

Sex and gender reporting in Australian health and medical research publications

Laura Hallam,^{a,b,*} Amy Vassallo,^{a,b} Clare Hallam,^b Kelly Thompson,^{a,c} Janani Shanthosh,^{a,b} Louise Chappell,^b Zoe Wainer,^{d,e} Robyn Norton,^{a,f} Mark Woodward,^{a,f} Cheryl Carcel^a

^aThe George Institute for Global Health, University of New South Wales, Sydney, Australia

^bAustralian Human Rights Institute, University of New South Wales, Sydney, Australia

^cNepean and Blue Mountains Local Health District, Sydney, Australia

^dThe University of Melbourne, Faculty of Medicine, Dentistry and Health Science, Melbourne, Australia

^eThe Victorian Department of Health, Public Health Division, Melbourne, Australia

^fThe George Institute for Global Health, Imperial College London, London, United Kingdom

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Abstract

Objective: This study aimed to determine how sex and gender are being incorporated into Australian medical research publications and if this is influenced by journals endorsing the International Committee of Medical Journal Editors (ICMJE) guidelines, which contain criteria for sex and gender reporting.

Methods: Analysis of original research articles published in Australia's top 10 medical journals in 2020.

Results: From the 10 leading journals, 1,136 articles were eligible for analysis, including 990 human participant populations. Sex and/or gender were reported for 873 (88.2%) human populations, with 480 using conflicting terminology. Only 14 (1.6%) described how sex and gender were determined. The primary outcome, or key aim, was stratified by sex and/or gender for 249 (29.2%) participant groups and the influence of sex and/or gender on the results was discussed for only 171 (17.3%). There was no significant association between endorsement of the ICMJE guidelines and adherence to any sex and gender criteria.

Conclusions: Sex and gender are poorly incorporated into Australian medical research publications and was not improved by journals endorsing the ICMJE guidelines.

Implications for public health: Reporting and analysis of sex and gender data in health research in Australian medical journals requires improvement, for better health for all.

Introduction

Sex and gender influence diagnosis, progression, treatment and outcomes of many health conditions, as well as health behaviours and access and acceptability of healthcare.¹ Medical research has historically under-represented women^{2–4} or failed to examine the impact of sex and gender on health outcomes, leaving a data gap that there is now a push to fill.^{5,6} In order to reduce these data gaps and improve health outcomes for all, international research institutions are increasingly developing and implementing policies to encourage or mandate the incorporation of sex and gender into research.^{7,8} Despite these policies, studies have demonstrated data are still not routinely reported or analysed separately by sex or gender.^{9,10} Also, women, intersex (also known as variations of sex characteristics), transgender and gender-diverse

people continue to be underrepresented, or not identified, in experiments and data collection.^{9,11,12}

A 2017 analysis and subsequent Call to Action identified that Australian health and medical research funders and journals largely lacked specific policies on sex and gender¹³; although, some of the top journals recommended or required that authors adhere to the International Committee of Medical Journal Editors' (ICMJE) 'Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals' (ICMJE Guidelines).¹⁴ These guidelines outline how authors should account for lack of knowledge about the impact of sex and gender on health and disease by ensuring representative populations and considering sex and gender throughout the research cycle.¹⁴ Not adhering to these guidelines perpetuates past exclusion and leaves data gaps unfilled, which reduces the availability of evidence to inform gender-

*Correspondence to: Laura Hallam, 5/1 King St, Newtown, 2042, NSW, Australia; e-mail: lhallam@georgeinstitute.org.au.

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sensitive clinical guidelines and public health programs, impacting health outcomes. Our aims were to a) determine the extent to which the ICMJE requirements related to sex and gender are being addressed in original research articles published in Australia's top ten medical journals in 2020 and b) assess if the journal endorsing the ICMJE guidelines increased incorporation of sex and gender in order to identify if and how policy and practice can be improved.

Methods

Journal policies

The journals selected were previously identified as Australia's top 10 medical journals based on Journal Citation Reports.¹³ A web-search was used to determine if each journal recommended or required adherence to the ICMJE guidelines (Appendix 1).

Search strategy and screening

Research articles published by the 10 journals in 2020 were identified from Scopus using the 'Article' filter. The title and abstract were screened for inclusion by two reviewers, with conflict resolved by discussion and consensus. Eligibility criteria were full original research articles with humans, animals or cells as research subjects assessing a health-related outcome that was not a sex-specific health condition. During screening, articles were excluded if they were the wrong article type (for example, a commentary, editorial, review (including systematic reviews and meta-analyses), case report, image of the month, medical education or humorous article; n=451), were about a sex-specific condition (n=42) or contained no subjects or outcomes of interest (not including human, animal or cell subjects, for example surveying institutions rather than individuals, or surveying medical professionals about their employment rather than health outcomes; n=54). A further 14 articles were excluded upon full text review. Examples of the application of this inclusion criteria and the article inclusion flow chart are presented in the Supplementary file (Table S1, Figure S1).

Data extraction

Full text review and data extraction were undertaken according to a protocol, developed through an iterative process (see Table S2 and Figure S2, Appendix 1). Studies were classified as preclinical (basic science, animal or cell studies, including human derived cells and tissues), observational (no interventions) or experimental (controlled interventions). Subjects of the study were classified as humans, animals or cells. If an article contained multiple subjects, these were extracted separately and considered separate subject groups. Data was then extracted for a series of sex and gender criteria based on our interpretation of the ICMJE guidelines for each subject group. See Supplementary file for notes on interpreting terminology.

Two reviewers extracted data for a validation set of 20 articles using the protocol. Answers were compared and the protocol amended to increase clarity and refine definitions. A further 10 articles were examined by both reviewers using the amended protocol, with an inter-reviewer agreement of 90%. The remaining articles were divided between two reviewers and reviewed separately, with uncertainties discussed between the reviewers and decisions made by consensus.

Data analysis

Adherence to the ICMJE guidelines for each criterion was calculated per subject group and reported using descriptive statistics. The percentage of females/women/girls was calculated and analysed for each study design.

The extent to which each criterion was met was calculated for all journals who endorsed the ICMJE guidelines and all who did not. To assess whether there was an association between the journal recommending or requiring the ICMJE guidelines and the ICMJE criteria being met, chi-square tests were conducted for each criterion directly from the guidelines. This excluded the criteria regarding the use of additional sex or gender categories and statistical analysis as these were not directly mentioned in the guidelines. The analysis and chi-square tests were conducted only for human subjects, due to low numbers of animal and cell subjects in journals with the ICMJE guidelines. All analyses were conducted in SPSS. Results were considered significant when $p < 0.05$.

No ethics approval was required for this study.

Results

Journal policies

Of the 10 journals, five contained a general reference to following the ICMJE Guidelines in their author instructions (Table 1). There had been no changes in reference to the ICMJE Guidelines since the 2017 search.¹³ The *Australian and New Zealand Journal of Public Health* instructions now contain a specific section that states "If gender differences are not documented in an article, where relevant, authors should justify this exclusion in a cover letter".¹⁵

Article information

After screening and full text review 1,136 articles were eligible for analysis. These were unevenly distributed between journals (range 34-237, Table 1). Most articles were observational studies (787), with 121 experimental studies and 228 preclinical studies. Ninety-four articles had more than one subject group, giving 1247 total subject groups to analyse, with 990 humans, 157 animals and 100 cells.

ICMJE criteria – animals and cells

Sex was reported for 2/100 (2.0%) cells and 126/157 (80.3%) animals, with 113/126 (89.7%) animal subject groups being single-sex, 88 of

Table 1: Details of each included journal and eligible articles.

| Journal | ICMJE Guidelines Recommended or Required | Included Articles (n) |
|--|--|-----------------------|
| <i>ANZ Journal of Surgery</i> | Yes - Required | 233 |
| <i>Medical Journal of Australia</i> | Yes - Required | 34 |
| <i>Australian and New Zealand Journal of Psychiatry</i> | Yes - Recommended | 67 |
| <i>Australian and New Zealand Journal of Public Health</i> | Yes - Recommended | 43 |
| <i>Respirology</i> | Yes - Recommended | 67 |
| <i>Clinical and Experimental Ophthalmology</i> | No | 80 |
| <i>Clinical and Experimental Pharmacology and Physiology</i> | No | 161 |
| <i>Immunology and Cell Biology</i> | No | 37 |
| <i>Journal of Gastroenterology and Hepatology</i> | No | 237 |
| <i>Journal of Paediatrics and Child Health</i> | No | 177 |

Table 2: Count and proportion of articles adhering to each of the ICMJE criteria, as interpreted by the authors, for human participants. Data reported are n/(total subjects applicable for each criteria), (%).

| ICMJE Criteria | Humans N (%) |
|--|-----------------|
| Reported sex and/or gender of study participants | 873/990 (88.2) |
| Described how sex and/or gender was determined ^a | 14/873 (1.6) |
| Reported additional sex and/or gender categories ^a | 11/990 (1.3) |
| Single-sex and/or gender ^a | 20/873 (2.3) |
| Studies that justified including only one sex and/or gender | 14/20 (70.0) |
| Primary outcome stratified by sex and/or gender ^{a b} | 249/853 (29.2) |
| Justified not stratifying | 34/604 (5.6) |
| Statistical analysis to assess effect or association of sex and/or gender ^{a b} | 319/853 (37.4) |
| Not applicable (qualitative studies) | 13/853 (1.5) |
| Discussed influence of sex and/or gender on their results | 171/990 (17.3) |
| Results were stratified and discussed | 101/249 (40.6) |
| Results were statistically analysed and discussed | 106/318 (33.2) |

^aExcluding studies where sex or gender was not reported.

^bExcluding single-sex/gender studies.

which were males only. Studying one sex was justified for only two (1.8%) animal subject groups (Table S3).

ICMJE criteria – human participants

No articles in the analysis provided definitions of sex or gender. Sex or gender were reported for 873/990 (88.2%) of the articles involving human participants, with 351/990 (35.5%) reporting sex, 41/990 (4.1%) reporting gender and 480/990 (48.5%) using conflicting or interchanging terminology within their methods and results (Table 2). Despite the high level of reporting, only 14/873 (1.6%) had descriptions of how sex or gender were determined.

Eleven articles reported additional sex and/or gender categories, using a variety of terminology, including 'A gender not listed', 'Indeterminate', 'Intersex', 'Neither identifying as male or female', 'Non-binary', 'Other' and 'Transgender'. Three of these articles reported zero participants in their reported category. Of the articles that did report participants in their additional category/ies, one of the articles was specifically aimed at assessing the impact of their intervention on transgender participants (2.3% of their sample identified as transgender). Another compared men and women with individuals who 'did not identify as either male or female' and the other articles just noted very small numbers of participants in their additional category (generally <1%).

Only 20/873 (2.3%) of human participant groups were single-sex and/or gender but 14 of these provided a justification for this inclusion criteria. Of the single-sex and/or gender studies, half were men/males only and half women/females only.

Results for the primary outcome or key aim were stratified by sex and/or gender for only 249/853 (29.2%) of human participant groups, with only 34/604 (5.6%) of those that did not stratify their results justifying not doing so. However, 319/853 (37.4%) performed a statistical analysis to assess the effect, association or conduct a comparison based on sex and/or gender.

The influence of sex and/or gender was only included in the discussion of 171/990 (17.3%) of the articles. For results that were stratified, 101/249 (40.6%) had discussion about sex and/or gender,

while for those that conducted a statistical analysis, only 106/318 (33.2%) addressed the influence of sex and/or gender on their results in the discussion.

Inclusion of females/women/girls

Participants were 41–60% females/women/girls in 339/683 (49.6%) of observational and (55/108) 50.9% of experimental studies. Thirteen of 30 preclinical studies had only 21–40% females/women/girls. Overall, 289/821 (35.2%) of studies had less than 40% females/women/girls compared to 126/821 (15.3%) with over 60%, showing a skew towards females/women/girls being a minority of included participants rather than a majority. The remainder of the participants in these studies were males/men/boys, except for small numbers of individuals identified by another sex and gender category in 11 studies.

Impact of ICMJE guidelines

Overall, adherence to the ICMJE criteria was similar between journals with and without recommending or requiring the guidelines (Figure 1). The proportion of articles justifying single-sex and/or gender studies had the greatest variation between journals with and without the guidelines, largely due to small sample sizes. Results were not significant for any of the criteria, indicating that presence of the guidelines was independent of whether each criterion was fulfilled (Table S4).

Discussion

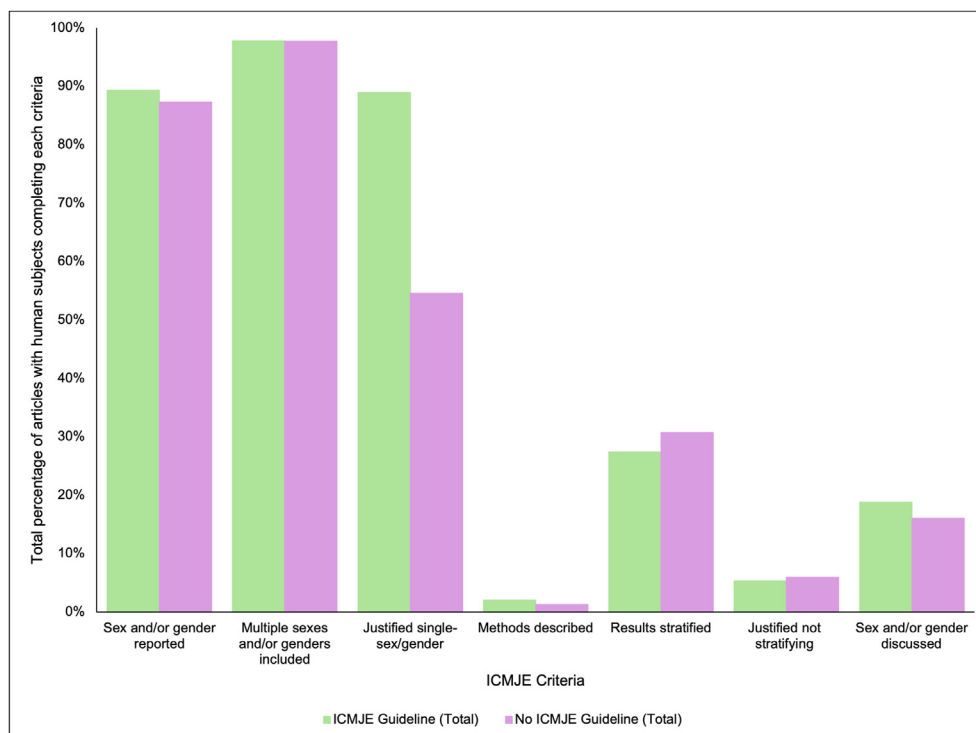
We found that most of the ICMJE criteria about sex and gender are poorly addressed and the journal endorsing the guidelines did not lead to greater adherence. While reporting of sex and/or gender was high for human participants (88.2%), sex and gender terminology was undefined, inconsistent and methods were generally not described. There was a skew towards underrepresentation of females/women/girls in human studies. Key results were mostly not stratified or analysed by sex and/or gender and the influence of these factors on the results not discussed. Additional strategies are needed to increase the influence of policies and support changes in research practice in Australia.

Implications

Research practice

Any future policy development, capacity building and education should target areas of research practice involving sex and gender that need strengthening. While reporting participant sex and/or gender demographics was generally high (88.2%), no articles defined sex or gender, 48.5% of reporting for human participants used conflicting terminology and only 1.6% described data collection methods. More deliberate use of language and improved understanding of sex and gender definitions will assist researchers in collecting and reporting accurate and inclusive data¹⁶ and forming appropriate conclusions. Including explanations of terminology is particularly critical when reporting additional sex and gender categories, where terminology is often evolving, and may be specific to a cultural context or group. Current Australian best practice for sex and gender data collection is a two-step method with separate sex and gender questions and minimum of three categories.¹⁷ Where relevant and appropriate, a specific question should be used to determine if participants have variations of sex characteristics (also known as intersex).¹⁷

Figure 1: Percentage of articles with human participants completing each ICMJE criteria, compared between all journals who do and do not require or recommend the ICMJE guidelines.



ICMJE criteria relating to the results and discussion of the research papers were not frequently addressed. Results were stratified by sex and/or gender for only 29.2% of participant groups. Stratified data is critical for identifying sex and/or gender-based disparities and informing research priority areas. Presenting these data in the main text or the supplementary allows it to be utilised for future analyses or meta-analyses.¹⁸ Further, only 17.3% of articles discussed the influence of sex and gender on their results, which is essential for contextualising findings, identifying clinical significance and recognising the limitations of the study in drawing conclusions. Sex or gender-based similarities, differences or disparities have important implications for public health and clinical care and this should be highlighted by authors.

Inclusion of females/women/girls as participants was relatively equal to males/men/boys but there was a skew towards lower representation of women. Researchers designing study protocols and recruiting participants should actively aim to recruit representative populations and attempt to ensure representation of all sexes and genders, if applicable to their research question. This may involve addressing both research/trial and personal/patient barriers to participation such as imagery used in recruitment materials, time commitment, location, travel arrangements and caring responsibilities.¹¹ The impact of exclusion criteria, such as being pregnant or breastfeeding, older age or presence of co-morbidities may also limit eligibility of women.¹⁹ This results in a clinical quality and safety vacuum, leaving treating clinicians to make an educated guess when treating these populations, potentially leading to poor health outcomes.

Research policy

Our analysis showed that journals requiring or recommending the ICMJE guidelines did not have a significant association with whether the studies published in that journal adhered to the criteria. This aligns with Merriman et al.'s analysis of global health and medical journals.⁹ The sex and gender content of the ICMJE guidelines is not highlighted by any of the journals and as it is dispersed throughout the document, many authors and reviewers may not have read all the criteria. Journals should either specifically recommend the sex and gender content of the ICMJE guidelines be adhered to, recommend a sex and gender specific guideline, such as Sex and Gender Equity in Research (SAGER),⁷ or develop and publicise their own sex and gender policy as recently done by the *Nature* journals.²⁰ Further, any policies and guidelines should be supported by implementation and evaluation plans to actively facilitate change. In implementing their new policy, *Nature* is actively raising awareness with authors and reviewers, aiming to understand current practice and seeking feedback on any challenges that arise in addressing sex and gender considerations.²¹ However, while it is important that journals implement and enforce their policies and guidelines at the publication stage of research, changes in research practice need to be encouraged or mandated by institutions across the sector at earlier stages in the research process. Internationally, research funders have been leaders in shifting research practice to better consider sex and gender, developing implementation strategies including requiring incorporation of sex and/or gender in the grant application process or to receive funding including justification for exclusion, mandatory training for investigators and appointment of a sex and gender

champion.⁸ These strategies employed by the Canadian Institutes of Health Research's Sex- and Gender-Based Analysis policy has led to a substantial increase in sex and gender being addressed in grant applications.²² Further, researchers need knowledge and skills to adhere to these guidelines, appropriately design their studies, report and analyse their results. Organisations across the health and medical research sector could provide resources that support researchers, editors and peer reviewers in implementing policy and guidelines, including the ICMJE guidelines.^{23–25} Research organisations, including universities and medical research institutes, can play an important role in educating students and staff about sex, gender and health,²⁶ and in developing new methods of considering sex and gender in research design.⁵ There is a role for all organisations in the sector to assist in increasing awareness of the complexity of these concepts and how they are relevant to human health and disease to ensure that they are duly considered by researchers, clinicians and policymakers throughout the medical research and translation pipeline.

Strengths and weaknesses

We have provided a thorough and systematic assessment of the adherence to the sex and gender criteria in the ICMJE guidelines across an entire year of research articles published in Australia's top 10 medical journals. Our analysis has added to the literature by assessing the influence of the frequently endorsed ICMJE guidelines and directly comparing journals with and without the criteria. Our study has several limitations which should be considered when interpreting the results. We have applied the ICMJE criteria to all articles in our sample, however, some of these criteria would not be appropriate for all studies, and so we would not expect 100% of articles to meet every criteria. Authors or reviewers may have made decisions about sex and gender reporting depending on their specific research question or population under study that we were unable to assess, or sex and gender may have been considered in the research design in a way we were unable to capture with these criteria. We have not assessed the quality of the papers, including whether statistical analysis was appropriate, if content in the discussion drew appropriate conclusions, or if justifications for not addressing the criteria were valid. Therefore, even if papers did address the criteria, that does not mean it was scientifically sound, as demonstrated by Garcia-Sifuentes and Maney, who showed that many studies that claim to have found sex differences had not conducted the appropriate statistical analyses to back up their claims.²⁷ We excluded articles on sex-specific conditions as most of the ICMJE criteria do not apply to them but acknowledge that these conditions would be applicable to transgender, gender-diverse and intersex people who may be excluded from or hidden in current research and subsequent clinical guidelines. This study focused on assessing sex and gender reporting as these factors have been the focus of efforts to change research practice to be more inclusive and gender sensitive and criteria for addressing sex and gender are outlined in detail in the ICMJE guidelines. However, there is increasing focus on considering intersectionality in health and medical research and so future analyses of published Australian research and future policies and guidelines directing health and medical research practice should address the intersection of sex and gender with other sociodemographic factors, including those mentioned in the ICMJE guidelines, such as race, ethnicity and age. Future work should also aim to understand how

policies can be developed and implemented to have the greatest influence on changing research practice.

Conclusion

Our analysis has shown that the sex and gender criteria in the ICMJE guidelines are poorly followed by publications in Australia's top medical journals and that the journal recommending or requiring authors to follow these guidelines does not significantly increase adherence to these criteria. Despite a Call to Action¹³ addressing the lack of specific sex and gender policies in the Australian journal landscape, little has changed and further work is needed to improve policy, educate researchers and support changes in research practice across the health and medical research sector.

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Ethics

Ethical approval was not required for this study.

Conflict of interest

MW is a consultant to Amgen, Kyowa Kirin and Freeline.

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Appendix A Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.anzjph.2022.100005>.