

# Sex and Gender Reporting in Health Research: Why Canada Should Be a Leader

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## ABSTRACT

Sex and gender have been demonstrated to influence all domains of health, from basic mechanisms of disease development to health service utilization. It is therefore no longer acceptable to ignore sex and gender issues in health research reports if these reports are to be deemed accurate. Funding agencies and journals have been identified as primary change agents in health research systems. Canada is making progress on the funding side of the equation – applicants to Canada’s federal health research funding agency are required to justify why sex and gender are relevant or not to their research designs. We argue that it is now time for Canada’s leading health research journals to follow suit. We have a unique opportunity in Canada to demonstrate leadership in doing science better with sex and gender – and we should not let it be missed.

**KEY WORDS:** Sex; publishing; research design; policy

La traduction du résumé se trouve à la fin de l'article.

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Every cell is sexed and every person gendered – and we can no longer operate as if this fact of life does not matter for research. A critical mass of evidence now makes it irrefutable that sex and gender influence all domains of health, from basic mechanisms of disease development to health service utilization.<sup>1</sup> This puts us in a situation all too common in the research enterprise: we have the evidence, but moving it into practice and policy is challenging, slow, and hard to scale up. A recent series of commentaries in *Nature* and *Science* have identified funding agencies and journals as primary change agents to drive the routine integration of gender and sex in health research<sup>2-5</sup> – essentially, front- and back-end portals to system change. At the Canadian Institutes of Health Research (CIHR), we are making change on the funding side of the equation. We now call upon Canadian journals to join our efforts. Specifically, we urge journals to adopt sex and gender reporting requirements in their editorial policies.

We have a unique opportunity in Canada to demonstrate leadership in doing science better with sex and gender, and we should not let it be missed. Our funding infrastructure is far ahead of other countries when it comes to sex and gender. We are the only country in the world with a specific funding institute dedicated to gender, sex and health research – CIHR’s Institute of Gender and Health. In December 2010, we modified the standard CIHR grant application module to include fields that require all applicants to state whether they are considering gender and/or sex in their research designs and to justify why or why not. The Health Portfolio of the Government of Canada has had a Sex and Gender-Based Analysis Policy in place since 2009. Health Canada’s guidance document on the inclusion of women in clinical trials has recently been updated and is currently being finalized. Yet, we know this is not enough. Evidence from our neighbours to the south indicates that after 15 years of the NIH (National Institutes of Health) poli-

cy to include women in clinical trials, only 28% of the resulting publications reported on the basis of sex/gender.<sup>6</sup> Funded research does not exist in a vacuum; “publications are currency in science and so if reporting on sex is valued this will feed back into research design and practice.”<sup>7</sup> We need Canada’s top health research journals to complete the cycle.

Just last year, the US National Institute of Medicine (IOM) took a major leap in moving this issue forward with a workshop on sex-specific reporting of scientific research. The daylong meeting brought together editors of highly-ranked scientific journals with funding agency representatives, researchers, and policy-makers from various sectors. The meeting itself was an important gateway to change; some journal editors had already implemented reporting requirements related to sex and gender, others left the workshop committed to raising the issue with their editorial boards. While the report on the workshop put forth several practical recommendations (e.g., identify the sex of study samples or populations, be it animals, cells, people; report if a study is single-sex in the title/abstract), the discussions highlight the slippery slope between analysis and reporting. We contend that reporting alone is a valuable starting point for the type of incremental change that will transform our health research system. Reporting can help drive further change by illuminating gaps in knowledge which may spark new sex- and gender-based analyses of previously “answered” questions.

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Reporting about sex and gender is quite simply more accurate; more accurate reporting means that more accurate conclusions can be drawn. Barnett Kramer, Editor-in-chief of the *Journal of the National Cancer Institute*, notes in the IOM workshop report that good science means that every study must be replicable and to do this one must know certain details about sex.<sup>7</sup> Methodological choices about sex and gender in relation to study population or analytical approach should be reported and justified, as with any other methodological choices. The sex of study participants should not be left to the reader to infer, but should be stated plainly.

In line with an argument put forth by Jon Levine, Editor-in-chief of *Frontiers in Neuroendocrinology*, in the IOM workshop report,<sup>7</sup> we are calling for policies that put the onus on authors to provide a rationale for how they consider sex and gender; peer reviewers then can decide what the impacts of those choices are in terms of the rigour of the study. We suggest that a helpful starting point for journals might be to ask authors, in reporting their studies, to consider questions akin to those we utilize in the CIHR grant application module:

1. Are sex (biological) considerations taken into account in this study?
2. Are gender (socio-cultural) considerations taken into account in this study?
3. If YES, please describe how sex and/or gender considerations are considered in your [study results].
4. If NO, please explain why sex and/or gender are not applicable to your [study results].

While the Uniform Requirements for Biomedical Journals fail to account for gender, by subscribing to these guidelines, the *Canadian Journal of Public Health* has taken a step toward including sex and gender. The Requirements state that: "Where scientifically appropriate, analyses of the data by variables such as age and sex should be included."<sup>8</sup> Also, in relation to the selection and description of participants, authors are asked to explain why they include certain variables, such as sex, when they do. We are asking Canadian journals, including the *Canadian Journal of Public Health*, to go even further: incorporate explicit sex and gender reporting requirements that minimize caveats and oblige authors to unambiguously tell us the information we need to know in order to judge "to whom the evidence applies."<sup>9</sup>

The impact of reporting cannot be underestimated. Without appropriate sex-based reporting, we would not know that a drug as commonplace as aspirin differentially reduces the risk of cardiovascular disease by reducing ischemic stroke in women and myocardial infarction in men.<sup>10</sup> Furthermore, it is well documented that reporting at the level of primary studies has ripple effects in terms of what is replicated at the level of systematic reviews.<sup>9</sup> The CIHR Institute of Gender and Health is currently funding the

Campbell and Cochrane Equity Methods Group to consider issues related to sex and gender in systematic reviews, but without better primary studies, changing review protocols will have little real impact.

Better reporting with sex and gender is critical to ensuring that publications are not just an end product in the knowledge translation cycle, but that the evidence they present can be used to improve the health of literally everybody. It is time now for journals to catch up to funders.

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## RÉSUMÉ

Il est prouvé que le sexe et le genre influencent la santé sous tous ses aspects : des mécanismes fondamentaux de l'évolution des maladies à l'utilisation des services de santé. Il n'est donc plus acceptable de faire abstraction du sexe et de la problématique homme-femmes dans les rapports de recherche en santé si l'on veut qu'ils reflètent la réalité. Les organismes de financement et les revues sont reconnus comme étant les principaux agents de changement dans le système de recherche en santé. Le Canada fait des progrès du côté financier de l'équation – les demandeurs auprès de l'organisme fédéral canadien qui finance la recherche en santé sont tenus d'expliquer la pertinence (ou non) du sexe et du genre dans leur modèles de recherche. Nous faisons valoir qu'il est temps pour les grandes revues de recherche en santé du Canada d'emboîter le pas. Nous avons une occasion unique, au Canada, de faire preuve de leadership en améliorant la science par le sexe et le genre; il ne faudrait pas laisser échapper cette occasion.

**MOTS CLÉS :** sexe; édition; conception de la recherche; politique