Best Brains EXCHANGE

Exploring the Development of a Canadian Breast Implant Registry

Meeting Summary

Health Canada Santé Canada

Canada

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Background

Breast implants are medical devices used to make breasts similar, increase breast size or reconstruct breasts after a surgical procedure, such as a mastectomy. Health Canada regulates the sale of medical devices in Canada. This includes breast implants.

Most people who receive breast implants identify as women. However, gender-diverse individuals also receive breast implants.

Physicians, researchers and people with lived experience have previously called upon the government to establish a breast implant registry. Such a registry was also recommended by the Scientific Advisory Committee on Health Products for Women. This committee advises Health Canada on current and emerging issues regarding women's health.

Meeting overview

A virtual Best Brains Exchange (BBE) meeting was held on March 7, 2023. Senior policymakers, subject matter experts and health care system stakeholders shared their knowledge on health registries and patient notification processes.

Presentations by Canadian speakers focused on the opportunities, lessons learned and challenges involved in developing and maintaining Canadian patient tracking initiatives. They also emphasized how important it is to:

- identify the registry's purpose and how information will be used
- secure ongoing funding
- encourage stakeholders to participate in the registry
- determine the information that should be provided in patient notifications
- protect patient privacy

International speakers talked about how their jurisdictions developed and put into operation their respective breast implant registries. These registries are used for various purposes, such as for research or patient safety notifications. They are also funded, hosted and operated differently.

The international speakers also offered the following advice:

- define the registry's scope
- secure long-term funding
- involve surgeons in its development
- make it mandatory for patients to opt in, if possible

Discussion themes

Meeting participants talked about the **multiple factors** that should be considered when establishing a breast implant registry:

1 Purpose

- determine if the registry will be used for research or patient safety notification purposes, or for both

2 Framework

- identify the organization that will host the registry by considering the legislative authorities that collect, hold, appropriately share and publish health information
- secure consistent ongoing funding

3 Creation

- use an approach that centres on and benefits the patient
- use many forms of communication, if possible, to notify patients about safety-related issues

4 Level of stakeholder engagement

- include many different stakeholders in registry discussions, such as:
  - clinicians
  - surgeons
  - manufacturers
  - regulatory colleges
  - people with lived experience
- engage with as many partners as possible to ensure support for a registry and its success

5 Participation

- mandate that all physicians, including those from private clinics, submit data
- encourage patients to opt in but also make it possible for them to opt out in accordance with Canadian privacy legislation requirements

6 Data collection and governance

- recognize that oversight of health data across jurisdictions is complex
- consider how information could be transferred between various databases and jurisdictions, as health care is a provincial and territorial responsibility and Canada does not have a national health record system
- explore data-sharing agreements among provinces, territories and private health clinics, taking into consideration the legislative changes that may be needed

7 Data security and privacy

- establish mechanisms to protect patient information and maintain patient privacy
- engage with patients in how their information is being stored, protected, shared and published

Conclusion

The BBE meeting explored the development of a Canadian breast implant registry.

Meeting participants supported a registry, but outlined the challenges and complexities of doing so, including the many legislative and operational factors that must be considered. More discussions on this complex and critical issue should be held.