International Importance of Robust Breast Device Registries

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Background: Breast implants are high-risk devices that have been at the epicenter of much debate and controversy. In light of the Poly Implant Prothèse crisis, data registries among 11 national societies around the world are cooperatively calling for the urgent need to establish robust national clinical quality registries based on international best practice within a framework of international collaboration.
Methods: A survey was conducted on the historic and current status of national breast device registries. Eleven countries participated in the study, illustrating different data collection systems and registries around the world. Data collection was designed to illustrate the capabilities of current national registries, with particular focus on capture rate and outcome reporting mechanisms.
Results: A study of national breast implant registries revealed that less than half of the participating countries had operational registries and that none of these had adequately high data capture to enable reliable outcome analysis. The study revealed that the two most common problems that discouraged participation are the complexity of data sets and the opt-in consent model.
Conclusions: Recent implant crises have highlighted the need for robust registries. This article argues the importance of securing at least 90 percent data capture, which is achievable through the opt-out consent model. Since adopting this model, the Australian Breast Device Registry has increased data capture from 4 percent to over 97 percent. Simultaneously, it is important to foster international collaboration from the outset to avoid duplication of efforts and enable the development of effective international early warning systems. (*Plast. Reconstr. Surg.* 135: 330, 2015.)

Breast implants are classed as high-risk devices and are used with increasing frequency globally in cosmetic and reconstructive procedures. From available data extrapolation, it is estimated that annually over 1 million implants are inserted globally. Despite the increase in implant procedures and the devices being high risk, there are currently no reliable or epidemiologically sound data with which to measure accurately their performance after implantation.

A lesson learned from major global breast implant crises over the past 30 years is the need to improve patient safety. In doing so, it is essential to have a high capture rate of reliable data at a national level that are internationally comparable.

From the Association of Plastic and Reconstructive Surgeons of Southern Africa; the Irish Society of Plastic Surgeons; the American Society of Plastic Surgeons; the German Society of Plastic, Reconstructive and Aesthetic Surgeons; the Austrian Society for Plastic, Aesthetic and Reconstructive Surgery; the French Society of Plastic, Reconstructive and Aesthetic Plastic Surgeons; the Dutch Society of Plastic Surgeons; the Department of Epidemiology and Preventive Medicine, Monash University; the Breast Implant Registry Pilot, Clinical Practice Research Datalink, Medicines and Healthcare Products Regulatory Agency; the British Association of Plastic, Reconstructive and Aesthetic Surgeons; the Swedish Association of Plastic Surgeons; the International Breast Implant Registry; the American Plastic Surgery Foundation; and the New Zealand Association of Plastic Surgeons.
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This is only reliably achievable through an opt-out patient consent process that automatically registers institutions, surgeons, and patients, who can exercise full discretion to opt-out.

With a number of countries currently developing registries founded on best practice, and others with registries in evolution, it is now necessary for the international medical community to collaborate on setting international benchmarks. Such mutually beneficial collaboration will amplify data sets and provide a more effective global early warning system of implant-related problems. In addition, improved collaboration will help mitigate the duplication of efforts and provide greater confidence when comparing outcomes of different devices, surgeons, and institutions.

HISTORY OF GLOBAL IMPLANT CRISES

Historically, in the absence of reliable data, controversies surrounding breast implants have quickly become major global crises. In the 1980s and 1990s, the Dow Corning crisis resulted in a series of class action lawsuits that culminated in a multi–billion dollar class action settlement that forced the implant manufacturer into bankruptcy protection.[1] Allegations that silicone breast implants produced by Dow Corning caused breast cancers and systemic disease were only disproved much later by epidemiologically sound evidence.[2]

In an attempt to avert another crisis, a number of breast implant registries were spawned in the 1990s aiming to collect outcomes data that could monitor the safety of these devices. To date, almost all of these registries have ceased operation. Universally, these registries adopted an ineffective opt-in (optional) model, with some also imposing a cost to patients. Being optional and at a personal cost acted as disincentives for inclusion and thus data capture rates were unacceptably low.

These limitations of the early registry models were revealed during the Poly Implant Prothèse crisis from 2010 to 2012, when a French implant manufacturer used non–medical grade silicone in the production of thousands of implants. Heightening the scare, Poly Implant Prothèse implants were suspected to have had a higher rupture rate than other implants. At explantation, their rupture patterns were extreme (Fig. 1), and many had a milky suspension of uncertain composition (Fig. 2). When compared with the sales data for Poly Implant Prothèse implants, it was revealed that the original Australian opt-in registry (that imposed a $25 fee per implant to patients) had only captured 3.4 percent of the Poly Implant Prothèse implant population.[3] In the absence of robust registry data, it took concerted scientific efforts to determine the relative risk of these devices.[4,5] Such extensive testing in the absence of prospective data proved time consuming and expensive because a plethora of potentially noxious chemical levels needed analysis (Fig 3).[4]

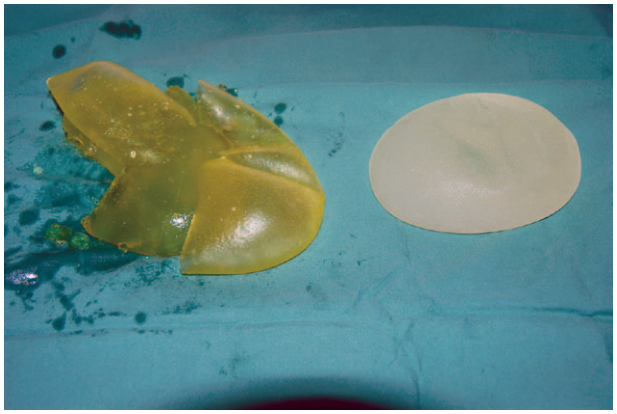

Fig. 1. A ruptured Poly Implant Prothèse implant with extreme rupture patterns next to an intact implant.

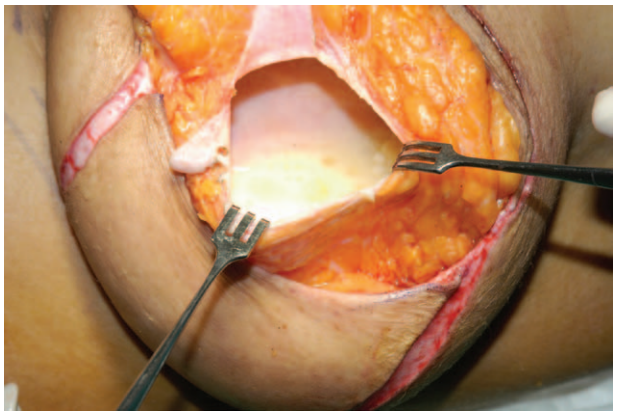

Fig. 2. Milky suspension of uncertain composition found in a cavity around a Poly Implant Prothèse implant.

Further investigation revealed that many other national registries also experienced similar problems of low data capture. Without reliable and epidemiologically sound data, the Poly Implant Prothèse crisis paralleled the Dow crisis and quickly escalated to another global public scare.

LIMITATIONS OF EXISTING REGISTRIES: AN INTERNATIONAL PERSPECTIVE

Currently, there are a number of different data collection systems and registries for breast implants and implantable devices around the

Monocyclic Aromatic Hydrocarbons	Halogenated Aliphatic Hydrocarbons	Trihalomethanes
Benzene	Chloromethane	Chloroform
Toluene	Vinyl chloride	Bromodichloromethane
Ethylbenzene	Bromomethane	Dibromochloromethane
m & p-Xylenes	Chloroethane	Bromoform
o-Xylene	Trichlorofluoromethane	
Styrene	1,1-Dichloroethane	**Polycyclic Aromatic Hydrocarbons**
Isopropylbenzene	Dichloromethane	Naphthalene
n-Propylbenzene	trans-1,2-Dichloroethene	
1,3,5-Trimethylbenzene	1,1-Dichloroethene	**Oxygenated Compounds**
tert-Butylbenzene	2,2-Dichloropropane	Acetone
1,2,4-Trimethylbenzene	cis-1,2-Dichloroethene	Vinylacetate
sec-Butylbenzene	Bromochloromethane	2-Butanone (MEK)
4-Isopropyltoluene	1,1,1-Trichloroethane	4-Methyl-2-pentanone (MIBK)
n-Butylbenzene	Carbon tetrachloride	2-Hexanone (MBK)
	1,1-Dichloropropene	Methyl tert-Butyl Ether (MTBE)
Halogenated Aromatic Hydrocarbons	1,2-Dichloroethane	
Chlorobenzene	Trichloroethene	**Other Compounds**
Bromobenzene	1,2-Dichloropropane	Carbon disulfide
2-Chlorotoluene	Dibromomethane	
4-Chlorotoluene	cis-1,3-Dichloropropene	
1,3-Dichlorobenzene	trans-1,3-Dichloropropene	
1,4-Dichlorobenzene	1,1,2-Trichloroethane	
1,2-Dichlorobenzene	Tetrachloroethene	
1,2,4-Trichlorobenzene	1,3-Dichloropropane	
1,2,3-Trichlorobenzene	1,2-Dibromoethane	
1,2,3,4-Tetrachlorobenzene	1,1,1,2-Tetrachloroethane	
	1,1,2,2-Tetrachloroethane	
	1,2,3-Trichloropropane	
	1,2-Dibromo-3-chloropropane	
	Hexachlorobutadiene	

Limits of detection: Oxygenated Compounds and Carbon disulphide, 100 µg/L; m & p-Xylenes, 20 µg/L; all other compounds in Table 1, 10 µg/L.

Fig. 3. Volatile organic compounds not detected in samples of Poly Implant Prothèse silicone gel breast implants, after testing by the Therapeutic Goods Administration. [From Parliament of Australia. The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants. Available at: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2010-13/implants2012/index. Accessed December 11, 2013.]

world. A survey of national breast device registries was sent to 17 national plastic and reconstructive surgery societies, with responses collected from 12 participating countries, including Australia, Austria, France, Germany, Ireland, Israel, The Netherlands, New Zealand, South Africa, Sweden, the United Kingdom, and the United States. Information relating to the Danish registry has also been included for comparison (Table 1).

The study of national breast implant registries revealed that only half of the participating countries had introduced registries following the Dow Corning crisis and less than half of these were still operational. Common to these registries was a low accrual of both patients and clinicians and thus their data were epidemiologically unsound. A conspicuous problem discouraging clinician participation was the complexity of their data collection forms. Often, clinicians are keen to capture as much information as possible through multipage data entry forms; however, this can act as a disincentive for participation.[6] A common registry maxim is "less is more"; fewer primary data requests will generate more compliance and therefore a higher capture rate and ultimately more data, both primary and secondary.

For patients, the opt-in consent model is also a major disincentive, particularly if a financial impost is associated with registration.[6] A study in 2004 suggested that the traditional method of opt-in recruitment will limit population uptake to approximately 30 percent.[7] In many countries, cosmetic and reconstructive breast surgery is performed by surgeons from a range of backgrounds. However, to date, no registry has attempted to involve all clinician groups to capture data from

the entire patient population. To ensure total capture, all clinicians performing this type of breast surgery must be included in a registry, and this is achievable through an opt-out consent process.

CALL FOR ROBUST CLINICAL QUALITY REGISTRIES

Since the Poly Implant Prothèse crisis, the call for tighter regulations around medical devices and the establishment of registries for outcome tracking has gained considerable traction internationally.[6,8,9] The European Commission is considering tighter legislation and rules regarding medical devices and has identified the need to track these devices, further proposing new regulations to be adopted and fully implemented by 2014 to 2015.[10] The United Kingdom Department of Health's *Review of the Regulation of Cosmetic Interventions* published in April of 2013 made the recommendation that a breast implant registry be established within a period of 12 months, with a view to extending it to other cosmetic devices as soon as possible.[10]

As a result of the Poly Implant Prothèse crisis, the Australian Senate commissioned an inquiry into the government's regulation of medical devices and subsequently recommended the Department of Health to "establish an opt-out Breast Implant Registry as a priority. The design of such a registry should be based on the National Joint Replacement Registry."[11]

In addition to the need for tighter regulation and monitoring of high-risk devices, the establishment of registries can produce a distinct cost-saving benefit for governments. Through a study of 13 disease registries across five countries, the Boston Consulting Group demonstrated the potential for registries to provide at least a 10-fold cost saving per year in public health spending. Their methodology was based on expert interviews, observation, and analysis of published and unpublished data. Where the existence of registries was associated with improvements in health outcomes, the authors sought to estimate savings from the improvements achieved; whether through revisions avoided, as per the Swedish Hip Arthroplasty Register; or through direct medical costs avoided by preventing *Pseudomonas* infection in cystic fibrosis patients, as per the U.S. Cystic Fibrosis Foundation Patient Registry.[12]

TEMPLATE FOR INTERNATIONAL BEST PRACTICE

In response to growing concerns around Poly Implant Prothèse implants, the Australasian Foundation for Plastic Surgery, in collaboration with Monash University's Department of Epidemiology and Preventive Medicine, began to develop an international best practice Breast Device Registry, including cosmetic augmentation and cancer reconstruction devices (breast implants and tissue expanders.) In line with the Senate's recommendation, the Breast Device Registry is based on an opt-out patient consent model to aim for complete population capture.[11] The opt-out model has long been proven effective by the Australian Orthopaedic Association's National Joint Replacement Registry, which established national data collection in 2003, with data capture rates reliably above 97 percent.[13]

In consultation with a range of stakeholders, the Australian Breast Device Registry has refined a primary minimum data set of only those fields required for outcomes assessment. The methodology also enables validation of its population capture against hospital records. It uses a short "tick-and-stick," single-page data collection form to lessen clinician burden, and provides data protection assurance by being compliant with Australian national security standards (International Organization for Standardization 20071/2).

The new Australian Breast Device Registry is currently being piloted at seven sites, with 1031 patients contributing data. It is due to expand to 11 sites in mid 2014 and 55 sites by the end of 2014.

Through international collaboration and the sharing of registry design, The Netherlands is currently developing a breast device registry based on the Australian minimum data set. The registry will have significant outcome tracking capabilities and will produce epidemiologically sound data for analysis. Data collected will help set a national benchmark to measure performance. Clinicians, clinics, and producers will be measured against benchmarks that identify parties who are overperforming or underperforming. This system has proven effective in other Dutch registries; benchmarking within the Dutch colon cancer registry has resulted in a 30 percent reduction in the mortality rate.[14]

The success and sustainability of a registry are strongly dependent on two critical factors: the availability of sustainable funding to maintain its management and operation, and the establishment of robust governance structures to ensure proper oversight over the registry's operations and management.[15] To ensure transparency and accountability, a multidisciplinary governance committee chaired by an independent custodian is recommended. The governance committee

Table 1. Current Status of National Breast Implant Registries

Country	Approximate No. of Implants Inserted per Year	Registry Status	Opt-Out/ Opt-In	Percentage of Implants Captured	Outcome Tracking Capabilities	Registry in Development
Austria	Unknown	Registry currently operational	Opt-in	Unknown	Limited	
Australia	Approximately 18,000	Registry currently operational	Opt-in	<5%	Limited	Yes; the Breast Device Registry is based on international best practice with a capture rate of >97%
Denmark	Unknown	Registry no longer operational (1999–2007)	Opt-in	Unknown	Limited	
France	Approximately 3000	Never had an official national registry	NA	NA	NA	Yes; the French Society of Plastic, Reconstructive and Aesthetic Surgeons is currently looking to develop an opt-out registry modeled on the Australian registry as developed by the Australasian Foundation for Plastic Surgery
Germany	Unknown	Never had an official national registry	NA	NA	NA	Yes; strict data confidence legislation may affect ability to implement opt-out registry under the custodianship of an independent institution
Ireland	Approximately 3000	Never had an official national registry	NA	NA	NA	Yes; Ireland is exploring the possibility of implementing an opt-out registry modeled on the Australian registry as developed by the Australasian Foundation for Plastic Surgery
Israel	Unknown	Uses the International Breast Implant Registry	Opt-in	Unknown	Limited	
Netherlands	Approximately 25,000	Never had an official national registry	NA	NA	NA	Yes; The Netherlands has secured government funding to establish an opt-out registry modeled on the Australian registry as developed by the Australasian Foundation for Plastic Surgery
New Zealand	Approximately 2000	Never had an official national registry	NA	NA	NA	Yes; provisionally, New Zealand is exploring the possibility of implementing an opt-out registry modeled on the Australian registry as developed by the Australasian Foundation for Plastic Surgery
South Africa	Approximately 9,500	Never had an official national registry	NA	NA	NA	
Sweden	Approximately 11,000	Never had an official national registry	NA	NA	NA	Phase I of a national breast implant registry has concluded; phase II of the pilot commenced October 18, where reoperation data are collected at selected pilot clinics
United Kingdom	Unknown	Registry no longer operational (1999–2005)	Opt-in	Unknown	None	
United States	Approximately 359,000	National BIR no longer operational (2000–2007); TOPS Breast Implant Module is currently operational	Opt-in	TOPS Breast Implant Module capture rate approximately 4%	Limited	Yes; the Plastic Surgery Foundation in collaboration with a consortium of stakeholders is currently developing an opt-out national breast implant registry

NA, not applicable; BIR, Breast Implant Registry; TOPS, Tracking Operations and Outcomes for Plastic Surgeons.

should comprise representatives from all key stakeholder groups, including all clinician groups involved in breast surgery, government, medical insurers, and industry.

IMPORTANCE OF INTERNATIONAL COLLABORATION

With a number of countries in the process of developing breast device registries, and others with registries in nascent stages of operation, the opportunity exists to consolidate international collaboration to establish global standards for data collection and outcome tracking. A collaborative approach to sharing registry science and registry data can help support and enhance the effectiveness of emerging and existing breast device registries, and avoid the duplication of efforts.[6] In addition, the adoption of an internationally agreed minimum data set and agreed data point definitions will enable the development of evidence-based international early warning systems.

The orthopedic experience of recalling the DePuy articular surface replacement hip prostheses demonstrates the importance of gaining—from the outset—international agreement over a minimum data set and an internationally endorsed data dictionary.[16] The DePuy articular surface replacement and Poly Implant Prothèse crises show that a uniform minimum data set with an agreed dictionary of registry terminologies is critical to addressing global quality-of-care issues. Such collaboration is now well established in the orthopedic arena by means of the International Society of Arthroplasty Registries and similarly for cardiac patients through the Utstein template used by cardiac resuscitation data collectors.[17]

INTERNATIONAL COLLABORATION OF BREAST REGISTRY ACTIVITIES

The International Collaboration of Breast Registry Activities was established by the Australasian Foundation for Plastic Surgery to encourage and foster a collaborative approach to registry science and registry data in relation to breast device surgery. Current members of the International Collaboration of Breast Registry Activities comprise nine national specialty societies from Australia, Austria, France, Ireland, The Netherlands, New Zealand, South Africa, the United Kingdom, and the United States, and three major national bodies: United Kingdom's National Health Service, the U.S. Plastic Surgery Foundation, and Australia's Monash University. As a collective, the objectives of the International Collaboration of Breast Registry Activities are to assist the development of national registries and to enhance their international quality outcome tracking capabilities. To date, the International Collaboration of Breast Registry Activities has designed and distributed freely a minimum data set form and a comprehensive data dictionary, and has also offered registry design expertise pro bono to all participating countries.

CONCLUSIONS

Breast implants are high-risk devices distributed and implanted internationally. The failure of any implantable medical device can have profound global implications. Without reliable and epidemiologically sound data, misinformation about a device can quickly escalate into an international crisis. In addition to the high cost to governments and industry, such crises cause considerable anxiety to patients. Recent history has highlighted the need for a collaborative approach to addressing the limitations of existing registries and to foster the development of emerging robust registries. International collaboration has the ability to enhance quality outcome tracking and provide evidence-based international early warning systems. To this end, the establishment of effective national breast device registries combined with international collaboration has the ability to significantly improve health outcomes for patients with implantable breast devices globally.

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