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The Case Against the National Breast Implant Registry

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The new National Breast Implant Registry (NBIR) is promoted by the American Society of Plastic Surgeons and the Plastic Surgery Foundation as essential to patient safety.[1] The US Food and Drug Administration (FDA) supports the NBIR as one way to collect real world data on the safety and performance of breast implants.[2]

The NBIR was discussed at the FDA Hearing held on March 25 and 26, 2019.[3,4] A 27-minute highlights video is available online.[5] Dr Andrea Pusic, former president of the Plastic Surgery Foundation, made the case for this registry.[5] She testified that the NBIR "collects high-quality structured data using internationally agreed-upon data definitions and core elements" while "focusing on fluidity." A key point of her presentation was that the NBIR "can and will advance our understanding of breast implant illness."

Several of the FDA panelists expressed skepticism.[5] Dr Rebecca Rogers, a panelist and associate chair of Women's Health at the University of Texas, Austin, cautioned that entering data into registries is very laborious. She related experience from urogynecology, in which a number of registries have struggled because of the burden it places on busy physicians. She asked whether we really need another registry and whether it is worth the time and cost. Dr Pusic replied that the NBIR case report form is very short and "this information is extremely important to patient safety, and we [plastic surgeons] are willing to enter this data."

Dr Karla Ballman, a panelist and chief of Biostatistics and Epidemiology at Weill Cornell Medicine, cautioned, "I think it's a lofty goal and I think that there are really impassioned people that will do this, but to make it mandatory for everyone without any sort of incentive, do you really think that's realistic?"[5] Dr Ballman questioned the need for a complete census. She suggested that, from a statistician's perspective, a better option would be a high-quality representative sample with complete data rather than trying to include everyone. She referenced the shortcomings of the National Cancer Database and the broadly based CancerLinQ.[6]

Dr Pusic responded that the case report form[7] just adds a very few key questions beyond the already-mandatory device tracking information.[5] She did not specify those questions. The form itself was not presented. It is not clear that the panelists, who called for brevity, realized just how brief the form really is. The form includes patient identification information (name, birthdate, address, phone number, and social security number), physician information, and device data obtained using a barcode scanner application. Procedure details include the surgery date; operation; reason for reoperation; incision placement; use of drains; and inclusion of acellular dermal matrix, surgical mesh, or fat grafting. Under the personal medical history tab, only the following questions are asked: patient history of breast cancer; previous radiotherapy; use of a tissue expander; smoking status; history of medical issues; and whether the patient has diabetes, cardiac disease, lung cancer, renal disease, hypertension, or rheumatoid arthritis.[7] Among more than 80 symptoms and signs of breast implant illness (BII) (eg, memory loss, brain fog, fatigue, joint pains, rash),[8] none are recorded on the NBIR case report form.

Dr Ballman asked, "How would that [the NBIR] get at questions of breast implant illness or the genetic predisposition? How would this database be able to answer those questions?" Dr Pusic replied, "Those would be nested substudies within the greater architecture of the NBIR and those would be questions to be answered directly by women in that substudy, not by their physicians." Dr Ann Marilyn Leitch, a panelist and professor of surgery at the University of Texas, Southwestern Medical Center, countered, "I thought that the validation of disease processes, a specific diagnosis of a rheumatologic disorder, would have to be verified by physicians." Dr Pusic responded that a limited cohort of patients in a substudy could have their diagnoses verified by a physician.[5]

A major concern of the panelists was the lack of a control group. Dr Marc Lippman, a panelist and professor of oncology and medicine at Georgetown University Medical Center, warned that collecting a massive amount of data and then not knowing what to compare it with would be a catastrophe.[5]

It is reasonable to ask, why not implement a registry out of an abundance of caution? One reason is that the data entry for a very common operation wastes the time of health care personnel. Today, doctors spend more time on electronic record keeping than with patients.[9,10] This bureaucratic burden is implicated in professional burnout.[11]

Who pays for this registry? The 3 major breast implant companies in the United States (Allergan, Mentor, and Sientra) sponsor it,[1] creating a conflict of interest. Companies pass along the cost to the customer. Breast implant prices

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are already inflated by all the subsidies that manufacturers pay to plastic surgeons, our societies, our meetings,[12] and now to this expensive registry.

At the FDA Hearing, Madris Tomes, a former FDA Adverse Events Subject Matter Expert for Devices and Manufacturer and User Facility Device Experience, testified against the value of registries, referencing 120 breast implant registries worldwide.[5] She commented that registry data are not free and not publicly available. Moreover, when outcomes are unexpected, a registry does not always measure that outcome. Tomes cautioned that reporting to a registry does not replace adverse event reporting by physicians. Instead of another registry, she recommended testing capsular tissue in cases of suspected BII and doing so without industry funding. Similarly, Magnusson et al[8] recommend examination of the implant, capsule, and peri-implant tissues, including toxicology, and genetic sequencing of patients, in addition to implant surveillance, to learn more about BII.

A major problem for any registry is the inclusion rate. A benchmark for evidence-based medicine is 80%.[13] If a large number of implanted patients are not counted, reliability is compromised because the experience of sampled patients may differ from the experience of the total patient population (sampling bias).[13] It is estimated that 25% of breast augmentations are performed by nonplastic surgeons,[5] who are less likely to participate.

Cooter et al[14] believe that a high capture rate can only be achieved through a process that automatically registers institutions, surgeons, and patients, who can opt out if desired. In the 1990s, numerous opt-in breast implant registries were initiated, and almost all failed because of low capture rates.[14] A previous NBIR (2000–2007) is defunct.[14] Inclusion rates may be as low as 30%.[14] Complex data forms discourage participation.[14]

Despite these limitations, some investigators advocate mandatory participation in the registry, including Dr Pusic.[5] Such a measure would no doubt improve the participation level, although patients who decline to participate would still be missed. Even with mandatory physician participation, other problems persist. Data reporting, which may be delegated,[7] is not audited. The denominator (ie, total number of breast implants) is unknown. Not all patients are entered. Consecutive patients are essential to any clinical study to avoid sampling bias.[15]

Adequate follow-up is another consideration. Cosmetic surgery patients are notoriously unwilling to keep long-term appointments, especially for research purposes.[16] There is no provision for scheduled follow-up appointments as part of the NBIR. Core studies that do not provide a financial incentive for patients have suffered from severe attrition.

Dr Binita Ashar, FDA director of the Division of Surgical Devices, in a recent interview with *Plastic Surgery News*, explained that the registry infrastructure can be used to "embed clinical trials."[17] It is not clear how this would work. A trial typically features a control group or at least treatment cohorts that may be compared.[15] Clinical trials require institutional review board (IRB) approval. The NBIR does not have IRB approval.[1] Obtaining IRB approval in view of the registry's exempted status[1] creates a problem for investigators.

Correct terminology is important. A "nested substudy"[5] implies that the NBIR database is a study. It is not. It is a database. Similarly, there are no embedded clinical trials[17] in the NBIR because the registry is not a trial. According to the Western Institutional Review Board and the registry Web site, the NBIR is a project that does not involve research.[1]

Personal information is supposed to be deidentified to fulfill the requirements of IRBs and the Health Insurance Portability and Accountability Act. Protection of identity extends to patient names, birthdates, phone numbers, addresses, and social security numbers. How does one conduct a study on deidentified patients? One would need to access the names and phone numbers, and then contact patients and their physicians who have diagnosed a rheumatologic disorder, for example, as part of a "deep-dive nested substudy."[5] Patients should not be relied upon to provide medical diagnoses. One study found that only 20% of self-reported diagnoses of connective tissue diseases are confirmed by medical records.[18]

The barcode scanner facilitates transmission of the implant device data to the NBIR. According to the Web site, this device information is simultaneously forwarded to the implant manufacturers,[19] a process that is still in development (at the time of this writing, Mentor implant data cannot be entered). Patient-reported data are not yet included. Plastic surgeons must continue to complete the device tracking information and send this information directly to the manufacturer, as mandated by the FDA. Therefore, the NBIR device tracking function duplicates an existing requirement.

Using the NBIR, plastic surgeons scan the barcode located on the implant box. This barcode is different from the paper form contained within the box. Faxing a copy of the completed paper form to the manufacturer ensures that the correct information is forwarded because the box must be opened to access the form and implant labels, as opposed to scanning a box that is never opened. As all plastic surgeons are aware, it is not unusual for a different implant to be selected at the last minute before surgery. Of course, barcodes do not indicate actual fill volumes for saline implants.

Adding a second pathway to device tracking information causes confusion if the implant records differ between the NBIR database and the manufacturer records. Introducing another record-keeper creates 2 databases that are both incomplete (if surgeons start sending device information solely to the NBIR), instead of a single complete manufacturer database. Unlike manufacturer device tracking, the NBIR does not capture implants inserted outside the United States.[19]

The NBIR's exemption from IRB oversight was granted on the basis that the registry does not constitute research but rather serves as a quality improvement initiative.[1] Research is defined by the government as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[20] The NBIR is evidently a quality improvement initiative for the purpose of obtaining IRB exemption but becomes research when it comes time to gather and incorporate data into a research study.

An exemption from IRB review allows the registry to sidestep important protections for patients. Alarmingly, women are not asked for their permission to participate. There is no provision for patients to be informed about the registry. Patients do not sign a consent form. Consequently, personal identification information, including name, address, phone number, birthdate, and even social security number, is sent to the registry without their knowledge. The social security number information is not a required field, but it should not even be requested because it is of no possible value to the registry and is an understandable security concern for women in this age of data hacking and identity theft.

Patients are automatically enrolled in the NBIR to increase participation as an opt-out rather than opt-in registry, boosting compliance. Patients can discontinue their (unsolicited) participation, but the already-entered data are not deleted.[19] Women who find that their personal information has been sent to a third party without their permission are likely to be aggrieved by this violation of their privacy. Institutional review boards were introduced to protect patients from abuses of this very nature.

The NBIR warns that if patients discontinue their enrollment, they may not receive safety updates from the implant manufacturer and their implant warranty may be jeopardized.[21] In truth, the warranty is in effect even if the patient does not participate in the NBIR, because plastic surgeons are required to submit the device information directly to the manufacturer if they do not participate (and even if they do). In any case, warranties are linked to the date of surgery, not to the device tracking information.

With regard to research on breast implant–associated anaplastic large-cell lymphoma, the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology

registry and the FDA Manufacturer and User Facility Device Experience database are available. The NBIR is not designed for reporting cases of breast implant–associated anaplastic large-cell lymphoma.

The creation of this registry was evidently a political decision. The NBIR serves as a public relations tool to highlight patient safety, especially in the wake of a device recall. No doubt the concept originated in a boardroom and without a dissenting opinion at the table. The NBIR did not evolve from properly informed scientific debate, because there has been none. Distracting jargon (eg, "national infrastructure," "multistakeholder initiative")[5] and platitudes ("Help shape the future of plastic surgery")[1] abound.

In truth, no registry that does not include a control group or questions about symptoms and signs of BII is capable of improving our knowledge base. It is not clear that reporting device data to the NBIR rather than directly to the manufacturer represents an advantage. The law of unintended consequences may prove otherwise. Patient privacy needs to be protected. Evidence-based medicine must take precedence over boardroom-based medicine. At a minimum, we need to have the debate before embarking on a predictable boondoggle.

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