



Editorial guidelines for Sex And Gender Equity in Research (SAGER)

*How improved reporting
can influence research outcomes
and contribute to
a more equitable approach
to research across disciplines*



**Paola De Castro*,
Shirin Heidari**, Thomas Babor*****

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Communication, Medicine, and
Ethics (COMET) • Aalborg
University, Denmark, 4 – 6 July 2016

EASE Gender Policy Committee

**National Institute of Health, Italy,*

***Reproductive Health Matters, UK*

****School of Medicine, Univ. of Connecticut,, USA*





Objective

1

*Promote awareness of
sex and gender differences
in research*

2

*Understand why we need
to **report** them properly
as an important contribution
to **research & innovation***

EDITORS

Roles and responsibilities



As gate keepers of science, editors have helped **shape** the scientific record and promote more **transparency, accountability** and **ethicity** in science through international **standards** and **recommendations** designed to ensure a more transparent and complete reporting of scientific findings...

EUROPEAN ASSOCIATION OF SCIENCE EDITORS

the umbrella of the three authors of this presentation



an international community of individuals and associations
from **diverse backgrounds**, linguistic traditions and professional experience
in **science communication and editing**

Mission

To improve the global standard and quality of science editing
by promoting the value of science editors and supporting

- professional development
- research
- collaboration.

<http://www.ease.org.uk/>

Excellence and Accountability in Science Editing

Editorial recommendations and guidelines



Recommendations to facilitate complete and transparent reporting of CT results.



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

STrengthening the Reporting of OBservational studies in Epidemiology



STROBE Statement
Strengthening the reporting of observational studies in epidemiology

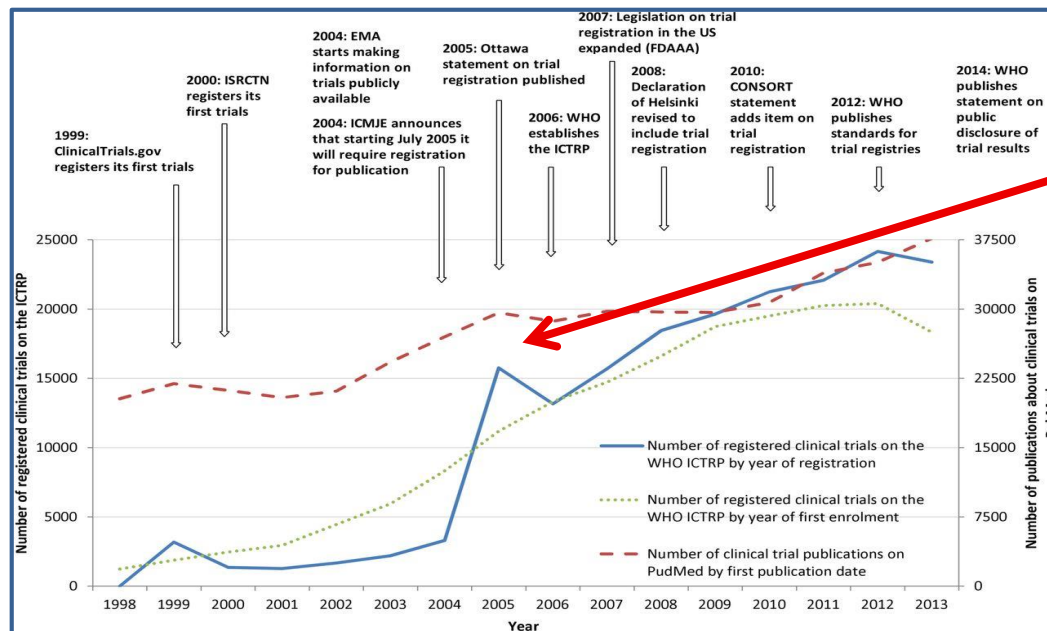
The ARRIVE guidelines
Animal Research: Reporting *In Vivo* Experiments



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.



SEX and GENDER *matter*

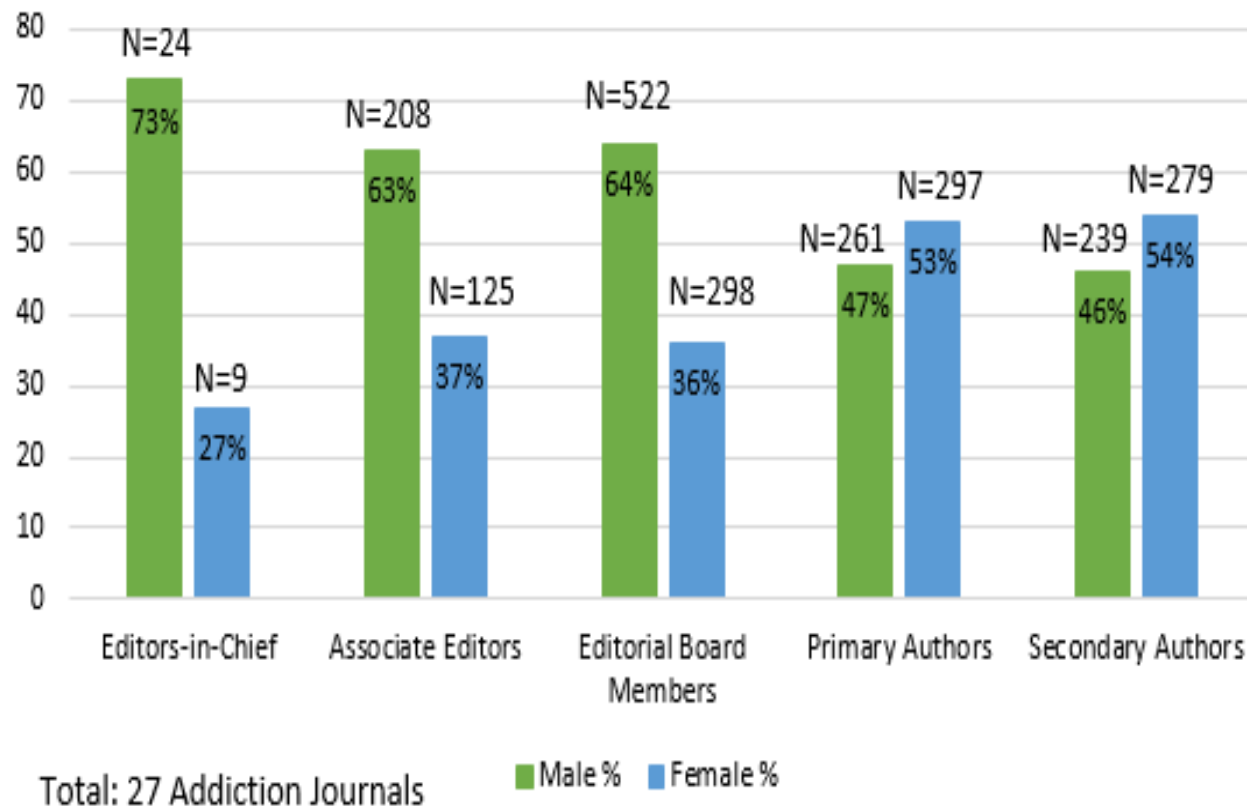
Starting from TERMINOLOGY

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...

ISAJE Member Journal Editorial Hierarchy Distribution



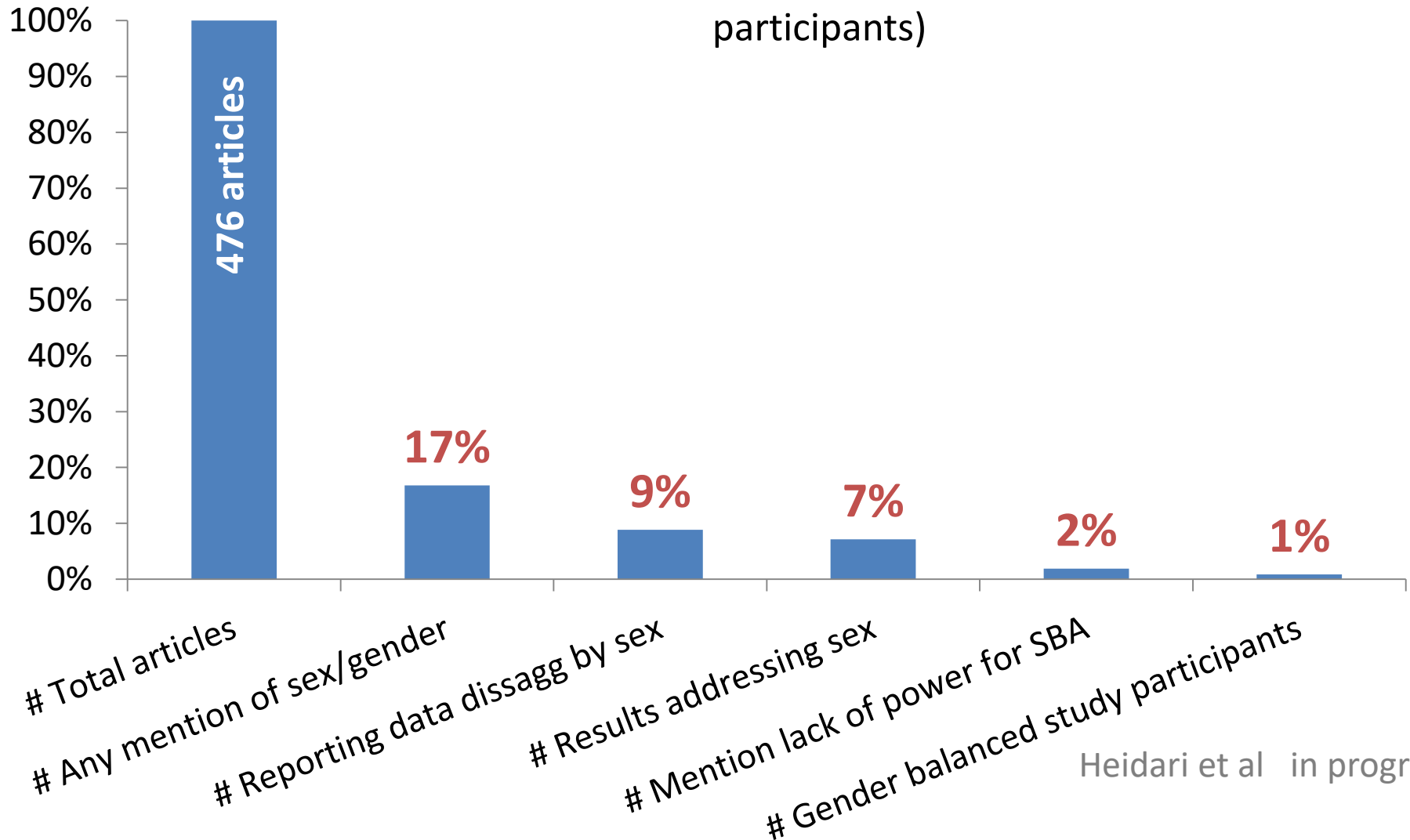
Effects of underreporting of sex and gender differences

Examples

- **drugs have different metabolism in man 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 as well as men** are important determinants of health and well-being, but they are often underestimated.

Sex/Gender bias in reporting in articles of clinical studies with antiretrovirals

(after excluding a number that did not even mention the sex of the participants)



Heidari et al in progress

Harm due to poor sex/gender reporting!



“...**women are at much greater risk of complications and failure**
after total hip resurfacing arthroplasty

the result suggests that **clearer scientific reporting**
would have prevented harm to many women

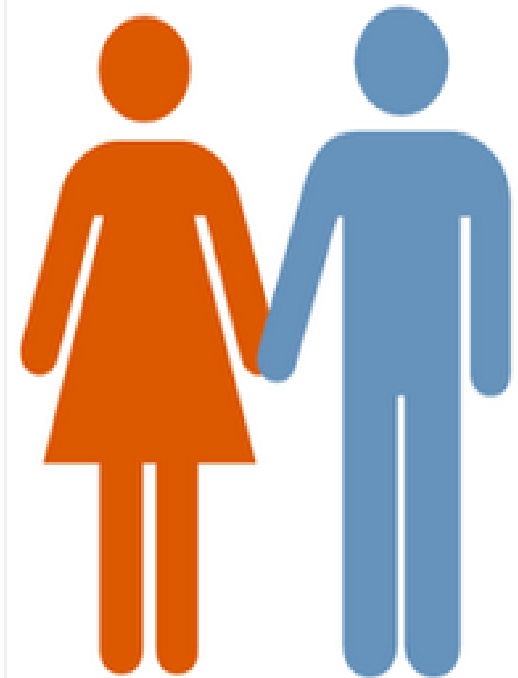
We probably do not know the full extent of the harm we may be causing because
the **reporting of results by gender is so inconsistently performed** in medical and
surgical trials in our specialty.”

Leopold et al Clin Orthop Relat Res (2014) 472:391–392

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.





THE BIG CHALLENGE

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

EASY ANSWER
considering that

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

So, the EASE GPC ...



EASE Gender Policy Committee

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



INFO

<http://www.ease.org.uk/about-us/organisation-and-administration/gender-policy-committee>

EASE Gender Policy Committee

Vision

Greater gender balance in science and publishing practices for enhanced quality, diversity and transparency, for science to remain at the forefront of innovation.

Mission

To advance sex/gender reporting and gender balance in editorial management on a global level, and across disciplines.

Nature's sexism

The editors of this publication need to improve how we reflect women's contributions to science. For this, we must inject an extra beep into our thinking.

Evaluate gender equality in journals

The European Association of Science Editors established a gender policy committee last year to develop a set of standards for adoption by scientific journals. As co-chairs of the committee, our first step is to invite science editors to contribute to a survey of gender-equality policies in their journals (see go.nature.com/wor7ks; survey closes on 10 April).

In this survey, we ask editors for their views on considering sex and gender in experimental design and data analysis, and on presenting data that are broken down by sex. Information is also requested on gender balance and its promotion among editorial staff, editorial boards and peer reviewers.

Our hope is that all journals will eventually follow *Nature's* example in promoting gender equality in science (see www.nature.com/women).

Shirin Heidari Journal of the International AIDS Society, Geneva, Switzerland.

shirin.heidari@iasociety.org

Tom Babor University of Connecticut School of Medicine, Farmington, Connecticut, USA.

WHY A GUIDELINE ON SEX AND GENDER EQUITY IN RESEARCH?

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- 1** In any field of research,
from medicine to biology, humanities and social sciences,
physical and environmental sciences,
sex and gender differences play a very important role
and
- 2** **influence the research outcome** in a variety of ways
with direct implications
on the **economic and financial sides**
yet
- 3** sex and gender aspects are generally
overlooked and underreported

So what?

Let's be SAGER!

Adopt the SAGER Guidelines

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

Research Integrity and
Peer Review

REVIEW

Open Access



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

Published in 2016, Research integrity and Peer review

Objectives of SAGER guidelines

1

promote **sex/gender reporting** and gender balance in editorial management on a **global level**, and **across disciplines**, in scientific communication

2

establish a **methodological framework for reporting** sex and gender differences (or similarities) targeting **authors, editors and peer reviewers** for improved reporting

HOW?



SAGER guidelines, step by step

Survey, 2013



- **map** existing editorial gender policies (instructions to authors and reviewers) and composition of editorial boards, peer reviewers and staff
- **opinions** towards the adoption of gender policies.

Development, 2014-5



- **Meeting (Athens), teleconferences, e-mails** to agree on final recommendations and draft article

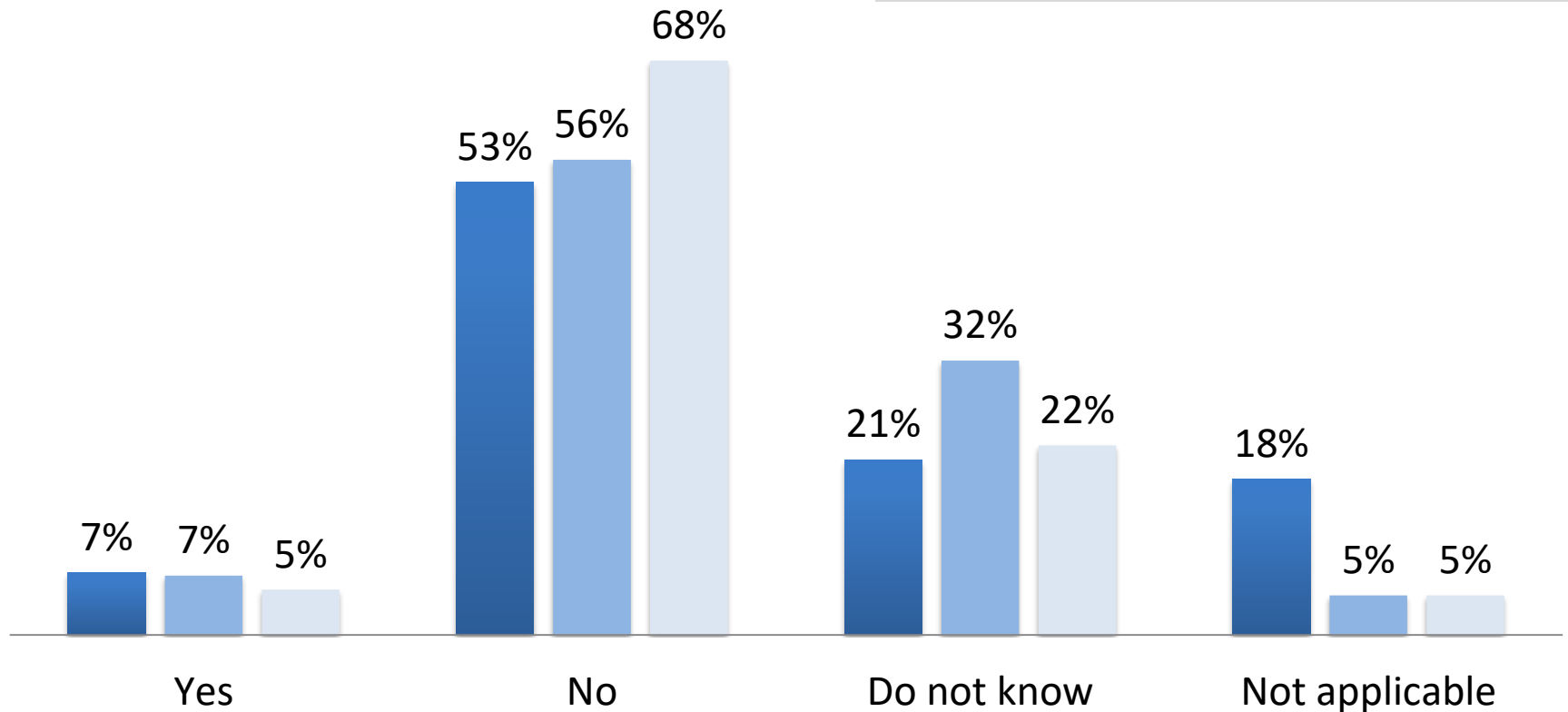
Publication, 2016

Adoption, 2016-17

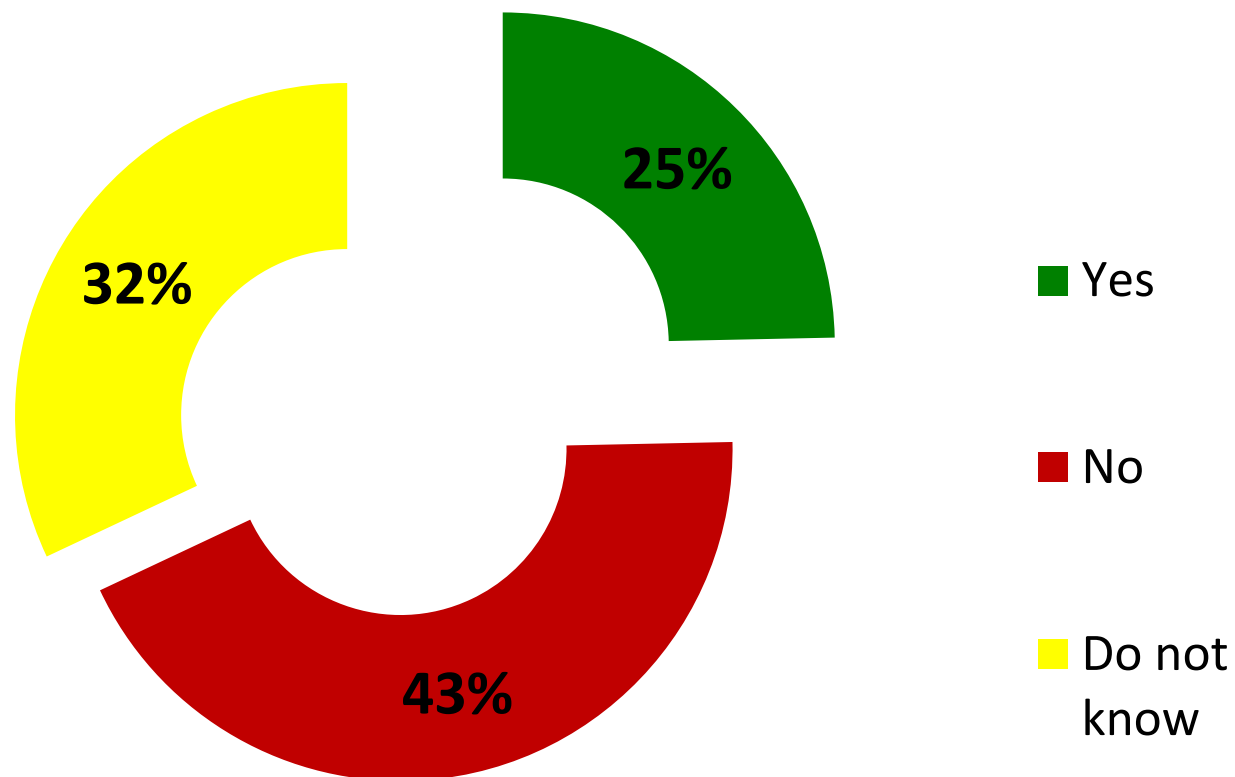
Survey results: overview of existing gender policies

- Instructions for Authors
- Composition of editorial staff/boards
- Pool of peer reviewers

Only 7 journals indicated that they had one or more sex/gender policies out of 661 unique journals!



Question: Do you think inclusion of data disaggregated by sex should be **included in instructions for authors** as a matter of routine across all journals/publishers?



A majority (75%) are unwilling or unsure to introduce sex and gender considerations as requirements in Instructions to Authors.



SAGER Recommendation # 1

Terminology

Exercise care in the terminology used to describe research methods and explain results in order to **avoid confusing sex with gender**

SAGER Recommendation # 2

Title and Abstract

If only one sex is included in the study, 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



SAGER Recommendation # 3

Introduction

Where appropriate, it should be reported if sex and/or gender differences ***are expected***

SAGER Recommendation # 4

Methods

How sex and gender were taken into account *in* the ***design*** of the study should be clearly stated, including reporting of representation of males and females.

The ***reasons for the exclusion*** of males or females should be justified.

SAGER Recommendation # 5

Results

- Data should be routinely presented **disaggregated** by sex.
- Where appropriate, meaningful sex/gender based **analyses** should be reported regardless of positive or negative outcome.
- The **reasons for lack** of any gender analysis should be justified.

Recommendation # 6

Discussion

- The implications of sex/gender analyses should be discussed.
- And it should be indicated whether lack of such analyses could have affected the *results*.



SAGER Recommended Actions for Editors to Implement Reporting Policies

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

AUTHORS' CHECKLIST for gender-sensitive reporting

FOCUS ON

- Research approaches
- Questions and hypothesis
- Literature Review
- Research methods
- Ethics

Appendix 2

Table 2 Authors' checklist for gender-sensitive reporting

Research approaches ✓

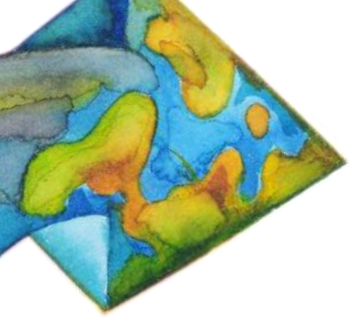
- ✓ Are the concepts of gender and/or sex used in your research project?
- ✓ If yes, have you explicitly defined the concepts of gender and/or sex? Is it clear what aspects of gender and/or sex are being examined in your study?
- ✓ If no, do you consider this to be a significant limitation? Given existing knowledge in the relevant literature, are there plausible gender and/or sex factors that should have been considered? If you consider sex and/or gender to be highly relevant to your proposed research, the research design should reflect this

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

The EASE GPC is open to innovation and collaboration

The **Canadian Institute of Gender and Health** launched its **online training module on sex and gender in biomedical research for scientists and peer reviewers** (Sept 2015) (<http://www.cihr-irsc.gc.ca/e/49347.html>).





How can isaje contribute?

1

Support the crucial role of **reporting sex and gender in research** to foster innovation and reduce waste in research

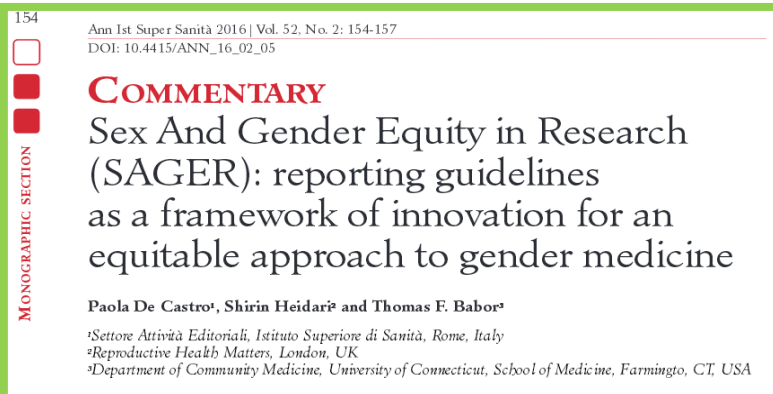
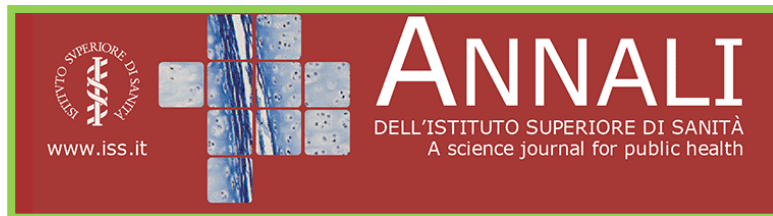
2

Promote the adoption of the **SAGER guidelines** to:

- encourage clarity of terminology,
- improved reporting of S&G disaggregated data in all sections of journal articles:
study design, data analyses, reporting of results and interpretation of findings

Ongoing activity after publication of the guidelines

- Awareness & Adoptions (also spontaneous)
- Dissemination/Conferences/Webinars
- Training
- Publications



"If working with only one sex or gender, then specify that, and explain why."

Despite improvements, female scientists continue to face discrimination, unequal pay and funding disparities.

22 | NATURE | VOL 495 | 7 MARCH 2013

BY HELEN SHEN

The Gender Gaps

in scientific research & scientific publishing

Sex bias in trials and treatment must end

Gender inequalities in biomedical research are undermining patient care. In the first of three related pieces, **Alison M. Kim**, **Candace M. Ting** and **Teresa K. Woodruff** call on journals, funding agencies and researchers to give women parity with men, in studies and in the clinic.

NATURE | Vol 465 | 10 June 2010

www.nature.com/nature

Vol 465 | Issue no. 7299 | 10 June 2010

Putting gender on the agenda

EMBO reports VOL 13 | NO 7 | 2012

Biomedical research continues to use many more male subjects than females in both animal studies and human clinical trials. The unintended effect is to short-change women's health care.

COMMENTARY

Open Access

Gender-sensitive reporting in medical research

Heidari et al. *Journal of the International AIDS Society* 2012

<http://www.jiasociety.org/content/15/1/11>

Nature's sexism

The editors of this publication need to improve how we reflect women's contributions to science. For this, we must inject an extra loop into our thinking.

COMET Conference • University of Aalborg (Denmark) July 4-6, 2016

THE LANCET

Issue 31 | October 2010 | Pages 612-613 | November 2, December 1, 2011

"The Lancet encourages researchers...to plan to analyse data by sex, not only when known to be scientifically appropriate, but also as a matter of routine."

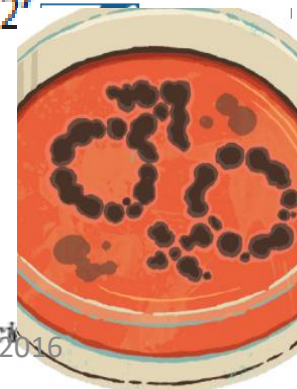
See Editorial page 612

nature

Male and female cells can behave differently — it is time that researchers, journals and funders

Cell sex matters

1 AUGUST 2013 | VOL 500 | NATURE | 23



Sexes deal differently with infection

OMEDICAL RESEARCH

Quirks of immune system pose medical conundrum.

BY SARA REARDON

The immune systems of men and women respond very differently to infection — and scientists are taking notice. Research presented last week at a microbiology meeting in Boston, Massachusetts, suggests that the split could influence the design of compounds before exposing them to influenza virus has revealed further clues, says Sabra Klein, an endocrinologist at Johns Hopkins University in Baltimore, Maryland. Only the cells from females responded to the hormones and off the virus (J. Peretz *et al. Am. J. http://doi.org/bj5w*; 2016).

23 JUNE 2016 | VOL 534 | NATURE | 44

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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.



What's that smell? The presence of a male scientist can influence research results.

Health Policy and Planning

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How to do (or not to do)... gender analysis in health systems research

Rosemary Morgan^{1,*}, Asha George¹, Sarah Ssali², Kate Hawkins³, Sassy Molyneux^{4,5,6} and Sally Theobald⁷

+ 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.

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

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that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring^{1,2}.

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

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.....

MORE...



Thank you

Special thanks to
Pablo Picasso
for visual inspiration!

CONTACT US:

secretary@ease.org.uk

paola.decastro@iss.it

Names and email addresses of
EASE GPC members are
on EASE website www.ease.org.uk