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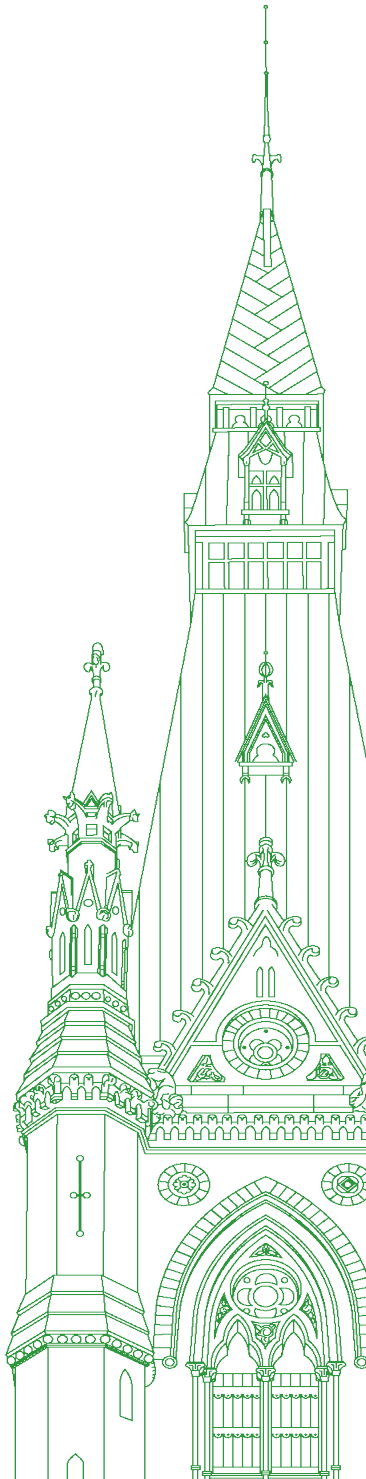

Chair: Mr. Sean Casey

Standing Committee on Health

Tuesday, April 25, 2023

● (1105)

[*English*]

The Chair (Mr. Sean Casey (Charlottetown, Lib.)): I call this meeting to order. Welcome to meeting number 63 of the House of Commons Standing Committee on Health.

Today we will start the study of the oversight of medical devices (breast implants) registry with a briefing from departmental officials during the first hour. We will then proceed to committee business in camera during the second hour.

In accordance with our routine motion, I'm informing the committee that all remote participants have completed their required connection tests.

For the benefit of our panel, I want to make you aware that we have a convention in the committee that the member might interrupt you if you give an answer that's longer than the question. If you get a short question, please try to give a short answer. There is some flexibility, but I want to make you aware that it's how we operate here.

Today we have from Health Canada, David Boudreau, director general, medical devices directorate, health products and food branch; from Canada Health Infoway, Abigail Carter-Langford, chief privacy and security officer; and from the Canadian Institute for Health Information, Juliana Wu, director, acute and ambulatory care information services.

Thank you for being with us today as we embark on this study.

We're going to start with you, Mr. Boudreau. You have five minutes for an opening statement. The floor is yours.

[*Translation*]

Mr. David Boudreau (Director General, Medical Devices Directorate, Health Products and Food Branch, Department of Health): Mr. Chair, thank you for the opportunity to appear before you today to give you an update on the work Health Canada is doing as the regulator of medical devices to support the safety of breast implants in Canada. We recognize that breast implant safety is important.

Today, I would like to tell you more about Health Canada's role in regulating medical devices; some considerations for a breast implant registry in Canada; and finally, the actions the department has taken to improve safety and mitigate the risks associated with breast implants.

Health Canada's regulatory responsibility, under the Food and Drugs Act and the Medical Devices Regulations, is to make sure that medical devices on the Canadian market meet the applicable quality, safety and effectiveness requirements. We do this prior to their licensing and we continue to monitor them once they are on the market.

Manufacturers of medical devices must comply with the safety, effectiveness, quality and labelling requirements of the regulations in order to sell their devices in Canada. When we issue a medical device licence, it means that its benefits outweigh the potential risks and that the potential risks have been reduced as much as possible. When an increased or new risk with a licensed medical device is identified, Health Canada takes the appropriate action.

Our work is supported by new provisions in the regulations that came into effect in 2019 and 2021, which include: mandatory reporting of medical device incidents by hospitals; and enhanced post-market surveillance, such as requiring registrants to submit summaries that assess the risk-benefit profile of their medical devices.

It is important to note that the delivery of health care services and the regulation of health care professionals is a provincial and territorial responsibility. Health Canada does not provide individual medical advice or regulate the medical practice of physicians.

I would like to now address the concept of a breast implant registry. While registries are often used to support research, it is not a common mechanism to monitor the safety of medical devices. The Canadian Joint Replacement Registry is the only medical device registry in Canada. It supports clinical research and it is managed by the Canadian Institute for Health Information.

A breast implant registry could be proposed for two different broad purposes. It could serve to support patient safety certifications, also referred to as “track and trace”, or have a research purpose, or both.

Health Canada participated in a recent Best Brains Exchange that examined the question of a registry for breast implants. The discussion highlighted the complexity of a breast implant registry and there was no consensus on next steps. Potential challenges were discussed including privacy, data sharing related to the management of personal health information, as well as the role of private clinics—which hold most of this health information.

Even in the absence of a registry, the data available to Health Canada through medical device incident reports and the scientific literature has allowed us to take decisive actions when required.

Here are four concrete actions Health Canada has taken to improve safety and mitigate risks: performing safety reviews of breast implants in 2017, 2019 and 2022—this led us to suspend licences for macrotextured breast implants due to an increased risk; requesting yearly reports from manufacturers to help identify potential new or increasing risks; requesting updates to breast implant labelling, including a patient decision checklist; and sharing information about breast implants with the public via different tools, such as our website and a subscription service.

In addition, following the announcement of Health Canada's medical device action plan in December 2018, the department established the Scientific Advisory Committee on Health Products for Women in 2019. Through the deliberations of this committee, we have gathered information about breast implants, including patient testimonials.

These actions for breast implants are a significant investment in risk assessment and management activities by the department and go beyond what is typically performed to manage risks for other medical devices.

I want to close by thanking the committee for conducting this study, and for inviting the Government of Canada to provide remarks.

Thank you, Mr. Chair.

● (1110)

The Chair: Thank you, Mr. Boudreau.

[*English*]

Next, from Canada Health Infoway, we have Ms. Abigail Carter-Langford.

Go ahead.

Ms. Abigail Carter-Langford (Chief Privacy and Security Officer, Canada Health Infoway): Juliana will speak first.

Thank you.

The Chair: Thank you.

Juliana Wu, director, acute and ambulatory care information services, you have the floor.

Ms. Juliana Wu (Director, Acute and Ambulatory Care Information Services, Canadian Institute for Health Information): Good morning, everyone.

Thank you for the opportunity to appear before you today with my colleagues from Health Canada and Canada Health Infoway on the important topic of breast implant safety in Canada.

My organization, the Canadian Institute for Health Information, or CIHI, is an independent, not-for-profit organization created by provinces, territories and the federal government almost 30 years ago. Our core mandate is to deliver comparable and actionable information to accelerate improvements in health care, health system performance and population health in Canada.

We have over 30 data holdings, and our collection of personal health information is limited to the purposes of our mandate, which is around health system performance measurement and reporting.

Some examples of our work include reporting on wait times for priority surgeries, annual health spending in Canada, health workforce information and the impact of COVID-19 on health systems across the country. Ultimately, we work to provide information to help improve health care systems and the health of Canadians.

To the subject of today, first and foremost, CIHI recognizes the importance of breast implant safety for Canadians, and we hope our experience in managing a medical device registry can help inform this discussion.

CIHI manages several clinical registries, including the Canadian joint replacement registry for hip and knee joint replacements, with over 137,000 surgeries performed every year across Canada. The registry collects information on devices such as artificial hips and knees that were implanted in each patient.

The registry was established in 2001 from a collaboration between CIHI and the Canadian Orthopaedic Association. It started out with voluntary participation from orthopaedic surgeons and evolved over time as several provinces mandated the submission of data directly from health facilities.

Of note, this joint replacement registry is not a safety recall registry. CIHI as an organization is not set up or provided with the mandate to perform such care-related functions. The goal of our joint replacement registry is to support evaluation of the costs and outcomes of the medical devices and to inform clinical best practices and service delivery for these surgeries.

From our experience in managing several registries at CIHI, we think there are several key considerations in establishing a new breast implant registry.

Number one, it would be very important to establish clear objectives and intended purposes for the registry. Tracking and tracing implants to facilitate safety recall notices versus measuring health service activities and outcomes are two very distinct objectives, with very different implementation pathways and considerations.

Number two, understanding how data can flow from private surgeons' offices all the way to patient notification is also important. We know that about 85% of breast implant procedures in Canada are performed in private settings. The willingness from both the providers and the patients to participate in this registry would be necessary for it to be effective in achieving its traceability goals. Also, data collection and flows from private clinics do not readily exist today in Canada and will require substantial foundational work to explore a legislative framework and the infrastructure required.

With that, I thank the committee for the interest in CIHI and for the opportunity to be here today. I'll be happy to answer your questions.

Thank you.

The Chair: Thank you.

We'll go to you, Ms. Carter-Langford, for the next five minutes, please.

Ms. Abigail Carter-Langford: Mr. Chair and members of the committee, thank you for having us speak to you today on this important women's health issue.

At Canada Health Infoway, we want to ensure that all Canadians have equitable access to excellent health care and health information. We believe that a more connected and collaborative system is a healthier system.

Infoway brings a pan-Canadian focus to improving the patient experience, improving the health of Canadians and unlocking value for the health system. Since our founding, Infoway has been working to develop consistent standards for electronic health records and to make sure those records can be accessed securely by patients.

Canadians who have access to their personal health information have more control in managing their own health, and improving access to health information is critical in helping Canadians live healthier, happier lives. With greater access to personal health information, patients can better track and understand their overall health and conditions, better manage their health, have more informed and productive conversations with their health care providers and enjoy fewer in-person visits to a doctor or emergency room. This means better service, better patient experience and better outcomes.

By integrating digital health into the health care experience, we can unlock more efficient and accessible models of care. We can facilitate faster, more seamless and secure information sharing.

The numbers speak for themselves, and 44% of people who have accessed their personal health information said they avoided at least one in-person visit to a doctor or a hospital. The problem is that only one-third of Canadians have access to their health information electronically.

To ensure that more Canadians can access their records, Canada Health Infoway is building a pan-Canadian road map that will lay out the concrete steps that the federal government, along with the provinces and territories, will need to take to deliver a patient-centric model for safe, secure access management of health information.

To do this, Canada Health Infoway has identified a number of near-term projects that we think will help us to address these objectives. They include working to make sure patient data can be easily transferred among the various hospital, provincial and private practitioner databases safely, and building a system so that referrals and consults to specialists are streamlined.

The pan-Canadian road map will inform and guide all jurisdictions to progress toward the same standards, allowing each to do so at their own pace but ensuring a consistent standard among those jurisdictions.

Thank you to the committee for allowing Infoway the opportunity to share some of the knowledge we've gleaned from that work on an important topic such as the breast implant registry.

I look forward to answering any of your questions.

Thank you.

● (1115)

The Chair: Thank you.

[*Translation*]

The committee is conducting this study pursuant to a motion introduced by Mr. Thériault.

Mr. Thériault, since you switched places with Mr. Kitchen, we'll start with you, for six minutes.

Mr. Luc Thériault (Montcalm, BQ): Thank you very much, Mr. Chair.

Mr. Boudreau, when I listen to you, I get the impression that Health Canada is doing everything it needs to do to keep women safe. Yet when I read the literature, it's funny, but I get the opposite impression. For example, on September 8, 2021, the U.S. Food and Drug Administration, or FDA, ruled that all implants, whether they are filled with saline or silicone and whether they have a smooth or textured surface, can cause cancer such as lymphoma or squamous cell carcinoma.

What have you done to verify this since then?

Mr. David Boudreau: We're obviously very interested in everything happening internationally and what is been discovered in terms of breast implant safety. We are in touch with our colleagues at the FDA in the United States about this. In Canada, there have been no reported cases of this type of carcinoma. At this time, we don't have enough evidence or signals to change our interpretation of the risk-benefit profile of these devices.

Mr. Luc Thériault: If I understand correctly, nothing could be done, because you don't have what it takes to document things.

The FDA recognizes breast implant disease. Does Health Canada also recognize this disease? If not, why?

Mr. David Boudreau: Health Canada is currently doing a risk assessment on breast implant disease. A risk assessment will be released in the coming months on Canada's position in terms of this disease, but at this time we have no shared position on the issue.

Mr. Luc Thériault: The FDA evaluates the same materials you do. Based on the precautionary principle, shouldn't what the FDA discovers with the means it has cause you to act quickly?

Mr. David Boudreau: We will move swiftly when we deem it necessary, based on our assessment of discussions with our international partners. At this point, we don't have enough data to take any action other than what's already being done. Monitoring is taking place. Incident reports are evaluated on a regular basis by the department. There is no basis yet to change our approach to breast implant licensing.

Mr. Luc Thériault: As I said earlier, some of the risks associated with breast implants are known to include cancer, such as lymphomas and others. It's therefore essential that women be informed. We currently have no standard consent form in Canada. Plastic surgeons can write their own version of informed consent.

Given the fact that some implants were to be banned and what I just told you about the FDA statement on September 8, 2021, why hasn't Health Canada been proactive and established a consent form that would allow women and plastic surgeons to check off boxes together, resulting in informed consent? Do you plan to do this in the very near future? It's not hard to do.

● (1120)

Mr. David Boudreau: The department is ensuring that manufacturers make instructions available to women, along with a form called a checklist, so that women can engage in an informed discussion with their surgeon or physician. That is already provided and women have access to it.

Health Canada is currently working on a version that will also be available on its website. Patient group representatives were actually involved in this development. The form will provide an even more consistent and uniform approach for all women when they want to discuss the risks of breast implants before surgery.

Mr. Luc Thériault: You're aware that the vast majority of informed consent forms speak to the potential side effects of anaesthesia and surgery, but not to the harmful effects associated with implants. All of the women who are testifying now, who have had problems eight, 15 even up to 20 years later, have said that they were not informed. Are you concerned about this? Are you going to remedy it with a form you will require for every surgery?

Mr. David Boudreau: As I said, we are very concerned about this. Right now, we have a form and a checklist that go with the implant when it's given to the surgeon. It's actually part of the medical practice to make sure that the conversation about the risks of the implant takes place between surgeon and patient, and that it covers not only the surgery, but also the risks of the implant. This checklist, which is given to the surgeon and the patient, addresses the risks related to cancer, including the lymphomas you referred to. They are mentioned in it.

It now includes a sidebar on—

Mr. Luc Thériault: You can't be sure they are discussing that. You don't get to see the checklists once they've been filled out.

Mr. David Boudreau: It's really part of the medical practice to have this conversation between patient and surgeon.

Mr. Luc Thériault: The consent form could be the gateway to an eventual registry. This would register the implant used, and also ensure that the patient did in fact give consent despite the high risks. We have to remember that implants carry very high risks.

Without a registry, how can we be sure eight, 10, 15 or 20 years down the line that we can link cancer, lymphoma and other problems to breast augmentation undergone all those years earlier?

The Chair: Mr. Boudreau, Mr. Thériault's time is up. Please give us a brief response.

Mr. David Boudreau: A registration card is already given to the surgeon and the patient. It allows the patient to give the card to the manufacturer and keep a copy of it so that she has information on the implant used. This also allows the manufacturer to follow up with the surgeon and patient as needed if there are recalls or other such events.

[*English*]

The Chair: Thank you.

Next, it's six minutes for Ms. Sidhu, please.

Ms. Sonia Sidhu (Brampton South, Lib.): Thank you, Mr. Chair, and thank you to all the witnesses for appearing in front of the committee.

My first question is for Health Canada. My colleague was asking about this, and you said there is a checklist. How does Health Canada ensure that all health care professionals who perform breast implant procedures are properly trained and qualified?

● (1125)

Mr. David Boudreau: It's not for Health Canada to determine how the practice of medicine is applicable. This really falls under the provincial and territorial health authorities to ensure this.

Ms. Sonia Sidhu: Thank you.

You talked in your testimony about a scientific advisory committee. Can you tell us what the role of that scientific advisory committee is?

Mr. David Boudreau: This is a scientific advisory on women's health products. It was established back in 2019 following the media situation that took place on implantable devices back at the end of 2018. The committee is composed of health care professionals and individual patients, as well as individuals who are familiar with women's health products.

The committee was able to provide recommendations to the department when it came to specific issues, for instance, related to breast implants and/or meshes.

Ms. Sonia Sidhu: Thank you.

Can you provide any data on complications and adverse events associated with breast implants in Canada?

Mr. David Boudreau: We have a medical device incident reporting mechanism that exists in Canada. We have hospitals that are mandated to file incident reports and manufacturers that are also mandated. We can also receive reports, on a voluntary basis, from Canadians and other parties. These are the foundation for signal detections in Canada for any issues or problems related to health products, including medical devices.

Ms. Sonia Sidhu: How does Health Canada monitor and track the safety of breast implants once they're on the market?

Mr. David Boudreau: One of the mechanisms in place to ensure the safety of breast implants once they're on the market is to assess these reports that are filed to the department related to incidents.

Another aspect would be to keep assessing the scientific literature, as well as engaging with international partners who also have incident reporting mechanisms in place and looking for literature in this context.

Ms. Sonia Sidhu: My next question is for Canada Health Infoway. What challenges or limitations might be associated with the implementation of a central breast implant traceability registry, and how could these be addressed?

Ms. Abigail Carter-Langford: Some of the challenges are a bit foundational. This is one of the more complex problems we would see in digital health. That came out of the conversations in the best brains exchange that was hosted.

As Juliana noted in her comments, one of the areas where there's perhaps less connectedness to the broader digital health ecosystem is the private practitioner's office. That first point of connection needs to be addressed to ensure that, in private surgeons' offices, where the majority of these types of procedures are being taken, the data is rendered accessible to the broader system.

You see work in the provinces and work being supported by Canada Health Infoway and Health Canada to remedy that information pathway, so we can start to see that information percolate up and get greater connectivity between the private physician's office, which is privately paid, and the rest of the system. If we look at where we still have, in Canada, some outstanding gaps, that's one of those prime pieces. That's one piece of the equation—making sure that information is broadly accessible and can be shared with others. That is a problem being tackled now, particularly coming out of COVID and the understanding of the importance of that kind of information. That's one area of improvement.

Another area of improvement is in connecting the patient to that information. As I mentioned, again, there's a fair bit of work under way. There are also some opportunities for legislative modernization, particularly at the provincial level, to ensure that Canadians' right of access to their health information is better facilitated and facilitated electronically.

There are also some practical issues. We've had some conversations about consent, and CIHI's data infrastructure is based not on a consent model, recognizing the importance of health system use of information. In practice, though, there's variability in how consent is obtained, and that is a process. Some work would need to be done to look at the rates of consent expected for those women who are receiving those procedures and how that information can translate into broader system holdings, like those at CIHI or at the provincial level.

● (1130)

Ms. Sonia Sidhu: Thank you.

Is there anything else you want to say to the committee?

Ms. Abigail Carter-Langford: I suppose what I would I say, if you'll forgive me, is that this is a complex problem, but it represents an example of a number. It is our perspective from a road map as Infoway that the opportunities to better augment the readiness across the system improve those pathways of information through the system to the patient. There's some foundational work that should be addressed, and addressed in partnership with the provinces, that would have the knock-on effect of improving the conditions for a registry like this one.

The Chair: Thank you.

Dr. Kitchen, you have six minutes.

Mr. Robert Kitchen (Souris—Moose Mountain, CPC): Thank you, Mr. Chair, and thank you all for being here. It's greatly appreciated, as are your comments.

As you're aware, we're looking at a study here on dealing with medical devices. We've heard a number of different aspects of where you've looked at it. What I think we're hearing from you is that you've discussed a registry but really haven't come to a decision on whether you should do it or not, and that there are challenges.

There are many countries around the world that have registries in this area and are doing it. For example, Australia has had it in place since 2015.

I'm wondering if you have looked into those registries and discussed with those countries avenues to advance this for Canada.

Mr. David Boudreau: Is the question for me?

Mr. Robert Kitchen: Sure, Mr. Boudreau.

Mr. David Boudreau: We did look into this. During the best brains exchange event, colleagues from the U.S., the U.K and the Netherlands were able to provide more information about how they were able to implement and the challenges they faced. I will give you some concrete aspects that were discussed.

For the U.S., for instance, their registry is for research purposes and not for traceability purposes, and it's not something that is mandated. It's basically something for which a patient would need to give consent. There is really nothing to oblige patients to enrol. They have a low participation rate in the U.S., and because of that they aren't able at this time to fully leverage their registry for research purposes and/or for signal detection. This is one of the aspects that was communicated to us.

In the U.K., for instance, they had the registry back in the 2000s. They had to cancel their registry because, at the time, they had a very low participation rate and were unable to leverage their registry for research purposes. They started a registry again just a few years ago. The main change between then and now is that they have a single system for patient information. It is not decentralized anymore. They have better ways to ensure data sharing and the full participation of patients in their registry, which is not the case in Canada.

We were able to learn more about some of their challenges, what their journey has been and how they have been able to implement or, in some cases, fully change the approach they had taken before.

Mr. Robert Kitchen: Thank you.

In my years of practice, and when I finally stop practising.... I'm old school. I'm paper. In my practice, when we were starting to transition to computer.... You've touched on it a bit: There's getting that information from the practitioner as well as getting the information from the patient, both of which need to be consent-informed.

I've seen where some of the registries around the world have basically said you can opt in or opt out, and it's up to the individual. That's a big concern from a consent point of view. Number one, if the patient agrees to be there, what information is being protected? Can they opt out at any particular time? How do they protect that privacy aspect? It's a huge challenge from a data-sharing point of view, not to mention from a research point of view.

I'd like comments on that.

Ms. Abigail Carter-Langford: You actually gave a far better synopsis of the issues than I probably would have, if you'll forgive me.

That is the heart of it. When we think about consent, it is both an act and a process.

When we look at Canadian support for health system planning and that kind of thing, we are relatively strong, but it's far from 100%. A lot of that comes down to issues of trust and familiarity. Even in the context of an individual consenting to their treatment, there are complexities, and that's where that process piece kicks in.

Often, one of the concerns we hear in the context of our conversations is about making sure there's an appropriate balance between what we ask of the patient from a consent perspective and how much time the clinician is spending with the patient, with the predominant focus of that conversation being about care.

There are a number of process considerations that come with asking for consent in setting up a registry like this. Perhaps from a literature standpoint it may make more sense for the patient notice component of it, like opting in to receive information about your implants and the future of that device relative to health system planning, where the rate—and Juliana can speak far more directly to this—of less than 100% likelihood of consent would impact the quality of the registry that came out of it.

● (1135)

Mr. Robert Kitchen: Thank you. I appreciate that.

Ms. Wu, perhaps you can touch on that as well, but I will throw another part in, because you sort of talked about the joint replacement registry. We were particularly talking about hips and knees, or was that purely on hips? Do we have it on knees?

Ms. Juliana Wu: We have it on hips and knees.

Mr. Robert Kitchen: It's hips and knees. Okay.

Ultimately, it is that data, that information, and I'm wondering if you could expand on that.

Ms. Juliana Wu: Yes, and I can comment a bit on the consent piece, as well.

Given its role around health system performance management and statistical analysis, CIHI is able to collect a lot of data without patient consent and primarily for that purpose, governed under either health information, related privacy legislation in the provinces, or public sector legislation. The whole idea of flowing patient consent from private settings to an organization such as CIHI or any other organization is challenging right now. I don't think we really have those options.

The Canadian joint replacement registry is a joint and hip replacement registry. It started out based on surgeon participation, so it was voluntary at that time, and we struggled with coverage, to be honest, in the early years, because there was no mandate. It was only when several provinces began mandating data submission on these surgeries to CIHI that we saw coverage climb up to about 73% or 74%. Understandably, without sufficient coverage, even using the data for signalling is ineffective, and obviously not enough if there's no full participation for a safety recall.

It's all tied together. It's a complex problem to get consent from the patient, to get providers' infrastructure set up to collect consent, maintain consent, and manage the withdrawal of consent if patients decide to switch out their decision. Then, how that governance is going to flow through, from the patient to the private surgeon to the organization that hosts the data, is challenging to figure out.

The Chair: Thank you, Ms. Wu.

Mr. Davies, you have six minutes, please.

Mr. Don Davies (Vancouver Kingsway, NDP): Thank you, Mr. Chair, and thank you to the witnesses for being here.

Mr. Boudreau, I'd like to start with you. Can you confirm how many Canadian patients have been impacted by breast implant recalls in the last decade?

Mr. David Boudreau: The department does not hold this information. Patient information is with provinces and territories. We communicate risks on our website, so that this is broadly communicated to health care professionals and Canadians, and we have—

Mr. Don Davies: If I can interrupt, I was talking about recalls.

Mr. David Boudreau: Yes, so the recalls are being—

Mr. Don Davies: Does your agency not...? Are you not responsible for regulating medical devices?

Mr. David Boudreau: We're responsible for regulating medical devices, and we've been communicating the recalls on our website. Then it would be with the manufacturers and the health care professionals to communicate with the patients directly. The department does not hold patient information.

Mr. Don Davies: I guess it would be fair to say that in Canada we have no idea, on a national basis, how many recalls happen in a given year with regard to breast implants.

Mr. David Boudreau: I'm sorry. I just want to clarify.

We have understanding of the recalls, so we know for which devices the recalls are taking place and for what reasons they're taking place, but we wouldn't be able to know the patients impacted.

Mr. Don Davies: You don't know how many. Is that correct? Okay.

A 2018 Toronto Star/CBC/Radio-Canada investigation revealed previously unreleased federal data showing that at least 1,400 Canadians had died over the previous decade in incidents involving various medical devices, with another 14,000 reported injuries. Can you confirm how many injuries and deaths related to breast implants have been reported across Canada over the last 10 years?

● (1140)

Mr. David Boudreau: We would have this information. I don't have it with me, but this is something we could communicate.

Mr. Don Davies: Can I ask you to send that to the committee for us? Thank you.

I think my friend, Monsieur Thériault, spoke about the linkage between breast implants and cancers. I'm more familiar with the linkage between breast implant leakage and the autoimmune disorders that are associated with that. Does your organization have any idea of the number of incidents across Canada of leakages of these implants and the number of allegations of autoimmune disorders that may be associated with that?

Mr. David Boudreau: Again, this is information we could look into and provide to the committee.

Mr. Don Davies: Thank you.

My colleague, Dr. Kitchen, mentioned other countries that have implemented breast implant registries of some type. My preliminary look indicated that Australia, Germany, Italy, the Netherlands, Sweden and the United Kingdom have all implemented breast implant registries. I think you touched on this, Mr. Boudreau, but has Health Canada evaluated the effectiveness of breast implant registries in those jurisdictions, and are there any best practices that Canada could adopt from them?

Mr. David Boudreau: Yes, we've looked into this. Just recently, as I said, in March 2023, we conducted a best brains exchange and had discussions with the U.S., the U.K. and the Netherlands. They were able to provide information on how they were able to implement their registry in their jurisdictions.

Mr. Don Davies: In the 2021 medical devices action plan progress report, Health Canada noted that the mandatory reporting and expansion of the Canadian medical devices sentinel network had not yet been expanded to include private clinics. I think that's been touched on. Given that medical procedures involving breast implants are most often performed in private clinics, why aren't they included in these measures?

Mr. David Boudreau: Acknowledging that the CMDS network at this time is related to only hospitals, the department will be looking into and has been looking into whether or not to expand this to private clinics. At this time, no decision has been taken on expanding this to private clinics.

Mr. Don Davies: I'm trying to understand why, though. I mean, obviously it's not jurisdictional, because hospitals are regulated by the provinces. Why would we have mandatory reporting expansion in the area that does not perform the most implants? Why wouldn't you start with the venues where we know that breast implants are being implanted?

Mr. David Boudreau: The expansion to mandatory reporting by hospitals was not necessarily only focused on breast implants. It was also focused on reporting on adverse events from drugs and medical devices, so health products more broadly. That led the department to start there, with hospitals. There might be expansions in the future, but this is not something that is currently being planned.

Mr. Don Davies: Documents obtained by CBC News show that the federal government has wavered on establishing a medical device registry for decades. CBC wrote:

> In a letter exchange dating back to 1988, the federal department Health and Welfare Canada, Health Canada's predecessor, said it was looking into creating a national breast implants registry, but it warned “costs could be considerable.”

Can you confirm how much Health Canada estimates it would cost to establish a national breast implant registry and whether or not costs remain a central disincentive to that establishment?

Mr. David Boudreau: The cost question is something that the department has not looked into. There are so many other questions that would need to be clarified before looking into the cost. First, which federal institution would be well placed to implement a registry? What type of registry would it be? Would it be for research or traceability purposes? Then there's the involvement of the provincial and territorial health authorities, etc.

I think, with all these considerations at this time, it's not possible to have information on the cost. What we know, though, is that it would be quite expensive.

Perhaps my colleague from CIHI could provide more information on the costs related to the only registry we have for medical devices.

Ms. Juliana Wu: I don't think I can comment on cost estimates either, given that so many other pieces have to be done first in terms of foundational work.

The Chair: Thank you.

Mr. Jeneroux, you have five minutes, please.

Mr. Matt Jeneroux (Edmonton Riverbend, CPC): Thank you, Mr. Chair.

I guess I'll jump in off that question. It wasn't going to be my first question, but I'll go with that.

Has the department, CIHI or Infoway done an economic analysis on what this would or could cost?

I'll start with you, Ms. Carter-Langford.

● (1145)

Ms. Abigail Carter-Langford: No.

Mr. Matt Jeneroux: Mr. Boudreau.

Mr. David Boudreau: As I said before, Mr. Chair, we're not at the stage to discuss costs. We haven't established, for instance, which federal institution would be in a position to do this. There are so many other factors related to the complexity that were discussed by my colleagues here that—

Mr. Matt Jeneroux: Mr. Chair, that's a really long “no”.

Ms. Wu, you haven't done anything....

Ms. Juliana Wu: That's right.

Mr. Matt Jeneroux: Forgive me, but this has been a private member's bill issue since 2004. You would think that at least somebody would have done an economic analysis on what this potentially could cost. I'll just leave that for you. We're going to write a report on this and essentially submit that.

In a media report in 2019, the then president of the Canadian Society of Plastic Surgeons said that the CSPS believed a tracking system for breast implants was needed.

I'll start with you, Mr. Boudreau. Do you think this is an issue? Do you think there are women who are suffering right now because of this issue? A simple yes or no is also....

Mr. David Boudreau: We're certainly preoccupied by the health of Canadians and women with breast implants.

Mr. Matt Jeneroux: I think that's yes. I'll go with yes.

Ms. Carter-Langford, do you think that this is an issue that women are facing?

Ms. Abigail Carter-Langford: I don't know that I have sufficient expertise specifically in breast implant registries to comment on the relationship between a breast implant registry and the health of Canadians. There's no question that Canada Health Infoway is concerned about the health of women and Canadians generally.

Mr. Matt Jeneroux: Ms. Wu, do you think that this is an issue?

Ms. Juliana Wu: I've heard from patients with lived experience, but a connection to a registry or other measures is to be determined.

Mr. Matt Jeneroux: I'll go with yes from everyone, I guess.

I think that most people around this table agree that there are women suffering, and it's unfortunate that there's not something in place or hasn't been something in place. Regardless of the reasons within government, jurisdictionally or whatever, I think that, from a compassionate level, there are women who are suffering right now because of this, and we have been, I guess as a Parliament, bringing issues like this forward since 2004 to try to find some path forward.

When it comes to some of your opening comments, Mr. Boudreau, on the purpose of this being research-based or tracking-based—I think of patient safety notifications—both of those seem legitimate to me. I would think either of those, preferably both, would be sufficient reasons for this to be set up.

There is support from, obviously, the association. CSPS, as was said, back in 2019, indicated that this would be helpful. It seems that since 2018, Health Canada has embarked on a number of these reforms.

I'm curious as to your opinion first, Mr. Boudreau, on the fastest way to implement something like this. Is it to go right to the CSPS and say, like in the U.S., that they are responsible for this and that we will help with what we can, or is it going to the provinces? What is the best and fastest way to do this?

Mr. David Boudreau: I'd like to make a clarification.

When the committee indicated here that we haven't done anything, that's not the case. We've been able to provide more information on the Health Canada website about the risks. We've been able to meet with the scientific advisory committee on women's health products and then make some clear updates, for instance, a data blog, on breast implants and on cancer. We were also able to provide work on the checklist for patients.

To this question that is also asked about what would be needed for us to implement a registry, we were able to discuss before all the complexities related to data sharing related to privacy of information, as well, that my colleagues also mentioned to the committee.

● (1150)

Mr. Matt Jeneroux: There are a blog and a checklist, all this since 2004. I don't think it's necessarily Mr. Boudreau's fault, and I don't mean to take it out on you, Mr. Boudreau, but this has been going on for a long time, and the fact is that those are the only things that seem to have been done on this.

Kudos to Mr. Thériault for bringing this forward.

The Chair: Thank you.

Mr. David Boudreau: Mr. Chair, it's not only that. I could expand on it, but I was also instructed to give very short answers. If you'd like me to expand, I could also expand and provide more information—

The Chair: Mr. Jowhari can give you that opportunity.

Mr. Jowhari, you have the next five minutes.

Mr. Majid Jowhari (Richmond Hill, Lib.): Thank you, Mr. Chair, and thank you to the witnesses.

Building on the same theme, we heard from Madam Wu the fact that we need to do so many foundational things before we start looking at the registry.

Then I heard from you, Mr. Boudreau, the fact there are two different purposes a registry could have. One is for research and the other one is for what is called track and trace, for recalls.

Then we heard from you, Madam Carter-Langford, the fact we need to make sure we look at the integration of all these data between the private practitioners and the patients, who hopefully will opt in so it will increase the numbers, and from the provinces that are gathering that information and sharing it.

It looks like between all three organizations, a lot of conversation and a lot of thought has gone into this, yet we haven't had any, let's say, real action taken on it.

When I look at the fact that we've only had one registry and that's for joint replacement.... I look at many other implants that we use, as human beings. I went through cataract surgery. I had a new lens put in my eye. It got recalled, so I had to go back and do another one. There was nothing from the government. I just got a call and my eyesight had started deteriorating.

Having said all of that as a background and with the fact that we really need a clear objective, why do those two objectives seem to be in so much conflict, as far as track and trace and research, that they can't join hands and start working on this registry for both purposes? What is so fundamentally different about those two that a single registry cannot handle it?

Any of you can comment on that.

Ms. Juliana Wu: I can go first.

I think a single registry with both purposes could happen. The fundamental question is around how the information and the data are going to flow. That requires a legislative and privacy review. That would also determine which organization can hold it.

The challenge between safety recall versus research.... Using CIHI as an example, CIHI as an organization can potentially host a registry focused on research and system performance reporting. We are not in the world of patient safety recalls, so depending—

Mr. Majid Jowhari: You would have to work with the province.

Ms. Juliana Wu: Yes, that might be one option. I think determining the pathway of how this is going to be implemented, who can hold it and who can govern the registry would depend on the objectives.

Mr. Majid Jowhari: What's the barrier to those two objectives coming together and working across all those levels? At the end of the day, we live in Canada, so there should be some co-operation.

Go ahead.

Ms. Abigail Carter-Langford: There is a fundamental legislative structure issue. The way our historical privacy legislation and the provinces have been built considers the delivery of health care—with one governance structure, one oversight and one set of permissions—and research and health system use entirely separately.

We see some really great work in progress at the provincial level to recognize that we're looking at our legislative structures the wrong way. It needs to be from the patient outward. Right now, with the way our health system privacy legislation is structured, it's not built to enable that. It's built to treat those two functions not as a continuum, but as two very separate activities. That's why you'll see, as Juliana described, registries in research in one area very separate and segregated from clinical use, like track and trace.

Mr. Majid Jowhari: Mr. Boudreau, you were talking about some of the jurisdictions and said you'd had an opportunity to explore and get their feedback. You talked about how the jurisdictions that were successful were successful because they had a single patient registry.

If I understood you correctly, that means all the health information of an individual is carried in that record, whether it's for medical, for implant or for anything else. Did I understand you right?

● (1155)

Mr. David Boudreau: Maybe I can clarify.

In the U.K., the approach that has been taken is one where there is centralized patient information. There is one file for an individual, as opposed to having this decentralized, as it is here in Canada. It's easier in that context when it comes to implementing a registry and ensuring data sharing, because it's all coming from one source, as opposed to here in Canada where we have a decentralized health care system, with each province having authority over patient information.

Within a province, there is also the complexity or the notion around private clinics versus hospitals. This is another area. For instance, some provinces might actually have to look into regulation or legislation to even have access to private clinic information.

That comes back to the complexity we were talking about. If we were looking into implementing a registry for patient notification purposes in Canada, these would need to be addressed.

The Chair: Thank you, Mr. Boudreau.

Mr. Thériault, you have two and a half minutes.

[*Translation*]

Mr. Luc Thériault: Thank you, Mr. Chair.

Mr. Boudreau, earlier you talked about recalls and, when I listen to you, I get the impression that you are more responsible for the devices than for the health of patients.

You tell me that currently we don't have the data we need, but 85% of procedures are done in private settings and only 15% of procedures, those in hospitals, must be reported. So you're saying that, as a Canadian, you can't see the basis for the U.S. Food and Drug Administration, or FDA, statement on September 8, 2021, that all types of implants, whether they're filled with saline or silicone, and whether they have a smooth or textured surface, cause cancer. You say you don't know, but you are only collecting data from 15% of the settings that do procedures.

Don't you find that's not very reassuring for women? Do you really think a woman who wants to get implants for reconstruction and has dealt with cancer would have a substantive objection to participating in a registry?

Mr. David Boudreau: I'm not in a position to say what patients think. What I can say is that we also have a subscription system in place so women can receive alerts and information about recalls. The system also gives them information about our data blog, as well as any new or increased risks relating to breast implants.

Mr. Luc Thériault: In the section of your website on the risks associated with breast implants, you talk about anaplastic large cell lymphoma, and you recommend a breast exam. What does that have to do with anything? You know very well that that kind of cancer can't be detected with a breast exam. It's an autoimmune disease that affects the inside of a woman's body, but not necessarily one particular location of it.

Could you not at least copy the risks in the FDA's published information a little more carefully and talk about these lymphomas a little more specifically, instead of saying that there aren't many cases. The reason not many cases are reported to you is that you're only working from data provided by settings that do mandatory reporting, which is only 15% of the settings that do such procedures.

Mr. David Boudreau: Health Canada and the Canadian government were precisely among the first to mandate incident reporting by hospitals. This is not a common practice in the rest of the country—

Mr. Luc Thériault: Why not include private clinics?

Mr. David Boudreau: We are not there yet.

[*English*]

The Chair: We'll go to Mr. Davies, please, for two and a half minutes.

Mr. Don Davies: Thank you.

I'm not sure if you've covered this, but to clarify it in my mind, the United States and the European Union have been working to assign unique bar codes to medical devices as a first step to eventually track them through the supply chain.

Can you confirm whether the Government of Canada is pursuing a similar approach?

● (1200)

Mr. David Boudreau: Mr. Chair, we are looking into the notion of a unique device identifier system in Canada. We've started investigating and assessing how this is being performed by other regulators, including the FDA in the U.S.

Mr. Don Davies: A 2018 report from CBC News quoted Nova Scotia surgeon Dr. Alex Mitchell as saying there's “no reliable medical device identification in Canada at present.” Dr. Mitchell noted that when a device is recalled, it could take months to review hospital records, usually paper-based, to find and contact affected patients.

In your view, could Canada provide faster notification to patients by creating a digital medical device registry?

Mr. David Boudreau: At this time, when it comes to communicating directly with patients, this is something that provinces and territories have authority over. The department is providing information as quickly as possible to Canadians through notices on the risks. This is something whereby we are able to at least inform Canadians when there are changes to a risk profile or a device.

Mr. Don Davies: I have one last general question. Unlike a lot of medical devices, there was pervasive class action litigation over breast implants, both in the United States and Canada. Tens of thousands of women have joined these lawsuits, and there have been multi-hundred-million-dollar settlements by breast implant manufacturers.

Does that weigh into your thinking at all in terms of the urgency? I note that we've created the first registry for hips. Does it not make sense to do breasts first?

I was going to ask if there is a gendered aspect to this. As far as I know, there have been no mass class action suits against hip replacement manufacturers.

Why is it so slow on breast implants, given the litigation and the injuries that have occurred to date?

Mr. David Boudreau: Again, the government was in a position to assess the risk profile of these devices through means other than registries.

Also, just to bring back this notion that I've indicated, it's not because they have a registry, for instance in the United States, that they are actually able to leverage the registry for the purpose of single detection and/or for the purpose of research, because of the low participation rates.

In Canada, the approach we've been taking was positive. We were able to take decisive actions in, for instance, suspending macrotextured implants when we were able to correlate the risk profile to a type of cancer.

The Chair: Thank you, Mr. Boudreau.

Next we'll go to the Conservatives.

Mr. Aboultaif, you have five minutes, please.

Mr. Ziad Aboultaif (Edmonton Manning, CPC): Thank you.

The first question that comes to mind is on the medical equipment that is used for this practice. Is it Canadian made? Do you know where the supplier is?

Mr. David Boudreau: There are four manufacturers that are licensed in Canada. These implants are not manufactured in Canada.

Mr. Ziad Aboultaif: Do you know the source? They are licensed to be used in Canada, but do we know where they are made?

Mr. David Boudreau: As I said, they are not manufactured in Canada.

Mr. Ziad Aboultaif: Yes, I know, but do you know where they are manufactured?

Mr. David Boudreau: I can get back to the committee. My understanding is that they would be manufactured in the States.

Mr. Ziad Aboultaif: Okay.

When was the last time we examined these types of equipment to make sure they are safe and not causing any health or other issues?

Mr. David Boudreau: If I understood the question correctly, we're looking for inspection on site...? An inspection on site took place in 2018. That was in the context of making sure the manufacturers were reporting medical device incidents. We had inspectors who were able to visit manufacturing sites at that time.

Mr. Ziad Aboultaif: What is the normal protocol for Health Canada if there is any leakage of a report that those products are not safe? What are the measures?

Do you stop? Do you instruct the clinics to stop using them? How do you handle that?

Mr. David Boudreau: Yes, when the department is informed of a risk and that risk is greater than the benefit, this is where we would be taking some decisive action.

That would be including recalls, suspensions of licence or changes of labels. There are many actions that could be taken to address the situation.

Mr. Ziad Aboultaif: Do you have enough experts in the department to do the proactive measures to make sure of these? There will always be new products coming. They could be more advanced. They could be up to date. How do you make sure that when a product is new, it's up to date and safe for the patients?

● (1205)

Mr. David Boudreau: Mr. Chair, the regulations allow the departments to make sure that the devices are safe, effective and of good quality before they are marketed. This is a premarket evaluation—a scientific evaluation that is being conducted by government scientific individuals.

The requirements for breast implants are the ones for the higher-risk devices, the class IV devices. We have expertise at the department for conducting this premarket scientific evaluation. We also have the expertise, once the devices are marketed, to continue monitoring their safety and effectiveness on the market.

Mr. Ziad Aboultaif: If there's a product that is approved by the FDA or by the European Union and it's coming to Canada to be used here, do you take the reporting from those countries into consideration when you are examining the product, or do you just go by your own self-conduct?

Mr. David Boudreau: We consider the marketing history of medical devices and how and where they were regulated by other trusted regulators. This would be part of the premarket scientific evaluation, these considerations.

Mr. Ziad Aboultaif: In the integration of making sure that the whole process is safe, it takes the industry, the department, Health Canada in general and the provinces, plus the practitioners. Where do you see the problem that is standing in the way of making sure we have a registry that is going to really solve the problem, as other countries have done?

Mr. David Boudreau: Well, we've touched on a number of challenges that we've been facing in Canada, should we be looking into implementing a registry for breast implants. They include data sharing, the privacy of data, identifying the purpose of this registry, and also identifying the federal institution that would be best placed for implementing and maintaining a registry like this one.

Mr. Ziad Aboultaif: This is a direct question.

If I'm listening today to all of this conversation and testimony, I would conclude that the industry is the problem, as far as standing in the way of making sure that we have a registry is concerned.

Is my conclusion correct? Do you think there is any truth to that?

Mr. David Boudreau: I can't really speak to the industry, but I don't think this is the case. In the context of previous conversations, I don't recall industry suggesting that a registry should not be implemented.

The Chair: Thank you, Mr. Boudreau.

The last round of questions for this panel will come from Dr. Hanley for the next five minutes.

Mr. Brendan Hanley (Yukon, Lib.): Thank you, Chair, and thanks to the witnesses, all three of you, for appearing.

Looking at Mr. Thériault's original motion for this study, there are two parts. First is to look at the improvements that have been put in place since tightening Health Canada's rules. You've touched on some of those. Second is to look at the feasibility of establishing a central breast registry. I think both parts of this motion are important. We want to keep the focus on what the problem is that we are trying to solve and whether the solution is the registry or something else.

The key question is whether a registry could effectively add to our capacity to monitor and respond to safety issues around breast implants, if not other medical devices. I see the answer to that question is not straightforward due to the many limitations that you have brought forward.

I want to go back to the first part, mandatory reporting by hospitals and post-marketing surveillance.

Mr. Boudreau, can you give a brief overview on how much difference these provisions have made? Recognizing that we don't know what we don't know, is there a sense that the safety signal reporting has improved, that there's more exchange, that we're comparable to other nations with a registry? I'm sure this would have been the subject of the best brains exchange that you referred to. Maybe you could give me a sense of that.

Mr. David Boudreau: Yes. The system we have in place, I would say, is robust enough for the department to conduct risk assessments based on the information we're receiving through medical device incident reporting. Manufacturers are mandated to do this, and hospitals are as well. Not only are the manufacturers mandated to do this, but there are also conditions imposed on their licence, whereby they need to report on cases of breast implant cancer.

With all of this information, I believe the department is really in a position to conduct risk assessments. I would say this is highly comparable to other regulators in the world.

● (1210)

Mr. Brendan Hanley: Thank you.

Can you comment on the Health Canada email system? There's a notification system. How does that add to the effectiveness of the system?

Mr. David Boudreau: If we're talking about the subscription approach, basically, in this context, Canadians can subscribe to receive emails or notifications about changes to web pages and recalls related to breast implants, as well as changes to our data blog on breast implant cancer. It's a mechanism for receiving targeted information on breast implants and the risk profile of breast implants.

Mr. Brendan Hanley: What would be the subscription rate? Do you know? What's the sign-up compared to the denominator?

Mr. David Boudreau: I could get back to the committee with this information.

Mr. Brendan Hanley: Thank you.

I want to turn to the foundational changes. I think, Ms. Carter-Langford, you referred to that.

This ties in very much with many of our studies, particularly our workforce crisis study and also recent budget commitments on modernizing our health care data system. Clearly, there's a lot of work to do.

I wonder if you could talk about some of the key steps and challenges, both in improving patient accessibility to their own medical information and in the exchangeability, the data-sharing mechanisms, either within a jurisdiction, within a region or, for that matter, across the country.

Ms. Abigail Carter-Langford: Thank you very much.

In Canada we've made a tremendous amount of progress in making sure that the tools used at the bedside directly with the patient are predominantly electronic. We've done a great job of getting that foundational layer of digital health information.

As you rightly note, we are at the point of starting to make those connections. There is a fair bit of practical work that can be done to ensure that, regardless of what system is being used in a physician's or a surgeon's office, the data is being codified and standardized in a way that it can then be connected. Those connections and that standards-based work can occur across provinces or within provinces.

We believe that creating that standardization and facilitating that standardization between tools is a critical part of building that foundation.

Another piece, as I've noted, is modernizing some of the legislative structures and implementing practical processes to get that one-third of Canadians who have access to their health information electronically closer to 100 per cent, which we think would be beneficial.

Those are the two areas of focus. There is also, certainly, further legislation optimization work around interoperability that would enhance.... We have digital information across this country. We now need to make sure it's standardized and connected.

Thank you.

The Chair: Thank you very much, Ms. Carter-Langford.

That concludes the rounds of questions. I want to thank our witnesses for being here with us today. It gives us a good foundation as we embark on this study, and some sense of the areas that we want to pursue in more depth with the panels yet to come.

Thanks for being with us, and thanks for the patient way in which you've responded to the questions.

Mr. Boudreau, you're signalling that you might have something you wish to add. Go ahead.

Mr. David Boudreau: Yes, if possible, Mr. Chair, thank you.

I just want to mention something else to the committee. The only way a registry would be beneficial to Canadians would be if it got full participation from all the different players. That would include provinces, territories, health authorities, private clinics, patients and manufacturers. Basically, it would need to have full participation. If you don't have a high participation rate, the registry won't be useful for signal detection or research purposes. Only individuals who have registered would be able to provide information through traceability.

The Chair: Thank you, Mr. Boudreau.

I think that's a good note for us to end on. It will be a discussion that we will undoubtedly have with the witnesses who come to future meetings.

Colleagues, we will suspend while we go in camera for committee business.

Thanks again to our witnesses. The meeting is suspended.

[*Proceedings continue in camera*]