Applying an SGBA+ lens to medical device regulation

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Background

- Devices can prevent, diagnose, cure or treat medical conditions
- Some devices have caused harm, several specific to women
- Research shows that few studies of device safety and efficacy reported participant sex, age or ethnicity
- Diversity can influence device safety/performance. It is important to:
  - Test devices among diverse patients prior to wide-spread sale and use
  - Monitor the attributes of patients who experience device-related harm
  - Communicate with healthcare professionals and patients about who is at risk of potential harms
- By order of the Minister of Health, Health Canada developed an Action Plan on Medical Devices, including analysis of how regulatory policies and practices across the device lifecycle address SGBA+

Purpose

AIM

Explore how SGBA+ is considered in Health Canada regulatory policies and processes across the medical device lifecycle

OBJECTIVES

1. Analyze internal and external documents used by Health Canada for regulatory decision-making across the device lifecycle for the presence and absence of SGBA+ details
2. Identify opportunities to improve SGBA+ reporting in general and device-specific documents targeting industry, Health Canada staff, healthcare professionals and patients, and strategies needed to promote and support SGBA+ considerations by all.

SGBA+ domains

Domain	Definition
Sex	Biological female or male
Gender	Perceived roles, behaviours, expressions and identities of women, men and gender-diverse persons
Intersectional factors	Interact with sex and/or gender: age, race, ethnicity, culture, immigration status, education, income, employment, marital/partnership status, ability (versus dis-ability), sexual orientation, urbanity/rurality, region of residence

Methods – content analysis

General documents included:

- Most used by Health Canada to report, monitor, review and communicate evidence of device safety/efficacy and device-related incidents
- Guidance documents, standard operating procedures and forms used by industry or Health Canada staff

Device-specific documents included:

- Sampled devices known to be associated with device-related incidents
- Women-specific: breast implants, transvaginal mesh, IUD birth control devices
- General: pacemakers, knee implants
- Retrieved from 8 publicly-available databases; for example: Drug & Health Product Register (Regulatory Decision, Safety Review), Clinical Information on Drugs & Health Products, Medical Device Incidents, Recalls & Safety Alerts, Health InfoWatch

Results – general documents

- 56 documents (1,461 pages, mean 25.6, median 17.0, range 1 to 231)
- Few addressed SGBA+ (6.7% sex, 11.1% gender, 15.6% intersectionality)
- Those that did provided scant details:
  - Referring to research participants, “Have the clinical studies been performed in special populations?” and “If applicable, information about patient selection criteria”
  - *Considerations for Inclusion of Women in Clinical Trials and Analysis of Sex Differences* addresses only sex in the testing stage of the device lifecycle
- Advice not consistent for industry and HC staff across documents for the same task (e.g. Causality Assessment App 1 advises HC staff to consider gender, age and ethnic origin but corresponding industry guidance and HC forms do not)
- OVERALL: Documents used by industry to prepare applications or reports, and forms/templates used by HC staff to review applications or reports largely contain no requirements for SGBA+ information

Results – device-specific documents

- 50 documents (most half to one page copied-and-pasted from web sites)
- None addressed SGBA+ (sex indirectly addressed only because some devices specifically used in biological females; for example, IUDs); for example, none of the following described characteristics of participants/affected persons:
  - Reports in Medical Device Incidents and Recall & Safety Alerts
  - One-page Safety Review of IUDs noted 24 studies and 19 Canadian reports of suppressed lactation
  - 111-page Clinical Evaluation report of transvaginal mesh included 50 studies and 473 complaints involving 467 serious injuries
- Multiple sources are not linked, provide overlapping information, but offer incomplete information about SGBA+
- OVERALL: Documents shared with healthcare professionals and patients offer no details of whether devices are safe for diverse persons, whether HC independently reviewed data provided by industry, risks to diverse persons, or if/what action is warranted by healthcare professionals/patients for device-related problems

Recommendations

- 105-page report: 14 Tables and 10 Appendices
- 341 recommendations to address specific gaps in general documents
- Numerous high-level recommendations to address gaps in device-specific documents and related sources/databases
- 20 overall recommendations (+ many additional sub-recommendations) on how to update sources, documents, policies and processes
- Numerous recommendations for knowledge translation; for example:
  - Rather than relying on one guidance document (e.g. Considerations), include prompts for SGBA+ throughout all documents, standard operating procedures and forms/templates to emphasize importance and prompt reporting/review
  - Educate via document updates, worked examples and training (e.g. CIHR modules)
  - Engage stakeholders in planning, updating and training

Strengths and limitations

Strengths

- Rigorous content analysis methods
- Fully documented data extraction and analysis processes
- Compliance with standards for conducting and reporting content analysis
- Researcher expertise in content analysis and knowledge translation, and knowledge of the medical device lifecycle based on prior research
- Planned and conducted in partnership with Health Canada representatives

Limitations

- Sampled only general documents recommended by Health Canada and specific documents for select devices available through publicly-available sources (access to internal documents not granted by Health Canada)
- Offered recommendations to address SGBA+ gaps and how, but not content for updates, which is beyond the scope of this project

Implications

- Numerous recommendations may not be easy to digest or prioritize
- Complex multi-level challenges:
  - System – requirements for additional information places additional burden on industry, which conflicts with encouraging medical device trials in Canada; in part, Canadian regulatory processes must be in line with international practices
  - Organizational – updating documents may require considerable time and effort, and possibly an overhaul of policies, standard operating procedures and underlying information systems / databases
  - Individual – change is difficult and may be met with reluctance/resistance by industry representatives and HC staff
- Considerable knowledge translation targeting all stakeholders will be required including communication, education and engagement

Many thanks

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