Accurate reporting on sex and gender in health research is integral to ensuring that health interventions are safe and effective. In this study we assessed the extent and nature of reporting about sex and/or gender in a sample of Canadian randomized controlled trials. This work connects directly to the Gender Summit goals of gender equality in research, and explores one facet of the ways gender equality is embedded in study design, data analysis, and reporting.

1. Relevance
In Canada and internationally, governments, research organizations, journal editors and health agencies have called for more inclusive research, provision of sex-disaggregated data, and the integration of sex and gender analysis throughout the research process. Sex and gender analysis is generally defined as an approach for considering how and why different subpopulations (e.g., of diverse genders, ages, and social locations) may experience health conditions and interventions in different or similar ways.

2. Aims & Objectives
The objective of this study was to assess the extent and nature of reporting about sex and/or gender, including whether sex and gender analysis (SGA) was carried out in a sample of Canadian randomized controlled trials (RCTs) with human participants.

3. Methods
Two reviewers screened 256 records of 1,433 records from a MEDLINE search limited to January 2013 to July 2014, to identify the first 100 RCTs that were either identified in the trial publication as funded by a Canadian organization or which had a first or last author based in Canada. Data were extracted in duplicate during an initial training period for 10% of the RCTs; once agreement was reached, the remainder of the data was extracted by one person and verified by a second.

4. Results
The median sample size of the RCTs was 107 participants (range 12 - 6085). While 98% of studies described the demographic composition of their participants by sex, only 6% conducted a subgroup analysis across sex and 4% reported sex-disaggregated data. No article defined “sex” and/or “gender.” No publication carried out a comprehensive sex and gender analysis.

5. Conclusions
Findings highlight poor uptake of sex and gender considerations in the Canadian RCT context and underscore the need for better articulated guidance on sex and gender analysis to improve reporting of evidence, inform policy development and guide future research.

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