SAFETY IN HEALTH

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Medical device registries for breast implants - where to?

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Abstract

This comment discusses the requirements, challenges and limitations for setting up medical device registries for breast implants. Previous experiences, notably the PIP implant scandal in 2010, revealed the inaccuracy and inefficiency of the majority of breast registers in place, and resulted in a rethinking of how registries should work. Quality registries monitor the three Ps: person (eg. patient, surgeon), part (eg. device) and place (eg. hospital). Setting up a register requires a minimum agreed dataset and clearly defined endpoints (eg. revision) of a permanently implanted medical device (eg. breast implant) by means of a medical intervention (operation) readily recorded in a routine procedure, where a direct causal and logical relationship between the malfunction of the device and revision operation exist. Apart from the technical realization, the hurdles for setting up a registry are predominantly found in the political, ethical, financial, and governing spheres. The possible benefits of a working registry for the stakeholders might be evident, and include a market overview (industry), recall mechanism (surgeons, industry, and patients), benchmarking (surgeons, hospitals) legal, quality management (governing body), as well as regulatory control (government). However, the impact of the data accuracy can be limited by the span (eg. national vs. international) of and participation (opt-in vs. opt-out) in a given registry. Future efforts should take into account past experiences and build upon international collaborations to develop optimal solutions for improving patient safety.

Keywords: Implant registry, Implant register, Medical device, Regulation, Legislation, Recall, Plastic surgery, Patient-reported outcome, Radiofrequency identification tags, RFID

Background

The global medical aesthetic devices market was valued at USD 1.8 billion (US dollars) in 2009 and is forecast to reach USD 2.9 billion in 2016. The largest share is attributed to breast implants, of which the market valued at USD 936.5 million in 2013 and is forecast with a compounded annual growth rate of 6.08 percent for the period 2013–2018 [1,2].

Breast implants are classified as high-risk medical devices. In 2013, 290224 breast augmentations with breast implants (+1% vs. 2012), 23770 implant removals (augmentation only) (+10% vs. 2012), as well as 95589 breast reconstructions (+4% vs. 2012), 18 223 implant removals (reconstruction only) (+10% vs. 2012) were performed in the United States. The data were obtained from a questionnaire distributed to 23700 American Board of Medical Specialties certified Physicians/Surgeons, of which a total of 801 active physicians returned the questionnaire. Survey results were combined with the Tracking Operations and Outcomes for Plastic Surgeons database, responses aggregated and extrapolated to the entire population of more than 24500 board certified physicians most likely to perform cosmetic and reconstructive plastic surgery procedures [3]. These numbers do not include so-called "out-of-spectrum" procedures by non-board certified clinicians performing cosmetic surgery [4].

The methodology to retrieve data on breast implants is, however, not solidly evidence-based, and it is striking that there are currently no instruments available to accurately measure their outcome after implantation. For example, when performing a PubMed search (last performed on 30 December 2014) with the terms "implant register" and "implant registry" only 4.7% (19/404) and 9.4% (61/648) contained the word "breast", respectively.

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The list of questions suggests three of particular interest in the context of breast implants, which cannot be reliably answered due to scarce evidence available.

List of questions

- What is the recommended in-vivo lifespan of a breast implant?
- How effective are antibiotics in reducing capsular contracture?
- How many PIP implants were inserted until 2010?

The so-called *Poly Implant Prothèse* (PIP) crisis in 2010, where low-grade industrial silicone was used for implants with a higher than normal rupture rate, highlighted the problem of recall by Institutions alone, and underlined media's beneficial effect in improving recall [5]. The Australian breast implant registry revealed that less than 4% of these implants were captured in an opt-in (voluntary type of data entry), triggering a revision of the system [6].

A lesson learned from major global breast implant crisis in 2010 was the need to improve patient safety and patient traceability.

Realism vs. idealism

Ideally, registries collect variables for risk adjustment, indicators to assess quality of care, and finally outcome data by using an opt-out system to achieve a high-capture rate, which allows benchmarking of current complication and revision rates and evaluate concerns about implant composition, defects or disease associations verified with access to a large dataset.

Outcome registers monitor specific endpoints, which can be readily recorded by the consequence relevant for monitoring a complication [7]: in implants this is revision surgery for managing that complication, which can be divided into for example, wound revision, implant removal or exchange. Quality registries expand on this and aim to monitor the three Ps: person (eg. patient, surgeon), part (eg. device) and place (eg. hospital).

The data collected need to be based on a minimum data set, comparable to an universal industry standard (as seen with SD cards in the information technology sector), which allows comparing of data ("like with like"). Data definitions should be simple and concise, and industry should support a unique ID system across all manufacturers. Outcome needs to be clearly defined and recordable in routine clinical settings. Prerequisites for installment of outcome registries are in the List of Prerequisites for installment of an outcome registry. Problems with data security concerns could be overcome by linking unique identifier implant IDs to the registry without revealing actual personal data of patients.

Prerequisites for installment of an outcome registry*

- Permanently-implanted medical device that can only be removed, exchanged or repaired by means of a medical intervention (=revision).
- Causal and logical relationship between a malfunction (of the implanted medical device) anda medical intervention for its correction (revision).
- Implant failure leads to an intervention (=endpoint), which is readily documented in a routine procedure.

*Adapted from EAR-EFORT (European Arthroplasty Register - European Federation of National Associations of Orthopaedics and Traumatology).

Stakeholders (Table 1) in the market traditionally share a hesitant approach towards ubiquitous control. Governmental incentives for developing an implant registry strongly depend on legislative priorities and financial considerations especially in strained economic times. On the one hand, industry stakeholders are interested in an actual market share overview. On the other hand, surgeons could benchmark their implant-revision performance, and patients were finally able to participate in an automobile industry-grade recall system following self-triggered registration. With varying degrees of interest present and notably lobbying groups focusing on respective advantages, it seems difficult to create a registry just out of voluntary participation (e.g., by medical societies, "bottom-up-approach"). Past experiences have revealed that a pure voluntary involvement for the participation in a registry (opt-in) produced an insufficient dataset (re: PIP crisis). Governmental legislation giving the registry the option

Table 1 Stakeholders

Stakeholders	Benefits	Prerequisite
Registry	Reporting function	Independent body
Patients	Product recall, electronic implant identification	Opt-out (=mandatory entry)
Surgeons	Product recall, implant failure rate, benchmarking	Minimum dataset
Hospitals	Maintenance of certification, government accreditation	Implementation of registry data entry forms in hospital IT systems
Industry	Product recall, market share	Unique identification for implants as industry standard
Insurance	Product recall, implant failure rate	Acceptance by other stakeholders
Government	Patient safety, regulatory instrument	Legislative framework, data protection

to perform as an independent body could be more promising ("top-down-approach"). This so-called "independent body" could be a nominated trustworthy institution, for example a university, a specialist department or a dedicated data collection agency with expertise in large epidemiological data. The term "opt-out" refers to the way, in which agreement for inclusion into a registry database works and differs from informed consent (e.g., for a medical intervention). It is actually an institutional permission to allow all doctors and patients to automatically enroll onto a registry, with appropriate explanation via an explanatory statement, unless they opt-out.

Several challenges (see List of Challenges) exist not just among the stakeholders, but also in the lobbying groups themselves. Breast implants are not just used by one single surgical specialty, and differing interests by respective medical societies might hinder collective action towards the development of a single national registry. Negative sentiment and suspicion might also derive from surgeons themselves irrelevant of their organizational representation, particularly when there is more than one group involved performing operations with breast implants. A common problem discouraging clinician participation was the complexity of data collection forms trying to capture as much information as possible, varying by surgical specialty, instead of a "less is more"-approach; less primary data requests will generate more compliance and therefore a higher capture rate and ultimately more data. Additionally, the transfer of, for example, European law into national legislation within the European Union might prove challenging due to differing interpretations of data protection and its implementation. In this context, the sharing of data on an international level needs to consider ownership issues. Central to the development of a functioning registry is the trust of every stakeholder in the independence of its board, which can be accomplished by access of each lobbying group to the governing board with periodical rotations in its management. While the security of servers and solidity of data entry is key, so is the regular maintenance and review of data, requiring implementation of alarm triggers to identify underperformance or even risks for patients at an early stage. Clearly defined outcomes should ideally be more than the revision endpoint itself, because there may be patients with implants with bad outcomes, who have not had a revision, and this could be included by the use of patient-reported outcomes as well as specific triggers for revisionary surgery going beyond the pure malfunctioning of a medical device (eg. capsular contracture causing a breast deformity by the tissue surrounding an implant).

List of challenges

- Negative sentiment from clinicians.
- Collaboration among specalties.
- Ethical approval.
- Consent processes.
- Data set compatibility.
- Database build.
- Privacy issues.
- Data ownership.
- Pilot study.
- National rollout.
- Legislation.
- Registry governance.
- Compliance internationally.
- Outcome tracking.
- Registry costs.

Learn from the past, be ready for the future

A purely technical focus of a medical device does not suffice to evaluate outcomes in medicine, it is therefore necessary to include medical parameters and patient-reported data as a requirement to receive a “whole picture” of evidence for the future analysis of breast implants. Unique identifiers for devices (from industry) and interventions (from surgeons) without revealing personal data could become more than just read-only transducers and stakeholders could profit from it as a dynamic monitoring tool. The challenges faced by medical tourism will demand cooperation going beyond national initiatives and all stakeholders could benefit from international collaborations. This drive has already spawned international initiatives among national plastic surgery societies, national health services and national health regulatory agencies [8]. This leading role is inherent to plastic surgeons as representatives of the specialty predominantly involved in and associated with the use of breast implants, but requires to recruit other groups of clinicians to shoulder the efforts in developing orderly standards of care and quality for the patients' benefit. The new frontier incorporates patient-reported outcomes along with information technology triggered developments like radiofrequency identification tags to innovate the generation of truly objective data. This will facilitate the production of automated reporting from intelligent data mining to anticipate future trends of breast implants, be it sales, improved outcomes or even adverse reactions. Future efforts should take into account the past experiences made, create innovative incentives (see List of Incentives), and build upon international collaborations to develop optimal solutions for ultimately improving patient safety.

List of incentives

- Opt-out (mandatory data entry).
- Electronic implant ID (linked to registry).
- Product recall triggered by industry/surgeons/ government with automated notifications to patients.
- Integration of patient-reported outcomes.
- Innovative product concepts (e.g., radio frequency identification tags).

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

DBL and RC 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to be published; and 4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Both authors read and approved the final manuscript.

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