Summer School: How to be a Peer reviewer?

University of Warwick, 10-14th September 2018

Day 2 - Key considerations for reviewers

Sex and gender dimension in peer review: can you be SAGER?



Paola De Castro, Director of the Publishing Unit Istituto Superiore di Sanità, Rome (Italy)

University of Warwick • Summer school: How to be a peer reviewer • September 10-14, 2018



Talk about...

1 Why SEX and GENDER matter

2 *Editors' responsibility* as science keepers and agents of change



How the **SAGER** guidelines can help scientists (authors, editors, referees) to address the issue

Research Integrity and Peer Review

REVIEW

Open Access

CrossMark

Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use

Shirin Heidari¹, Thomas F. Babor^{2*}, Paola De Castro³, Sera Tort⁴ and Mirjam Curno⁵

Abstract Background: Sex and gender differences are often of ation and Here is the scientific reporting, as well as in general science com ability of research findings and their applicability to clinical pra This article describes the rationale for an international set of quid ch to the whole story, reporting of sex and gender in research across discip Methods: A panel of 13 experts representing nine co ries of editors, teleconferences, conference presentations and a 2-da but we will scientists and other members of the international pul a literature search on sex and gender policies in scientific publis Results: The Sex and Gender Equity in Research (SAC discover it for reporting of sex and gender information in study design, data a Conclusions: The SAGER guidelines are designed pri uscripts, but step by step they are also useful for editors, as gatekeepers of scie r into all manuscripts as an integral part of the editorial proces Keywords: Sex, Gender, Guidelines, SAGER, Scientific research, scientific publishing, Gender bias, Equity

Background

Sex and gender are important determinants of health and well-being. Sex refers to a set of biological attributes in humans and animals that are associated with physical and physiological features including chromosomes, gene expression, hormone function and reproductive/sexual anatomy [1]. Sex is usually categorized as female or male, although there is variation in the biological attributes that constitute sex and how those attributes are expressed.

Gender refers to the socially constructed roles, behaviours and identities of female, male and gender-diverse people [1]. It influences how people perceive themselves and each other, how they behave and interact and the distribution of power and resources in society. Gender is

* Correspondence: babor@uchc.edu

³Department of Community Medicine, University of Connecticut School of Medicine, Farmington, CT 06030-6325, USA Util bit of when a first particular is a when and of the anticle

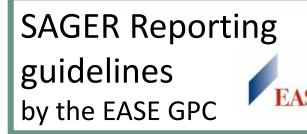
Medicine, Farmington, CT 06030-6325, USA Full list of author information is available at the end of the article usually incorrectly conceptualized as a binary (female/ male) factor. In reality, there is a spectrum of gender identities and expressions defining how individuals identify themselves and express their gender. A glossary of terms is provided in Appendix 1 to define the meaning of sex, gender and related terms.

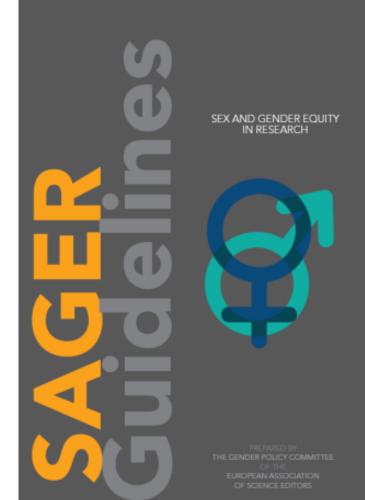
Sex and gender interactions influence health and wellbeing in a variety of ways. They both impact environmental and occupational risks, risk-taking behaviours, access to health care, health-seeking behaviour, health care utilization, and perceived experience with health care, and thus disease prevalence and treatment outcome. In addition, it is well-known that pharmacokinetics and pharmacodynamics of pharmaceutical agents differ between sexes, resulting in differential adverse event profiles and further impacting treatment outcomes. Thus, sex and gender are critical determinants of health [2].



0.2016 Heldah et al. Open Access This ancicle is distributed under the terms of the Creative Commons Ambundon 40 International License (http://creativecommons.org/licenses/by/40/), which permits unsetzicted use, distribution, and septoduction in any modium; provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons Fublic Domain Deduction waker therefore a creative Commons Fublic Lomain beduction waker and therefore accessing 100 anytics to the data mark exactly link to the Creative Commons Public Domain Deduction waker cared to the data mark exactly link to the clean wake exactly link to the data mark exactly link to the data mark exactly link to the accessing to the data mark exactly link to the data mark exactly

University of Warwick • Summer school: How to be a peer review er







established in 2012 in recognition of the gender bias in science and science communication and the need to improve sex- and gender-sensitive reporting in science

EASE Gender Policy Committee

INFO

http://www.ease.org.uk/about-us/organisation-andadministration/gender-policy-committee

University of Warwick • Summer school: How to be a peer reviewer • September 10-14, 2018



GPC activity



Work to advance **gender- and sex-sensitive reporting** and **communication** in science

- → **better science**, whether in the life, natural or social sciences
- → enhanced evidence-based practices, interventions and opportunities, for both women and men
- → foster **responsible research** and **innovation**

The EASE GPC has adopted the acronym **SAGER** to express its work

Sex And Gender Equity in Research

SAGER Guidelines – Gender equity in the editorial workforce Networking, Advocacy, Dissemination - Monitoring and evaluation



The starting point Sex and gender matter

Sex and gender are **important factors** in **any field of science** and **influence** many aspects of our lives.

Yet, academics, researchers and the wider society have a **different understanding of gender issues**, and do **not always have a clear notion** of the **implications** of sex and gender based differences, starting from an improper use of terminology.



The Gender Dimension in Research

How confident are you about...

- Sex and gender (definitions)?
- Gender identity?
- Sex- and gender-based analysis
- Sex-disaggregated data?

2 minutes to discuss it with your neighbours

Starting from TERMINOLOGY

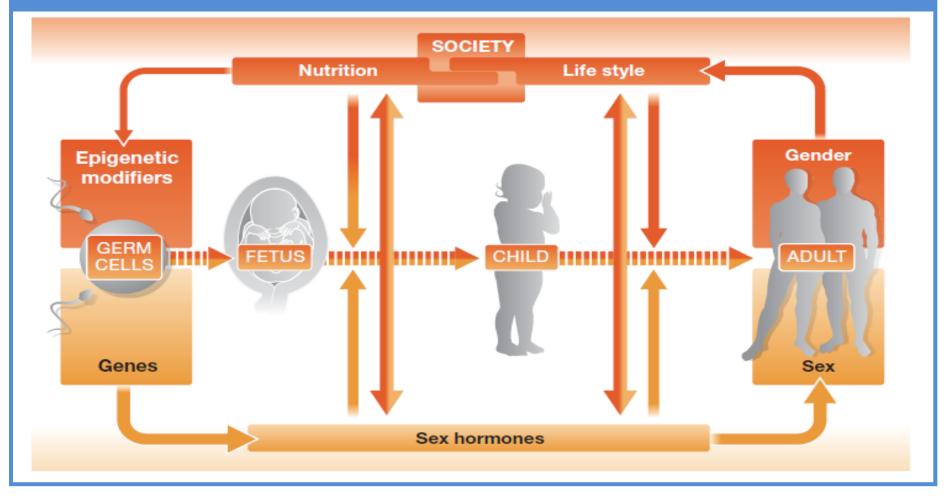
Sex refers to a set of biological attributes in humans and animals that are associated with physical and physiological features including chromosomes, gene expression, hormone function, and reproductive/sexual anatomy.¹ Sex is usually categorized as female or male, although there is variation in the biological attributes that constitute sex and how those attributes are expressed

Gender refers to the socially constructed roles, behaviours and identities of female, male and gender diverse people.¹ It influences how people perceive themselves and each other, how they behave and interact, and the distribution of power and resources in society. Gender is usually incorrectly conceptualized as a binary (female/male). In reality, there is a spectrum of gender identities and expressions defining how individuals identify themselves and express their gender.

Gender identity, Gender bias analysis, gender sensitive analysis, gender perspective, Sex and Gender-Based Analysis, Sex-disaggregated data, Sexism, Transgender Persons, Transexual persons, Transgenders...

Sex is biological, gender is social BUT it is complicated

COMPLEX INTERDEPENCENCY OF SEX AND GENDER



Source: Vera Regitz-Zagrosek; Sex and gender differences in health EMBO reports 2012



THE LANCET,

FEBRUARY 24, 1973

GENDER DIFFERENCES

GENDER or sex differences are well recognised in almost every area of medicine, but, despite an enormous growth in knowledge of the mechanisms underlying sexual differentiation over the past 25 years,¹ they are still poorly understood.



Effects of underreporting of sex and gender differences

- drugs have different metabolism in men and women but lack of gender balance in clinical trials of drugs results in insufficient information on sex differences prior to approval and marketing
- **Car safety tests**, often based on male standards, show different risk for injuries among females
- **the effects of chemicals in the environment** have been studied predominantly in men, although they can have deleterious effects on women's reproductive health
- the needs, behaviours and attitudes of women and attitudes of women and attitudes of women and attitudes of women and and attitudes of women attitudes of women and attitudes of women attitudes of

Examples

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

In 2014, the Mary Horrigan Connors Centrer 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 Sex-Specific Medical Research Why Women's Health Can't Wait

A Report of the Mary Horrigan Connors Center for Women's Health & Gender Biology at Brigham and Women's Hospital





Effects of underreporting of sex and gender differences

2 minutes to provide additional examples from your experience

The problem

Sex and gender influence research outcomes and should be studied under different perspectives to ensure that outcomes are applicable to both men and women and do not harm one another.

Yet sex and gender differences are **usually underreported** in research findings and scientific communication.

\rightarrow Lack of reproducibility \rightarrow waste in research



Reproducibility

*"replication is what separates the rigor of science from the squishiness of pseudoscience"**

The methods section "should aim to be sufficiently detailed such that others with access to the data would be able to <u>reproduce</u> the results" (ICMJE, 2016)

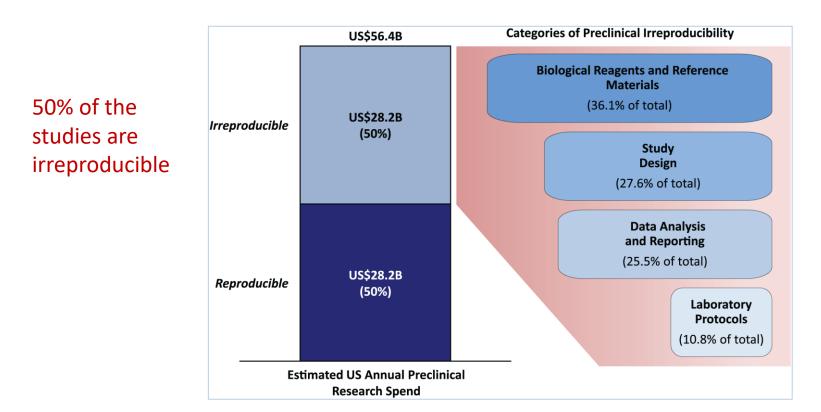


*http://www.newyorker.com/magazine/2010/12/13/the-truth-wears-off

Reproducibility in Preclinical Research

Low reproducibility rates within life science research undermine cumulative knowledge production and contribute to both delays and costs of therapeutic drug development.

Estimated US preclinical research expenditure and categories of errors that contribute to irreproducibility.



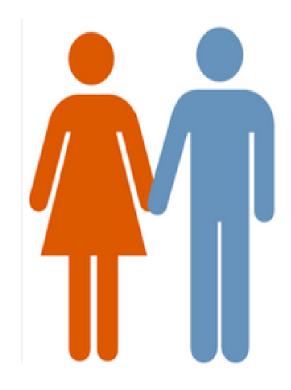
Freedman LP, Cockburn IM, Simcoe TS (2015) The Economics of Reproducibility in Preclinical Research. PLoS Biol 13(6): e1002165. doi:10.1371/journal.pbio.1002165

PLOSU niversity of Warwick • Summer school: How to be a peer reviewer • September 10-14, 2018

Reasons for concern

Both **sex and gender** are important **determinants of health** and disease, which are often **ignored** in scientific research, and more importantly in reporting of research

There are significant **gaps in knowledge** in part because of a general **orientation** of scientific attention to the **male side** of the sex/gender equation.







Health Policy and Planning

ABOUT THIS JOURNAL CONTACT THIS JOURNAL SUBSCRIPTIONS

CURR

Oxford Journals > Medicine & Health > Health Policy and Planning > Advance Access > 10.1093/h



Who's talking about your research, whe Altmetric data now available on Healt Click on the donut to uncover your in

How to do (or not to do)... gender analysis in ⇒

rkosemary Morgan¹,*, Asha George¹, Sarah Ssali², Kate Hawkins³, Sassy Molyneux^{4,5,6} and

+ Author Affiliations

- *Corresponding author. Department of International Health, Johns Hopkins Bloomberg School of Public Health, 615 N. Wolfe Street, Baltimore MD 21205-2179, USA. E-mail: rosemary.morgan@jhu.edu

Accepted March 14, 2016.

Male Scent May Compromise Biomedical Studies

or a female experimenter was present. "We were stunned by the results," he says. The rodents showed significantly fewer signs of pain (an average of a 36% lower score on the grimace scale) when a male researcher was in the room than when a female researcher-or no researcher at all-was there.





NIH plans to enhance reproducibility

Francis S. Collins and Lawrence A. Tabak discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

612 | NATURE | VOL 505 | 30 JANUARY 2014

L L that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring^{1,2}. © 2014 Macmillan Publishers Limited. All rights reserved

have been hobbled. This has compromised the ability of today's researchers to reproduce others' findings.

Richard Horton, Owing up to gender equality. Lancet, March 2018

There are moments to admit failure. Gender equality is one of those moments

•Gender equality matters because it is a human right.

•Equality in the workplace is inherently just and good.

- •Gender is one of the most important determinants of health.
- •Gender equitable workplaces deliver better results.

About the Lancet

Although our journals group has made statements of commitment to gender equality in editorials and comments, we have not defined gender in any Lancet institutional policy.
We do not explicitly address gender in our work practices.
We do not insist that all research we publish includes sex-disaggregated data. Our journal advisory boards vary in the degree to which they have achieved gender parity. More positively, most Editors-in-Chief of Lancet journals are women

A good synthesis of the state of the art

Gender blind reporting is common and is waste of research

Are we turning a blind eye to Gender Blind Reporting?

- Sex of subjects is not reported
- Sex of subjects is reported but data are not presented disaggregated by sex
- Analysis ignores any potential sex/gender differences and data are presented as if they were of general applicability

Nieuwenhoven and Klinge, Scientific Excellence in Applying Sex- and Gender-Sensitive Methods in Biomedical and Health *Research Journal* of Women's Health 2010



OVERGENERALIZATION



GENDER IMBALANCE IN AUTHORSHIP

The gender gap in first authorship of research papers

BMJ 2016 ; 352 doi: http://dx.doi.org/10.1136/bmj.i1130 (Published 02 March 2016) Cite this as: *BMJ* 2016;352:i1130



AN OLD STORY

Women have been attending medical school in numbers equal to or greater than those of men.....

Editorial committee, referee panels, workplace...

THE LANCET May, 2018

COMMENT | VOLUME 391, ISSUE 10132, P1754-1756, MAY 05, 2018

The gendered system of academic publishing

Jamie Lundine 🖾 🛛 Ivy Lynn Bourgeault 🖉 Jocalyn Clark 🖉 Shirin Heidari 🖉 Dina Balabanova

DOI: https://doi.org/10.1016/S0140-6736(18)30950-4 💿 🦲 Check for updates

Gender is a sociocultural and economic concept and an institutionalised system of social practices that translates into different experiences and uneven advantages for men and women at the individual, organisational, and societal levels.¹ This system manifests as the persistent gender pay gap, endemic sexual harassment,² and the proverbial glass ceiling limiting women's representation and advancement in social and economic life. Academia, including academic publishing, is not in gendered system of social practices.

Acac and promotion. The academic publishing process is neans through com purportedly built upon objectivity³ and presumed hor of a paper revie gender neutrality. Yet, despite growing numbers of in-chief are in reco women in the research workforce, most authors,⁴ peer objectivity³ and editors at academic journals are men.⁷⁻⁹ reviewers,^{5,6} and editors at academic journals are men.⁷⁻⁹

academic journals are men 7, 8, 9 Bersity of Warwick • Summer school: How to be a peer reviewer • September 10-14, 2018

Ridgeway CL • Correll SJ

Unpacking the gender system a theoretical perspective on gender beliefs and social relations. *Gend Soc.* 2004; **18**: 510-531

Crossref • Scopus (516) • Google Scholar

Х

European Commission > Funding, Tenders > Funding opportunities > Funding programmes > Horizon 2020 >



•Fostering gender balance in research teams, to close the gaps in the participation of women.

•Ensuring gender balance in decision-making, to reach the target of 40% of the underrepresented sex in panels and groups and of 50% in advisory groups.

•Integrating the gender dimension in research and innovation (R&I) content, helps improve the scientific quality and societal relevance of the produced knowledge, technology and/or innovation_niversity of Warwick • Summer school: How to be a peer reviewer • September 10-14, 2018 25

Gender equality is a human right

Where is the responsibility?

The scientific community should become aware of their responsibilities and encourage the endorsement of **remedies to address sex and** gender inequities in reporting research across disciplines.



Quick survey by raising hands

Did you ever consider such responsibility to address sex and gender inequities in reporting research before?







EASY ANSWER considering that

THE BIG CHALLENGE

How can editors/reviewers contribute to achieve sex and gender equity in research?

- Editors set rules
- Authors must comply with them if they wish to have their article published
- Authors need to publish

So, the EASE GPC ...

Editorial recommendations and guidelines



CME INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals.

Recommendations to facilitate complete and transparent reporting of CT results.



PRISMA

TRANSPARENT REPORTING of SYSTEMATIC REVIEWS and META-ANALYSES

To ensure transparent and complete reporting of systematic reviews and meta-analyses

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

uator

network

STrengthening the Reporting of OBservational studies in Epidemiology



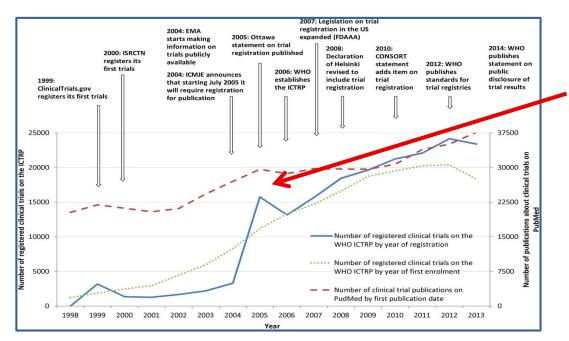
University of Warwick • Sumn

September 10-14, 2018

EDITORS AS AGENTS OF CHANGE

The story of clinical trials as an example

In 2005, the **International Committee of Medical Journal Editors** (ICMJE) initiated a **policy requiring investigators to deposit information about trial design** into an accepted clinical trials **registry** before the onset of patient enrollment... and included a requirement for registration in the Uniform Requirements



Increase in registered clinical trials and publications about clinical trials on PubMed (1998 – 2013)

Before that, trials registration was the exception; now it is the rule.

Key considerations for peer reviewers Sex and gender reporting

ICMJE Recommendations updated (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"**

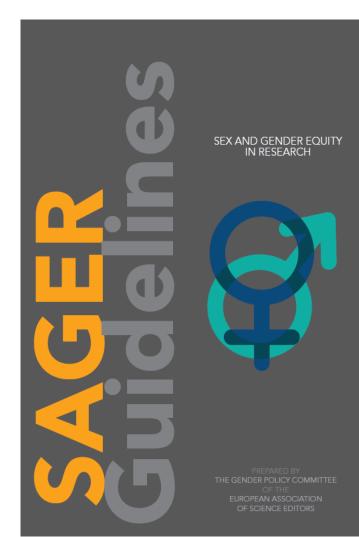
Results

"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"





UNDERSTANDING SAGER Reporting Guidelines



Power point available for Your presentations

WHERE WHY WHEN ? WHO 1 HOW WHAT

Gender Policy CommitteeEASEEuropean Association of Science Editors

University of Warwick • Summer school: How to be a peer reviewer • September 10-14, 2018



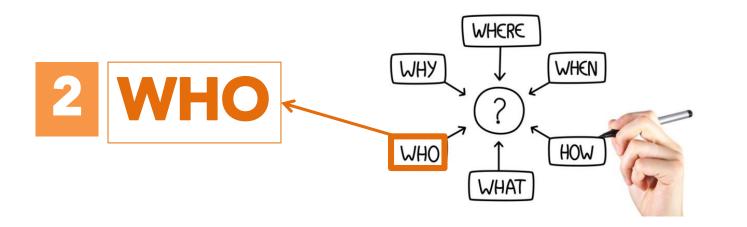
SEX AND GENDER MATTER

YET Sex and gender differences are often OVERLOOKED AND UNREPORTED

in scientific research design, implementation and reporting, and in science communication

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**



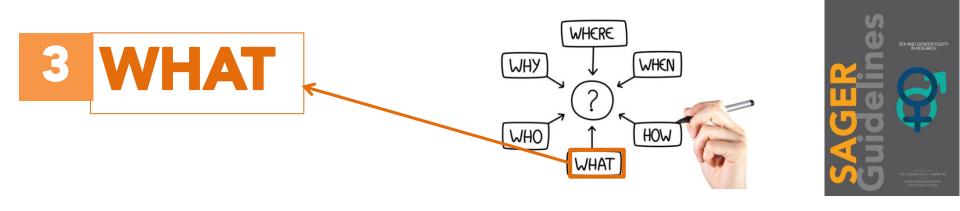


AUTHORS, EDITORS, PEER REVIEWERS

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

They need all to become fully aware that **SEX AND GENDER MATTER** and share such responsibility through the use of the Guidelines (authors and referees) and their adoption (editors)





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 designed and conducted similarly at this level of distinction.



They will help authors, editors and referees:

- Use the correct **terminology** (sex and/or gender)
- Improve study design, implementation and reporting
- Allow the correct **implementation of research results** thus contributing to an equitable use of resources and reduction of waste



At all stages of research



- study design, implementation, reporting
- peer reviewing
- research implementation



Where to find more about the SAGER Guidelines?

Full article: Heidari et al. Research Integrity and Peer Review, 2016

- Flyer and presentations: EASE GPC website
- **Equator** website, among published guidelines
- National Library of Medicine, among NLM reporting guidelines
- Instructions for authors of journals who adopted them

Citations in editorials and other articles: JAMA, The Lancet Psychiatry, Annali dell'Istituto Superiore di Sanità, Addiction Journal, BMC Medical Research Methodology and others

Translations in Spanish, Portuguese; Korean, Chinese (in preparation)

Where to endorse the SAGER Guidelines in less than 1 minute

GPC website:<u>http://www.ease.org.uk/about-us/gender-policy-committee</u> Highly recommended to foster adoption by journal editors

Recommendations per section of the article

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 and/ or gender differences may be expected

4. Results

Where appropriate, data should be routinely presented disaggregated by sex and gender. Sex- and genderbased analyses should be reported regardless of positive or negative outcome. In clinical trials, data on withdrawals and dropouts should also be reported disaggregated by sexi: How to be a the interpretation of the results.

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

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 further **discuss the** implications of the lack of such analysis on 39

SAGER checklist for authors (referees)

Research approach

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?

Research questions & hypotheses Literature review Research methods Ethics

Adapted from Canadian Institute of health **research**

University of Warwick • Summer school: How to be a peer reviewer • September 10-14, 2018

40

Recommended actions FOR EDITORS to implement reporting policies

1. Adopt the guidelines as a formal policy in Instructions to Authors

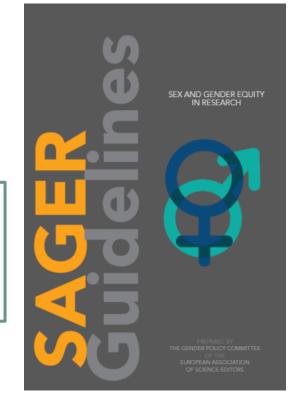
SAGER

- 2. Screen initial submissions to determine whether sex/gender is relevant to the topic of the study; if so, determine whether the issue has been addressed adequately enough to proceed with peer-review
- **3. Encourage peer reviewers** to consider journal's sex/gender policy in the evaluation of manuscripts.
- 4. Train editorial staff on the importance of sex/gender sensitive reporting

Now it is up to you... to be SAGER

If we have time \rightarrow hands on

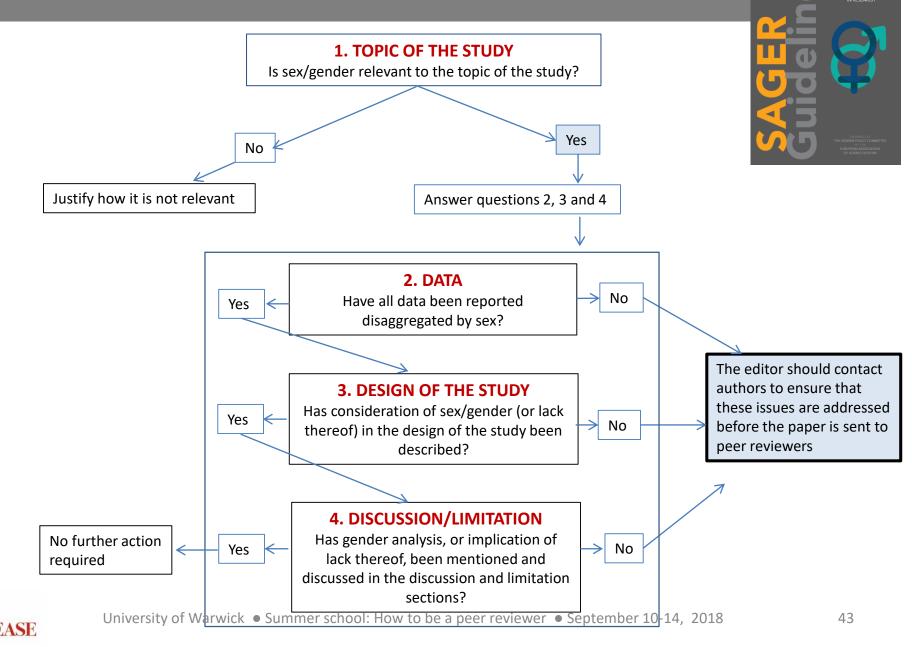
- Receive photocopies of an article submitted for publication (for teaching purposes only)
- Read it quickly, keeping in mind the SAGER Guidelines
- Discuss it with your neighbours
- Formulate recommendations to editors



In all the other cases...

- Be a SAGER author/researcher (terminology, research design, research reporting)
- Be a SAGER reviewer (flowchart, follow all points indicated in the Guidelines)
- Be a SAGER editor (endorse and implement the Guidelines)

SAGER Flowchart for editors/ peer reviwers



ENDORSE THE SAGER GUIDELINES

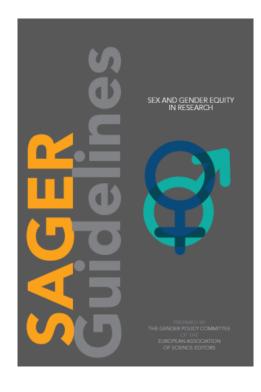
EASE Gender Policy Committee

http://www.ease.org.uk/communities/gender-policy-committee/	http://wv	vw.ease.org	.uk/comm	unities/ger	nder-policy	/-committee/
---	-----------	-------------	----------	-------------	-------------	--------------

Scroll homepage GPC

FASE

Please sign here to endorse the SAGER guidelines.	
Name:*	
Email address:*	
Journal name or institution:*	
SIGN	









Paola De Castro, Director of the Publishing Unit Istituto Superiore di Sanità, Rome (Italy) paola.decastro@iss.it