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Sex and gender reporting

Why does it matter?



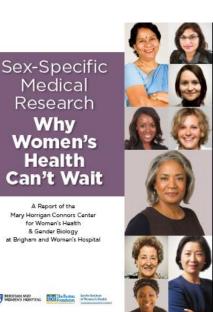
Men and women are not the same

They experience disease differently and respond to treatment differently, e.g. women who smoke have a higher risk of coronary heart disease than do men who smoke (Lancet 2011: 378: 1297-305)

Inclusion of women in clinical trials was mandated by the US National Institutes of Health in 1993

BUT

In 2014, the Mary Horrigan Connors Center for Women's health and gender biology at Brigham and Women's hospital noted that sex differences are frequently excluded or inadequately addressed, especially in early stage research









ICMJE Recommendations updated (shown here in bold) Dec, 2016

Selection and Description of Participants "Because the influence of such variables as age, sex, or ethnicity is not known at the time of study design, researchers should aim for inclusion of representative populations into all study types and at a minimum provide descriptive data for these and other relevant demographic variables. Ensure correct use of the terms sex (when reporting biological factors) and gender (identity, psychosocial or cultural factors), and, unless inappropriate, report the sex and/or gender of study participants, the sex of animals or cells, and describe the methods used to determine sex and gender"

Results "Separate reporting of data by demographic variables, such as age and sex, facilitate pooling of data for subgroups across studies and should be routine, unless there are compelling reasons not to stratify reporting which should be explained"

Discussion "Discuss the influence or association of variables, such as sex and/or gender, on your findings, where appropriate, and the limitations of the data"



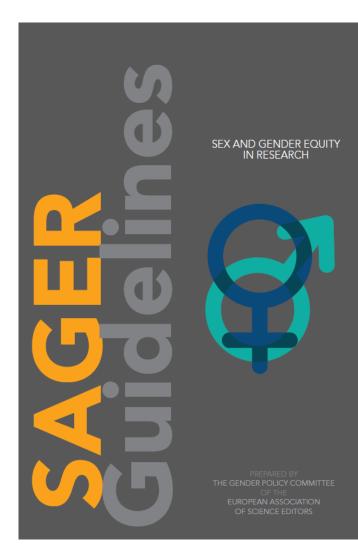


To help authors, peer reviewers and editors address this problem, the European Association of Science Editors developed the SAGER Guidelines – Sex and Gender Equity in Research

The rationale for the SAGER Guidelines and how they should be applied were described in

Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use Shirin Heidari, Thomas F. Babor, Paola De Castro, Sera Tort and Mirjam Curno *Research Integrity and Peer Review*. 2016. 1:2 DOI 10.1186/s41073-016-0007-6



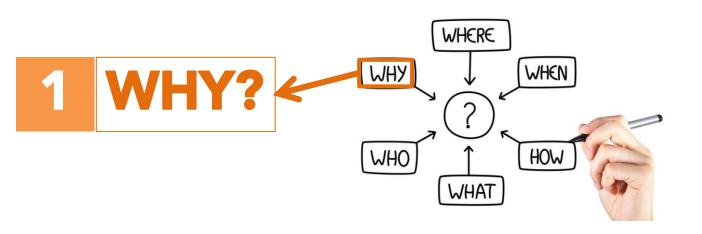


UNDERSTANDING SAGER Reporting Guidelines





Gender Policy Committee EASE European Association of Science Editors

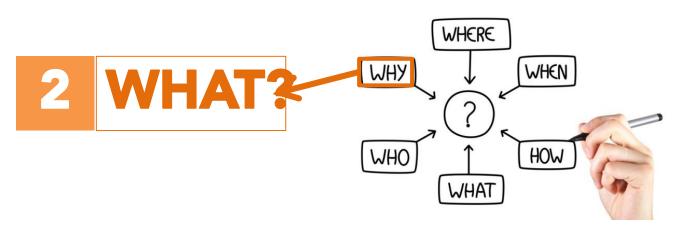




SEX AND GENDER MATTER

Rigour Replicability Transparency Inclusion

Without sex and gender based analysis, the generalizability of research findings and their applicability to clinical practice are limited, in particular **for women, but also for men**

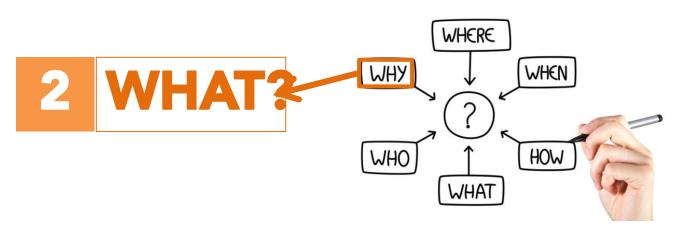




SEX IS BIOLOGICAL

Chromosomes Gene expression Hormones Anatomy



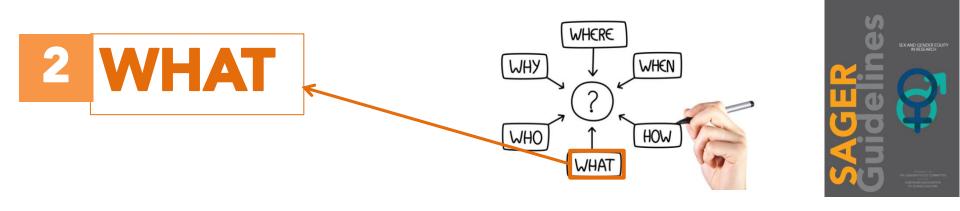




GENDER IS

Stereotypes Norms Roles Behaviours Identities



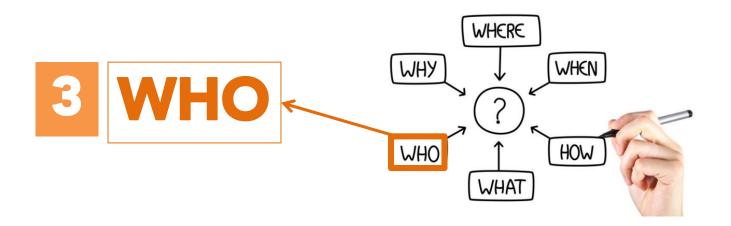


GENERAL PRINCIPLES

Authors should use the terms **sex and gender** carefully to avoid confusion.

Where the subjects of research comprise organisms capable of **differentiation by sex**, the research should be designed and conducted in a way that can reveal sex-related differences in the results, even if these are not expected.

Where subjects can be **differentiated by gender** (shaped by social and cultural circumstances), the research should be conducted similarly at this level of distinction.



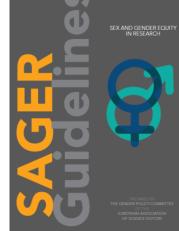


AUTHORS, PEER REVIEWERS AND

Also organizations that fund and conduct research, policy makers, society







They will help authors, editors and

Use the correct terminology (sex or gender)

Improve study design and reporting

Improve generalisability and correct implementation of research findings





At all stages of research

Study design and analysis

Reporting and publication

Implementation





SAGER reporting guidelines in practice

Recommendations per section of the article

Recommendations for editors

Authors' checklist for gender-sensitive reporting



SAGER Recommendations per section

1. 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 or gender, the title and the abstract should **specify the sex** of animals or any cells, tissues and other material derived from these and the **sex and gender of human** participants

2. Introduction

Authors should report, where relevant, whether sex or gender differences may be expected



3. 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

SAGER Recommendations per section



4. 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.

5. Discussion

The potential implications of sex and gender on the study results and analyses should be discussed. If a sex and gender analysis was **not** conducted, the rationale should be given. Authors should **discuss the implications** of the lack of such analysis on the interpretation of the results.





Research approaches

Are the concepts of gender and/or sex used in the research project?

If yes, are the concepts of gender and/or sex defined explicitly? Is it clear what aspects of gender and/or sex are being examined in the study?

If no, do you consider this to be a significant limitation? Given existing knowledge in the relevant literature, are there plausible gender and/or sex factors that should have been considered?

Heidari et al. *Research Integrity and Peer Review*. 2016. 1:2 DOI 10.1186/s41073-016-0007-6



Where to find more about the SAGER Guidelines?

Heidari et al. *Research Integrity and Peer Review*. 2016. 1:2 DOI 10.1186/s41073-016-0007-6

Shirin Heidari TED talk: Why sex and gender matter in research 5 March 2018

Endorse the SAGER Guidelines

We encourage endorsement by all those involved in the scientific enterprise and in communication and explanation of science and scientific achievement, including journal editors, researchers, broad media and broadcasters.

EASE Gender Policy Committee

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