SEX AND GENDER IN HEALTH RESEARCH: AUSTRALIA LAGS BEHIND

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IGNORING sex and gender differences in medical research has the potential to compromise accuracy and put patients at risk, and Australia lags behind other countries in instituting policies and practices which require the integration of sex and gender analyses in grants and journal publications, according to the authors of a Perspective published online today by the Medical Journal of Australia.

"Historically and consistently across a broad-range of health domains, data have been collected from men and generalised to women," wrote the authors, led by Dr Zoe Wainer, Head of Public Health and Medical Director at Bupa, and Dr Cheryl Carcel, Clinical Research Fellow at the George Institute for Global Health at UNSW Sydney.

"Failure to appreciate the differences between and across the sex and gender spectrum risks compromising the quality of care and increasing costs due to inappropriate allocation of resources."

A growing number of countries, including the United States, Canada, Ireland and Germany, have introduced policies and practices that require the integration of sex and gender analyses in competitive research grants and publications in journals. In the US, for example, three organisations have been key contributors:

- the Organization for the Study of Sex Differences (www.ossdweb.org), which enhances knowledge of sex and gender analyses in health by facilitating interdisciplinary communication and collaboration among scientists and clinicians;
- the International Society of Gender Medicine (www.isogem.eu), which connects national and professional societies dedicated to the study of sex- and gender-specific differences in health; and
- Gendered Innovations in Science, Health and Medicine, Engineering, and Environment (Stanford University and the European Commission; http://genderedinnovations.stanford.edu), which provides tools and training to enable clinicians, researchers and policy makers to understand and undertake sex and gender research.

The Canadian Institutes of Health Research requires all grant applicants to respond to mandatory questions about sex and gender in research proposals. They also provide online training modules on sex and gender in biomedical research for scientists and peer reviewers. In the UK, The Lancet has "published a commentary on editorial policies with respect to sex and gender analyses that proposed guidelines for medical journals, including accurate use of sex and gender terms and reporting of sex, gender or both in study participants and the sex of animals and cells".

In Australia, the National Health and Medical Research Council (NHMRC) and Diabetes Australia have policies on the collection, analysis or reporting of sex- and gender-specific health data. However, only the NHMRC specifically recommended the analysis and reporting of sex- and gender-specific data. Four of the 10 Australian journals interviewed by the authors "did not have policies on the collection, analysis and reporting of sex- and gender-specific health data". Six of the 10, including the MJA, indicated they either followed the reporting guidelines of the International Committee of Medical Journal Editors or the Animal Research: Reporting of In Vivo Experiments guidelines.

Wainer and Carcel and colleagues made a raft of recommendations, including:

- University and other higher education ethics committees should ensure that implementation of sex and gender analyses in research is managed as an ethical issue;
- The Council of Presidents of Medical Colleges should ensure that medical colleges include evidenced-based sex and gender integration in clinical guidelines, requirements for funding for research, training and professional development;
- The Therapeutic Goods Administration should require all new applications for registration to address sex and gender differences;
- all federal and state health departments and agencies align their data collection practices with the Australian Government guidelines on the recognition of sex and gender and the Australian Bureau of Statistics Standard for Sex and Gender Variables;
- The NHMRC Australian Health Ethics Committee should review content relating to sex and gender in the National Statement on Ethical Conduct in Human Research and revise as required to ensure that the implementation of sex and gender analyses in research is managed as an ethical issue;
- Health funding bodies including the Independent Hospital Pricing Authority and Medicare should consider sex and gender analyses in cost-weighting calculations;
- The Australian Commission on Safety and Quality in Health Care should undertake to include integration of sex and gender data collection and analyses in guidelines for Clinical Quality Registries and ensure adherence to practice according to clinical guidelines, where sex and gender differences occur in accreditation standards;
The Medical Research Future Fund, the NHMRC, and other federal and state government health funders, as well as the National Heart Foundation of Australia, Cancer Council Australia, Diabetes Australia, and other health-related, not-for-profit funders and researchers should promulgate the development of policies and practices, requiring consideration be given to the inclusion of sex and gender analysis, or demonstrate why it is not required, and guidelines to address the implementation of sex- and gender-specific clinical care and health promotion and prevention;

Funders should develop a funding pool to cover the extra costs associated with including sex- and gender-specific analyses and they should make funding available to train researchers and clinicians in how to undertake research that includes comprehensive sex and gender analyses;

Australian-based, peer-reviewed journal editors should develop and monitor the implementation of policies to ensure researchers include sex and gender in reporting of research;

Health industry stakeholders, such as pharmaceutical companies and medical device companies, should ensure that all new products are developed, consistent with US Food and Drug Administration regulatory policies, requiring the involvement of both males and females in clinical trials and the integration of sex and gender analyses.

"In the absence of implementing these, there is a risk that Australia will fail to keep pace with the rest of the world and, in turn, will become increasingly less competitive when applying for funding from international bodies and will reduce international partnership opportunities with overseas organisations," the authors concluded.

"By implementing these recommendations, Australia will align with other nations in improving health research and practice to the benefit of the women, men, girls and boys of Australia. This is not simply a women's or men's health issue, but an issue for all Australians."

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