

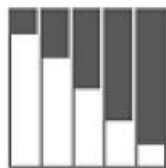


Minimising waste: *Sex and Gender Equity in Research* (SAGER) guidelines

by the EASE Gender Policy Committee

Paola De Castro, Italian National Institute of Health

Equator/EASE expert session – 28th September 2015



REWARD

Reduce research **W**aste and **R**eward **D**iligence

<http://www.reward.ac.uk/>

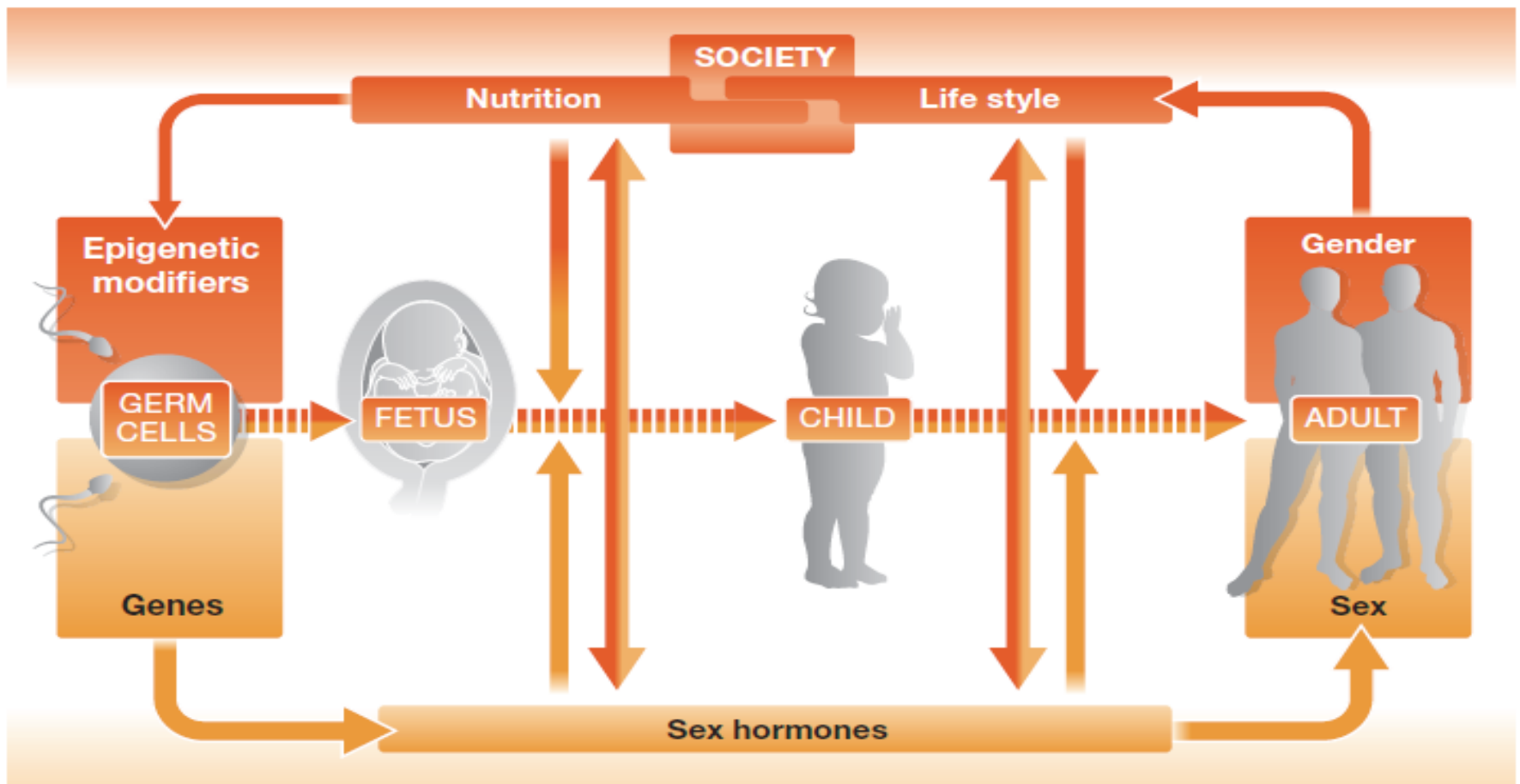


Enhancing the **Q**Uality and **T**ransparency **O**f health
Research

<http://www.equator-network.org/>

**Increasing value and reducing waste
in biomedical research conference
28th – 30th September 2015, Edinburgh**

COMPLEX INTERDEPENDENCY OF SEX AND GENDER



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

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

The Gender Gaps

in scientific research & scientific publishing

"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."

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. Tingen** 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

nature

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

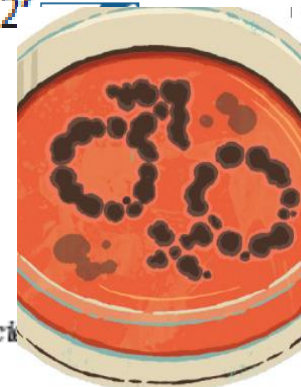
Heidari et al. *Journal of the International AIDS Society* 2'

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

Male and female cells can behave differently — it is time that researchers, journals and funders | **Jeth Pollitzer.**

Cell sex matters

1 AUGUST 2013 | VOL 500 | NATURE | 23



MIND THE GENDER GAP

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

BY HELENSHUN
22 | NATURE | VOL 495 | 7 MARCH 2013

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.

BEWARD / EQUATOR Conference
Edinburgh 28-30 September 2015

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

Objectives of the presentation

1

To show the crucial role of **reporting sex and gender in research** to reduce waste in research (→REWARD)

2

To promote the **SAGER guideline** to:
encourage clarity of terminology,
improved study design, data analyses,
reporting of results
and interpretation of findings



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.

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.

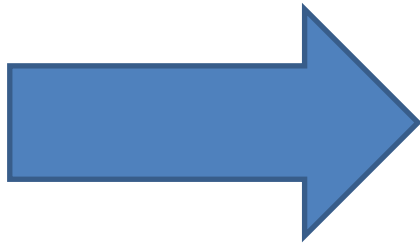
Our hope is that all journals will eventually follow *Nature's* example in promoting gender equality in science (see www.nature.com/women).

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.

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



**GPC meets REWARD
Conference objectives**

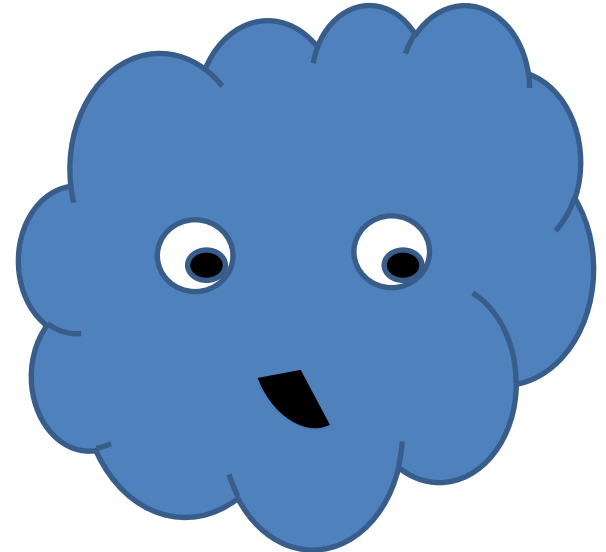
Assumptions

- 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?

We need a “SAGER” vision

S — Sex
A — And
G — Gender
E — Equity in
R — Research



The EASE Gender Policy Committee
has adopted the acronym SAGER to express its work

SAGER Guidelines

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 and editors** for improved reporting

WHY?

Effects of underreporting of sex and gender differences

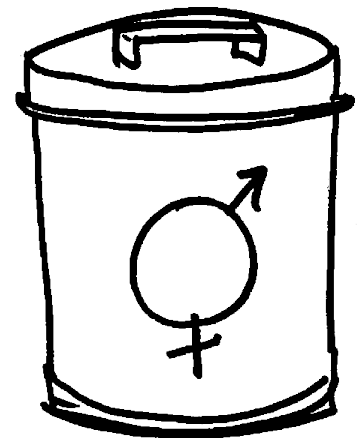
Examples

- **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.

Waste in research due to lack of sex/gender reporting

- RCTs receiving US federal funding published in nine prominent medical journals in 2009 Studies. Of 86 articles included:

75% of the studies did not report any outcomes by sex



Source: Geller et al. J Women's health 2011

Harm due to poor sex/gender reporting!



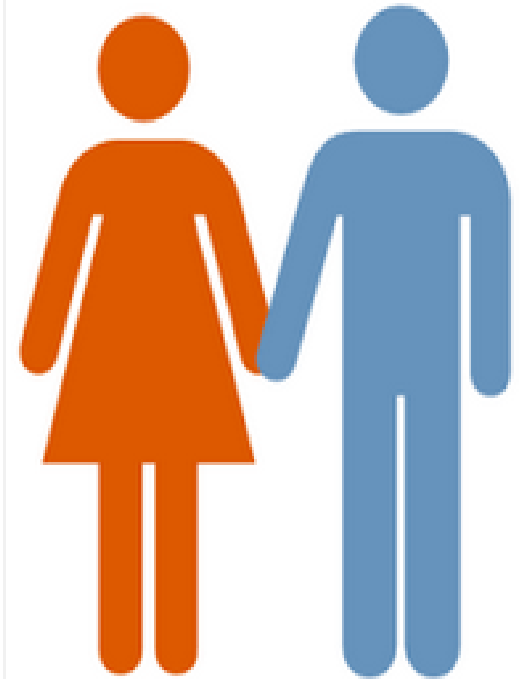
“We **learned only belatedly that women are at much greater risk** of complications and failure after total hip resurfacing arthroplasty [4], and the result suggests that clearer **scientific reporting would have prevented harm** to many women. We probably do not know the full extent of the harm we may 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

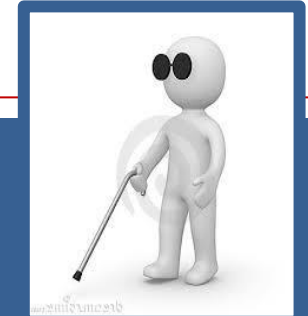
Reasons for concern

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.



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

DANGER

OVERGENERALIZATION

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



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

Approval by GPC, 2015



Publication

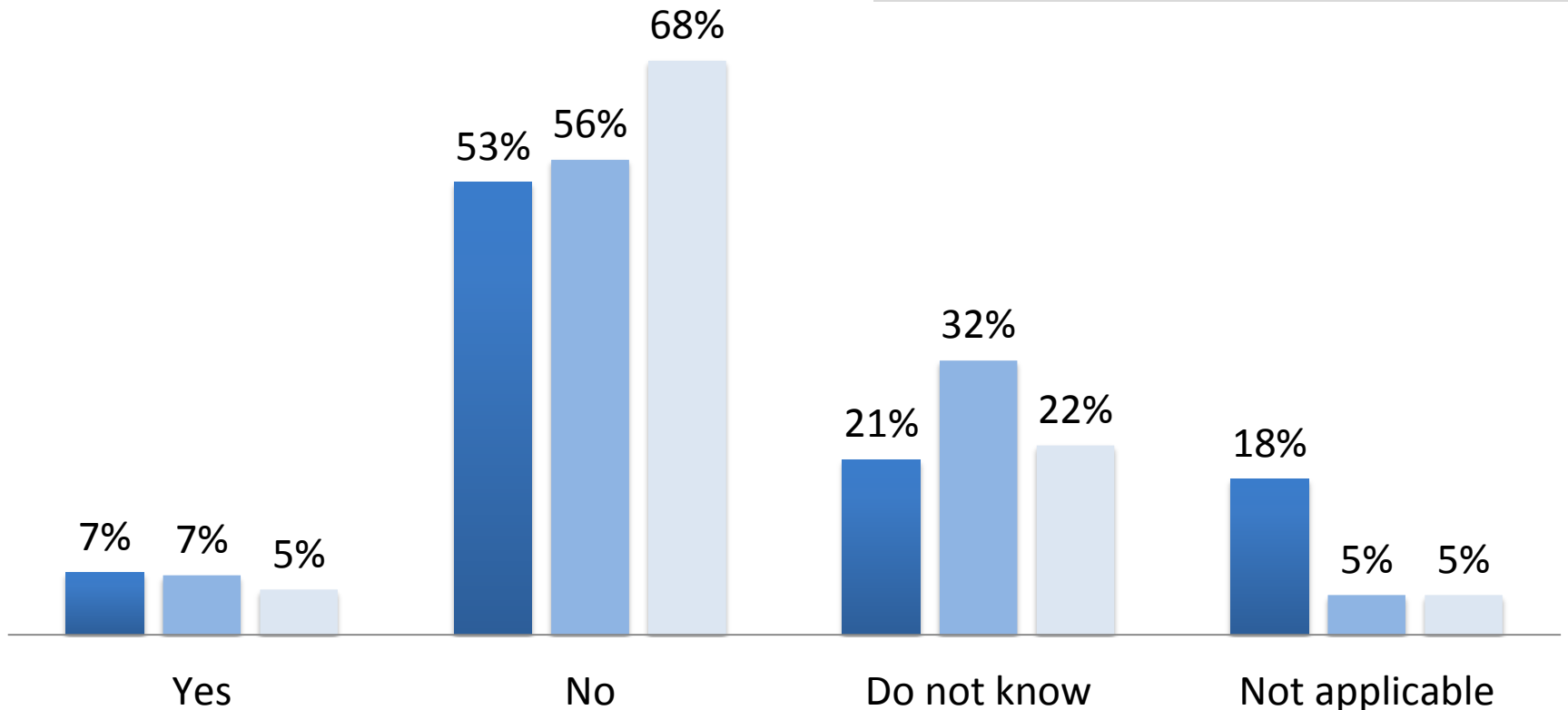
Dissemination

Implementation

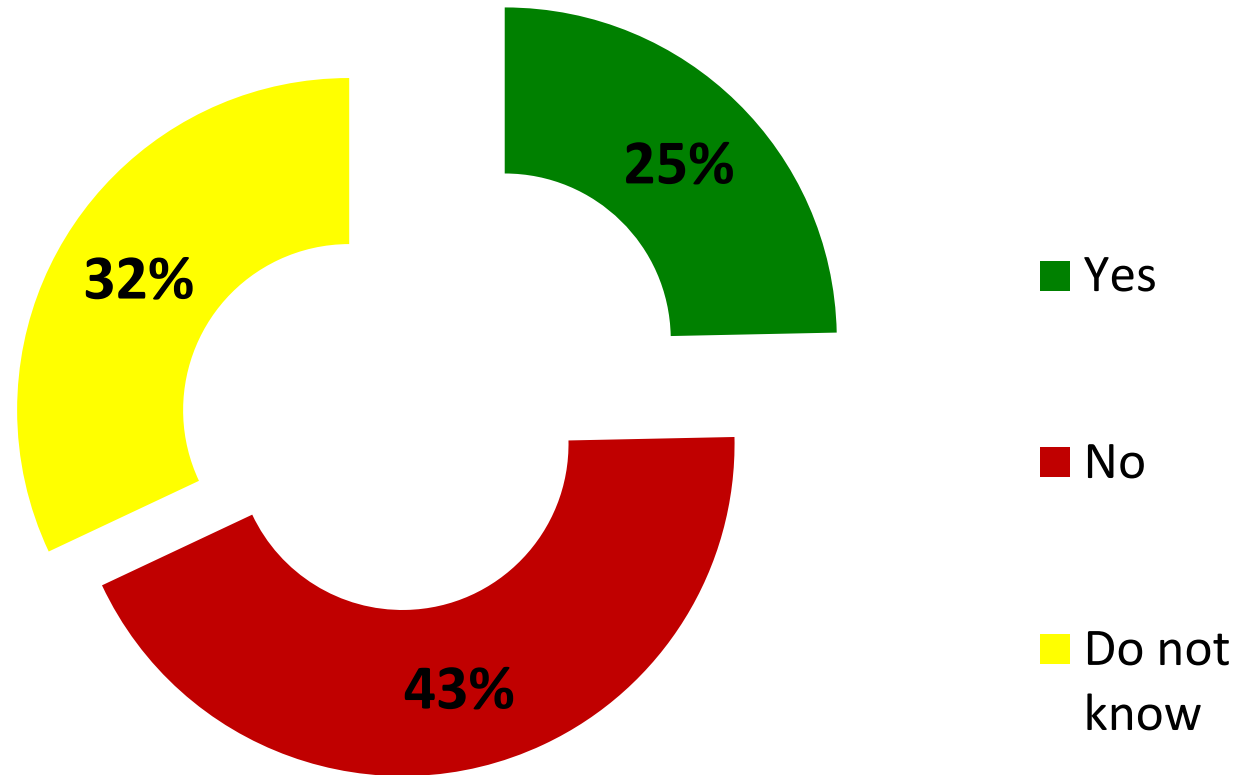
Survey results: overview of existing gender policies

- 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.

Development of the guidelines on Sex and Gender Equity in Research (SAGER)

Modus operandi

- **Keyword searches** to identify journals that had specific policies on sex and gender.
- Scanned **websites** of journals that have an explicit sex/gender focus
- Consulted journal **articles** and expert committee reports
- Reviewed **policies of peer-reviewed** journals already known to the Gender Policy Committee
- **Synthesized** current policies and recommendations into reporting guidelines

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

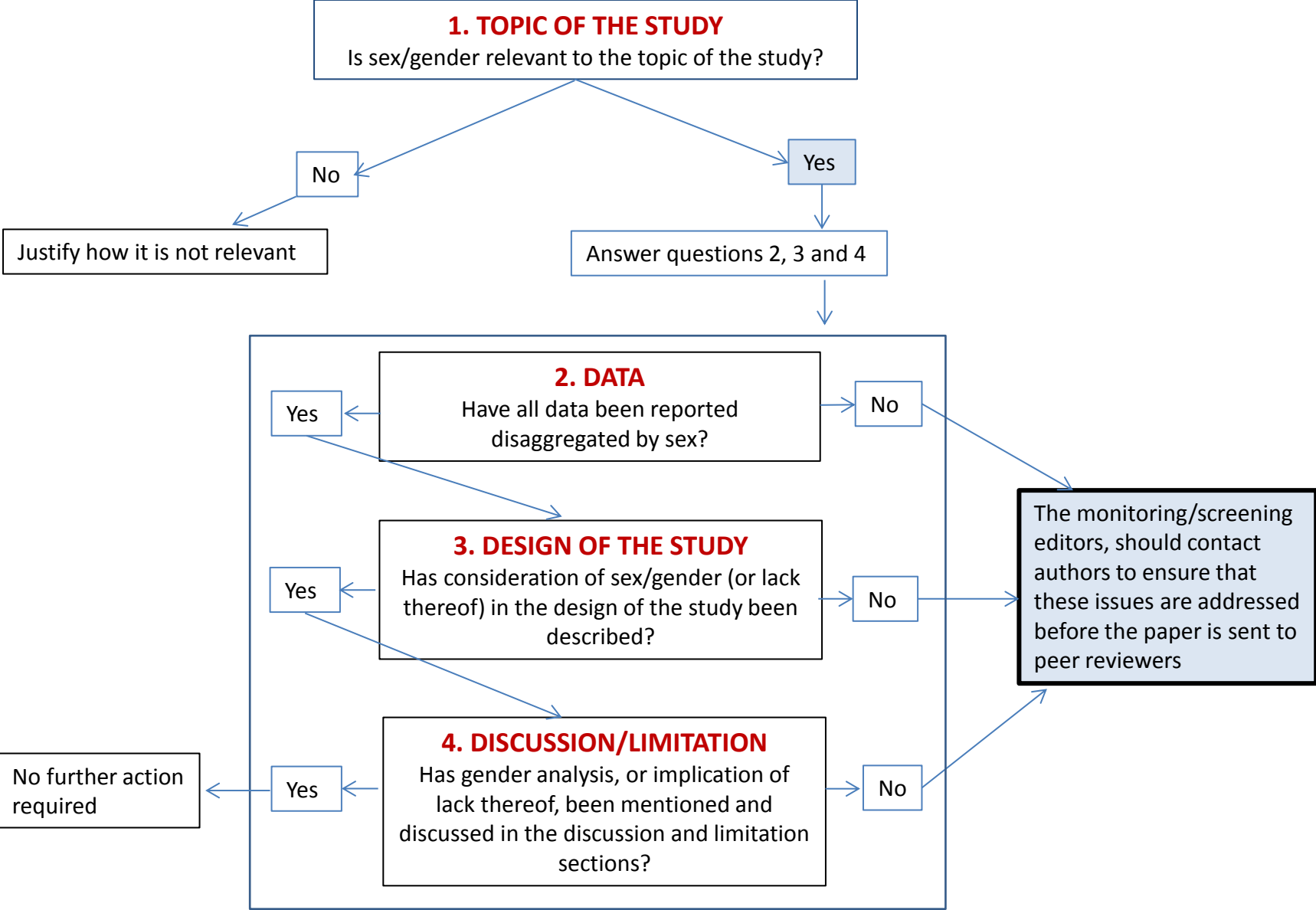
Discussion

- 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

SAGER flowchart guiding editors' initial screening of submitted manuscripts



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Reporting guidelines under development

The following guidelines are currently being developed:

- [PRISMA Harms: improving harms reporting in systematic reviews](#)
- [Guidelines for reporting the impact of patient and public involvement in research](#)
- [REporting Manualised INterventions for Dissemination and Evaluation \(REMINDE\) Statement](#)
- [CONSORT Extension for Social and Psychological Interventions: CONSORT-SPI](#)
- [The REporting of studies Conducted using Observational Routinely-collected Data \(RECORD\) statement](#)
- [STROBE checklist for conference abstracts](#)

Continuing

- [STARD for Abstracts: Essential items in reporting diagnostic accuracy studies in journal or conference abstracts](#)
- [SAGER \(Sex and Gender Equity in Research\)](#)
- [Reporting of orthotic \(splinting\) interventions](#)
- [Reporting guidelines for implementation research and operational research](#)
- [Reporting of Home Visiting Effectiveness/Efficacy Research \(RoHVER\)](#)
- [COS-STAR: a reporting guideline for studies developing core outcome sets](#)

SAGER final draft was approved by the GPC in 2015

- Looking for a suitable journal to publish it
- Implementation
- Dissemination

Suggestions welcome!



Final considerations

SAGER (Sex and Gender Equity in Research) will

- raise **awareness** about sex and gender differences in research,
- contribute to **reduce waste**
- stimulate opportunities for **innovation**.

Thank you

CONTACT US:

secretary@ease.org.uk

**Name and email addresses
of EASE GPC members on
EASE website**

