



COMMENTARY

Sex And Gender Equity in Research (SAGER): reporting guidelines as a framework of innovation for an equitable approach to gender medicine

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Abstract

Sex and gender are important determinants of health and influence research findings in a variety of ways, yet they are often overlooked and underreported. This oversight limits the generalizability of research findings and their applicability to clinical practice. The objective of this paper is to point out how journal editors can influence better reporting of sex and gender in research by establishing a methodological framework directly addressing authors of scientific publications, as well as referees, and indirectly affecting all the stakeholders in the research cycle, from funders to policy-makers and citizens. Such a framework is represented by the Sex And Gender Equity in Research (SAGER) guidelines, developed by the European Association of Science Editors (EASE) to encourage a more systematic approach to the reporting of sex and gender in research across disciplines. The paper includes the rationale and basic principles of the SAGER guidelines.

Key words

- sex
- gender
- guidelines
- SAGER
- scientific publishing
- gender bias
- equity

SEX AND GENDER ARE OVERLOOKED AND UNDERREPORTED, WHERE DOES RESPONSIBILITY LIE?

Sex and gender and their interactions play a very important role for the health and wellbeing of individuals and, subsequently, impact public health. Sex and gender are in fact important determinants of health, and influence research findings in a variety of ways. Yet, sex and gender are generally overlooked and underreported in research across disciplines. This oversight limits the generalizability of research findings and their applicability to clinical practice, in particular for women, but also for men.

Drugs, for example, are metabolised differently in men and women, and can result in different adverse event profiles, treatment responses and treatment outcomes. Lack of gender balance in drug trials and the failure to consider sex and gender in design of these trials result in insufficient information being available prior to approval and marketing. Safety tests of car seats, often based on male standards, show different risk for injuries among females; the effect of chemicals

in the environment have been studied predominantly in men, although they can have deleterious effects on women's reproductive health. These are but a few examples that demonstrate that the needs, behaviours and attitudes of women as well as men are important determinants of health and well-being, yet they are often underestimated [1]. Sex- and gender-blind reporting presents a serious threat that limits the generalizability of research and causes an avoidable waste of resources [2]. Any research effort which does not take into consideration sex and gender dimensions (when ever applicable, in the study design, data analyses, results and interpretation of findings) is incomplete and in some cases can harm the "planetary health", a new science that takes into account the interdependence of human and natural systems [3]. The research community needs to become aware of their responsibilities in this regard and this issue should be taken more seriously also in science communication to the general public [4].

Disparities in research participation are well documented (see, for example, the recent article on women

participation in HIV trials [5]), and they are widely debated also in the lay press.

As a matter of fact, scientists must address gender equality in all fields of research also to adjust the balance in male-dominated careers [6].

For a variety of socio-cultural reasons, many scientists still do not have a clear notion of the implications of existing differences, starting from an improper use of terminology: sex refers to a set of biological attributes in humans and animals, usually categorized as female or male [7]; gender refers to the socially constructed roles and influences how people perceive themselves and each other, how they behave and interact, and how power and resources are distributed in society [8].

When sex and gender differences are not considered in research design, it is less feasible to analyse and report the results by sex and gender. Lack of meaningful sex and gender analysis can negatively affect applicability and generalisability of research findings, and limit their future use.

There is an increasing recognition that sex and gender are significantly impacting health and the burden of disease. The WHO Roadmap for action 2014-2019 states the necessity of integrating equity, gender, human rights and social determinants across the WHO in all programmes, offices and key management processes. It specifically emphasizes the need to promote disaggregated data analysis and health inequality monitoring, and to provide guidance on the integration of sustainable approaches, which are gender-responsive [9].

Within this framework, it is important to take action and encourage the endorsement of remedies to address sex and gender inequities in research reporting.

The objective of this short note is to point out how journal editors can influence better reporting of sex and gender by establishing a methodological framework targeting researchers and authors of scientific publications, as well as referees and journal editorial staff, and indirectly affecting all stakeholders in the research cycle, from funders to policy-makers and citizens. Such a framework is represented by the Sex and Gender Equity in Research (SAGER) guidelines, produced by the European Association of Science Editors (EASE) to encourage a more systematic approach to the reporting of sex and gender in research across disciplines.

EDITORS AS AGENTS OF CHANGE AND INNOVATION IN RESEARCH

It is important to recognise that editors, as gatekeepers of science, can act as agents of change and promote innovation through their journal policies influencing what research will be published and how.

Editors play a fundamental role in disseminating research output, striving to guaranty the quality and integrity of published articles, in respect to both ethical and technical issues; to do so, they set rules and journal editorial policies, which are based upon internationally recognised editorial standards, guidelines and recommendations [10]. The instructions for authors are part of such editorial policies and authors need to respect them if they wish to have their articles published in a journal. Also the referees, contributing to the peer review

of journal articles, as well as editorial board members and editorial staff as a whole, should respect and follow the journal rules and policies. Without entering into the details of the complex issues associated with editorial work (e.g., research integrity, replicability, transparency, authorship, conflicts of interest, plagiarism, scientific fraud, peer review, copyright, licence agreements, editorial formats), here we wish to point out how editorial guidelines can directly affect research. Just consider that ethical review procedures and approvals are now a universal requirement for human and animal research, in part because of journal requirements.

The editor's role in the registration of clinical trials will provide the best evidence of how editors can influence research practice. Since 1978, the International Committee of Medical Journal Editors (ICMJE, www.icmje.com) has been developing requirements for publication of biomedical articles according to editorial best practices (since then, the ICMJE publishes and regularly updates the "Uniform requirements", also known as "Vancouver style", recently re-named as "Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals"). In 2005, the ICMJE included a policy requiring investigators to deposit information about trial design into an accepted clinical trials registry before the onset of patient enrolment and included the requirement for registration in the "Uniform Requirements" as a prerequisite for publication. Although registration of public and private trials in the Clinicaltrials.gov was mandated by the US FDA since 2000, before the ICMJE requirement, clinical trial registration was rather the exception; now it is the rule. A study published in 2015 reports the trends in global clinical trial registration in different parts of the world from 2004 to 2013, and clearly shows the sharp increase of registrations after the ICMJE announced in 2004 that it would require registration of clinical trials as a condition for publication [11]. Also the number of publications about clinical trials in Medline increased accordingly.

A wide range of guidelines to improve the quality of research reporting is included on the Equator (Enhance the Quality and Transparency Of health Research) network website (<http://www.equator-network.org/>).

RATIONALE FOR SAGER GUIDELINES

The SAGER guidelines were developed by the European Association of Science Editors (EASE), an international community of individuals and associations from diverse backgrounds, linguistic traditions and professional experience in science communication and editing (www.ease.org.uk). The EASE mission (redefined in 2015) is to improve the global standard and quality of science editing by promoting the value of science editors and supporting professional development, research and collaboration.

Recognizing the importance of reporting sex and gender in research, the EASE established a gender-balanced and diverse Gender Policy Committee (GPC) in 2012, including 13 members from 9 countries representing various types of expertise.

The GPC mission is to:

- advocate better reporting of gender and sex differences and/or similarities in scientific research;
- promote gender mainstreaming (and better science) through inclusion of sex and gender considerations in policies and standards for scientific publishing;
- encourage gender balance among reviewers, on editorial boards, and in editorial offices.

Gender- and sex-sensitive reporting and communication in science will not only contribute to the quality of science, whether in the life, natural or social sciences, but will also enhance evidence-based practices, interventions and opportunities for all genders.

The GPC vision is greater gender diversity in science and publishing practices for enhanced quality, diversity and transparency for science to remain at the forefront of innovation.

A key task of the GPC is to review existing guidelines and propose applicable standards to contribute to sex and gender equity in research, hence the SAGER guidelines [1].

Over a three year period (2012-2015), the GPC developed a set of guidelines following an online survey of 716 journal editors, a literature review on sex and gender policies in scientific publishing (62 journal policies and 25 other sources of published material), expert advice and consultations of EASE members and the broader scientific and editorial community.

The Committee decided to produce a first set of guidelines addressing sex and gender in research conduct and reporting, and will develop a second set addressing gender imbalances within the scientific publishing community.

The SAGER guidelines, published in 2016, have the objective to provide researchers and authors with a tool to standardize sex and gender reporting in scientific publications. They are also aimed at editors as a practical instrument to evaluate research manuscripts and as a vehicle to raise awareness among authors and reviewers. They apply to all research with humans, animals (although strictly speaking all humans are animals) or any material originating from humans and animals (e.g., organs, cells, tissues), as well as other disciplines whose results will be applied to or used by humans such as, for example, mechanics and engineering [1].

A second set of guidelines are expected to be produced in 2016 to address gender inequalities in editorial teams, boards and pool of reviewers. For updated information visit EASE GPC website (www.ease.org.uk/about-us/organisation-and-administration/gender-policy-committee).

HOW CAN AUTHORS AND EDITORS BENEFIT FROM SAGER GUIDELINES?

The SAGER guidelines represent a comprehensive procedure to improve reporting of sex and gender information in study design, data analyses, results and interpretation of findings. They are designed primarily to guide authors in preparing their manuscripts and encourage editors to integrate assessment of sex and gender into all manuscripts as an integral part of the editorial process.

The SAGER guidelines are based on the following basic principles:

- appropriate use of *terminology* (sex versus gender) in any part of the article to avoid confusion;
- *differentiation* of research subjects by sex and gender, and a meaningful analysis to reveal differences and similarities whenever possible in the results, even if not initially expected.

The guidelines envisage specific recommendations for any section of the article according to the widely used IMRAD (Introduction, Material and methods, Results and Discussion) format, as well as for title and abstract (Table 1). The full explanations of such recommendations and additional information are reported in the source article [1].

The guidelines also include a set of questions for authors to facilitate manuscript preparation and allow them to check whether sex and gender issues are properly addressed and reported in their manuscripts. The check list is also available at EASE website: <http://www.ease.org.uk/publications/sex-and-gender>.

The SAGER guidelines also propose a list of questions that can help journal editors in the initial screening of submitted articles, offering an opportunity to contact authors to improve the reporting of sex and gender prior to peer-review, if they have not followed the guidelines. The questions allow editors to consider

Table 1
SAGER recommendations according to the sections of the journal article [1]

Section	Recommendation
Title and Abstract	If only one sex is included in the study, or if the results of the study are to be applied to only one sex and gender, the title as well as the abstract should specify the sex of animals or any cells, tissues, and other material derived from these, and the sex/gender of human participants.
Introduction	Authors should report, where relevant, whether sex and/or gender differences may be expected.
Methods	Authors should report how sex and gender were taken into account in the design of the study, whether they ensured adequate representation of males and females, and justify the reasons for any exclusion of males or females.
Results	Where appropriate, data should be routinely presented disaggregated by sex and gender. Sex and gender-based analyses should be reported regardless of positive or negative outcome. In clinical trials, data on withdrawals and dropouts should also be reported disaggregated by sex.
Discussion	The potential implications of sex and gender on the study results/analyses should be discussed. If a gender analysis was not conducted, the rationale should be explained. Authors should further discuss the implications of the lack of such analysis on the interpretation of the results.

the topic of the study (are sex and gender relevant?), reporting of data (are data reported disaggregated by sex and gender?), design of the study (are sex and gender considered, or is it explained why they are not?), discussion/limitation (are sex and gender analyses or lack thereof mentioned and discussed?). The guidelines encourage editors and peer reviewers to consider these issues during the review process.

FINAL CONSIDERATIONS

Journal editors can play an important role for a more equitable approach to sex and gender issues in research through the development and recommended use of reporting guidelines. This will contribute to increased value and reduce inefficiency in research, a major concern of all stakeholders that can only be approached through collaborative efforts [12].

We strongly recommend authors to become aware of the implications of sex and gender in research and follow the SAGER guidelines for more complete and relevant reporting; we also recommend that editors endorse and adopt the SAGER guidelines by integrating them in their instructions to authors, encouraging authors of all papers to present data disaggregated by sex and, where applicable, to conduct a gender analysis explaining sex and gender differences or similarities adequately. Academic institutions, research funding and research performing organizations as well as regulatory

bodies can also play a role in the collaborative effort towards gender sensitive research by including sex and gender considerations in their policies and procedures. Finally we encourage all readers of this article to use and disseminate the SAGER guidelines and contact us for any suggestions for improvement or collaboration. Reporting guidelines can contribute to create valuable research that makes a difference!

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Conflict of interest statements

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