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FEATURE ARTICLE BREAST

History of the Australian Breast Device Registry

Rod Cooter AM MBBS, MD, FRACS (Plast) 0000-0002-5875-0977,[1,a] Shiv Chopra MBBS, MRCS, FRACS (Plast) 0000-0002-4733-8020,[2] Gillian Farrell MBBS, FRACS (Plast),[3] Susannah Ahern MBBS (Hons), FRACMA, PhD 0000-0001-9413-6897[4]

[1] *Department of Surgery, University of Adelaide, South Australia, AUSTRALIA; St Andrew's Hospital, Adelaide, South Australia, AUSTRALIA; Department of Epidemiology and Preventive Medicine, Monash University, Victoria, AUSTRALIA*

[2] *The Royal Marsden Hospital, Chelsea, London, UNITED KINGDOM; International Collaboration of Breast Registry Activities (ICOBRA); The Royal Brisbane Hospital, Brisbane, Queensland, AUSTRALIA*

[3] *Department of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, AUSTRALIA; Peter MacCallum Cancer Centre, Melbourne, Victoria, AUSTRALIA; Plastic Surgery, Royal Darwin Hospital, Tiwi, Northern Territory, AUSTRALIA*

[4] *School of Public Health and Preventive Medicine, Monash University, Victoria, AUSTRALIA*

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Introduction

Everything we do as clinicians carries some risk, and when we use implantable medical devices, the risk is compounded. The risks related to medical devices are classified by national regulators on a scale of I to III, according to the device's potential to harm patients. Breast implants are classified as high-risk class III devices.[1] As plastic surgeons are the predominant users of breast implants, it is our collective responsibility to understand and respect these risks by ensuring that patients are fully informed by accurate, reliable, unbiased quality data.

Since breast implants were first introduced in the 1960s, several sentinel events have arisen from adverse patient safety experiences that could have been prevented or reduced with access to high-quality clinical data.[2] Well-designed clinical quality registries (CQRs) are a rich source of such data, but unfortunately, this level of evidence has not been available for any of the negative events involving breast implants in the past decades.

The need to collect accurate data on high-risk devices has been highlighted by several poorly performing implantable devices that cause significant harm to patients, notably orthopaedic devices, where registry data acts as an 'early warning' signal.[3] It has been said that best-practice protocols tell us what we should do, but registries tell us what we are doing. Following the Dow Corning crisis in the 1990s, several national breast implant registries were formed by plastic surgery societies around the world. The Australian Breast Implant Registry (BIR) was developed in 1997 as an opt-in (that is, voluntary) registry where patients were charged a moiety per implant. At the time of the Poly Implant Prothèse (PIP) crisis in 2010, there were over 30,000 registrations in the

[a] Corresponding author: Rod Cooter AM MBBS, MD, FRACS (Plast); rodney.cooter@plasticsurgeryadelaide.com

BIR. However, when the dataset was interrogated to retrieve PIP implant-related information, only 3.4 per cent of 13,000 PIP implants were recorded in the BIR database.[4]

The inability to track patients and their implants from registry information is a global problem because breast implant registries everywhere face the same dilemmas. We approached all major national plastic surgery societies in the US, UK, Europe, South America and Asia, and countries that had set up registries in the 1990s, but all had either abandoned them or found them unable to help with PIP data. This was disturbing because these faulty devices had slipped through the regulatory nets of all the countries involved, so investigations were underway to uncover how this had happened in such a widespread manner internationally.

Rationale for a new breast implant registry

In 2012, an Australian senate inquiry was called on to investigate the perceived shortcomings of our regulatory system in tracking the use of 13,000 PIP implants and their recipients throughout Australia.[5] The Australian Society of Plastic Surgeons (ASPS) was approached to provide evidence at the inquiry and presented a case for a new and more comprehensive breast implant registry to replace the BIR. Recommendation nine of the report was:

> *The committee recommends that, in light of the Poly Implant Prosthèse breast implant recall, the Department of Health and Ageing 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.*

Prior to the Federal Government committing any funding, however, it was a mandatory requirement that any new registry should include all surgical groups involved in this type of surgery: breast surgeons, plastic surgeons and cosmetic surgeons. Each of these three groups were represented on the Chief Medical Officer's PIP investigating panel; therefore, a collaborative plan was instituted to design the new implant registry as an *opt-out* national system (that is, all patients are included unless they choose not to be) compliant with international best practice. Advice was sought from our orthopaedic colleagues who had established a successful opt-out National Joint Replacement Registry in 1999, which became fully national in 2002.[6] One of our early hurdles was securing start-up funding while we waited for financial support from the Federal Government. This was provided by the Australasian Foundation for Plastic Surgery (AFPS) and after further campaigning for over two years, ongoing funding was finally secured from the Department of Health and Aging as per the recommendation from the 2012 senate inquiry. After a process of due diligence to select a robust registry provider, Monash University's Department of Epidemiology and Preventive Health was our chosen collaborator because of their extensive experience managing registries and willingness to collaborate and offer support to establish a pilot program—again financially supported by the AFPS.

The pilot program was shown to be a successful collaborative effort that incorporated all stakeholders (the three surgical groups, Department of Health and Aging, Therapeutic Goods Administration (TGA), industry via Medical Technology Association of Australia (MTAA), patient advocates, registry scientists and administrators), all of whom had representation in the steering committee of the proposed registry.[7]

The new registry, named the ABDR, includes data on implants as well as tissue expanders used in breast reconstructions and other adjunctive materials such as acellular dermal matrices (ADM) and fat grafting.

Lessons

Seven key areas were identified as major challenges in the establishment of the ABDR. These related to: 1. hospital-approval processes 2. funding 3. minimum dataset 4. data management 5. clinician leadership 6. emerging risks—such as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and 7. outcome measurement.

Hospital approval processes

The process of obtaining hospital approval to gather data was pivotal in the first stage of establishing a new registry. Approval processes, however, can be slow to implement because there are three major obstacles to overcome: human research and ethics committee (HREC) approval, hospital research governance approval, and patient consent.

Each institution where data collection is proposed must have initial HREC approval. The ABDR was established at the same time as the National Health and Medical Research Council (NHMRC) national mutual acceptance (NMA)

scheme. The ABDR sought approval from 18 separate HREC committees across Australia.[8]

In addition to ethics approval, data collection cannot commence without governance approval from each institution. This is a separate process in which each hospital reviews the ABDR's application, considering issues such as privacy, and determines whether it will support its staff to undertake the required registry work. For the ABDR, there were approximately 300 contributing sites.

Ideally, patient consent should be opt-out for registry data collection. This approach is deemed appropriate when the research activity is likely to be compromised by a participation rate that is not near complete.[9] Each patient must be fully informed about the registry before their data are entered into the registry and at the time their data are received by the registry. All patients retain the right to opt out at any time. Most well-designed CQRs have very low opt-out rates, often below 1 per cent.

Funding

The start-up costs of a registry can be considerable. Sustainable funding is critical for the long-term viability of a registry and should be considered in the earliest stages. Funding may be obtained from societies or philanthropic organisations for the pilot or proof-of-concept phases. The costs to consider include: start-up costs for study design; management of institutional ethics and governance applications; building a database; transferring, entering, storing and analysing data; and outcome measurement systems. Many of these costs continue to lead to significant long-term registry expenses.[10,11]

Minimum dataset

While somewhat counter-intuitive to many clinicians, 'less is more' is the mantra for data points in the design of a CQR. There were many iterations of the data collection form to select the least possible number of data points. The proposed datasets were scrutinised by several experienced plastic surgeons to ensure the validity of the inclusion of each data point in the core spine. Each data point to be collected had to be justifiable from the literature, and each required a definition understood by all end users without ambiguity of interpretation. All registry data points had to be epidemiologically sound so that if any number of data collectors were to re-collect the data, they would enter the same information. In addition, the registry staff had to understand the dataset and the definition of each point.

The simplicity of the data collection process is critical. 'Tick and stick' data collection forms were designed to effectively reduce completion times. While recognising that online data entry via a computer or smartphone application could be more efficient for the core data points, a paper form was the simplest to implement while the registry was being established and rolled out nationally. A pilot study was designed to test the efficacy of the minimum dataset based on its ease of interpretation, collection and transfer.[12]

Data management

Fundamental to the successful launch of the ABDR was the need to reassure the contributing clinicians (plastic surgeons, breast surgeons and cosmetic surgeons) that all data transferred into the registry would be secure and only retrievable by registry staff at the central repository at Monash University.

Rolling out the registry and educating all end users about the data collection processes requires an ongoing effort by the Monash registry staff along with the clinical leads from each clinical surgical group.

Clinician leadership

Strong clinical leadership is essential for all registries, and with the three surgeon groups contributing to the ABDR, effective collaboration is a key requirement.[13] Each group is represented on the quarterly registry steering committees and are members of the monthly registry management committees. In addition to the clinicians involved, other important stakeholders include patient advocates, regulators, administrators, health department representatives, industry representatives, registry scientists, biostatisticians and software engineers. Clear communication with the end-user clinician group required information sessions to demonstrate the methodologies involved in collecting data. Other groups in these information sessions included patient advocates, nurses, administrators and clinicians-in-training. Consistent clinician leadership was required over the initial five-year period to ensure continuity and corporate memory, and to be able to answer clinically relevant questions during the interrogation of the registry data. Many peer-reviewed publications have already emanated from the registry's data, and these have often involved input from collaborative networks, both nationally and internationally. Furthermore, there has been successful liaison with craft-group societies and parent colleges for registry endorsement and support as a clinical quality audit activity.

Emerging risk

Quality indicators can be used to assess performance using registry data. A quality indicator is a measurable aspect of care that represents quality as determined by scientific research or expert opinion in its absence. Quality indicators can be considered as structures, processes or outcome measures. An emerging risk can be a device, individual clinician or an institution. CQRs require a well-constructed policy that clearly outlines how to address devices, clinicians and institutions that are found to be outliers. The formulation of such a policy must involve relevant craft groups, societies and colleges, and the policy must have clear verification, communication and escalation components. Much work has been done to define quality indicators relevant to the ABDR and other similar registries to enable benchmarking.[14]

Outcome measurement

Pivotal to all CQRs is the measurement and reporting of outcomes to key stakeholders. The ABDR has reported reconstructive and cosmetic surgery outcomes in annual reports since 2016. These reports provide revision rates for both types of surgery as well as for a range of devices including implants with and without mesh, and implants with different surface characteristics. Reporting outcomes at a device level is challenging given the thousands of devices in use. However, the ABDR is currently collaborating with the TGA to finalise a device classification system that will enhance reporting. This will improve device level reporting outcomes and identify variations that can be notified to regulators and clinicians. Surgeons need sufficient annual feedback to satisfy the college requirements for an audit activity. They want to check their operative rates for complications using de-identified aggregated data sets. Industry manufacturers and device distributors are interested in assessing the safety and revision outcomes of their devices compared to the aggregate. Hospital administrators seek data to ensure that their institutions perform within the appropriate parameters.

International collaboration

Early designs of the ABDR were freely shared with our international surgical colleagues, as it was clear that all other surgical societies involved in breast implant work were grappling with the same challenges.[15] Currently, ABDR is considered a world-leading CQR that has become a template for several similar high-risk device registries globally, and our collaboration has generated greater insights into the value of well-designed registries.

With this in mind, the International Collaboration of Breast Registry Activities (ICOBRA) was formed, and its earliest manifestation was an agreement between 20 different groups, including national surgical societies, national regulators and research groups.[16] A series of meetings at various international venues ensued, and ICOBRA continues to go from strength to strength as new breast implant issues emerge, including anaplastic large cell lymphomas (ALCL) appearing around some textured surface implants and 'breast implant illness' (BII). The ICOBRA has now developed strong collaborative networks between Monash's ABDR and functioning registries in the Netherlands, UK, US, Sweden and Germany. Further links have been established to support other countries with registries in development, such as Austria, Italy and France. One of the seminal meetings of ICOBRA (also funded by the AFPS) was at the Monash campus in Prato, Italy, where 13 countries were represented to plan future collaborative projects. Subsequently, after several rounds of Delphi analysis conducted in conjunction with Monash registry scientists, an international minimum dataset and quality indicators were agreed upon by all the collaborators. In the future, we will be able to harmonise the pooled data with the benefit of all collaborating registries.[17,18] This is especially important for tracking and tracing patients as well as identifying causative factors more quickly in low-incidence problems such as ALCL.

Another innovative development in ABDR was the implementation of patient-reported outcomes (PRO) after collaborating with global leaders in this field at the inaugural PRO conference in Washington DC in January 2015, where stakeholders in PRO research met to determine future directions and advance cross-disciplinary collaboration.[19] A feasibility study was conducted at the ABDR using a five-question patient-reported outcome measures implant survey adapted from and in collaboration with pioneers of BREAST-Q.[20] The ABDR was the first national breast device registry to successfully use the BREAST-Q implant survey module to conduct PRO via text messaging.[21] The results have highlighted general satisfaction among patients with the outcomes of their surgery, and the data are available for research in conjunction with clinical data.

Vision moving forward

While early results from the ABDR are promising, we are currently aiming to collect international data on 1 million implants, which will be the largest ever study in this field of research.[22]

One of the most rewarding aspects of the ABDR has been to witness the formation of a national project that progressed from an initial concept to solve a deficit of surgical data through to fruition via a raft of transitional hurdles and to see it emerge as a pivotal part of a successful international collaboration. Our involvement with the International Confederation of Plastic Surgery Societies (ICOPLAST) saw ICOBRA transitioned from the AFPS into the ICOPLAST's patient safety committee to ensure the collaboration and its offerings are fully available to all 50 plus member societies.

As of 31 December 2022, over 100,000 procedures, 87,000 patients and 170,000 devices have been registered with the ABDR by nearly 600 surgeons at over 300 hospitals[23]

The next major challenge will be to streamline data entry using internationally compatible coding systems and universal scanning devices to improve data quality and allow real-time entry into registry databases. This would mean that surgeons can enter data directly and securely into the ABDR using their phones or portable electronic devices. Features in development that can assist in easier clinical data entry include optical character recognition (OCR) and quick response (QR) scanning. Both these features have the potential to improve the efficiency and accuracy of data entry, saving time for clinicians and registry support staff who review and modify incorrect entries. We hope that registry data pooled from multiple mature registries will provide device performance data to support the efforts of national regulators in pre- and post-device surveillance, and provide a rich source of information for further epidemiological research to improve patient safety.[24] Hopefully, these data will avert further escalating breast implant crises such as the 2010 PIP issue.

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Conflict of interest

The authors have no conflicts of interest to disclose.

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