Breast Implant Registries: A Call to Action

Ingrid Hopper, MBBS, PhD; Susannah Ahern, MBBS, PhD; Tu Q. Nguyen, MBiomedSc; Catherine Mulvany, BA, BBus; John J. McNeil, MBBS, PhD; Anand K. Deva, MBBS, MS; Howard Klein, MD, FRACS; Birgit Stark, MD, PhD; Hinne A. Rakhorst, MD, PhD; and Rodney D. Cooter, MD, FRACS

Silicone breast implants have evolved through five generations and over 240 styles of breast implants have been delivered to the marketplace.1 However, there are little high quality data with which to make reliable, evidence-based evaluations of the risks of breast implants, and to date, the advantage of one type over the other is uncertain. Clinical quality registries (CQRs) enable evaluation of device performance, safety, and quality of care for patients. Just as breast implants have evolved and improved over the last decades, so too has clinical registry expertise and technology.2 Registries now support improved data capture, data linkage, analysis and reporting, and are a recognized contributor to health systems that provide high-quality patient care.3 The current generation breast implant registries promises to improve long-term breast implant safety, but key stakeholder support and participation is critical.

Breast Implant Registries

Previous breast implant registries, established in the wake of the Dow Corning crisis in the 1990s, had fundamental design flaws. This limited their utility in identifying poorly performing devices requiring recall, brought to light by the Poly Implant Prothèse (PIP) crisis.3 The major design flaw was opt-in consent, meaning that patients and professionals registered on a voluntary basis, resulting in capture rates of typically less than 10% to 15% of the implant population.4 Poor data completeness due to burdensome data collection requirements associated with extremely large datasets and a lack of transparent audit processes also contributed.4-6 Internationally, a lack of agreement on a uniform set of minimum data fields made it difficult to compare or link data-sets. Registries were also compromised by deficient funding strategies, including withdrawal of industry or government funding. The Dow Corning and PIP health scares highlighted the need for more comprehensive epidemiological data with which to assess and monitor breast implants.

Clinical Quality Registries

CQRs, such as the Australian Breast Device Registry (ABDR), the Dutch Breast Implant Registry (DBIR), and the Swedish Breast Implant Registry (BRIMP) are a major

Dr Hopper is Head of Drug and Device Registries, Dr Ahern is Head of Registry Science Unit, Ms Nguyen is a Research Officer, Ms Mulvany is a Registry Coordinator, Prof. McNeil is the Head of School, and Prof. Cooter is an Adjunct Clinical Professor, Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Australia. Prof. Deva is the Head of Cosmetic and Reconstructive Surgery, Faculty of Health and Medical Sciences and Surgical Infection Research Group, Macquarie University, Sydney, Australia. Dr Klein is Immediate Past President, New Zealand Associations of Plastic Surgeons, Wellington, New Zealand. Dr Stark is Chief Physician, Department of Plastic and Reconstructive Surgery, Karolinska University Hospital, MK1 Karolinska Institutet, Stockholm, Sweden. Dr Rakhorst is the Head of Plastic, Reconstructive and Hand Surgery, MST Enschede and ZGT Almelo, The Netherlands.

Corresponding Author:
Dr Ingrid Hopper, Department of Epidemiology and Preventive Medicine, Monash University, 553 St Kilda Road, Melbourne, VIC 3004, Australia. E-mail: ingrid.hopper@monash.edu
advance on previous implant registries. They enable ongoing, systematic, and uniform collection of clinical data from patients undergoing breast implant procedures. CQRs differ from previous registry design in key ways, the foremost being opt-out consent. Near-complete inclusion of all eligible patients eliminates selection bias, and assures the validity of registry data. Opt-in consent requires consent from patients before the data can be included, while opt-out consent allows the enrolment of patients into the registry at the time of the procedure and presumes consent unless an individual actively withdraws it.

The effect of this change in consent practice is significant. The ABDR commenced national rollout of data collection in June 2015, and as of the end of December 2016 (a period of 18 months), the registry boasted more than 11,000 patients, with an opt-out rate < 1%. An additional 700 patients are added to the registry every month (ABDR, unpublished data). Further, while initial uptake was solely plastic surgeon led, there has been increasing engagement from cosmetic surgeons (undertaking 17% of the cosmetic augmentation surgeries tracked by the ABDR in 2016 compared to 6% of procedures in 2015), which further drives high procedural case ascertainment. Similarly the DBIR went live nationally in April 2015 and had registered over 17,000 surgeries and over 28,000 implants by December 2016. BRIMP started enrolling patients in May 2014 and has over 7000 primary surgeries with over 13,000 breast implants.

In practice, opt-out consent entails a number of steps. Patients must be informed of the registry during preoperative consultation and have the opportunity to opt out prior to surgery. To avoid potential for cherry-picking of cases, patients opt out of the registry themselves, not their surgeon. At the ABDR, patients are sent a Participant Explanatory Statement notifying them that their details have been received, and includes a prominently displayed toll free telephone number so they can opt out of the registry if they wish. Opt out is preferably undertaken by telephone so patients have the opportunity to ask questions. The DBIR uses an opt-out approach where data are collected using either an online form using secure techniques or using “batch uploads” where data are transmitted directly from hospital patient records. Data are collected and stored in a centralized database. As the registry is considered to be part of the patient file and is used to improve quality of care by auditing, no written consent is required. Patients are allowed to opt out.

A CQR can be conceptualized as a “spine and rib model” of data collection. The “data spine” is an epidemiologically sound minimum dataset with clearly defined, standardized data elements. The set of data points is limited in number, with each being objective and reproducible, so clinical judgement is not required. The core dataset is derived from consideration of the expected tasks and outputs that the registry provides. For example, the ABDR and BRIMP datasets comprise minimal data elements collected at a single point in time for each breast device surgery (implantation, reposition, or explantation) (Appendices 1-3, available as Supplementary Material online at www.aestheticsurgeryjournal.com). Collection of registry data is designed not to be burdensome for clinicians or their staff, or impractical to sustain in the long term. A concise data entry form is therefore crucial. “Data ribs” are time-limited additional sets of data added to the core dataset to answer particular questions. These may include more in-depth analysis of a particular surgical technique or implant characteristics, with such studies typically being limited to a few sites or hospitals.

The ABDR dataset has excellent completion rates for most demographic and clinical data elements. There is opportunity to review those data points less well collected, such as revisions and complications, as part of a continuous quality improvement process. Completion rates for patient details such as telephone numbers and email addresses, commonly omitted from the patient label, are lower. As long-term patient follow up is required, methods to address this are currently being investigated. The onus is on the patient to keep their personal details up to date, which can be entered through the website.

Registry data quality must be regularly validated for statistical reasons. The ABDR has been able to resolve missing data for critical fields via routine, manual checking of form completion, and follow up with surgeons’ rooms. Accurate case ascertainment is crucial, and can be achieved via monitoring against hospital procedure and diagnostic codes, or sales data if available. Regular audit of a sample of medical records from participating sites is also a viable approach. The DBIR validates against sales data uploaded on a weekly basis from industry, and so far, the majority of industry supports this system by active uploads. For the ABDR, processes for validating case capture are currently being established as the national rollout continues.

To ensure independence, CQR data custodianship is provided by financially independent organizations which are also independent of clinician groups, individual hospitals, or industry; such as a university or other academic/research organisation. The ABDR is housed within Monash University, the DBIR within the Dutch Institute of Clinical Audit, and BRIMP within the Registry Centre, Västra Götaland. This differentiates registry data from data derived from clinical trials sponsored by device manufacturers which may have reporting biases.

When adjusted for differences in patient case mix, mature registry data have been shown to improve provider performance via regular benchmarked reports of participating site and clinician outcomes, and has been associated with both development and increased adherence to
The power of registries was proven when the Conformité Européenne mark was withdrawn from Silimed in 2016. The DBIR determined the number of implants within hours, and provided these data to patients, institutions, and government.14

An evolving issue which requires further investigation is the link between anaplastic large cell lymphoma (ALCL) and breast implants. ALCL is considered rare,15 and calculation of incidence is hampered by lack of a denominator - the total number of implants. Registries help by providing this information, and as the registries mature, will act as a cohort study to provide information regarding causality. Registry data can be linked to other mandatory nationally reported datasets, such as cancer registries, which furthers our understanding of this disease without additional data collection by the surgeon. Identified cases can be further investigated with a larger dataset using an opt-in serious adverse event registry, such as the PROFILE registry in the United States,16 or a larger dataset using an opt-in serious adverse event registry, such as the Australian and New Zealand ALCL Taskforce database.15

Registries enhance patient safety through both monitoring of devices, leading to the identification of device design flaws and failures, and monitoring of provider performance that may impact on quality of care. A summary of the potential roles/tasks CQR for breast implants is provided in Table 1.

New surgical techniques are being integrated into everyday practice and will require close monitoring, such as fat grafting and acellular dermal matrices. Outcome measurements, an essential aspect of all CQRs, are currently being developed through the International Collaboration of Breast Registry Activities (ICOBRA) with internationally agreed quality indicators integrated with standardized patient reported outcome measures to allow comparisons that will accelerate improvement.13 An example of the power of registries was proven when the Conformité Européenne mark was withdrawn from Silimed in 2016. The DBIR determined the number of implants within hours, and provided these data to patients, institutions, and government.14

An evolving issue which requires further investigation is the link between anaplastic large cell lymphoma (ALCL) and breast implants. ALCL is considered rare,15 and calculation of incidence is hampered by lack of a denominator - the total number of implants. Registries help by providing this information, and as the registries mature, will act as a cohort study to provide information regarding causality. Registry data can be linked to other mandatory nationally reported datasets, such as cancer registries, which furthers our understanding of this disease without additional data collection by the surgeon. Identified cases can be further investigated with a larger dataset using an opt-in serious adverse event registry, such as the PROFILE registry in the United States,16 or the Australian and New Zealand ALCL Taskforce database.15

Registries can be pooled internationally to increase the total number of implant procedures in the dataset. To ensure consistency of breast device registry designs globally, the ICOBRA has developed an agreed core spine of data points with agreed definitions.17 Similarly, ICOBRA is currently investigating data-sharing technologies and processes among its member organizations to support ongoing international collaboration in breast device monitoring.

Universal hurdles to tackle in setting up a registry abound. Hospital ethics and governance approvals in Australia have been time consuming, slowing down national rollout of the ABDR. Ongoing funding is a constant concern, and the DBIR has elected to charge cosmetic patients 25 Euro per implant to ensure the long-term viability of the registry, while BRIMP and ABDR are reliant on funding from their national healthcare systems. Ongoing sustainable funding models to date remain elusive. Determination of appropriate clinical quality indicators is challenging, as process measures are generally easier to collect however outcome measures are arguably more meaningful. The most efficient and effective means of long-term patient follow up is yet to be determined.

In order for registries to be successful and deliver both the epidemiological data and clinical quality outcomes they promise, they must be strongly supported by stakeholders. In particular, uptake of the registry by surgeons is a key critical success factor. Endorsement from the relevant clinical organizations and specialty surgical societies has been instrumental in driving the development of these registries through facilitating buy-in from participating clinicians. Successful uptake of the DBIR was achieved by making compliance with the registry a requirement for membership to the Dutch Society for Plastic, Reconstructive and Hand Surgery (NVPC).10 Further incentives for surgeons to participate include allocation of Continuing Medical Education points and use of the registry logo on the practice website. Moreover, the ability to track patients, devices and major complications, capacity to compare one’s practice against peers in a protected environment and accrue goodwill associated with efforts to improve patient safety are in themselves incentives to participate. CQRs can also offer some protection for surgeons, as the implant that is not registered now may be a lawsuit in a few years’ time. Governments can promote compliance from hospitals and surgeons, such as through mandatory accreditation participation requirements for key clinical registries.

CONCLUSION

The popularity of silicone breast implants continues to rise. It is clear that concerns regarding their safety are best addressed through international collaboration of breast implant CQRs. As well as clinical and epidemiological benefits, the health economic benefits of such a collaborative approach include reduced surgical revision costs, improved procedural and device performance, and reductions in patient morbidity. Similar united registry efforts have led to effective recall and improved performance of orthopaedic implantable devices.18 This is a call to arms for breast surgeons, governments and device manufacturers - and an opportunity to revolutionize breast implant safety.
Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Acknowledgements

The authors gratefully acknowledge the assistance of Ms Marie Pase for data relating to the ABDR. The ABDR is funded by the Australian Department of Health.

Disclosures

Dr Hopper is supported by a National Health and Medical Research Council early career fellowship. Prof. Deva has previously coordinated research and been a consultant to Allergan (Irvine, CA), Mentor (Santa Barbara, CA), and Acelity (San Antonio, TX). Dr Rakhorst is a board member of the Dutch Breast Implant Registry, Treasurer of ICOPLAST, and current President of the Dutch Society for Plastic Surgery. Prof. Cooter is on the Board of Directors of ICOPLAST.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

REFERENCES