Canadian Institute for Health Information

Response to House of Commons Canada - Standing Committee on Health in the context of the study of oversight of medical devices (breast implants)

May 2023

Background

The Canadian Institute for Health Information (CIHI) is an independent, not-for-profit organization created by the provinces, territories, and federal government. Its mandate is to deliver comparable and actionable information to accelerate improvements in health care, health system performance and population health across the continuum of care.

CIHI is a secondary collector of health data primarily for reporting information on health system performance and the health of Canadians; it does not have a regulatory nor patient care delivery role. Several provinces and territories have enacted health information-specific privacy legislation that authorizes health care facilities to disclose personal health information – without patient consent – to CIHI for the purposes of health system use, provided that certain requirements are met[1]. In provinces and territories that do not have health information-specific privacy legislation in place, disclosure of data to CIHI is governed by public-sector legislation. This legislation authorizes health care facilities to disclose personal information to CIHI for statistical purposes, without an individual's consent.

It is under this mandate and authority that CIHI receives data for the Canadian Joint Replacement Registry (CJRR) and its other pan-Canadian data holdings.

Potential Breast Implant Registry in Canada

CIHI recognizes the importance of having data on breast implant surgeries to monitor breast implant safety and long-term outcomes. As the Committee heard in the testimonies, success criteria for a breast implant registry include having clear objectives; high data coverage and quality, standardized data; minimal data collection burden; and stable, long-term funding.

International exemplars show that an opt-out model will maximize patient participation in a breast implant registry. In the Canadian context, an opt-out registry will require creation or changes to legislation at the federal, provincial, and territorial levels to 1) describe provisions for an opt-out process and 2) mandate the submission of breast implant surgery data to the registry from private care providers.

In an opt-out model, the primary data collector (surgeons) must ensure that patients are informed of how their personal data may be used for the registry's purposes and submit records of patients who have not opted out of the registry. A process needs to be developed to manage subsequent withdrawal of consent, and patient contact for follow-up and/or notification.

[1] For example, CIHI is recognized as a prescribed entity under the *Personal Health Information Protection Act of Ontario*, so health information custodians in Ontario may disclose personal health information to CIHI without patient consent pursuant to Section 29 as permitted by Section 45(1) of the act.

Even with an opt-out registry, mandating data submission from care providers is needed to ensure coverage. In the CJRR example, the coverage increased dramatically when several provinces mandated the data submission to the CJRR. Legislation is needed at the federal, provincial, and territorial levels to compel data submission from both the private and public settings to the registry.

CIHI's Canadian Joint Replacement Registry (CJRR)

The CJRR is a pan-Canadian medical device registry for hip and knee joint replacements, which are high volume with over 137,000 surgeries performed every year across Canada. The registry collects information on devices such as artificial hips (e.g., acetabular and femoral components) and knees (e.g., tibial and femoral components) that were implanted in each patient. While there are helpful lessons learned from CIHI's experience operating the CJRR, it cannot be readily leveraged for the purpose of a breast implant registry due to the different nature of orthopedic vs. breast implant surgeries, and how health data flows and privacy legislation are set up across Canada.

Hip and knee joint replacements are publicly funded procedures that are largely performed in public settings (hospitals). Under existing provincial/territorial privacy or personal health information legislation, data can readily flow to CIHI from public settings without patient consent for the purposes of health system use, in accordance with CIHI's mandate. In contrast, an estimated 85% of breast implant surgeries are performed in private settings in Canada. Jurisdictional differences exist in legislation for data to flow to CIHI from private settings. Legislative changes at the federal, provincial, and territorial levels will be required to authorize the flow of data from private clinics to an organization such as CIHI without consent. CIHI is also not currently set up to manage opt-out or perform patient notification and track-and-trace functions.

Path Forward to breast implant registry in Canada

From our previous experiences setting up registries, foundational work is needed before establishing a successful registry. The crucial first step is to define and assemble the federal, provincial, and territorial legislative framework required to set up a regime that would enable data submission to an opt-out registry for breast implants. Extensive privacy review and complex legislative changes would be needed, with buy-in from various levels of governments, surgeons, and manufacturers. CIHI is pleased to continue to engage with Health Canada and provincial/territorial governments and provide support, for instance, in the development and implementation of data standards, informing data flow and management best practices, and advising on technology that can make data collection easier, such as using product libraries or barcode scanners for the medical device product information.

With the level of effort required to set up a registry of this nature, it is worth considering whether a broader set of implantable medical devices ought to be considered (e.g. pacemakers, coronary stents). Among stakeholders, a broader registry may be of interest to and aid the work of our colleague organization, the Canadian Agency for Drugs and Technology in Health (CADTH).