

Review

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The Sex and Gender Equity in Research (SAGER) guidelines: Implementation and checklist development

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Abstract

Understanding sex and gender differences is fundamental to rigorous and inclusive research, whether studying disease pathophysiology, sociodemographic determinants of health, or the benefits and harms of medical or social interventions. The inclusion of gender-diverse study populations has improved, but the reporting of sex and gender variables in research is still incomplete. The Sex and Gender Equity in Research (SAGER) guidelines, published in 2016, have been widely endorsed, but few scientific journals and organizations have incorporated them into formal editorial guidance and publication policies. To facilitate monitoring of and adherence to the SAGER guidelines in *Lancet* journals, we carried out an informal pilot study and developed a checklist to enable rapid editorial checks, promote uptake of the guidelines by other editors and journals, and raise awareness among peer reviewers and authors. By using this checklist as part of manuscript assessment and peer-review processes, journal editors can support best reporting practices when considering sex and gender as variables, improving the generalizability of the research they publish.

Keywords:

Editorial checklist, editorial process, gender equity, gender reporting, SAGER, sex reporting

Introduction

Historically, scientific research has neglected differences between male and female organisms and has placed a disproportionate focus on male models. Since the turn of the millennium, this male bias has been increasingly recognized as both unscientific and unethical,^{1,2} but the tendency to accept men as the norm in research remains a key source of gender inequity.³

Consideration of sex and gender differences is essential to scientific research.^{3,4}

Underrepresentation or even exclusion of women and gender-diverse people remains a problem in both clinical and social sciences.^{5,6} As such, despite increasing recognition of the importance of sex and gender as health determinants, the gender data gap remains and poses disproportionate risks to women and gender-diverse people—risks that include misdiagnosis and inappropriate treatment.⁶ Sex and gender differences also affect outcomes in engineering, technology, and socio-economic research.^{7,8}

Many research funders now require that sex and gender be balanced among study subjects or that authors provide justification for imbalances; for example, NIH Policy on Sex as a Biological Variable, Trans-NIH Strategic Plan for Women's Health Research.⁹ Regulatory agencies have issued guidance for trial sponsors¹⁰ to include underrepresented groups in clinical trials. There is also increasing emphasis on the need for research participants to accurately represent real-world patient populations with regard to sex and gender, racial identity, ethnicity, age, and sexual orientation, among others.¹¹ These policies are having a positive effect; according to the US Food and Drug Administration's annual report on the geographic, racial/ethnic, and gender diversity of participants in clinical trials,

participation of women in trials increased from 43% in 2015 to 51% in 2019.¹²

In 2015, the recognition that many papers did not report the sex or gender of participants in the study prompted a collaborative group of experts from the European Association of Science Editors (EASE) to develop the Sex and Gender Equity in Research (SAGER) guidelines,⁵ “a comprehensive procedure for reporting of sex and gender information in study design, data analyses, results and interpretation of findings.” Although endorsement of the SAGER guidelines quickly followed, uptake and incorporation of the guidelines into editorial policies have been slow, potentially due in part to concerns about mandating, shortage of time for editors, insufficient awareness, or technical barriers (for example, issues around incorporation of new requirements for authors into electronic submission systems).¹³ Large-scale changes are now under way; publishers such as Elsevier and Springer Nature are in the process of embedding the SAGER guidelines into their editorial and peer reviewer guidelines across hundreds of journals.^{14,15}

Implementation of SAGER guidelines

The Lancet journals observe the general guidance issued by the International Committee of Medical Journal Editors,¹⁶ but our journals do not currently mention sex and gender reporting in their information for authors sections. We have gradually developed in-house guidance on how best to implement the requirements of the SAGER guidelines. For example, we require that numbers of all genders – rather than of only one gender – be reported in tables of demographic data, and we encourage authors to provide information on how sex or gender data were collected and what options were provided for participant self-selection.

In 2021, the editorial teams of *The Lancet Rheumatology*, *The Lancet Haematology*, and *The Lancet Psychiatry* launched a pilot programme with the intention to be more vigilant about the reporting of demographic data by biological sex, gender, and ethnicity and to request that authors add sex-disaggregated or gender-disaggregated data for outcomes, adverse events, and patient-reported outcomes where appropriate.^{17,18} As part of the pilot programme, editors at *The Lancet Rheumatology* and *The Lancet Haematology* monitored compliance with the SAGER guidelines by all primary research articles and encouraged authors to report outcomes and adverse events' data disaggregated by sex and gender (typically included in appendices). It was left to the authors' discretion whether to add these data, acknowledging that this is not always appropriate or informative (for example, if the numbers were prohibitively small). The overriding goal of the pilot programme was to gauge both the feasibility of incorporating the SAGER guidelines into existing editorial workflows and the willingness of authors to comply with the additional requests.

At *The Lancet Rheumatology*, the editors focused on five categories: (1) inclusion of sex and gender data in the abstract, (2) inclusion of all reported sex or gender categories in tables presenting demographic data, (3) inclusion of sex-disaggregated or gender-disaggregated adverse events' data, (4) inclusion of sex-disaggregated or gender-disaggregated patient-reported outcome data, and (5) inclusion of analyses by sex or gender. As a proxy for author willingness, we calculated the proportion of original research articles that fulfilled these five categories before (January–May 2021 issues) and after (June 2021 – August 2022 issues) the publication of an editorial announcing our pilot programme.¹⁷ We did not include a formal measure of feasibility at this stage,

such as an analysis of the additional time required by editors to screen manuscripts and request data from authors, and for our production team to modify display items.

On the whole, authors were receptive to our requests and were willing to engage in a productive discussion with the editorial team about whether and how to incorporate sex/gender-disaggregated data into their reports. Of 56 relevant articles published in June 2021 – August 2022 issues, 46 (82%) included sex/gender data in the abstract, compared with none of the 20 articles published in January–May 2021 (Figure 1). For papers that reported adverse events, the inclusion of sex/gender-disaggregated data increased from 0% (0 of 13) of articles published in January–May 2021 issues to 28% (5 of 18) of those published in June 2021 – August 2022 issues. Likewise, articles that incorporated analysis by sex or gender increased from 5% (1 of 20) to 41% (24 of 59 articles). No studies that reported patient-reported outcomes included sex/gender-disaggregated data, either before or after announcement of the pilot programme, although the numbers of qualifying articles were small ($n = 3$ before vs $n = 6$ after). By contrast, the proportion of papers that included data for all sexes or genders in demographic tables was already high before we announced the pilot programme, and the proportion increased after the programme commenced (Figure 1).

Ultimately, to produce meaningful data, sex and gender considerations must be incorporated into the design of new trials and studies (and the statistical analyses associated with the studies). Nonetheless, efforts to improve the reporting of ongoing and completed studies represent a step in the right direction and will hopefully raise awareness among authors, regulators, and policymakers.

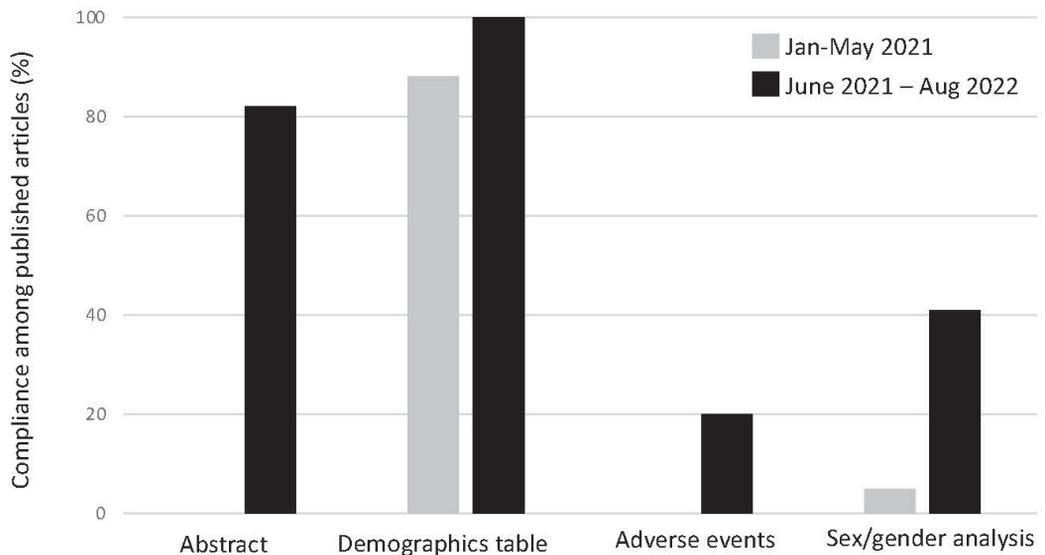


Figure 1. SAGER guideline compliance among articles published in *The Lancet Rheumatology*. Percentage of articles published in January–May 2021 (pre-pilot) and June 2021 – August 2022 (post-pilot) that reported sex/gender data in the abstract, separate data lines for individual sexes/genders in demographics tables, and sex/gender-disaggregated adverse events data and incorporated sex/gender into data analysis.

Development and use of SAGER checklist

As the pilot programme proceeded, we realized that implementation of the SAGER guidelines and monitoring compliance with them would be facilitated by a checklist. We therefore transformed the table from the original SAGER article⁵ into a list of points following the organizational structure of the [CONSORT checklist](#).¹⁹ We created two checklists, one for studies including human participants (Table 1) and one for studies that do not include human participants (Table 2), such as those in the fields of applied science and cell biology.

We also included requirements that went beyond the original SAGER table, as tested in the pilot study by the three *Lancet* journals, such as including data on the gender or sex of all participants in both the abstract and the baseline demographics table and adding sex and gender-disaggregated data and analyses to the appendix, regardless of outcome or whether these data and analyses were pre-specified.

The SAGER checklist should be made available to authors, with guidance on the reporting on sex and gender data clearly outlined in a journal's "Information for Authors." Providing authors with clear instructions will help to raise awareness of the importance of considering sex and gender in research and will help to clearly communicate the expectations of the journal.

From an editorial perspective, the SAGER checklist could be used at different stages of peer review and publication, depending on the workflow of the journal. At this stage, *Lancet* journals are using the checklist after the initial peer review has been completed and authors are invited to submit a revised manuscript; the editors communicate requests related to sex and gender reporting in the decision letter to authors. Ideally, the checklist would be used to screen manuscripts *before* commencing peer review, given the importance of having sex and gender data and analyses reviewed by experts. This

Table 1. SAGER guidelines checklist - studies with human participants			
Section/ Topic	Item number	Checklist item	Reported on page number
General	1	The terms sex/gender used appropriately	
Title	2	Title specifies the sex/gender of participants if only one included	
Abstract	3a	Abstract specifies the sex/gender of participants if only one included	
	3b	Study population described with gender/sex breakdown*	
Introduction	4a	If relevant, previous studies that show presence or lack of sex/gender differences or similarities are cited	
	4b	Mention of whether sex/gender might be an important variant and if differences might be expected	
	4c	The demographics of the study population with regard to sex/gender (eg, disease prevalence among male/female study participants) are outlined*	
Methods	5a	Method of definition of sex/gender (eg, self-report, genetic testing)	
	5b	Description of how sex/gender was considered in the design, whether authors ensured adequate representation of male and female study participants, justification of the reasons for any exclusion of male or female participants, or explanation if not considered. Justification of other sex/gender-specific interventions of study designs (ie, mandating contraception for women). * Explicit reporting of the scientific rationale for contraception requirements and exclusions for pregnancy and lactation should be required*	
Results	6a	Study population description with complete gender/sex breakdown for all categories considered*	
	6b	Where appropriate, data presented disaggregated by sex/gender, and sex/gender differences and similarities are described	
	6c	Sex- and gender-based analyses reported regardless of outcome (in main paper if pre-specified; otherwise in appendix)*	
	6d	For clinical trials, adverse event data disaggregated by sex/gender (in main paper if pre-specified; otherwise in appendix)*	
	6e	Patient-reported outcome data disaggregated by sex/gender (in main paper if pre-specified; otherwise in appendix)*	
	6f	For epidemiological studies, the effects of other exposures on health problems examined for all genders and analysed critically from a gender perspective	
	6g	Table 1 includes separate rows for male sex/gender, female sex/gender and other categories if collected*	
Discussion	7a	Potential implications of sex/gender on the study results and analyses, including the extent to which the findings can be generalized to all sexes/genders in a population	
	7b	If a sex/gender analysis not done, a rationale is given and implications of the lack of such analysis on the interpretation of the results are discussed	
Adapted from SAGER guidelines. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Research Integrity and Peer Review 1, Article number: 2 (2016) https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0007-6 . *These points extend beyond the original SAGER table.			

Section/ Topic	Item number	Checklist item	Reported on page number
General	1	The terms sex/gender used appropriately	
Title	2a	Title specifies the sex of animals or any cells, tissues, and other material derived from these	
	2b	In applied sciences (technology, engineering, etc.), the title indicates if the study model was based on one sex/gender or the application was considered for the use of one specific sex/gender	
Abstract	3a	Abstract specifies sex of animals or any cells, tissues, and other material derived from these	
	3b	In applied sciences (technology, engineering, etc.), the abstract indicates if the study model was based on one sex/gender or the application was considered for the use of one specific sex/gender	
Introduction	4a	If relevant, previous studies that show presence or lack of sex or gender differences or similarities are cited	
	4b	Mention of whether sex/gender might be an important variant and if differences might be expected	
Methods	5a	In cell biological, molecular biological, or biochemical experiments, the origin and sex chromosome constitutions of cells or tissue cultures are stated. If unknown, the reasons are stated	
	5b	For studies testing devices or technology, explanation of whether the product will be applied or used by all genders and if it has been tested with a user's gender in mind	
	5c	If relevant, description of how sex/gender was considered in the design	
	5d	For in-vivo and in-vitro studies using primary cultures of cells, or cell lines from humans or animals, or ex-vivo studies with tissues from humans or animals, the sex of the subjects or source donors is stated (except for immortalized cell lines, which are highly transformed)	
Results	6	For studies using animal models, present a sex breakdown of the animals*	
Discussion	7	If relevant, potential implications of sex/gender on the study results and analyses, including the extent to which the findings can be generalized to all sexes/genders in a population	

Adapted from SAGER guidelines. Sex and gender equity in research: rationale for the SAGER guidelines and recommended use. *Research Integrity and Peer Review* 1, Article number: 2 (2016) <https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0007-6>.
*These points extend beyond the original SAGER table.

approach would also alleviate concerns about the potential of new reporting requirements introduced at the revision stage to increase the burden on peer reviewers (for example, by requiring additional rounds of review). However, enforcing the SAGER guidelines before peer review might create a workflow bottleneck, depending on the proportion of compliant submissions.

Every point in the checklist might not be relevant to every study. Ideally, these points

should be considered at the stage of study design rather than at the time of reporting results. For studies that did not incorporate sex and gender dimensions in their design, sex-disaggregated or gender-disaggregated data and analyses should be discussed appropriately and interpreted with caution in case of lack of power to address these issues in a statistically meaningful way. Nonetheless, these data can still be illustrative and hypothesis-generating, which is why we believe that their inclusion in the appendix

of the paper is useful and potentially informative.

Discussion

Our efforts to implement the SAGER guidelines into our published articles were successful, and we hope that use of the checklist as part of the peer-review process (1) will help journal editors to contribute to standardizing terminology, (2) will support best reporting practices for inclusion of sex and gender as variables to ensure that sex/gender-specific eligibility criteria are justified, and (3) raise awareness in the community.

There have been other recent strategies implemented by journal editors to raise awareness and create opportunities for authors to disclose details on inclusion and diversity in research more generally. Since January 2021, Cell Press journals are inviting authors to complete an [inclusion and diversity form](#) that addresses not only the diversity of the scientific content of the paper but also that of the authorship and the contributions the authors made to the research. On the basis of the answers provided, authors have the option to include an inclusion and diversity statement in the published paper. The objective is to increase transparency in research conduct and reporting and to raise awareness of diversity and inclusion in academia by highlighting those publications with statements as a best practice.²⁰ Similarly, for articles published in the *New England Journal of Medicine*, authors are now required to prepare a supplementary table that provides background information on the disease, problem, or condition and the representativeness of the study group to be posted with the article at the time of publication online.¹¹ These new requirements represent a major step forward with regard to the transparency of research design and an increased focus on representativeness of patient populations.

A complex interplay exists between sex and gender and other dimensions of identity that contribute to inequality. Inclusive research and intersectional medicine should strive to understand how different aspects of identity – sex, gender, race, ethnicity, sexual orientation, disability, and socioeconomic and cultural factors – affect individuals. In this regard, the SAGER checklist can provide a model to accompany future iterations of the SAGER guidelines that integrate sex and gender with other relevant dimensions of identity to capture how the intersections affect health outcomes.

Data and data science are increasingly shaping our world and bringing about wide-ranging changes in research and health care. There is an urgent need to improve the integration of different dimensions of identity, including sex and gender, in data science. Although artificial intelligence has promised to revolutionize research output, these algorithms are only as good as the data on which they are trained. For example, when the assumption that the study cohort represents the target population is incorrect, existing biases can be exacerbated and incorrect associations made. Many examples exist of diagnostic algorithms that performed poorly when tested in women or people of colour because the algorithms had been developed using data sets skewed by sex or race;^{21,22} failure to use representative data sets affects all underrepresented identities and limits the applicability of the research. The SAGER checklist could be adapted for this type of research, but in its current format, it already provides key items to help make conclusions on the representativeness of the data and applicability of algorithms.

The realization of research that is truly inclusive starts with the study design.

Enforcing new requirements in study design will require the endorsement of funders, researchers, institutional review boards, and other organizations that produce data, as well as support from policymakers, advocates, and society as a whole.^{18,23,24}

Until intersectional research becomes the norm, we hope this checklist will facilitate reporting according to the SAGER guidelines by authors and scientific editors. Science is for everyone, and comprehensive reporting of sex and gender will highlight where studies are inadequate in their consideration of inclusivity.

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