Be SAGER!

increase relevance in research through *sex and gender equity*

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EASE Gender Policy Committee

European Association of Science Editors
EASE

HEIRRI

HIGHER EDUCATION INSTITUTIONS
& RESPONSIBLE RESEARCH AND INNOVATION • Barcelona, 18 March 2016

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- collaboration.

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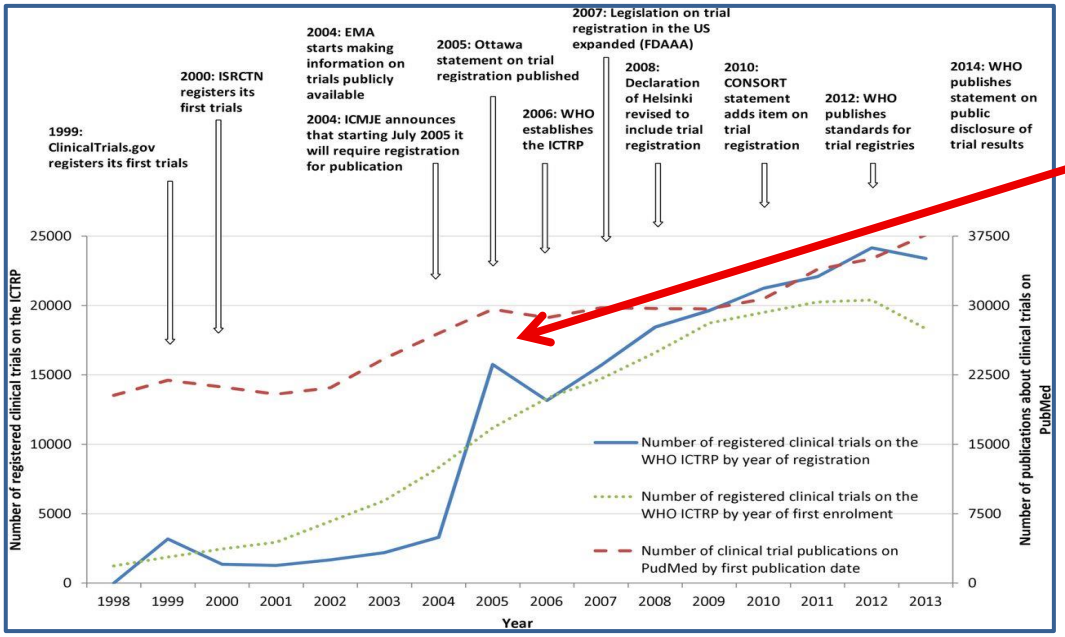
EDITORS AS AGENTS OF CHANGE

The story of clinical trials

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 requirement for registration in the Uniform Requirements

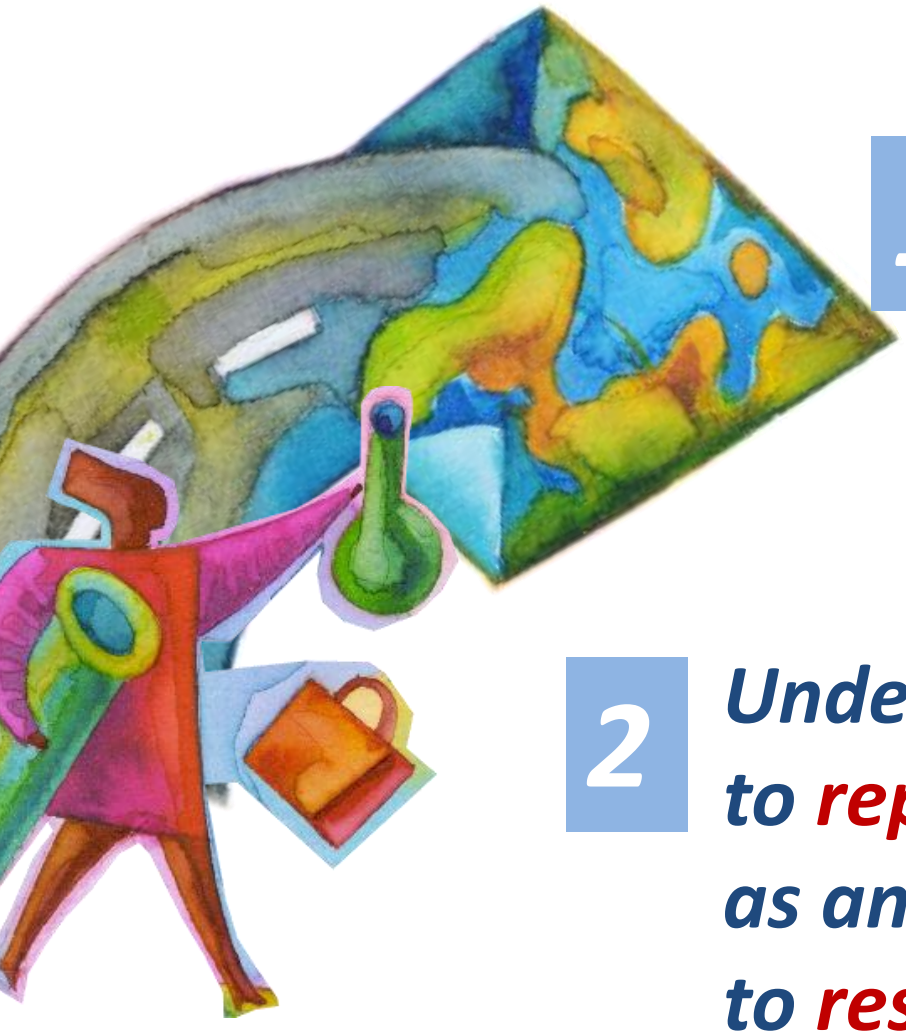


Increase in registered clinical trials and publications about clinical trials on PubMed (1998 – 2013)

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

Roderik F Viergever, and Keyang Li BMJ Open 2015;5:e008932

OBJECTIVES of the presentation



1 ***Become aware of sex and gender differences in research***

2 ***Understand why you need to report them properly as an important contribution to research innovation***

TERMINOLOGY MATTERS

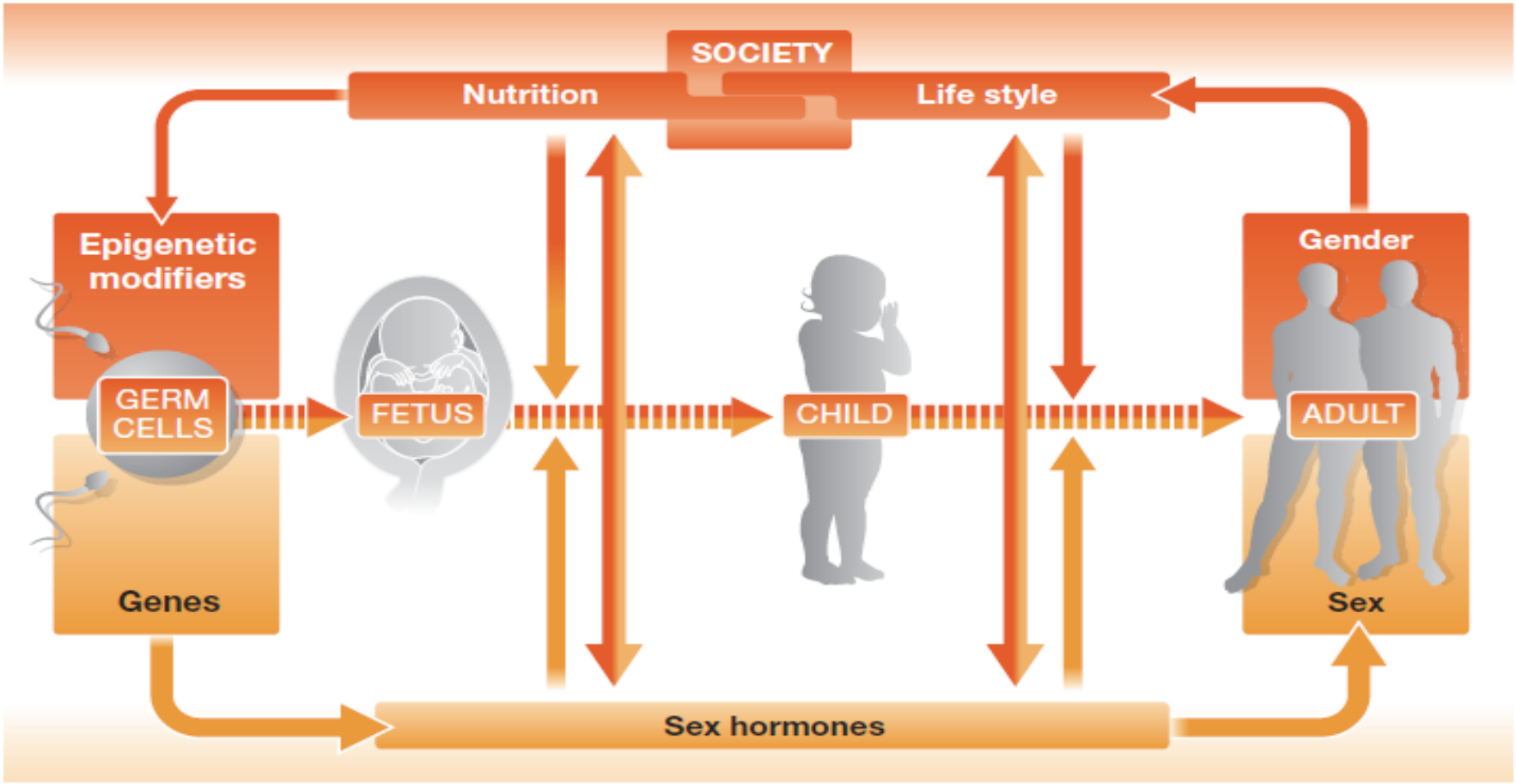
Sex refers to a set of biological attributes in humans and animals that are associated with physical and physiological features including chromosomes, gene expression, hormone function, and reproductive/sexual anatomy.[1] Sex is usually categorized as female or male, although there is variation in the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

Canadian Institutes of Health Research (CIHR); 2012

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

COMPLEX INTERDEPENCENCY OF SEX AND GENDER



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

The Gender Gaps

in scientific research & scientific publishing

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

THE LANCET

"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 Ju

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 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

MIND THE GENDER GAP

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

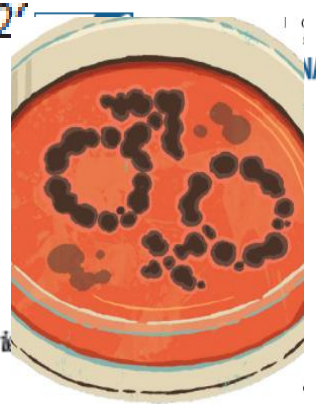
BY HELEN SHEN

22 | NATURE | VOL 495 | 7 MARCH 2013

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



Nature's sexism

The editors of this publication need to improve how we reflect women's contributions to sci

For this, we must inject an extra loop into our thinking.

ANIMAL RESEARCH

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.

www.sciencemag.org SCIENCE VOL 344 2 MAY 2014

PARITY OF AUTHORSHIP SHOULD BE A PRIORITY FOR JOURNALS, UNIVERSITIES, AND FUNDING AGENCIES

yet the gender gaps still exists in first authorship

Kathryn M Rexrode **BMJ**; 2016

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...

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

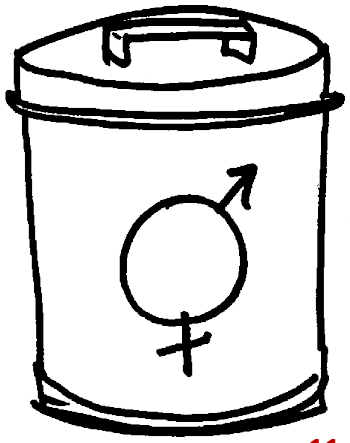
- **the effects of chemicals in the environment** have been studied predominantly in men, although they can have deleterious effects on women's reproductive health

- **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!

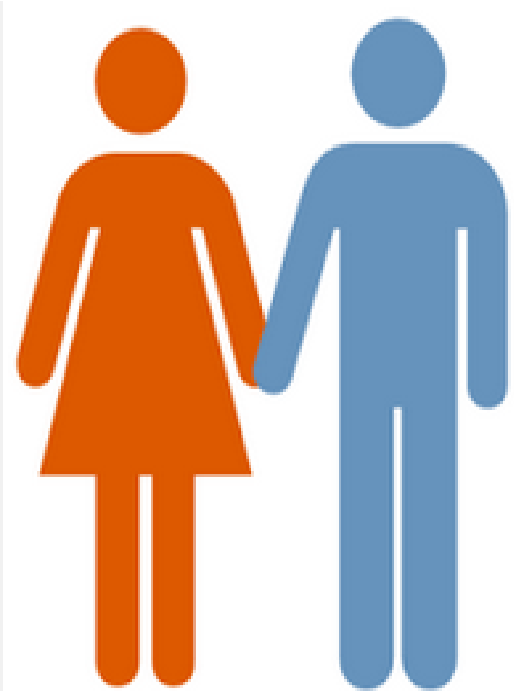
"We **learned only belatedly that women are at much greater risk** of complications and failure after total hip resurfacing arthroplasty [4], and the result suggests that clearer **scientific reporting would have prevented harm** to many women. We probably do not know the full extent of the harm we may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

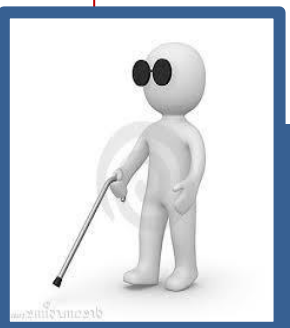
Reasons for concern

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 applicabilty**

DANGER

OVERGENERALIZATION

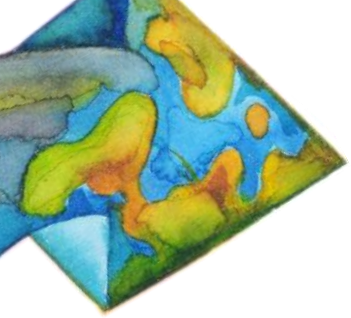
Nieuwenhoven and Klinge, Scientific Excellence in Applying Sex- and Gender-Sensitive Methods in Biomedical and Health *Research Journal of Women's Health* 2010

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



How can GPC contribute to RRI?

1

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

2

To promote the **SAGER guidelines** 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.

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.

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.*

7 MARCH 2013 | VOL 495 | NATURE | 47

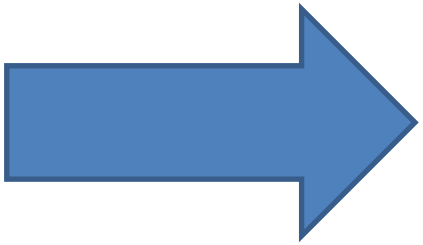
GPC activity

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

→ **better science**, whether in the life, natural or social sciences

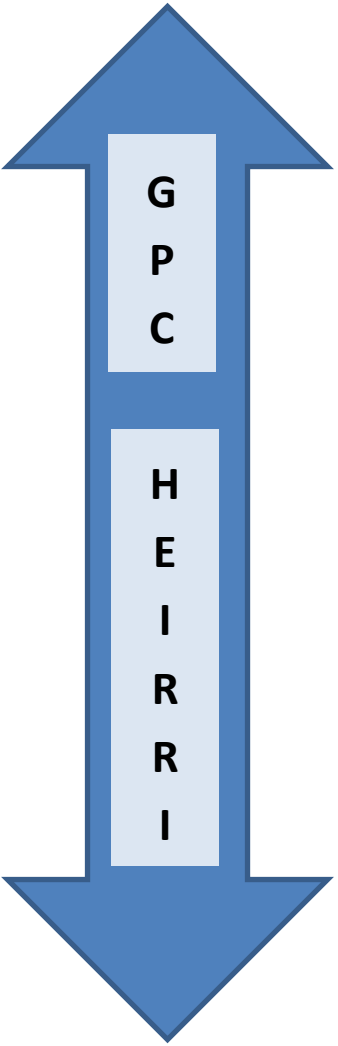
→ enhanced **evidence-based** practices, interventions and opportunities, for both women and men

→ foster **innovation** and **responsible research**



GPC meets HEIRRI 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

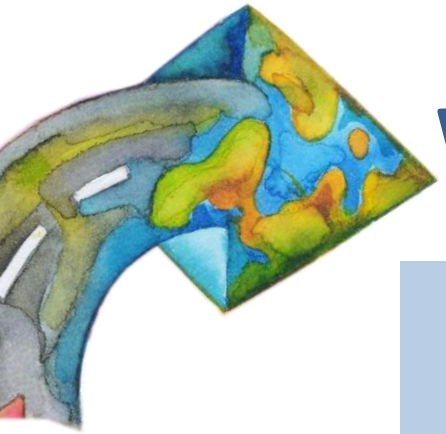
and

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

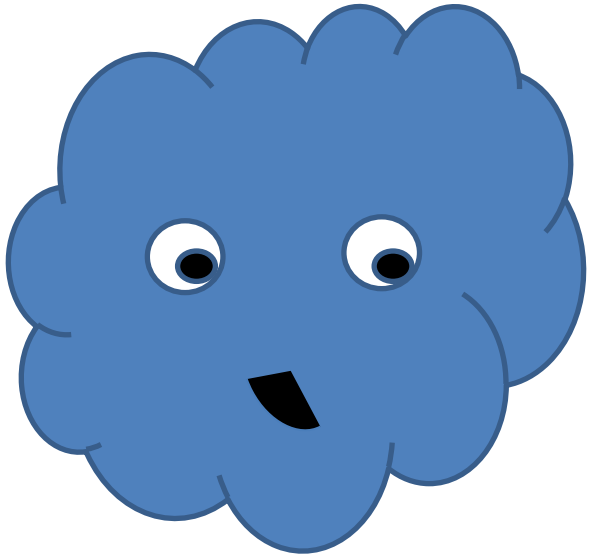
S — Sex

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,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

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

Approval by GPC, 2015

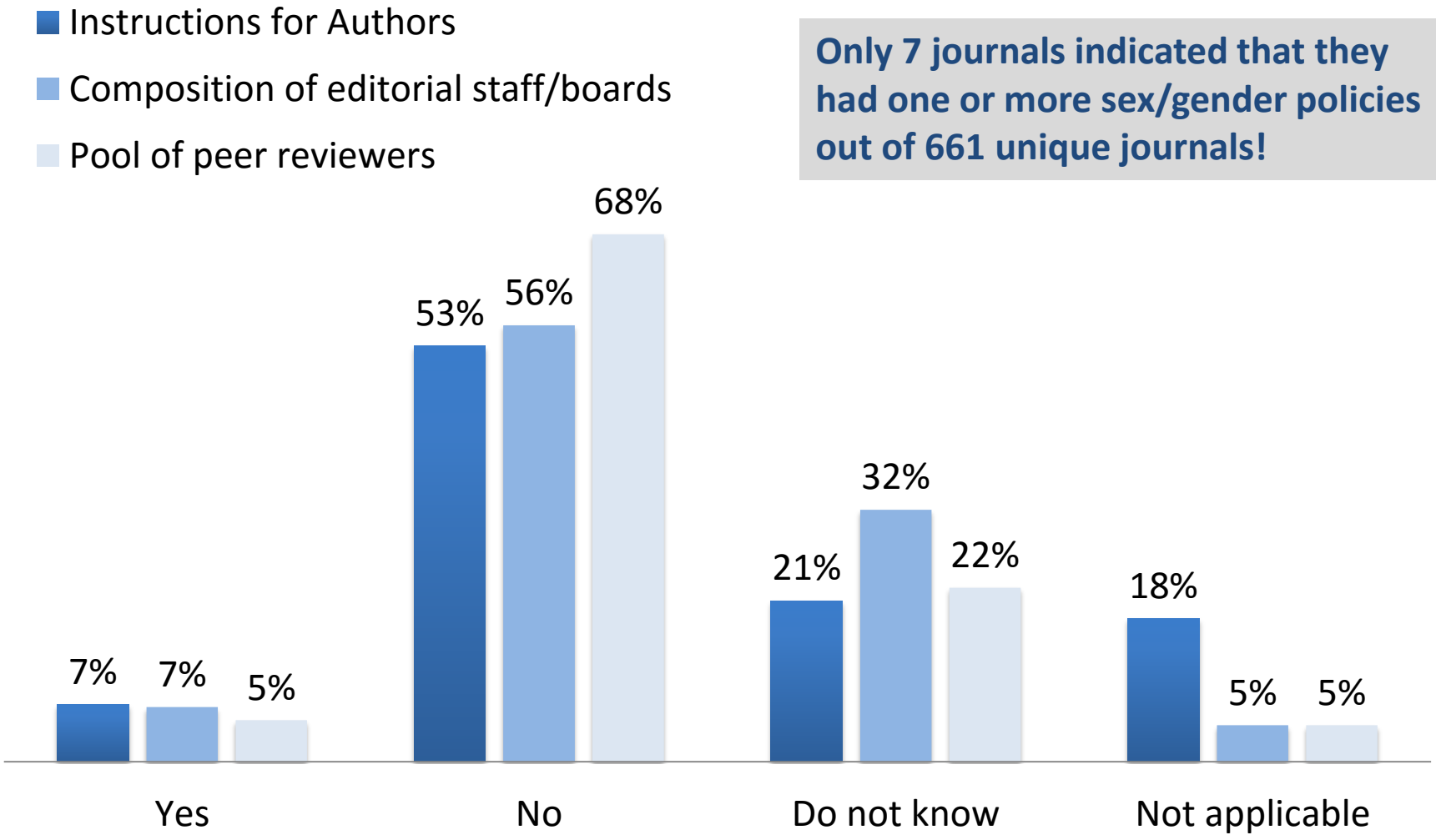
Article submitted

Publication

Dissemination

Implementation

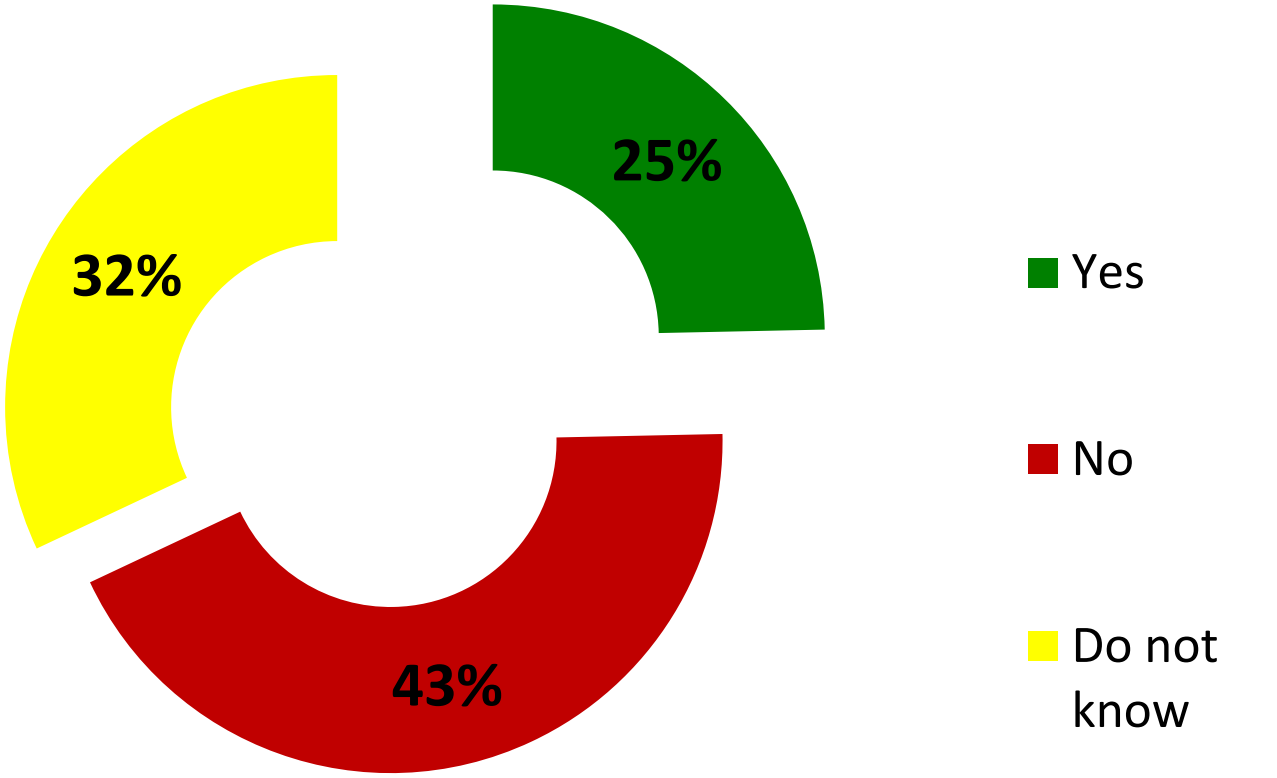
Survey results: overview of existing gender policies



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

All sample groups

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.

All sample groups

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

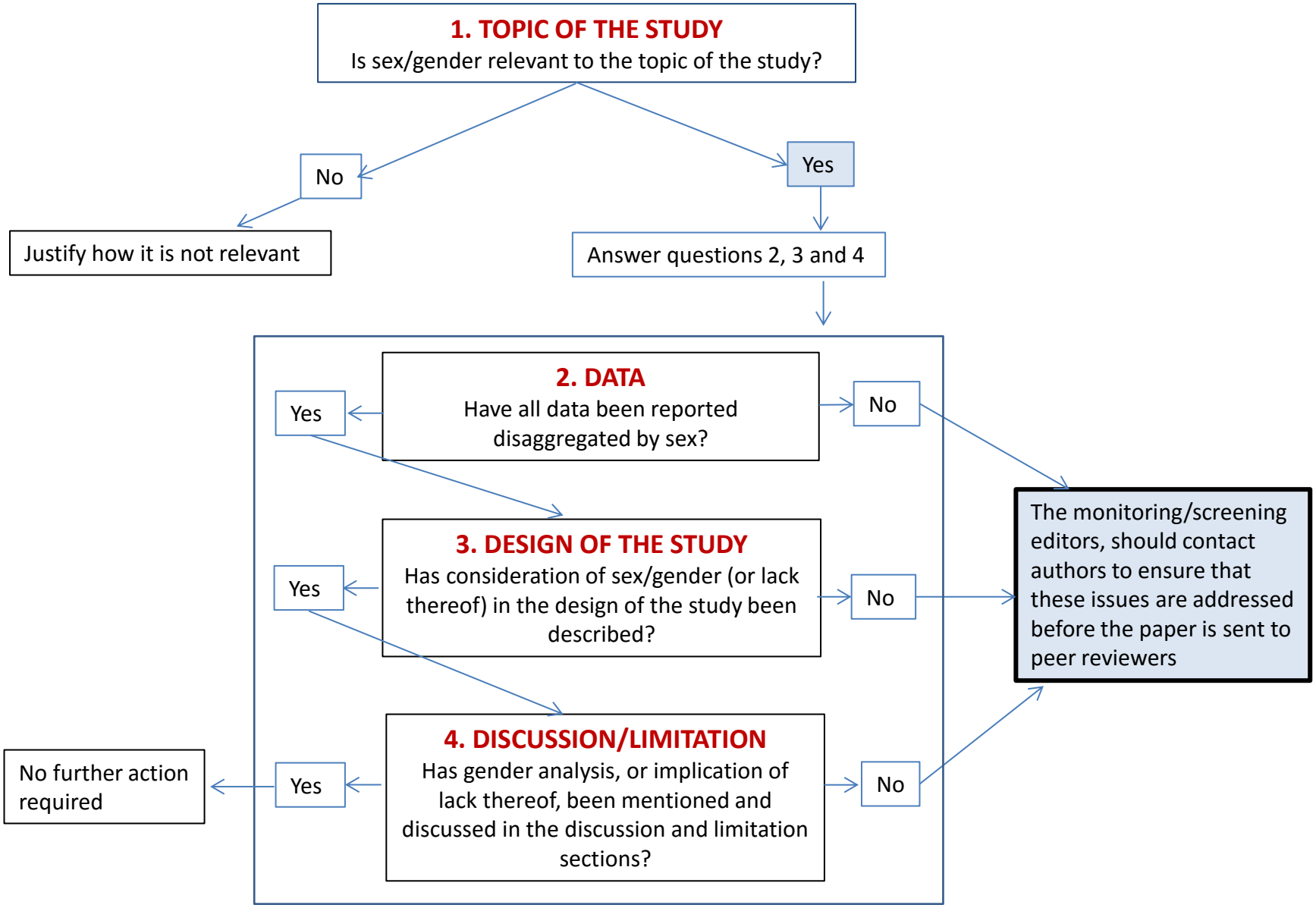
Discussion

- 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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Home > Library > Reporting guidelines under development

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

- 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

BREAKING NEWS

The article on SAGER guidelines was accepted for publication in BMC **Research Integrity and Peer review (OA)**
(in press 2016)

NEX STEPS

- **Dissemination**
- **Implementation**
- **Gender equity in the workplace**

Sex and Gender Questions already available on EASE website

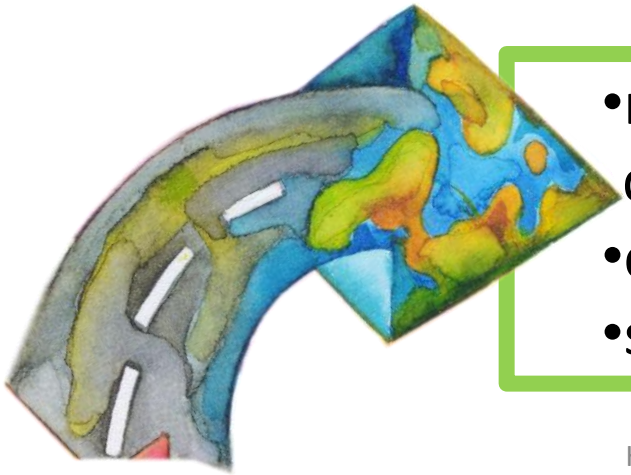
The EASE GPC is open to innovation and collaboration

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).

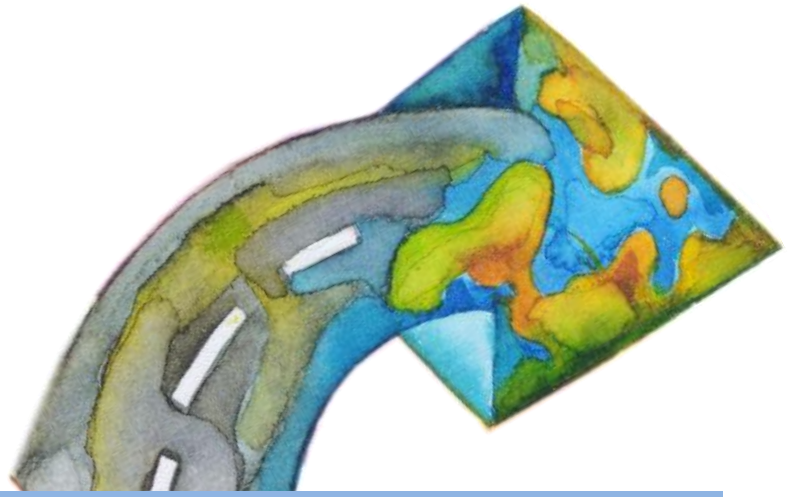
Final considerations

BE SAGER: increase relevance in research through sex and gender equity

Implement and disseminate the guidelines
Use them as training tool for researchers



- 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

SCIENCE VOL 308 10 JUNE 2005

Vive la Différence