EDITORIAL

Recommendation to include sex and gender equity in research (SAGER) guidelines in research, publications and healthcare

Lisa Cambridge

There has been a groundswell of change from the traditional interpretation of sex and gender in society, science and the law over the last decade. More recently we have seen global opinion question the validity of sex hormone testing at the Olympics and in New Zealand, legislative amendments to the Birth, Deaths, Marriages and Relationship Registration Act (1995) will change the legal requirements for changing name or gender on birth certificates.

The terms sex and gender are inextricably linked and used interchangeably, but the two terms are not equivalent. Sex – refers to the biological attributes of either male or female based on their respective genitalia and reproductive function. Gender - describes the personal relationship with oneself, their body, their behaviours, social and cultural experiences. Traditionally, a new-born's sex is assigned as either male or female at birth based on the baby's genitals, it is then presumed that the child's gender will fall into one of these two roles, depending on society and cultural constructs. The LGBTQIA+ (Takatāpui) (lesbian, gay, bisexual, transgender (whakawāhine, tangata ira tane, fa'afafine and fakaleiti), queer, intersex, asexual) (1) community add complexity to these biological and social concepts.

Both sex and gender play roles in health and well-being, treatment availability and outcomes, environmental and occupational risks, even down to the way we seek health care (2). Biologically, we exhibit physiological differences in cardiovascular, respiratory, immunology, endocrinology, musculoskeletal and renal systems (3). The actions of pharmaceutical agents, marker expression, laboratory reference ranges (4), life span and disease prevalence also differ.

Chromosomal and genetic variations not only influence the differentiation of reproductive organs but also gene expression. Disorders of Sexual Development (DSD) (5) describes conditions ranging from significant (e.g., Intersex) to mild variations where development of sex chromosomes, gonad or sexual anatomy are considered, atypical. It has been postulated that as many as one in a hundred people have a form of DSD but may never know unless trying to conceive or being treated for another medical condition. Intersex people are born with sex chromosomes that signal as male or female, but the anatomy displays the other. Families of intersex babies are under enormous emotional pressure to "chose a sex" by undergoing surgery, giving no opportunity for the child to develop gender identity naturally (6). The right to reproduce and body integrity lawsuits have been brought and won against these surgeries (7).

Any binary view has been surpassed by a swathe of literature on the multidimensional concepts of sex and gender. It has been shown in clinical research that failure to separate each sex and gender-specific data, limits the power of data analysis and valuable study samples, result in adverse consequences, poor quality findings and data loss (8). At the coalface of healthcare, a lack of knowledge or prejudice by healthcare professionals result in assumptions of a patient's appearance and poor decisions on the use of binary-specific reference ranges.

How the science community, conduct and report medical research and operate within healthcare, matters. Heidari et al (9) referred to editors as "gatekeepers of science" influencing the conduct of research and its publication and advocating guidelines for clinical trial registration and ethical consent. In this respect, international journals drive transparency, equity and gender-sensitive reporting in research and internationally by implementing and adopting policies like the SAGER (Sex and Gender Equity in Research) Guidelines. Summarised in Table 1, these guidelines are the result of surveys conducted by the Gender Policy Committee, established by the European Association of Science Editors (EASE) in 2012. Surveys focused on four policy areas; instructions for authors to separate out sex and gender data, editorial board gender policies, gender balance amongst peer reviewers and provision of a tool for reviewers to assess and standardise sex-specific, sex as a biological variable, or gender-specific analysis and reporting in scientific publications.

Table 1: SAGER Guidelines for Research Publications

Principle	Recommendation
General	Correct use of the terms, sex and gender.
	Research elements should be designed and conducted in a way to enable analysis of sex and gender-related differences in the results, even if unexpected.
Title & Abstract	If only one sex or gender is to be included in the study, then the sex of any cells, tissues or other material derived from these should be specified, if appropriate.
Introduction	Report where relevant whether sex and/or gender differences may be expected, if appropriate.
Methods	Report if or how sex and gender were considered in the design of the study, whether they ensured adequate representation and justify any reasons for exclusion (e.g., cell lines).
Results	Data should be represented separated by sex and/or gender. Analysis should be reported regardless of positive or negative outcome. In clinical trials, data on withdrawals should also be separated by sex and gender.
Discussion	Potential implications of sex and gender should be discussed in the findings as they relate to the results. If sex and gender analysis was not conducted, the reason should be given and implications, limitation of lack of interpretation should discussed.

Implementing these steps would influence and guide the profession (10,11) across all areas of healthcare from improving sex-specific reference ranges for example, liver enzymes, creatinine, haemoglobin, iron studies and cardiac troponin (12) that are affected by sex hormones and body size as well as the heterogeneity seen in transgender populations affected by hormonal or surgical therapies. To taking detailed patient histories for most appropriate treatment and modifying laboratory test forms to include sex assigned at birth as well as gender, patients undergoing hormone therapy, or had surgery.

If editors are the gatekeepers of science and journals the voice, then surely the downstream effects of implementing such policies and guidelines into author instructions are ten-fold for research, healthcare and patients? Consideration of sex and gender differences and similarities lead the science community to conduct and publish, robust research and innovation in healthcare, with greater precision, sensitivity and relevant analysis for better outcomes in health and well-being.

But the real bottom line is human dignity, the belief that all people hold special value that is tied to their humanity and are worthy of respect regardless of age, ethnicity, status, gender, and sex.

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