



Healthy Life Trajectory Initiative

Sex- and Gender-Based Analysis Plan

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1. Sex-and-Gender Based Analysis

Sex-and-Gender based analysis (SGBA) is an analytical process used in health research to determine whether interventions have differential effects by sex or gender. However, sex and gender are often considered the same and used interchangeably despite having different meanings.

Sex refers to a set of biological attributes in humans and animals. It is primarily associated with physical and physiological features, including chromosomes, gene expression, hormone levels and function, and reproductive/sexual anatomy (1).

Gender refers to the socially constructed roles, behaviours, expressions and identities of girls, women, boys, men, and gender-diverse people. It affects how people perceive themselves and each other, how they act and interact, and the distribution of power and resources in society. Gender identity is not limited to a binary (girl/woman, boy/man) or static -- it exists along a continuum and can change over time. There is considerable diversity in how individuals and groups understand, experience and express gender through the roles they take on, the expectations placed on them, their relations with others and the complex ways that gender is institutionalized in society (1).

1.1 CIHR - Sex- and Gender-Based Analysis in Research Action Plan

“The Canadian Institutes of Research (CIHR) SGBA Research Action Plan aims to systematically integrate an SGBA into CIHR-funded research to ensure that funded research is relevant and impactful for Canada’s diverse population” (2). The plan focuses on building capacity and strengthening expertise in SGBA within CIHR and the health research community. The goal is to ensure the research CIHR funds are relevant and impactful for Canada’s diverse population by building SGBA capacity and strengthening SGBA expertise within the research community and CIHR.

1.2 CIHR’s Key Considerations for Appropriately Integrating Sex and Gender in Research

1. ***Sex as a Biological Variable.*** CIHR recommends that applicants consider accounting for sex as a biological variable in basic science, clinical, health system and population health studies where appropriate (3). The following key considerations apply for rating the quality of integration of sex as a biological variable in the proposal to meet standards for rigour and reproducibility in science and to allow for the discovery of sex differences and their underlying mechanisms (3).

Strengths:

- A clear articulation that a phenomenon, condition or disease under study has, or does not have, a different incidence or prevalence based on sex
- Inclusion or recruitment of male and female cells, tissues, animals or humans when studying models of disease that affect males and females
- Documentation and analysis of the sex of the cells, tissues, animals or humans used in the protocol
- The proposed experimental design that disaggregates results by sex

- Builds on what is already known about sex differences as well as sex-related mechanisms in the field of study

Weaknesses:

- It does not provide a compelling justification for a single-sex study
- Ignores observed sex differences already reported in the literature or fails to build on published data in the design of the proposed studies
- Does not report the sex of the cells, tissues, animals or humans being studied
- Does not describe how sex will be accounted for and considered in the analysis plan
- Does not demonstrate a commitment to disaggregate the data by sex
- Conflates and/or confuses the terms sex and gender

2. *Integration of Gender as a Social Determinant of Health*. CIHR recommends that applicants consider accounting/addressing gender as a sociocultural determinant of health in the clinical, health system and population health studies where appropriate. The following key considerations apply for rating the quality of integration of gender as a sociocultural determinant of health in the proposal as a strength or a weakness:

Strengths:

- Literature review: reports what is known about gender, gender theories, and/or intersectionality in the field of study where relevant
- Methods: describes how gender will be measured or investigated in the population under study
- Recruitment method: addresses and mitigates bias
- Analysis describes how gendered sub-groups will be compared and that the findings will be reported separately in the results section
- Implementation and knowledge translation plan: considers aspects affected by gender

Weaknesses:

- Reports that gender is irrelevant without adequate justification
- Does not measure gender within the population under study when it is possible and relevant to do so
- Does not describe how gender will be accounted for and considered in the analysis plan
- Does not demonstrate a commitment to disaggregate the data by gender and/or present suitable subgroup analyses
- Conflates or confuses the terms sex and gender

2. Sex and Gender Science

SGBA policies have helped to build an emerging, transdisciplinary field of sex and gender science which brings together considerations of the body to illustrate the many sexed and gendered interconnected complexities of health (4).

2.1 Sex-and-Gender Based Analysis – Life-Course Perspective

What we know about the diagnosis, treatment, and prevention often comes from research on male cells, male mice, and men; however, differences between men and women in epidemiology, pathophysiology, clinical manifestations, psychological effects, disease progression and response to treatment characterize diseases (5). Sex is an essential modifier of biology and disease via genetic, epigenetic, and hormonal regulations. Gender is a determinant of patient and provider's behaviour, and sex and gender impact depression and suicide and the development of major chronic diseases such as heart disease, cancer, chronic pulmonary disease, stroke, and diabetes (5-8).

2.2 Sex and Gender Science Approaches

There are five types of sex and gender science approaches that can be considered.

1. *Sex-and-gender difference research*. Sex difference research identifies contrasting aspects of male and female bodies that impact health or bodily processes, conditions or diseases, responses to treatment or even longevity. Gender differences research is similar in that it typically contrasts the social and cultural experiences of men and women, boys and girls, and gender-diverse people to derive knowledge (4). Disaggregating data by sex and/or gender marks differences between females/women and males/men, which leads to an understanding of the roles of the biological and sociocultural factors in disease presentation and outcomes (9).
2. *Sex-and-gender-related factors research*. A sex-and-gender-related approach focuses on the components, factors and processes associated with sex or gender, focusing on the processes and elements of sex and gender that drive causal pathways (4).
3. *Sex/gender interactions*. Studying sex/gender interactions identify ways gendered social experiences can influence life processes (and vice versa), such as how to societal experience and behaviours like nurturance, competition, and assertiveness can change the expression of sex hormones like testosterone (10, 11). Such approaches can also examine how sexed characteristics (such as reproductive systems or anatomical features) can shape work, socioeconomic opportunities and health (4).
4. *Intersectional approaches*. Recently, the Government of Canada's Health Portfolio introduced an "SGBA Plus" to develop, implement, and evaluate the Health Portfolio's research, surveillance, legislation, policies, regulations, programs, services, and other initiatives (12). SGBA Plus is an intersectional approach to assess how factors such as sex, gender, age, race, ethnicity, socioeconomic status, disability, sexual orientation, cultural background, migration status, and geographic location interact and intersect with each other and broader systems of power. An intersectional approach reveals how intersecting identity factors, histories, power relations, distribution of resources, and individuals' lived realities contribute to differences in accessing health-related resources and health outcomes. A fundamental question to quantitative

intersectional research is whose experiences, outcomes, or processes must be examined or made visible (13). By investigating population heterogeneity in the context of social power and studying processes of oppression, discrimination and privilege, interventions can be tailored to be relevant to specific communities (13).

5. *Sex and gender minority populations*. The research focused on sexual and gender minority populations examines health and social issues of specific relevance for members of minority communities. Given the historical and ongoing oppression and marginalization of people based on non-normative sexual orientations, sexual identities, behaviours and non-normative gender identities and expression, there is much evidence documenting adverse health outcomes in both communities (4).

3. Sex-and-Gender Based Analysis in the HeLTI Consortium

HeLTI SGBA Goal and Objective

Goal: to generate, understand and apply evidence related to sex and gender-related factors and interactions that will inform international policy and decision-making for improving health and preventing non-communicable diseases (NCDs).

Objective: to apply an SGBA approach to trial domains, namely, research study design and data collection, analyses, knowledge translation and partnerships and patient/public involvement.

SGBA in Trial Domains

Domain #1 – Study design and methods

- Literature review: reports what is known about gender, gender theories, and/or intersectionality in the field of study where relevant.
- How sex and gender are considered in the design, e.g. In addition to maternal factors in child health, the role of fathers/partners is being studied, including the genetic/epigenetic and environmental factors.”
- A clear articulation that a phenomenon, condition or disease under study has, or does not have, a different incidence or prevalence based on sex
- Background knowledge about the study population
- How sex and gender are determined
- Inclusion/exclusion and recruitment methods address and mitigate gender bias; will the intervention’s reach extend to male, female, and transgender persons?
- Provider and research team SGBA training and capacity building – SGBA Training (free online competency modules from Institute of Gender and Health (IGH), <https://cihr-irsc.gc.ca/e/49347.html>)

Domain #2 –Analyses/results (see section #2)

- How sex and gender will be measured and analyzed in the population under study for example
 - Data disaggregation by sex.
 - Statistical analysis to assess the effect or association of sex and/or gender.

- Primary outcome stratified by sex and/or gender
- Analyzing the data by sex and gender differences and similarities.
- Describing how gendered sub-groups will be compared and that the findings are reported separately in the results section.

Domain #3 - Knowledge translation (Consider in HeLTI KT Plan)

- Implementation and knowledge translation plans consider aspects affected by sex and gender, e.g., how can gender roles help inform dissemination strategies?
 - KT Messengers – delivered by women only, men only, men and women separately or together?
 - Messaging – How can dissemination messages be crafted to respond to sex and gender-related factors?
 - Target policies and system change, e.g., addressing “gender gaps” in policies and systems
 - Target individual’s health behaviour change relevant to sex and gender
 - KT products including SGBA, gender, and gender-related results.
 - Align with IGH/CIHR Sex and Gender Knowledge Translation, <https://cihr-irsc.gc.ca/e/49933.html>
 - Publications reporting; journal guidelines on SGBA reporting –e.g., SAGER and ICMJE guidelines (14, 15)

Domain #4 –Partnerships and Patient/Public Involvement

- KT partnerships for policy and system scale-up and change
- Patient/public involvement health behaviours

4. Activities and Logic Model (template to be developed)

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