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Analysis of Allergan's Biocell Implant Recall in a Major University Breast Center

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Background: In May 2019, Health Canada released a national recall of all macrotextured breast implants that later became international in July 2019 regarding increasing accounts of suspected breast implant–associated anaplastic large cell lymphoma. In Canada, this recall targeted Allergan's Biocell implants. This report presents the postmortem of this comprehensive single-center recall, which had to be undertaken in a limited time.

Methods: Four months after the beginning of the recall, the authors analyzed the transcript of meetings to characterize the team assembled during the recall. Then, to reconstruct the systemic work plan as well as the crucial steps and actors of the recall process, a chronologic table of the 5 meetings held during the recall, agendas and transcripts of every meeting, electronic correspondences, and other documents created during the recall were consulted.

Results: Between 1996 and 2018, 1260 women were affected by the recall, meaning that they received Allergan's macrotextured implants. Ninety-two patients underwent explantation of the device or will undergo implant explantation. To this day, no patient was diagnosed with breast implant–associated anaplastic large cell lymphoma.

Conclusions: Our center's experience highlights the utmost importance of building a national breast implants registry. We recommend breast centers to develop preestablished crisis centers and train staff to better prepare for future device recalls and minimize waste of time. Finally, we believe that implants should be identified based on the characteristics rather than their brand name. *(Plast Reconstr Surg Glob Open 2020;8:e2906; doi: 10.1097/GOX.0000000000002906; Published online 25 June 2020.)*

INTRODUCTION

Medical devices benefit millions of people around the world, but they can also cause adverse events and incidents with serious consequences for all parties involved.[1] In Canada, medical device recalls frequently occur.[2] During a 10-year-period from January 1, 2005, to December 31, 2014, Health Canada released >7000 unique Recall Incident IDs.[2] In recent years, high-profile recalls have affected implantable cardioverter-defibrillator leads, hip protheses, lung surgery instruments, and breast implants.[3–6]

On May 28, 2019, Health Canada issued a report corroborating the association between breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) and macrotextured breast implants.[7] This statement was an update on a previous press release in February 2019 following increasing accounts of suspected BIA-ALCL cases in the past years.[8] In light of this development, Health Canada suspended the license for the only macrotextured implants available in Canada, Allergan's Biocell breast implants.[7] As a result, Allergan voluntarily recalled Biocell implants from Canadian markets in May 2019,[9] then from American markets and worldwide in July 2019 at the US Food and Drug Administration's request.[7,9]

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Our academic center is a nationally recognized breast center.[10–13] After the growing incidence of BIA-ALCL and before Health Canada's definitive reports,[14] the Department of Plastic and Reconstructive Surgery took action to recall all patients with Biocell implants. Logistical challenges to appropriately informing patients of this recall included a large number of implanted women, the fact that some medical records were electronic while others were paper files, and that Health Canada provided too precise instructions on how to proceed.[7]

In this report, we present a single-center recall study involving a cohort of patients who received Allergan's macrotextured breast implants from 1996 to 2018. Although the management algorithm of the patients is described, this study primarily focuses on the systemic work plan that was urgently developed to locate and notify patients for prompt counsel and care, as well as the preliminary results of the recall.

METHODS

To identify members of the team assembled during the context of the recall as well as the time it took to put together that team, the authors of this article analyzed the transcript of the first meeting. They later corroborated both the identity of the team members and the team assembly delay using a chronologic table of 5 meetings constructed during the recall.

Then, to reconstruct the systemic work plan, the authors combed through that same 10-page table of meetings to gain a chronologic understanding of the tasks undertaken by the team members. This table of meetings also contained agendas describing the task of every actor during crucial moments in the crisis. The investigators examined these agendas, in addition to the transcripts of 5 meetings and various electronic correspondences between the actors of the crisis, to pinpoint the crucial steps of the systemic work plan and the actors involved in every step.

To gain insight into the technical difficulties encountered during the recall and the solutions devised to counter those difficulties, the authors studied a detailed description of the data collection steps created by the administrative team during the recall.

The Center's communication strategy for the patients and public was evaluated by analyzing the training pamphlets created for the nurses who searched medical records and communicated with patients, including the interview algorithm, as well as the press releases and Frequently Asked Questions created for the media.

During this autopsy of the recall, which took place a few months after the events, the authors met on many occasions with members of the administrative team and the chief of the Plastic and Reconstructive Surgery Department to acquire a complete perspective on the genesis, unfolding, and aftermath of the crisis, as well as to synthesize the work plan retrospectively.

To perform a retrospective review of the patient cohort, it was essential to gather the following information: the number of letters sent to affected patients; the number of patients who contacted the center through the telephone line; the number of patients who requested and attended appointments with a surgeon; the conduct of the appointments; the number of patients who showed clinical signs of BIA-ALCL; and the number of patients who requested surgery for explantation of the device. This was achieved by prospectively collecting and analyzing clinical information from an Access database built during the recall, as well as from the patients' records.

Finally, basic statistical analysis was performed on the Access database using program requests. This study has been approved by the Institutional Review Board of the Research center of the University of Montreal Hospital Center.

RESULTS

Within the first days of the recall, our center assembled a team to handle the operations full-time. This group mainly comprised administrative personnel from the operating unit bloc, namely a Clinical Administrative Co-Manager, an Administrative Procedures Specialist, and the chief of Medical Archives Services. At a higher level, the director of the Plastic and Reconstructive Surgery Department, the director of the Breast Reconstruction Unit, members of the hospital's high administrative levels, and the Network Management Board of the Ministry of Health and Social Services were also involved.

The systemic work plan devised by the team for the 2019 Biocell implants recall went as follows:

1. identify patients who have received Allergan's Biocell macrotextured implants;
2. devise a communication plan with patients and physicians;
3. establish a toll-free telephone line with trained responders;
4. allocate specific time slots in the plastic and reconstructive surgeons' schedules for appointments with patients affected by the recall;
5. evaluate ways to access implant removal requests, both from symptomatic and asymptomatic patients; and
6. link the Plastic and Reconstructive Surgery Department with the Pathology Department and the Surgical Oncology Department for screening and follow-up.

To retrace all patients, the main team constituted a unit of 10 clinical nurses and 2 medical archivists to analyze the files, as well as other administrative agents to complete smaller various tasks.

Our patient range in the Biocell recall involved a population divided between 3 different sites since 1996[11] before being supplemented by a fourth site in 2017.[14,15] This meant that, until 2017, patient record numbers were spread across 3 physical sites (also called systems) and

contained a letter at the beginning of their sequence referencing their original site. In consequence, a patient could have >1 file open to her name if she was hospitalized in different sites. Furthermore, because our record management methods significantly evolved over the years, we had to retrieve different types of patient files, some of them dating back to the 1990s.

To ensure that we recognized patients instead of record numbers, it was necessary to find a primary key to connect different systems and ultimately obtain a unique identifier given by the healthcare provider.

From the outset, it was important to determine a clear communication strategy with patients, physicians, and the media. A separate team of administrative agents was immediately created to coordinate this specific aspect.

Letters were sent to all patients in the data bank as it was being built by the team of nurses. The content of our letter remained straightforward, focusing mainly on the importance of monitoring clinical symptoms using a reassuring tone. (**See annex, Supplemental Digital Content 1**, which displays a verbatim of the letter sent to patients affected by the Biocell breast implant recall in a major breast center, **http://links.lww.com/PRSGO/B405**) The message was written both in English and in French and signed by the Director of Professional Services of the hospital. Letters were dispatched using regular mail, and a "*confidential*" label was printed on the envelope.

Next, a telephone line and a crisis center were set to receive calls from all patients targeted by the letter and to respond to their needs. We employed a 1–800 number to allow patients outside of the province to call free of charge.

The second team of clinical nurses was trained to answer calls from patients, their families, and physicians according to a predefined algorithm (Fig. 1). When receiving a call, nurses transcribed patients' symptoms into specially designed panels and, after file verification, scheduled an appointment with their designated surgeon at the center. If a patient's surgeon was no longer on staff, another surgeon was assigned to see the patient.

Most notably, database monitoring was done regarding all calls that were received, their reason, the symptoms reported, the intervention, and/or reassuring, which was done by the nurse.

Specific time slots were reserved in the plastic and reconstructive surgeons' schedules for consultations with patients in the database who called the telephone line and requested an appointment. Priority was given to patients presenting symptoms.

Patient visits were conducted in accordance with the structure of a semidirected interview. Following a predetermined script, surgeons informed patients of BIA-ALCL epidemiology, emphasizing on the worldwide figures of the disease and the evolutive nature of those figures. They also explained warning signs of the disease and validated

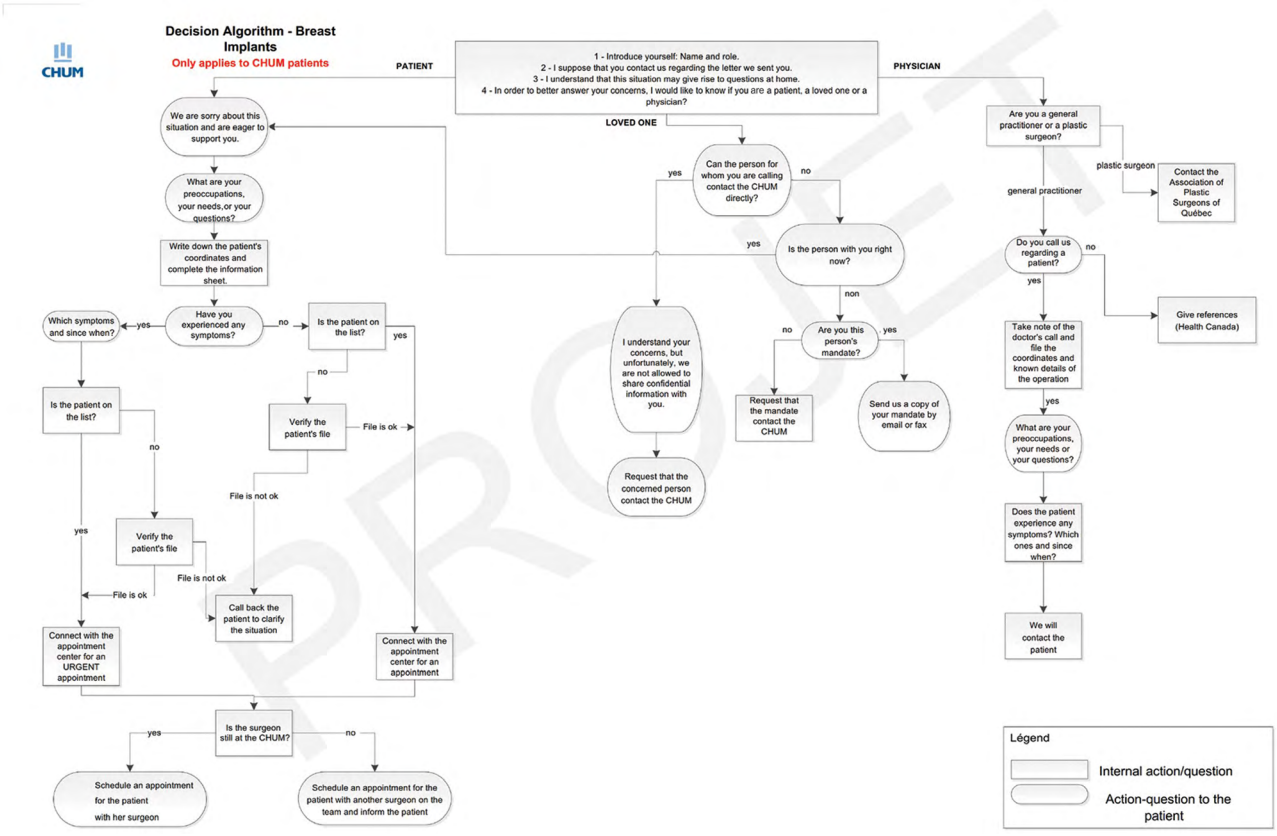

Fig. 1. Decision algorithm for responders of the crisis call center in the context of the Biocell breast implant recall in a major breast center.

patients' symptoms and concerns by offering reassurance and counsel. Physicians assured patients that they would remain in the databank and be reached should there be pertinent developments to the situation.

Additionally, a general clinical history comprising symptoms and problems arising since implantation was evaluated. Clinical data recorded by the nurse during the initial call were assessed by the surgeon during the appointment. Breast palpation was performed when necessary.

Surgeons offered 2 options to the patients: they could contact the crisis center if they encountered one of the warning signs described during the consultation or the center would contact them after a determined time to check up on their symptoms and anxiety levels. While surgeons did not suggest explantation in the absence of symptoms, all questions were answered as to allow patients to make informed decisions.

Women desiring removal of their Biocell breast implants, regardless of symptoms, were accommodated by our center. Since the recall process at our center took place in February and March 2019, months before Health Canada's decisive report in May 2019, it was decided, after meetings with Health Canada representatives, the Ministry of Health and Social Services, and the expert physician of the center, that clinical data and the patients' personal preferences would be the only criteria influencing the decision to explant during this recall.

As early as the first weeks of the recall, the chief of the department informed the surgical staff of supplementary time slots for appointments and surgery. When it came to answering demands for implant removal, we anticipated an impact on the operating list and distributed cases to minimize the impact on waiting lists and other operations at the department.

All patients who agreed to surgical exploration underwent explantation of their Biocell devices, copious lavage, and "en bloc" capsule surgery, with or without implant replacement. Furthermore, the Plastic and Reconstructive Surgery Department collaborated with the Pathology Department and the Oncology Department for potential screening and follow-up.

The patient identification process uncovered 1260 women who were affected by the recall, meaning that they received Allergan's macrotextured implants between 1996 and 2018. These were either women who were not operated at our center but were followed by one of the surgeons or private practice patients of one of our center's surgeons. Of these patients, none (0) were diagnosed with BIA-ALCL. Recall management data can be visualized in Figure 2.

Of the women affected by the recall, 1256 patients received a letter, meaning that 4 patients were excluded because they could not be located or had died. The median age was 57.29 years (range, 17–103).

Of the 1256 patients who received a letter, 920 (73.25%) called the toll-free telephone line. Of these women, 770 (61.31% of the patients who received a letter, 83.70% of those who called the crisis center) requested an appointment with one of our department's surgeons. Of

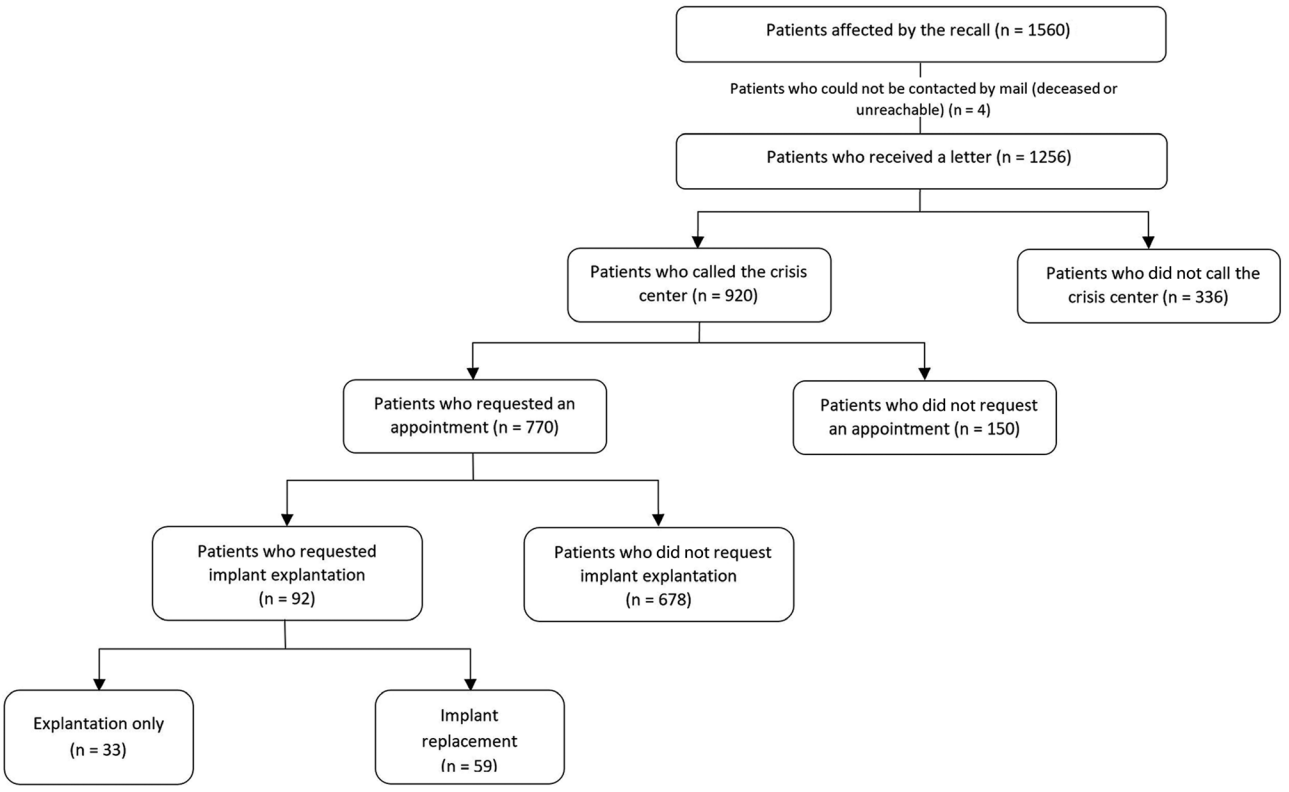

Fig. 2. Overview of recall management data for patients affected by the Biocell breast implant recall in a major breast center.

Table 1. Outcome of Telephone Calls to the Crisis Center during the Biocell Breast Implant Recall in a Major Breast Center

No. symptomatic patients	497
No. patients who reported chronic pain	65
No. patients who reported swelling	83
No. patients who reported a lump	87
No. patients who reported anxiety	356
No. patients who reported low levels of anxiety	165
No. patients who reported intermediate levels of anxiety	130
No. patients who reported high levels of anxiety	61
No. requested appointments	770
No. patients who requested an urgent appointment	183
No. patients who requested an appointment within 3 mo following the telephone call	2
No. patients who requested an appointment 3 mo or more following the telephone call	2
No. patients who indicated no preference regarding the delay between the telephone call and the appointment	583
Total number of calls	920

the patients who requested appointments, 183 demanded to be seen urgently, 2 requested appointments within 3 months, 2 requested an appointment 3 months or more following the telephone call, and 583 patients indicated no preference regarding delay between the telephone call and the appointment.

Of all women who requested a consultation, 497 (64.55%) experienced symptoms and 273 patients (35.45%) were asymptomatic. Out of all symptomatic patients, 65 patients (13.08%) reported chronic pain, 83 patients (16.70%) reported swelling, 87 patients (17.51%) reported a lump, and 356 patients (71.63%) reported anxiety. Among those, 165 patients (46.35%) had low levels of anxiety, 130 patients (36.52%) had intermediate levels of anxiety, and 61 patients (17.13%) had high levels of anxiety (Table 1).

Appointments with the surgeons took place during a period of 6 months. At the time of writing, accounts are available for 461 of the 770 scheduled appointments. At the term of the consultation with their surgeon, 192 women agreed on self-monitoring and scheduling a follow-up appointment if need be; 113 women chose self-monitoring and another scheduled follow-up appointment; 92 women opted for implant explantation; 25 women had smooth implants (as opposed to macrotextured implants) and were therefore not concerned by the recall; 24 women remained undecided and did not settle for a management plan; 7 women agreed to undergo further investigation (such as imagery or biopsy); 5 women chose capsulectomy; and 3 women had their implants removed without notifying our center (Fig. 3).

Surgeries for device explantation are still undergoing 9 months after the launch of the recall. During the process, 5 plastic and reconstructive surgeons were involved in the consultations and explantation surgeries. At the time of writing, 64 patients underwent explantation of the Biocell device and 28 patients are still awaiting surgery. Out of the 92 projected women who have been or will undergo implant explantation, 59 (64.13%) chose to have their breast implant replaced and 33 (35.87%) opted for definitive explantation without implant replacement.

To this day, no patient (0) was diagnosed with BIA-ALCL. Data acquisition and analysis continue.

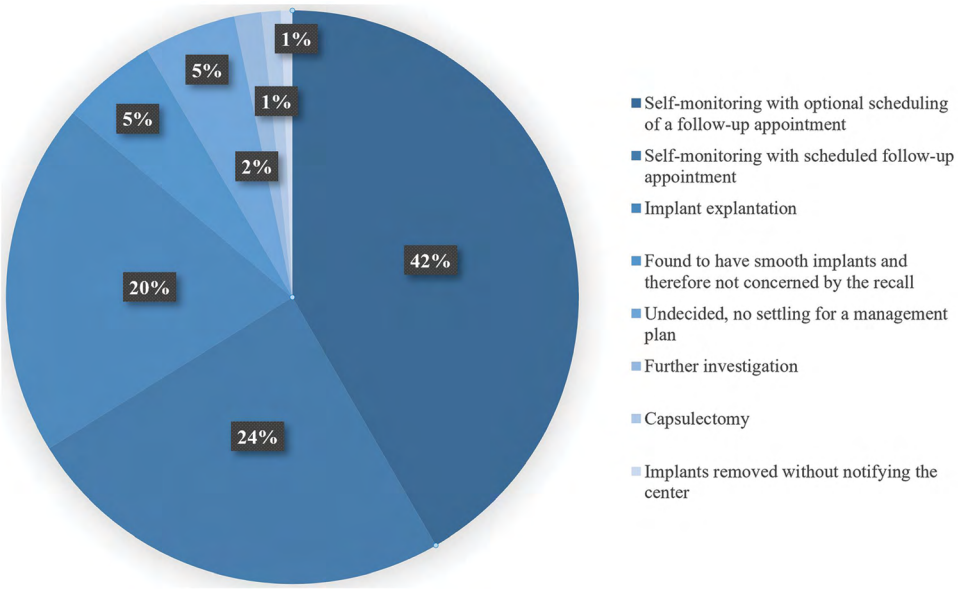

Fig. 3. Outcome of 461 appointments with the surgeon during the Biocell breast implant recall in a major breast center.

DISCUSSION

BIA-ALCL was first described in 1997.[16,17] Most sources consider it to be a rare cancer, affecting 1 in 30,000 women with breast implants every year.[17–19] Nevertheless, it seems to predominate in certain regions or clusters, such as in Australia, where the incidence is as high as 1 case per 1000 women with breast implants.[20] Following implant placement, the mean time to presentation is roughly 10 years.[18,19] Patients with BIA-ALCL usually display an isolated late-onset seroma,[21] an isolated new breast mass (8%), or both (7%),[17] although they can also suffer from capsular contracture,[22–24] axillary lymphadenopathy,[25,26] skin lesions,[27,28] and B-type symptoms.[29,30]

The most striking clinical outcome of our center's recall experience is that, despite having affected 1256 patients (to whom letters were sent), no case of BIA-ALCL has been detected for now. This reinforces the notion of case clusters affecting BIA-ALCL prevalence geographically and therefore suggests the hypothesis of an infectious trigger.[31]

The development of BIA-ALCL is a complex process, which likely stems from indolent infections, and engages various factors such as patient genetics, textured implant surface, bacterial contamination and subsequent biofilm growth, and immune response, eventually leading to chronic inflammation.[17,32,33] Another hypothesis includes chronic inflammation triggered by silicone particles.[34–36] We believe that surgical technique encompassing implant preparation and insertion technique constitute the main factors influencing differences of prevalence between centers.

A major logistical recommendation prompted by our involvement in the crisis is for major breast centers to develop preestablished crisis centers and train staff (whether administrative agents, physicians, nurses, or medical archivists) to better prepare for future device recalls and minimize time wasted. We also believe that hospital resources should be expressly allocated to recall operations when they do occur, namely specific time slots as well as surgical and administrative personnel.

This study is interesting from several perspectives. It is uncommon for such comprehensive, single-center recall data to be present and readily available for second-party evaluation. To our knowledge, no other large-scale study has been written in such detail about the systemic work plan and management of patients affected by the recall of a medical device, particularly when it came to the patient identification process. Although 1256 patients were directly involved in our recall, our team had to uncover 4038 files (3045 patients) in a very short span of time to deliver efficient and targeted care to all affected women.

This article might prove useful as a reference to other centers experiencing challenges such as a great number of patients potentially affected by a recall, the multiplicity of hospitals and systems, differences in record formats (paper and electronic), and/or an impractical primary key (file numbers instead of patient identifiers).

Our center's experience with the Biocell recall highlights the utmost importance of building a national breast implants registry in the event of another recall. This recommendation is motivated by the difficulties we encountered in identifying patients affected by the recall. On the one hand, patients' surgeons and places of residence changed over the years, with many of the women moving across the country and becoming harder to reach and notify. On the other hand, a significant lack of implant traceability in systems belonging respectively to the company (Allergan) and the hospital considerably hindered data collection.

During the recall process, it was revealed that Allergan bore other names in the past: McGhan and Inamed. Macrotextured implants under these companies' names were also used at our center from 1996 onward and were hence included in the recall process. Therefore, we believe that implants should be identified based on the characteristics rather than their brand name.

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REFERENCES

1. Zippel C, Bohnet-Joschko S. Post market surveillance in the German medical device sector—current state and future perspectives. *Health Policy*. 2017;121:880–886.
2. Gagliardi AR, Takata J, Ducey A, et al. Medical device recalls in Canada from 2005 to 2015. *Int J Technol Assess Health Care*. 2017;33:708–714.
3. Kramer DB, Xu S, Kesselheim AS. How does medical device regulation perform in the United States and the European Union? A systematic review. *Plos Med*. 2012;9:e1001276.
4. Curfman GD, Redberg RF. Medical devices—balancing regulation and innovation. *N Engl J Med*. 2011;365:975–977.
5. Maisel WH; Medical Device Safety Institute. Semper fidelis—consumer protection for patients with implanted medical devices. *N Engl J Med*. 2008;358:985–987.
6. Lahiri A, Waters R. Locoregional silicone spread after high cohesive gel silicone implant rupture. *J Plast Reconstr Aesthet Surg*. 2006;59:885–886.
7. Health Canada. Health Canada suspends Allergan's licences for its Biocell breast implants after safety review concludes an increased risk of cancer. 2019 [updated May 28, 2019]. Available at https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70045a-eng.php. Accessed January 16, 2020.
8. Health Canada. Health Canada will be updating its safety review of breast implants. 2019 [updated February 12, 2019]. Available at http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69052a-eng.php. Accessed January 16, 2020.
9. US Food and Drug Administration (FDA). The FDA requests Allergan voluntarily recall natrelle biocell textured breast implants and tissue expanders from the market to protect patients: FDA safety communication. 2019. Available at: https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue. Accessed January 17, 2020.
10. Quebec Breast Cancer Foundation. Quebec breast cancer foundation's awards of excellence. 2019. Available at https://ruban-rose.org/prix-an. Accessed January 16, 2020.
11. Parisé A. Rapport annuel de gestion 2016–2017. Montréal, Quebec, Canada: University of Montreal Hospital Center; 2017. Available at https://www.chumontreal.qc.ca/sites/default/files/2018-05/180522_rapport_annuel_2016_2017.pdf. Accessed January 16, 2020.

12. Beaulieu N. 2008–2009 Annual Report. Montréal, Quebec, Canada: University of Montreal Hospital Center; 2009 [cited January 16, 2020]. Available at https://www.chumontreal.qc.ca/sites/default/files/2018-05/180522_rapport_annuel_2008_2009_en_0.pdf.
13. UoMH Center. Centre intégré de cancérologie. 2009 [cited January 16, 2020]. Available at https://www.chumontreal.qc.ca/patients/cicc.
14. CHdlUdM (CHUM). Notre nouveau complexe hospitalier. 2019 [cited January 16, 2020]. Available at https://www.chumontreal.qc.ca/notre-nouveau-complexe-hospitalier.
15. Santé Montréal. The CHUM is moving to the new hospital. 2017 [cited January 16, 2020]. Available at https://santemontreal.qc.ca/en/public/news/news/the-chum-is-moving-to-the-new-hospital/.
16. Keech JA, Jr, Creech BJ. Anaplastic T-cell lymphoma in proximity to a saline-filled breast implant. *Plast Reconstr Surg.* 1997;100:554–555.
17. Leberfinger AN, Behar BJ, Williams NC, et al. Breast implant-associated anaplastic large cell lymphoma: a systematic review. *JAMA Surg.* 2017;152:1161–1168.
18. Brody GS, Deapen D, Taylor CR, et al. Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases. *Plast Reconstr Surg.* 2015;135:695–705.
19. Doren EL, Miranda RN, Selber JC, et al. U.S. epidemiology of breast implant-associated anaplastic large cell lymphoma. *Plast Reconstr Surg.* 2017;139:1042–1050.
20. AGDo Health. Breast implants and anaplastic large cell lymphoma: update: additional confirmed cases of anaplastic large cell lymphoma. [updated May 11, 2017; cited January 16, 2020]. Available at https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma.
21. Statistique Canada. Population and dwelling count highlight tables, 2016 census. 2016 [cited January 16, 2020]. Available at https://www12.statcan.gc.ca/census-recensement/2016/dp-pd/hlt-fst/pd-pl/Table.cfm?Lang=Eng&T=801&SR=1&S=3&O=D&RPP=25&PR=0&CMA=0#tPopDwell.
22. Lazzeri D, Agostini T, Bocci G, et al. ALK-1-negative anaplastic large cell lymphoma associated with breast implants: a new clinical entity. *Clin Breast Cancer.* 2011;11:283–296.
23. Wong AK, Lopategui J, Clancy S, et al. Anaplastic large cell lymphoma associated with a breast implant capsule: a case report and review of the literature. *Am J Surg Pathol.* 2008;32:1265–1268.
24. Santanelli di Pompeo F, Laporta R, Sorotos M, et al. Breast implant-associated anaplastic large cell lymphoma: proposal for a monitoring protocol. *Plast Reconstr Surg.* 2015;136:144e–151e.
25. Alobeid B, Sevilla DW, El-Tamer MB, et al. Aggressive presentation of breast implant-associated ALK-1 negative anaplastic large cell lymphoma with bilateral axillary lymph node involvement. *Leuk Lymphoma.* 2009;50:831–833.
26. Tardío JC, Granados R. Axillary lymphadenopathy: an outstanding presentation for breast implant-associated ALK-negative anaplastic large cell lymphoma. *Int J Surg Pathol.* 2015;23:424–428.
27. Miranda RN, Lin L, Talwalkar SS, et al. Anaplastic large cell lymphoma involving the breast: a clinicopathologic study of 6 cases and review of the literature. *Arch Pathol Lab Med.* 2009;133:1383–1390.
28. Alcalá R, Llombart B, Lavernia J, et al. Skin involvement as the first manifestation of breast implant-associated anaplastic large cell lymphoma. *J Cutan Pathol.* 2016;43:602–608.
29. Carty MJ, Pribaz JJ, Antin JH, et al. A patient death attributable to implant-related primary anaplastic large cell lymphoma of the breast. *Plast Reconstr Surg.* 2011;128:112e–118e.
30. Taylor KO, Webster HR, Prince HM. Anaplastic large cell lymphoma and breast implants: five Australian cases. *Plast Reconstr Surg.* 2012;129:610e–617e.
31. Adams WP, Jr. Reply: macrotextured breast implants with defined steps to minimize bacterial contamination around the device: experience in 42,000 implants. *Plast Reconstr Surg.* 2018;142:413e–414e.
32. Zucca E, Bertoni F, Vannata B, et al. Emerging role of infectious etiologies in the pathogenesis of marginal zone B-cell lymphomas. *Clin Cancer Res.* 2014;20:5207–5216.
33. Hart AM, Lechowicz MJ, Peters KK, et al. Breast implant-associated anaplastic large cell lymphoma: report of 2 cases and review of the literature. *Aesthet Surg J.* 2014;34:884–894.
34. Kaartinen I, Sunela K, Alanko J, et al. Breast implant-associated anaplastic large cell lymphoma—from diagnosis to treatment. *Eur J Surg Oncol.* 2017;43:1385–1392.
35. Clemens MW, Miranda RN. Coming of age: breast implant-associated anaplastic large cell lymphoma after 18 years of investigation. *Clin Plast Surg.* 2015;42:605–613.
36. Ye X, Shokrollahi K, Rozen WM, et al. Anaplastic large cell lymphoma (ALCL) and breast implants: breaking down the evidence. *Mutat Res Rev Mutat Res.* 2014;762:123–132.