SHIFING MINDS

Promoting Gender Sensitive Reporting of Scientific Data

Shirin Heidari, PhD
Chair – EASE Gender Policy Committee
Executive Editor / Sr Manager - International AIDS Society
25,281
Table 1 | Publications with sex and gender differences in the most frequent clinical entities

<table>
<thead>
<tr>
<th>Cardiology</th>
<th>Rheumatology/Immunology</th>
<th>Pneumology</th>
<th>Nephrology</th>
<th>Gastro-enterology/Hepatology</th>
<th>Neurology</th>
<th>Endocrinology</th>
<th>Oncology</th>
<th>Haematology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension (414)</td>
<td>Lupus erythematosus (68)</td>
<td>Asthma (140)</td>
<td>Renal failure (27)</td>
<td>Hepatitis B (22)</td>
<td>Multiple sclerosis (65)</td>
<td>Diabetes mellitus (447)</td>
<td>Skin carcinoma (45)</td>
<td>Anaemia (44)</td>
</tr>
<tr>
<td>Myocardial infarction (275)</td>
<td>Rheumatoid arthritis (41)</td>
<td>Lung cancer (116)</td>
<td>Diabetic nephropathy (11)</td>
<td>Hepatitis C (26)</td>
<td>Stroke (129)</td>
<td>Obesity (349)</td>
<td>Gastric cancer (25)</td>
<td>Leukaemia (49)</td>
</tr>
<tr>
<td>Atrial fibrillation (38)</td>
<td>Fibromyalgia (15)</td>
<td>Pulmonary hypertension (12)</td>
<td>Polycystic kidney disease (12)</td>
<td>Inflammatory bowel disease (13)</td>
<td>Epilepsy (56)</td>
<td>Hypothyroidism (33)</td>
<td>Bladder cancer (22)</td>
<td>Thrombocytopenia (6)</td>
</tr>
<tr>
<td>Coronary heart disease (207)</td>
<td>Sjögren's syndrome</td>
<td>Pulmonary embolism (110)</td>
<td>Renal artery stenosis (0)</td>
<td>Colorectal cancer (24)</td>
<td>Parkinson's disease (69)</td>
<td>Hyperthyroidism (16)</td>
<td>Thyroid carcinoma (16)</td>
<td>Purpura (2)</td>
</tr>
<tr>
<td>Cardiomyopathy (41)</td>
<td>Ankylosing spondylitis (11)</td>
<td>Sarcoidosis (6)</td>
<td>IgA Nephropathy (2)</td>
<td>Autoimmune Hepatitis (2)</td>
<td>Muscular dystrophy (11)</td>
<td>Morbus Addison/Cushing disease (5)</td>
<td>Pancreatic carcinoma (10)</td>
<td>Agranulocytosis (0)</td>
</tr>
</tbody>
</table>

Numbers in brackets refer to the number of publications.
Fig 1 | Complex interdependency of sex and gender in the human.

Source: Vera Regitz-Zagrosek; Sex and gender differences in health EMBO reports 2012
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, they are still poorly understood. One clinical sphere that
“Women appear to be more susceptible to this risk because they eliminate zolpidem from their bodies more slowly than men. ... FDA has informed the manufacturers that the recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien, Edluar, and Zolpimist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR).”
Why were these differences observed after approval and marketing?

1. Gender bias in clinical studies

HIV treatment studies (Antiretrovirals)
Median women: 19.2%

HIV Cure Studies
Median women: 9.9%

ARV trials funded, partially or wholly, by NIH, have significantly lower median proportion of female participants than non-NIH funded trials (15.3% vs 22.3% p=0.001).
Why were these differences observed after approval and marketing?

2. Gender bias in pre-clinical and basic science

Males still dominate animal studies

Many researchers avoid using female animals. Stringent measures should consign this prejudice to the past, argue Irving Zucker and Annaliese K. Beery, in the third piece of three on gender bias in biomedicine.

3. Gender bias in reporting

“...75% of studies in three highly cited immunology journals did not specify whether the animals used were male or female.”
“Research must systematically incorporate attention to sex and gender in design, analysis, and interpretation of findings” WHO 2009
EXAMPLE: Clinical trials registration

ICMJE policy on CT registration
13 Sept 2005

Clinical Trial Registration required by FDA in 1997

Source: Zarin et al NJEM 2005
Time for gender mainstreaming in editorial policies

Shirin Heidari¹*, Mirjam J Eckert¹, Susan Kippax², Quarraisha Abdool Karim³,⁴, Papa Salif Sow⁵, Mark A Wainberg⁶

The Journal of the International AIDS Society is proud to take a first step in this direction and feature such a policy on its website (http://www.jiasociety.org/info/about/) encouraging our authors to consider sex and gender differences in their study designs and requiring that gender analysis is presented in submitted manuscripts where applicable. Inclusion of this section in our journal’s instructions for authors is currently under negotiation with the publisher. We welcome peer reviewers in lending their support by ensuring that the aspect of gender is included in their overall assessments of a manuscript and highlighting the absence of it when necessary.
EASE Gender Policy Committee
Established by EASE Council in June 2012

Chairs: Shirin Heidari & Thomas Babor
Members: Rachel Carol, Paul Cummins, Mirjam Curno, Paola De Castro, Srecko Gajovic, Joy Johnson, Ravi Murugesan, Ana Marusic, Paul Osborne, Petter Oscarson, Ines Steffens, Kerstin Stenius, Chris Sterken, Sera Tort
Supporting members: Carina Sorensen, Meredith Sones

secretary@ease.org.uk
EASE Gender Policy Committee

• Mission:
  – Advocate for better reporting of gender and sex differences and/or similarities in scientific research
  – Promote gender mainstreaming (and better science) through inclusion of sex/gender considerations in policies and standards for scientific publishing
  – Promote gender mainstreaming and gender balance in editorial boards and editorial offices.

• Activities:
  – International Gender Survey (next presentation)
  – Development of Common Standards
International Gender Survey
Launched in spring 2013

- **Purpose**: to map existing editorial gender policies and opinions towards the adoption of such policies.

388 Unique journals - 114 Unique publishing houses

<table>
<thead>
<tr>
<th>Target group</th>
<th>Nr invited</th>
<th>Nr responded</th>
<th>Response rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EASE</td>
<td>429</td>
<td>167</td>
<td>40%</td>
</tr>
<tr>
<td>ISAJE</td>
<td>32</td>
<td>27</td>
<td>84%</td>
</tr>
<tr>
<td>100 journals</td>
<td>334</td>
<td>58</td>
<td>17%</td>
</tr>
<tr>
<td>Open</td>
<td>-</td>
<td>464</td>
<td>-</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>-</td>
<td><strong>716</strong></td>
<td>-</td>
</tr>
</tbody>
</table>
Statistical analysis of results

Statistical analysis performed using SPSS, to assess 2 overarching questions:

1. To what degree have journals adopted policies that integrate sex and gender considerations?

2. What is the readiness to adopt editorial policies related to sex and gender?
Overview of existing gender policies

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

All sample groups
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 for Authors.
Women are more in favour of gender policies than men

Gender of respondent significantly correlated with readiness to adopt gender policy in IfA
Reasons why sex disaggregation should NOT be included in ‘Instructions for Authors’

- “It's not applicable to all journals, only ones that publish research about people”
- “This policy will - paradoxically and unwillingly - create inequity for all other classes of 'different' humans”
- “I cannot see any reason whatsoever for doing it”
- “Not applicable to animals”
Do you think journals should have a gender policy concerning the composition of the editorial staff and boards?

- Yes: 40%
- No: 45%
- Unsure: 18%
Women are more in favour of gender policies than men

Significant correlation between gender of respondent and readiness to adopt gender policy with regard to composition of editorial board and staff

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>69%</td>
<td>41%</td>
<td>67%</td>
</tr>
<tr>
<td>31%</td>
<td>59%</td>
<td>33%</td>
</tr>
</tbody>
</table>

Woman (n=121)

Man (n=101)

Significant correlation between gender of respondent and readiness to adopt gender policy with regard to composition of editorial board and staff

OPEN group
So what next?

• Provide evidence and rationale for the implications of sex and gender bias in research reporting
• Provide guidance and recommendations for:
  – policies promoting reporting of sex and gender information in scientific publishing
  – policies and procedures to promote gender balance in editorial offices, editorial boards and pool of reviewers
• disseminate the Common Standard internationally and to monitor its implementation
Changing the “default assumption”:
There is a sex/gender differences until the contrary is proven.

“The absence of evidence is not the evidence of absence”
Carl Sagan
Thanks to members of the EASE Gender Policy Committee for their dedication and support, and in particular thanks to:

Carina Sorensen
Meredith Sones
Joy Johnson
Thomas Babor
Paul Osborne
Chris Sterken

CONTACT US:
Shirin.Heidari@iasociety.org
secretary@ease.org.uk