Red defiant! Your research is in resistance mode - give it a gender twist and turn it into a knowledge revolution!
31-60%	Fearless orange! You're on the right track, but you still need that brave touch of gender perspective. Dare to transform your research into an inclusive masterpiece!
61-100%	Bright green! Your research illuminates with the glow of equality. You are a powerhouse of gender perspective! Your efforts shine through inclusivity and sensitivity in your work

Figure 5. Formula for comprehensive and separate gender mainstreaming in biomedical research.

ical research, including specification of the type of research they conduct (basic, clinical, translational or public health), according to the of Canadian Institute of Health Research recommendations.[25] Investing in equal opportunities for all in science and care improves the dynamics and functioning of groups and attracts high-level research personnel.[31] Several initiatives and policies have been implemented to promote gender equality in scientific teams,[9,32] including mentoring programs, specific funding programs for women, and the implementation of gender quotas in R&D calls. However, the effectiveness of these policies varies and needs to be continuously evaluated and improved, making it imperative to create conditions and work cultures that allow all people, regardless of sex/gender, to have enriching careers with equal opportunities for advancement. These efforts attract and retain the best talent, encourages and motivates people to achieve a satisfying work-life balance and improve awareness and attitudes towards equality among health professionals.[33,34]

The HEIRES questionnaire collects data on sex, ethnicity and gender and incorporates the intersectional vision, taking into account socio-demographic variables (social class, ethnicity, religion or functional diversity), both in the sample content analysed in the studies and in the research team and type of institutions involved. In accordance with the NIH-Wide Strategic Plan for Research on Women's Health 2024-2028,[21] this procedure helps identify gaps and supports deeper investigation into traditionally understudied, underrepresented and underreported populations. HEIRES provides direct and objective feedback that quantifies the integration of the gender approach and stimulates a change in the policies of research teams and institutions to contribute to the promotion of re-entry, reintegration and retraining in health research careers,[21] committed to an equitable distribution of opportunities and resources.

Another essential and differentiating feature of the HEIRES questionnaire is its focus on the selection of journals for publication. It emphasizes a preference for journals or publications platforms that promote and uphold gender equality through key variables, such as the composition of editorial teams, the use of full names in the authorship, inclusive literature citation and inclusive language. The HEIRES survey becomes a tool to extend this strategy to gender equality to the composition of other committees for the organising of scientific congresses, societies or scientific tribunals.

The developed checklist offers several key advantages: 1) it provides a concise summary of concepts related to the gender perspective as a tool to help before answering the questionnaire; 2) promotes scientific excellence by supporting the development of

research that supports comprehensive, fair, transparent and truthful results; 3) fosters the formation of stable, diverse, and talented research teams by supporting the inclusion of people with diverse and atypical careers; 4) enables innovation by enhancing the creation of new approaches and better solutions to meet society's needs, and openness to new ideas; 5) advances the recognition and inclusion of gender diversity and the defence of human rights, thus contributing to better, more personalised and tailored health care, which also generates greater social cohesion; 6) raises awareness of gender mainstreaming across various fields, including basic, preclinical and clinical research translational studies and epidemiology and public health, while encouraging reflection on the diversity of patients and challenging stereotypes, taboos and fears in health research participation; 7) is simple and cost-effective requiring no additional resources, prior user training or the hiring of teams of staff specialised in gender or more complex technologies; 8) delivers immediate results through an automatic, objective global score indicating the level of inclusiveness and sensitivity to the gender perspective, along with feedback on a three-level green-orange-red scale; 9) it is multi-level as it can be used at any stage of a biomedical study, even in ongoing studies or those at an advanced stage of development, as it allows each block to be evaluated independently and accurately; and 10) provides a quality certificate that validates and supports biomedical science, research groups and institutions in their commitment to more inclusive and sustainable progress in line with global challenges and the 2030 Agenda,[35] the WHO,[10] and the NIH,[21] and other previously published guidelines.[14]

In conclusion, the HEIRES questionaire is presented as a verification tool to help researchers, scientific groups, institutions, publishers and policy makers to make science inclusive, transparent and fair, to improve biomedicine and bring it closer to the personalisation of each patient, to avoid the default consideration of all individuals as "single sex and gender beings" and to encourage the development of inclusive scientific career models, transforming the view of patients, researchers and health professionals towards a broader and more inclusive vision to improve public health.

Availability of databases and material for replication

Data made available for individuals requesting them.

What is known about the topic?

The SAGER and GATHER guidelines are a starting point for new questionnaires and recomendations to promote gender integration in health research focusing at specific stages, without covering the full research process and the team and organization involved.

What does this study add to the literature?

The HEIRES questionnaire is a unique and easy tool for quantifying the degree of gender mainstreaming. HEIRES covers all phases of research and raises awareness of areas for improvement for individual researchers and health professionals, the scientific group or institution to which they belong.

What are the implications of the results?

HEIRES results endorse researchers and institutions working to improve integrative health sciences and personalised medicine that meets individual patients' needs and ensures equality and social justice.

Editor in charge

Julia Rey-Brandariz.

Transparency declaration

The corresponding author, on behalf of the other authors guarantee the accuracy, transparency and honesty of the data and information contained in the study, that no relevant information has been omitted and that all discrepancies between authors have been adequately resolved and described.

Authorship contributions

C. Rius: conceptualization, data extraction and curation, formal analysis, investigation, methodology, project administration, visualization, writing original draft, review and editing. R. Lucas-Domínguez: conceptualization, data extraction and curation, formal analysis, funding acquisition, investigation, methodology, project administration, visualization, writing original draft, review and editing.

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Conflicts of interest

None.

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