CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

Health Canada / Santé Canada

Femmes et Égalité des genres Canada / Women and Gender Equality Canada

Best Brains Exchange – Agenda

EXPLORING THE DEVELOPMENT OF A BREAST IMPLANT REGISTRY

March 7, 2023 11:00am-4:00pm EST

[redacted]

Meeting ID: [redacted]
Passcode: [redacted]

Dial by your location
[redacted] **Canada**
[redacted] **Canada Toll-free**
Find your local number: [redacted]

Meeting ID: [redacted]
Passcode: [redacted]

Meeting Purpose & Objectives:

1. Understand the international breast implant registry landscape and registry use for patient safety notifications.
2. Identify lessons learned from domestic organizations to help determine whether a Canadian breast implant registry could improve patient safety notifications:
   a) The Canadian Joint Replacement Registry (the only Canadian national medical device registry)
   b) Canadian Blood Services
3. Discuss the benefits and drawbacks of developing a Canadian breast implant registry compared to other notification mechanisms.

Time	Item	Speaker
10:45-11:00am	**Registration**	
11:00-11:20am	**Opening Remarks** • Welcome from the BBE Facilitators and from WAGE • Land acknowledgement • Format/technical guidance (housekeeping) • Roundtable of introductions (in the chat) • Overview of the BBE objectives	**Facilitators**: [redacted] Health Canada [redacted] London Health Sciences Centre **Opening Remarks:** [redacted] Women and Gender Equality Canada

Best Brains EXCHANGE

Time	Item	Speaker
11:20-11:40am	**Scene-Setting Presentation: *Why are we here?*** Objective: Understand the perspective of SAC-HPW regarding establishing a national breast implant registry, as well as Health Canada's perspective regarding patient notification of a safety concern related to breast implants and other medical devices.	[redacted], [redacted] Centre of Excellence for Women's Health; [redacted] School of Population and Public Health, Faculty of Medicine, University of British Columbia [redacted] [redacted] Medical Devices Directorate, Health Canada
11:40-11:55am	**Grounding Session- Spotlight** Objective: Spotlight on persons with lived experience	[redacted] Women's Health Issues with Breast Implants
11:55-12:55pm	**Panel: What lessons can we learn from international breast implant registries?** Objective: To better understand international experiences associated with establishing and maintaining a national breast implant registry in relation to patient safety notifications.	[redacted] Clinical Audit, Data and Analytics, NHS England [redacted] US National Breast Implant Registry Steering Committee [redacted] [redacted] Scientific committee Dutch breast implant registry (DBIR)
12:55-1:25pm	**Lunch Break**	
1:25-1:40pm	**Patient Notification in Canada- Spotlight** Objective: Practical considerations for patient notification from the Canadian Blood Services	[redacted], [redacted] Medical Laboratory & Stem Cell Services Medical Affairs & Innovation, Canadian Blood Services
1:40-2:10pm	**Lessons learned from the Canadian Joint Replacement Registry** Objective: Facilitate identifying the key considerations and lessons learned from the only current Canadian national medical device registry, to help inform whether a breast implant registry would be the best option to support patient notification following a safety concern.	[redacted] [redacted] Acute and Ambulatory Care Information Services, Data Strategies and Statistics Division, Canadian Institute for Health Information [redacted] Manager, Joint Replacement Registry, Patient-Reported Outcomes and Experiences, Canadian Institute for Health Information
2:10-2:55pm	**Small Group Discussions:** **Discuss the feasibility of developing a Canadian breast implant registry** Objective: Better understand the feasibility and key considerations for developing a Canadian	Each group will spend 15 minutes on their primary discussion item/question and ten minutes on each of the other three questions. **Moderators:**

Time	Item	Speaker
	breast implant registry to support patient safety notifications.	[redacted], [redacted] Health Programs and Strategic Initiatives, Health Canada [redacted], [redacted] Research, Results and Delivery Branch, Women and Gender Equality Canada [redacted] [redacted] Medical Devices Directorate, Health Canada [redacted] [redacted] Bureau of Investigational Testing Authorization, Special Access Program and Post-Market Surveillance, Medical Device Directorate, Health Canada
2:55-3:05pm	**Transition to plenary / Health Break**	
3:05-3:40pm	**Report Back & Discussion: Next Steps** • Moderators from small group discussions will report back and provide three key takeaways from their group's discussion. • Following 15 minutes of reporting back, there will be a 20-minute moderated discussion using the same 4 questions asked in the small group discussions.	**Facilitators:** [redacted] **&** [redacted]
3:40-3:45pm	**BBE Evaluation** *(~5mins)*	
3:45-3:55pm	**Closing Remarks & Adjournment** *(~10mins)*	[redacted] [redacted] Medical Devices Directorate, Health Canada **Facilitators:** [redacted] **&** [redacted]

Best Brains Exchange – Objectives Backgrounder

EXPLORING THE DEVELOPMENT OF A CANADIAN BREAST IMPLANT REGISTRY

March 7, 2023, 11:00am-4:00pm EST

The **Canadian Institutes of Health Research** in collaboration with **Women and Gender Equality Canada** and **Health Canada**

Objectives

The Best Brains Exchange (BBE) will examine current evidence and bring together stakeholders from multiple sectors to determine if developing a Canadian breast implant registry would improve patient notification following the identification of a safety concern.

More specifically, the following objectives will be addressed:

1. Understand the international breast implant registry landscape and registry use for patient safety notifications.
2. Identify lessons learned from domestic organizations to help determine whether a Canadian breast implant registry could improve patient safety notifications:
    a) The Canadian Joint Replacement Registry (the only Canadian national medical device registry)
    b) Canadian Blood Services
3. Discuss the benefits and drawbacks of developing a Canadian breast implant registry compared to other notification mechanisms.

Background and Policy Context

In 2019, the Minister of Health established a Scientific Advisory Committee on Health Products for Women, following the announcement of a new Government Action Plan on Medical Devices, that lays out a three-part strategy to improve the safety and effectiveness of medical devices and to optimize health outcomes for patients (1). A recommendation of the Scientific Advisory Committee was to revisit the possibility of developing a registry to track the use, effectiveness, and safety of high-risk medical devices. In Canada, medical devices are categorized into four classes based on the risk associated with their use; breast implants are classified as Class IV, presenting the greatest potential risk.

A CBC 2018 report, *The Implant Files*, raised safety concerns about breast implants. In addition, Health Canada has completed a number of risk assessment and risk management activities on breast implants. For example, in 2019, Health Canada suspended authorization of some of these devices, and they were recalled by manufacturers, after growing awareness that some textured breast implants have been associated with a rare form of cancer called breast implant-associated anaplastic large cell lymphoma. However, Health Canada has heard that some Canadians with these implants were not contacted directly by treating physicians. Most breast implants are placed in private clinics for cosmetic reasons in healthy

individuals who may not be seen regularly by a physician. The public has demanded that the federal government improve tracking of who receives which type of implant, analyze the outcomes over time, and put in place a better system for personalized recall alerts, when warranted.

Comprehensive registries may support learning more about the safety of breast implants, and understanding real-world patient outcomes, or identifying safety signals through systematic data collection and ongoing surveillance. Health Canada has regulations in place that require both manufacturers and hospitals to submit breast implant-related adverse event incidents to permit the regulator to conduct safety reviews, and that require the manufacturer to recall and notify physicians who purchase breast implants, if the implants are found to be associated with injury or illness. However, unlike countries such as the United Kingdom, Australia, Sweden and the Netherlands, Canada currently keeps no central registry of who receives a breast implant and does not have a traceable approach for ensuring people with breast implants are notified personally if something goes awry since health care is a provincial and territorial responsibility.

Medical devices and their safety are one of the many influences on women's health and well-being. As such, raising the bar for breast implant safety, as a health policy issue that primarily impacts women, is of relevance and importance to the Government of Canada's performance and progress towards gender equality under the Gender Results Framework (GRF), and to Women and Gender Equality Canada (WAGE), in support of the GRF's sixth pillar which aims to reduce poverty and improve the health outcomes of women and gender-diverse people. As Centre of Expertise for Advancing Gender Equality, and lead for the implementation of Government of Canada's Gender-Based Analysis Plus (GBA Plus), WAGE is pleased to support the exploration of this emergent topic using an intersectional, gendered lens.

While the development and maintenance of health registries do not fall within federal departmental mandates, both WAGE and Health Canada are committed to playing a role in bringing key players together to determine whether a registry or other safety monitoring mechanisms can be implemented in Canada to improve patient safety related to breast implants. The Best Brains Exchange is an important step for WAGE, Health Canada, and stakeholders to consider the longer term, inter-sectoral commitments and future direction within the context of each organization's mandate and in consideration of provincial and territorial contribution and partnership.

Need for Evidence

Several countries around the world have established, or are in the process of establishing, a breast implant registry. There are numerous research articles on implementation and lessons learned from these breast implant registries that contribute to the knowledge base on this issue. Depending on the country and healthcare context, breast implant registries are funded, hosted, and operated differently. Some registries are mandatory for all plastic surgeons, and others are opt-out or completely voluntary. Examples of these structures are key to examine as Canada considers the option domestically.

Within Canada, the Canadian Joint Replacement Registry (CJRR), managed by the Canadian Institute for Health Information (CIHI), is Canada's only national medical device registry. Launched in 2001, it is a collaborative effort with the Canadian Orthopedic Association that collects patient-specific information on outcomes and wait times for hip and knee replacement surgeries performed in Canada. Reporting is only

mandatory in select provinces (Nova Scotia, Ontario, Manitoba, and British Columbia) and voluntary in the remaining provinces and territories. In 2020–2021, national capture of hip and knee prosthesis data was 73.9%.

Another example of quality assurance for medical devices is the national quality report for transcatheter aortic valve implantation (TAVI). To understand the quality of care delivered to Canadians treated with TAVI, the Canadian Cardiovascular Society (CCS) launched a working group to identify and measure indicators of quality of care in 2014. The first Canadian National Quality Report, TAVI, was published online by the CCS in 2016. Since then, the TAVI Quality Working Group has published a best-practice toolkit to support quality implementation of TAVI care, added two new evidence-based TAVI quality indicators to the existing set and has continued working to align data definitions, establish data linkages, and address barriers to pan-Canadian comparisons with support from key partners including ICES (https://www.ices.on.ca/) and provincial registries. Lessons from TAVI may be helpful to this exercise.

This BBE will be an opportunity to analyze international lessons learned and better understand the Canadian landscape to determine whether developing a Canadian breast implant registry is the best approach for improving patient notification following the identification of a safety concern.

Anticipated Outcomes

This BBE will allow participants to:

- Better understand the international experiences associated with establishing a national breast implant registry to inform the feasibility of a Canadian registry.
- Facilitate identifying the key considerations and lessons learned from the only current Canadian national medical device registry to inform whether a breast implant registry would be the best option to support patient notification following a safety concern.
- Better understand the feasibility and key considerations for developing a Canadian breast implant registry to support patient safety notifications.

References

(1) Health Canada. (2018). Government of Canada. Health Canada's action plan on medical devices: Continuously improving safety, effectiveness and quality. Ottawa (ON). Retrieved from https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/medical-devices-action-plan.html Accessed 16 Sep 2022.

Best Brains Exchange – Presenter and Facilitator Biographies

[redacted]

[redacted]
Centre of Excellence for Women's Health
[redacted] **School of Population and Public Health, Faculty of Medicine, University of British Columbia**

[redacted]

[redacted]
Women's Health Issues with Breast Implants

[redacted]

www.breastimplantfailure.net

[redacted]

[redacted], Clinical Audit
Data and Analytics, NHS England

[redacted]

[redacted]

[redacted]US National Breast Implant Registry Steering Committee
Plastic and Reconstructive Surgeon

[redacted]

[redacted]

[redacted]

[redacted] **Scientific committee Dutch breast implant registry (DBIR)**
Plastic and Reconstructive Surgeon

[redacted]

[redacted] **Medical Laboratory & Stem Cell Services**
Medical Affairs & Innovation, Canadian Blood Services

[redacted]

[redacted]

[redacted] **Acute and Ambulatory Care Information Services (AACIS)**
Data Strategies and Statistics Division, Canadian Institute for Health Information

[redacted]

[redacted] Joint Replacement Registry, Patient-Reported Outcomes and Experiences, Canadian Institute for Health Information

[redacted]

[redacted]

Facilitators

[redacted]

[redacted] Health Canada
Professor of Medicine, Université de Montréal

[redacted]

[redacted] London Health Sciences Centre

[redacted]

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Best Brains Exchange – Échanges Meilleurs Cerveaux
Recommended Readings – Lectures recommandées

The following background readings are to provide context to the presentations and discussions that will take place at the Best Brains Exchange on March 7, 2023. These articles have been recommended by the experts who will present at the meeting. We hope that they may prove to be a helpful resource now or in the future. *Please note that it is not required or expected that you will have read all of these articles in advance of the meeting.*

L'objectif du présent document est de fournir un contexte pour les présentations et les discussions qui auront lieu à l'Échange des meilleurs cerveaux le 7 mars 2023. Les articles ont été recommandés par les chercheurs qui participeront aux présentations. Nous espérons que ces articles vous seront utiles aujourd'hui et dans le futur. *Veuillez noter que vous n'êtes pas tenu de lire l'ensemble des articles avant la rencontre.*

Reference List – Liste des références:

Presenter Recommendations – Recommandations des présentateurs

1. Australian Breast Device Registry Publications: https://www.abdr.org.au/publications/

2. Canadian Institute for Health Information. Data Quality Documentation for Users: Canadian Organ Replacement Register, 2011 to 2020 Data. Ottawa, ON: CIHI; 2021. Data Quality Documentation for Users: Canadian Organ Replacement Register, 2011 to 2020 Data (cihi.ca) / Institut canadien d'information sur la santé. Documentation sur la qualité des données à l'intention des utilisateurs : Registre canadien des insuffisances et des transplantations d'organes, données de 2011 à 2020. Ottawa, ON : ICIS; 2021 Documentation sur la qualité des données à l'intention des utilisateurs : Registre canadien des insuffisances et des transplantations d'organes, données de 2011 à 2020 (cihi.ca)

3. Canadian Institute for Health Information (2022). Joint Replacement. Joint replacement | CIHI / Institut canadien d'information sur la santé (2022). Remplacements articulaires. Remplacements articulaires | ICIS (cihi.ca)

4. Canadian Institute for Health Information (2022). Organ donation, transplantation and dialysis. Organ donation, transplantation and dialysis | CIHI / Institut canadien d'information sur la santé (2022). Don d'organes, transplantation et dialyse. Don d'organes, transplantation et dialyse | ICIS (cihi.ca)

5. The Dutch Breast Implant Registry (DBIR) annual reports: https://pubmed.ncbi.nlm.nih.gov/?term=dbir+breast

6. International Collaboration of Breast Registry Activities (ICOBRA). https://www.researchgate.net/project/ICOBRA-International-Collaboration-of-Breast-Registry-Activities

7. NHS digital (2022). Breast and Cosmetic Implant Registry. Breast and Cosmetic Implant Registry - NHS Digital

8. Swanson, E. (2021). The Case Against the National Breast Implant Registry. *Annals of Plastic Surgery*, *86*(3), 245. DOI: 10.1097/SAP.0000000000002743

9. Swedish National Quality Register for Breast Implants (2020). Breast Implant Register Annual Report 2020. https://registercentrum.blob.core.windows.net/brimp/r/BRIMP-Annual-Report-2020--SkgiRSNRXF.pdf

Other Resources -- Autres ressources

1. Breast Implant Illness and Failure Society Canada (2023). *Description: Support Group members share experience of not being notified of the recall, and finding out inadvertently years after the recall date. (PDF below)*

2. Breast Implant Illness and Failure Society Canada (2022). Miscellaneous Snippets- Clinical Specialists and Lived Experience Specialists. *(PDF below)*

3. Breast Implant Illness and Failure Society Canada (2023). Petition for a Breast Implant Registry. *(PDF below)*

4. ICOPLAST Confederation (2020). the Dutch Breast Implant Registry. https://youtu.be/41JWkf5_B9U *(Description: For the 2020 Taiwanese summit om breast implant registries, Prof. Marc Mureau explains the why, how and what of the Dutch Breast Implant Registry [DBIR]).*

5. ICOPLAST Confederation (2020). Introducing the International Collaboration on Breast Registry Activities ICOBRA. https://youtu.be/c0CYczk92lwf *(Description: In this presentation, the current lead of ICOBRA, Hinne Rakhorst, explains how ICOBRA is working hard to expand on evidence on breast implant safety to promote better outcomes for our patients).*

Breast Implant Failure & Illness Society - Canada

Advocacy for women adversely affected by breast implants

Support group members sharing their experience of not being notified of the recall, and finding out inadvertently years after the recall date. With the exception of one member who learned of the recall in 2019 the others learned of the recall between November 2022 and January 2023:

[redacted]

[redacted]

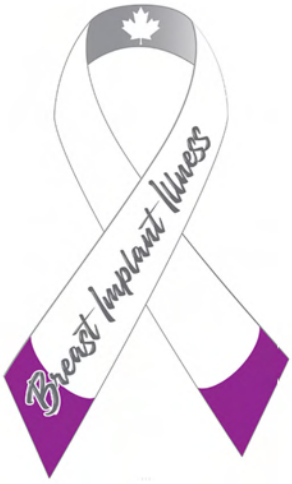
[redacted]

Group Member #3: [redacted]

[redacted]

[redacted]

[redacted]



Breast Implant Failure & Illness Society - Canada

Advocacy for women adversely affected by breast implants

Miscellaneous Snippets -
Clinical Specialists and **Lived Experience Specialists**

Note:
To prepare for this event I reached out to individuals with various field specialists for their thoughts. Their responses are presented below.

CLINICAL SPECIALIST OPINIONS:

Specialist opinion #1
(Pathologist)

In the Netherlands we have now a registration system, see article. But when you don't fill in everything then you get false info, so the honesty of the plastic surgeon is very important.
Concerning the findings in the article which suggest that BII is an uncommon indication for revision in women with silicone breast implants is fraudulent! Because in the Netherlands the NVPC denies BII and so their is no registration of the symptoms at all or heavy underexposed. Besides that the guidance of the FDA says it all, no one can deny that https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breast-implants-certain-labeling-recommendations-improve-patient-communication

So you have to make up your mind, it is very good to register, but you have to do it right!

Specialist opinion #2
(Plastic Surgeon)

Question one:
As a plastic surgeon are you in favour of, against, or indifferent to the creation of a Canadian breast implant registry?

Response:
Yes, I am in favour of a registry. But it should be noted that the American registry has not worked very well. Plastic surgeons really must be forced to register their patients. Otherwise, the registry does not serve a purpose.

Question two:
Do you see potential benefits of a Canadian BI registry?

Response:
Yes, to survey and document problems with breast implants as they occur.

Question three:
Do you feel the registry should be ‘op-in’ or ‘opt-out’, or mandatory enrolment?

Response:
Mandatory for the reasons mentioned above

Question four:
Who do you feel should be responsible for creating a registry, and who should fund and maintain it?

Response:
We should probably follow the Americans. Health Canada and the Canadian Society of Plastic Surgeons should be responsible for the registry. The funding should come from the breast implant companies since it is their responsibility to ensure breast implant safety.

Question five:
Are you familiar with breast implant registries in other countries and/or have an opinion on why some are successful while others have been less successful?

Response:
As I said, the American registry has not worked that well. A system must be created whereby plastic surgeons are FORCED to register their breast augmentation patients. Perhaps the warranty on the implants will not be respected until the patient is registered.

Question six:
What do you think would encourage surgeon participation in a Canadian BI registry?

Response:
I'm sorry to be rough with my words. But it is not a question of encouragement. It's a question of forcing plastic surgeons. Money is always the ultimate element that forces people to do things. If the patient is not registered, there is no guarantee on the breast implants.

Question seven:
What other notification options exist? Discuss the benefits and drawbacks of developing a Canadian breast implant registry compared to other notification mechanisms.

Response:
Plastic surgeons, declaring complications as they happen. There will be no denominator to establish safety. It will not work.

Question eight:
Do you have additional comments to add that aren't covered by the above questions?

Response:
Health Canada has already been criticized for being so slow to recognize the problems with breast implants. This would be an excellent opportunity to create a real registry that could make a difference for patient safety.

Question nine:
Why aren't plastic surgeons notifying patients of the textured breast implants recall?

Response:
I wasn't aware that plastic surgeons weren't notifying their patients about the recall. There was a lot of fuss in Montreal when Biocell was withdrawn from the market. But not much fuss since then.

Keep in mind that when Biocell implants were recalled, the incidence of the lymphoma was still considered to be quite rare. My colleagues who do not keep up-to-date (often the older ones) are probably not aware that the incidence of the lymphoma is now as high as one in 1-400.

Question ten:
What is the best communication method to inform plastic surgeons? (I'm presuming Emily is referring to safety notifications, etc.)

Response:
Probably a message from the Canadian Society of Plastic Surgeons. Most Canadian plastic surgeons are a member of that society. I'm not sure how to reach the rest of them.

Specialist opinion #3
(Plastic Surgeon - Online news article)

Quote:
"It's a violation of trust. I use those devices believing that the process that are in place are going to be followed. So if I report a ruptured implant to a manufacturer I would expect that that manufacturer would report that to Health Canada. .. Finding out this information is great for a relationship between surgeons and implant manufacturers." Dr Peter Lennox BC, Canada

Credit: CBC News Investigates - January 2022 'Thousands of suspected injuries tied to breast implants revealed in manufacturer data dump, CBC analysis finds'

https://www.cbc.ca/news/investigates/breast-implants-health-canada-allergan-mentor-1.6312587

Specialist opinion #4
(Plastic Surgeon)

Letter from September 30, 2019:

To those it should concern a great deal

I am writing to you from the perspective of a Canadian academic Plastic Surgeon who has developed a large practice in explantation of breast implants, primarily for patients with breast implant illness. As such, I have seen the CONSISTENT symptoms and suffering of these patients, heard of their many frustrations regarding breast implants and received many thanks following their explantation and subsequent improvement (in about 90-95% of patients). Understandably, I have become an advocate for these patients.

As you know, a clear association has now been established between textured implants and BIA–ALCL. Yet capsulectomies for textured implants are not covered by the RAMQ (government) as they are for ruptured implants and grade 4 contractures. It is not fair that patients with textured implants should have to pay for their capsulectomies when it is WE that allowed textured implants on the market. It seems outrageous to me that capsulectomies are covered for patients with ruptured implants (for primarily aesthetic reasons) but not to decrease the risk of developing a lymphoma. At the very least, capsulectomies for the Biocell implants by Allergan (with the highest risk of ALCL of one in 2800) should be covered by RAMQ.

My second point involves breast implants in general. Although I love my profession and I also continue to do breast augmentations, I am quite frankly embarrassed by the fact that my specialty has failed to elucidate breast implant illness, despite the fact that there have been patients complaining of similar such symptoms since the introduction of breast implants in 1962. The moratorium on gel implants was lifted in 2006 with the condition that the breast implant companies follow closely patients receiving breast implants to ensure their safety. Given the fact that breast augmentation is one of the most popular Plastic Surgery procedures in North America and that there is huge money involved in this market, it is no

surprise that the breast implant companies failed to adequately meet this requirement from the FDA.

Having said that, there are multiple small studies suggesting the safety of breast implants; however, the majority of these studies were either funded by breast implant companies or performed by consultants who are paid by those same companies. There is something inherently wrong in a system whereby we ask a company that is profiting from its product to assess that same product in a neutral fashion. Although I agree that the breast implant companies should fund the studies, the studies should be performed by neutral individuals who have nothing to gain financially, perhaps someone assigned by the government. I have recently been involved in literature reviews to assess the association between breast implants and various rheumatologic conditions. This is not the first time a literature review has been done on the subject and these are the same articles that are quoted regularly at meetings to discuss breast implant safety. If we exclude articles that are clearly biased (either funded by breast implant companies or performed by consultants who are paid by those same companies), we are left with only a few “neutral“, good quality articles, all of which suggest that breast implants do in fact increase risk of certain rheumatologic conditions.

And so, almost 60 years after the introduction of breast implants, we still don’t have basic answers like:
1) What factors predispose a patient to develop breast implant illness, estimated up to 5-10% of implant patients?
2) Do saline versus gel implants pose a higher risk for developing breast implant illness?
3) How can we treat patients with breast implant illness who do not improve adequately after explantation?

I implore you to make REAL changes to resolve these issues. For example, plastic surgeons performing breast augmentations could be mandated to submit their patients to a comprehensive questionnaire and bloodwork prior to augmentation. The same questionnaire and bloodwork would then be repeated 18 months following augmentation, particularly if any of the patients develop signs of breast implant illness. If my colleagues complain that this may scare patients away from performing the surgery, I would then argue that those same colleagues are not adequately informing their patients of potential risks with breast augmentation. If real changes are not

imposed by you, I fear that another 60 years may pass without any clarification of breast implant illness.

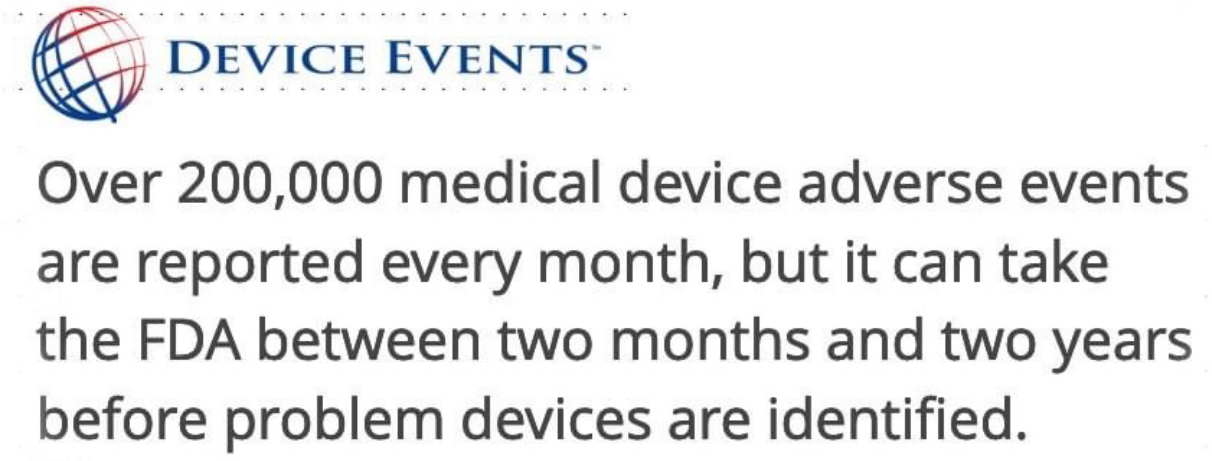
Thank you for your time and consideration.

Sincerely,

[redacted]

Specialist opinion #5
(Researcher - Data specialist)

- Publicly available data
- Up to date
- Physicians can see other doc's reported adverse events (without identifying patient information)
- Physicians understand that reporting to BIRegistry is not the same as reporting adverse events (they must do both)
- Data entered should be available in the registry database within 30 - 60 days
- Data should be free to researchers
- Need to have pretext fields (there's a code for BIA-ALCL but not for BII)
- Comments section and list of BII symptoms
- Registries collect known issues (BIA-ALCL / ruptures) .. whereas BII is vague and often not dx'd (lack of awareness in various doc specialties)
- Plastic surgeon associations us BIRegistries to generate revenue
- FDA not funded to review registry data
- 30 days to report / MAUDE within 30 days
- Months to years before data from a registry is seen
- How do doctors receive communications from Health Canada? Push notifications to doctors & get media to cover it.
- Only THREE Canadian adverse events showing in MAUDE database
- BIRegistry should be created, monitored, executed and funded by independent body and/or Health Canada



LIVED EXPERIENCE - Real World Specialists:

Note:
The following were suggestions for points of discussion from a Health Canada team member.

1) **Thoughts - from support group members** on how to encourage people to sign up for a registry:

'Opt out' registry with automatic enrollment

WHITE COAT SYNDROME: Plastic surgeons' attitudes towards a registry will play a role in persuading or dissuading patients from registry enrolment. **For decades Canadian consumers have gotten breast implants based on plastic surgeons telling them how safe implants are.** It would now go a long way for them to tell patients 'breast implants are high risk devices, with complications / failures that may not present for many years or decades. It's a good idea to join the registry so you can be contacted should anything come up later'. If plastic surgeons are supportive in their practices it will surely boost patient enrollment. And, truly, why would plastic surgeons choose not to do so (as patient safety is the ultimate concern). It's really wearing thin for women to be used in a massive experiment without guardrails being in place to protect them.

PROTECTION FROM DATA BREACHES:
To encourage patient participation in a breast implant registry there must be an assurance for protection of personal data. Many Canadians have been victims of health services / gov't data breaches, so that's a big concern that

could cause hesitation to participate in a registry. Participants must be safer not more vulnerable.

2) **Thoughts -** Speaking to disconnect of women not getting information regarding recall:

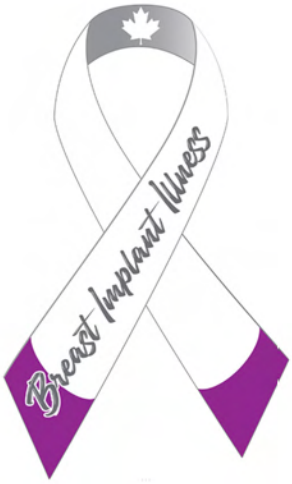
Question: Why aren't plastic surgeons notifying patients? What is the best communication method to inform ps's?

Member thoughts - plastic surgeons are not telling patients and giving mixed messages.

Plastic surgeon's thoughts: (See **Clinical specialist opinion #2**, Question nine)

Question nine:
Why aren't plastic surgeons notifying patients of the textured breast implants recall?

Response:
"I wasn't aware that plastic surgeons weren't notifying their patients about the recall. There was a lot of fuss in Montreal when Biocell was withdrawn from the market. But not much fuss since then."



Breast Implant Failure & Illness Society - Canada

Advocacy for women adversely affected by breast implants

PETITION FOR A BREAST IMPLANT REGISTRY:

([redacted], Quebec)

https://www.assnat.qc.ca/fr/exprimez-votre-opinion/petition/Petition-9981/index.html?fbclid=IwAR2g5NfTA3UHkIZm6C6YQ9-NJx-q-DYy_kl3cR92UiPZ3fyHdJxx7I1Z_N0

Translation:

Petition:
Implementation of measures to regulate the sale and placement of breast implants
To sign this petition, you must complete 3 steps:

Step 1: Fill out the form below the petition text and submit it (you must agree to the conditions for signing the petition before submitting the form).
Step 2: Check your email box and open the message sent by the Assembly.
Step 3: In this message, click on the link to register your signature.
You can only sign the same petition once.

Please note that it is preferable to use a computer to sign a petition electronically. In addition, it is recommended that you use a recent browser (Chrome, Safari, Firefox, Microsoft Edge). Internet Explorer is no longer supported on our website.

Text of the petition
CONSIDERING the increase in cancer cases and the appearance of new forms of cancer related to breast implants;

CONSIDERING that all persons suffering from serious health problems could be avoided;

CONSIDERING the lack of information necessary to make a free and informed decision regarding the risks associated with cosmetic surgery, including breast implants

CONSIDERING THAT a registry on medical devices (breast implants) has been requested for nearly twenty years

CONSIDERING THAT the life, health and safety of all women are important

WHEREAS surveillance was inadequate during the period and following the ban on silicone breast implants between 1992 and October 20, 2006

WHEREAS there is inaccurate, missing or under-reporting of complaints regarding breast implants

WHEREAS, the importance of responsible government is to ensure safety.

We, the signatories, call upon the Government of Quebec to :

Collaborate and engage with the federal government to prioritize obtaining the medical device (breast implant) registry to better monitor these devices;
Immediately suspend the sale of all breast implants on the Quebec market until the registry is obtained, in order to ensure the safety of all Quebec women;
Recognize the importance of disclosing all risks, even the rarest ones, with respect to cosmetic procedures including breast implants;
to put in place dissuasive and punitive penalties for plastic surgeons in Quebec who do not comply with the disclosure of all risks of cosmetic surgery.

Deadline to sign: May 27, 2023