BMJ Open

The pilot for the Australian Breast Device Registry (ABDR), a national opt-out clinical quality registry for breast device surgery

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-017778
Article Type:	Cohort profile
Date Submitted by the Author:	16-May-2017
Complete List of Authors:	Hopper, Ingrid; Monash University, Epidemiology and Preventive Medicine Best, Renee; Monash University, Epidemiology and Preventive Medicine McNeil, John; Monash University, Epidemiology & Preventive Medicine Mulvany, Catherine; Monash University, Epidemiology & Preventive Medicine Moore, Colin; Monash University, Epidemiology & Preventive Medicine Elder, Elisabeth; Monash University, Epidemiology & Preventive Medicine Pase, Marie; Monash University, Epidemiology & Preventive Medicine Cooter, Rodney; Monash University, Epidemiology & Preventive Medicine Evans, Sue; Department of Epidemiology and Preventive Me, Monash University
Primary Subject Heading:	Public health
Secondary Subject Heading:	Surgery, Epidemiology, Health services research, Research methods
Keywords:	breast implant registry, clinical quality registry, breast implant surgery, breast reconstruction, breast cancer, anaplastic large cell lymphoma

Cohort profile: The pilot for the Australian Breast Device Registry (ABDR), a national opt-out clinical quality registry for breast device surgery

Running head: Piloting the Australian Breast Device Registry

Authors names and qualifications:

Ingrid Hopper (MBBS PhD)[1], Renee L. Best[1] (BSc(Hons)), John J. McNeil[1] (MBBS, PhD), Catherine M. Mulvany[1] (BA/BBus.), Colin CM Moore (MBBS, FRACS)[2,3,] Elisabeth Elder (FRACS, PhD)[4,5], Marie Pase (BASc, GDipComSc)[1], Rodney D. Cooter[1,6,7#] (MD, FRACS), Sue M. Evans[1#] (BN, PhD).

[#] Joint senior authors

Affiliations:

[1]Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine (SPHPM), Monash University. [2] Australian Centre for Cosmetic Surgery, 4 Young Street, Neutral Bay, NSW, 2089, Australia. [3] Australasian College of Cosmetic Surgery, PO Box 36, Parramatta NSW 2124, Australia. [4] Breast Surgeons of Australia and New Zealand (BreastSurgANZ) 1207 PO BOX Randwick 2031, Australia. [5] Westmead Breast Cancer Institute, Westmead Hospital, NSW 2145, Australia. [6] Australian Society of Plastic Surgeons, Suite 503, Level 5, 69 Christie Street St Leonards NSW 2065, Australia. [7] Australasian Foundation for Plastic Surgery. Located at: Suite 503, Level 5, 69 Christie Street, St Leonards NSW 2065, Australia

Corresponding author:

Ingrid Hopper

Department of Epidemiology & Preventive Medicine, Monash University

99 Commercial Rd, Melbourne VIC Australia 3004

Telephone: (03) 9903 0569

Email: Ingrid.hopper@monash.edu

Word count: 2640

Abstract

Purpose: To establish a pilot clinical quality registry to monitor the quality of care and device performance for breast device surgery in Australia.

Participants: All patients having breast device surgery from contributing hospitals in Australia.

A literature review was performed which identified quality indicators for breast device surgery.

Findings to date: A pilot clinical quality registry was established in 2011 to capture prospective data on breast device surgery. An interim Steering Committee and Management Committee were established to provide clinical governance, and guide quality indicator selection. The registry's minimum dataset was formulated in consultation with stakeholder groups; potential quality indicators were assessed in terms of (a) importance and relevance (b) usability (c) feasibility to collect and (d) scientific validity. Data collection is by a two-sided paper based form with manual data entry. Seven sites were recruited, including one public hospital, four private hospitals and two day surgeries. Patients were recruited and opt out consent used.

Future plans: The pilot breast device registry provides high quality population based data. It provides a model for developing a national clinical quality registry for breast devices; its minimum dataset and quality indicators reflect the opinions of the broad range of stakeholders. It is easily scalable, and has formed the basis for other international surgical groups establishing similar registries.

Registration: Not applicable

Keywords: Breast implant registry, clinical quality registry, breast implant surgery, breast cancer, breast reconstruction, anaplastic large cell lymphoma

Strengths and limitations of this study

- This is the first opt out clinical quality registry for breast device surgery to have breast surgeons, cosmetic surgeons, and plastic and reconstructive surgeons contributing data. This model has become the model registry for several other collaborating countries.
- We outline the approach taken to establish a clinical quality registry for breast device surgery, including the establishment of a minimum dataset, quality indicators, governance, data security and reporting framework. This will assist other researchers developing their own clinical quality registry.

Introduction

Breast devices, incorporating breast implants and breast tissue expanders, are implanted under the breast tissue or chest muscle to form or improve the shape of a breast.(1) The majority of individuals undergoing surgery are young women, and data from the Australian Institute of Health and Welfare determined that 21,676 breast devices were inserted in Australia during the 12 month period July 2009 to June 2010.(2) Primary breast implant procedures are increasing each year, with a 9% increase recorded by the Australian Institute of Health and Welfare (AIHW) procedure statistics from the financial year 2008/09 to 2009/10, and a 60% increase between 2002/03 and 2009/10.(2)

Approximately 80% of devices are implanted for cosmetic purposes, about 17% of surgeries are performed to reconstruct the breast post mastectomy and 3% to correct congenital anomalies.(3) Implants are not considered to be lifetime devices, and it is estimated that at least 30% of annual implant procedures in Australia are revisions of previous implants.(2) As these are 'known' or expected complications, there is no requirement from the Australian regulator, the Therapeutic Goods Administration (TGA), for clinicians to report or record these revision operations as an adverse effect or incident. This represents a lost opportunity to gather data which can inform either early or long term device safety, as an increased rate of adverse events (such as rupture) may indicate a problem with the breast device or with the surgical technique used for implanting it.

Breast implants have been associated with a number of high profile health scares in the past. In the 1980s it was suggested that 'silicone' breast implants were linked to cancer, connective tissue disease, offspring defects, and neurologic disease.(4) Over 12,000 individual law suits were filed against breast implant manufacturer Dow Corning(5) leading to compensation payments totalling US $3.2 billion. Lack of objective scientific data on clinical outcomes related to silicone implants allowed anecdotal impressions to gain traction, strengthening in

1996 when laboratory studies suggested silicone gel could provoke an immune response in animals(6-8) and leading to the formation of several breast implant registries. Although epidemiological evidence has since proven these concerns to be unfounded, breast implant safety has remained controversial.(4, 9-11)

The well publicised Poly Implant Prothese (PIP) crisis brought these issue to prominence again.(12) In 2010 the French manufacturer of these implants was found to be substituting approved medical grade silicone with unapproved silicone gel. In response, regulatory bodies recalled the unsold implants, and several countries including France, Germany, Sweden, and the Czech Republic recommended a program of explantation. Also reported the same year was emerging evidence suggesting an association between breast implants (both silicone and saline filled) and anaplastic large cell lymphoma (ALCL),(13) and a cohort study of polyurethane coated breast implants suggested a link to breast cancer.(14)

These issues highlighted the urgent need for well-designed breast device registries. The existing registries failed to answer any questions arising out of the PIP crisis, and indeed it was extrapolated that only 3.4% of known PIP implants were captured in the Australian registry at the time.(15) An Australian Senate Inquiry into the PIP implants crisis recommended the establishment of a national opt-out registry for breast device surgery.(16)

We describe the development of this pilot national clinical quality registry (CQR) for breast devices in Australia and here we report the governance and operation of this registry and some findings to date.

Cohort description

A pilot Breast Device Registry was established in 2011 in Australia with the objectives of providing early identification of device adverse events at the earliest possible time point, benchmarking performance of clinicians implanting breast devices, providing risk mitigation for manufacturers, allowing immediate responses to safety concerns, patient tracking (by

providing a central repository to allow device recall) and to facilitate research towards improving patient safety.

Registry Governance: In March 2012 a stakeholder meeting was held to discuss governance arrangements and implementation methodology. In principle support was given by all members (Table 1). The breast device registry governance model was developed in accordance with the Operating Principles for Australian Clinical Quality Registries,(17) which had been endorsed by Australian Health Ministers in 2010.

Table 1: Stakeholder groups engaged throughout the development of the BDR

Stakeholder groups involved in preliminary meeting of the Breast Device Registry	
Clinical groups	Australian Society of Plastic Surgeons
	Breast Surgeons of Australia and New Zealand
	Australasian College of Cosmetic Surgeons
Government	Therapeutic Goods Administration
	Department of Health
Industry	Medical Technology Association of Australia
Insurers	Medical Indemnity Industry Association on Australia
Consumers	Consumer Health Forum
Academia	Epidemiologists from Monash University

A Steering Committee was established to identify a minimum dataset, determine methodology for data collection and to form a collaboration with stakeholders, agree on a funding model and to develop a governance platform, including a national Steering Committee. The Steering Committee membership comprised clinical governing bodies including those representing plastic surgeons, breast surgeons and cosmetic surgeons, Federal and State Governments including the regulatory sector (Therapeutic Goods Administration), the governing body of the device manufacturers and distributors, insurers of devices (product) and surgeons, policy drivers (Medicare) and academics with expertise in epidemiology and clinical registries.

Eligibility: Any person undergoing surgery involving the insertion or removal of a breast implant or breast tissue expander, reposition of an existing device, or surgery on a breast with

a device already inserted, at a participating site was eligible for inclusion in the registry, provided that their surgeon had agreed to contribute data to the registry. Patients' eligibility was definitively determined through reference to a list of relevant ICD-10 AM codes (Table 2).

Table 2 The ICD-10 AM codes as per the ABDR Data Extract and Transfer Instructions are:

Breast Surgery ICD-10 AM codes	
45524-00	Augmentation mammoplasty, unilateral
45528-00	Augmentation mammoplasty, bilateral
45527-00	Augmentation mammoplasty, following mastectomy, unilateral
45527-01	Augmentation mammoplasty, following mastectomy, bilateral
45539-00	Reconstruction of breast with insertion of tissue expander
45530-02	Reconstruction of breast using flap
45548-02	Adjustment of breast tissue expander Relocation of breast tissue expander
45548-01	Removal of breast tissue expander
45542-00	Removal of breast tissue expander and insertion of permanent prosthesis
45548-00	Removal of breast prosthesis Includes capsulotomy Excision of fibrous capsule Excludes that with replacement (capsulectomy)
45552-00	Replacement of breast prosthesis Includes: capsulotomy Excision of fibrous capsule Formation of new pocket

Consent: The BDR used an opt out consent model, which is a key element to large population capture.(18) All patients who had received a procedure involving a breast device at the particular institution were included in the registry, and patients could choose to opt out and remove their data from the registry. When a completed data collection form was received, the registry posted an explanatory statement to the patient at the address listed on the form. The explanatory statement used 'plain language' to explain the registry and provided clear details of the process for opting out, including the freecall telephone number and email address for opt out. The patient then had two weeks from sending of this second statement to advise the registry should they wish to opt out, and if this did not occur, then the

patient details were included in the registry. Opt out could occur later, in which case patient details were removed from the database.

Developing quality indicators and the minimum dataset: A literature review was undertaken to identify potential quality indicators relating to breast surgery against which the registry might report and the Steering Committee was asked to provide suggestions for possible reporting by the registry. Quality indicators identified in the literature and recommendations from clinical advisors formed a full ('maximum') list of proposed indicators. This list was discussed with the clinical specialty groups and each indicator then assessed against the following criteria (a) importance and relevance to clinicians (b) usability (c) feasibility to collect, and (d) scientific validity.(19) Table 3 lists the final quality indicators that were selected for collection and evaluation through the pilot project.

Table 3 Quality indicators selected to be tested by the Breast Device Registry

Outcome measures	Structural indicators	Predictor variables
• Rate of symptomatic revision • Rate of symptomatic revision due to Infection • Rate of symptomatic revision due to capsular contracture • Risk adjusted mortality rate	• Site type (public / private) • Site procedure volumes	• Device selection: brand, design characteristics e.g. shell, fill, texture • Indication for surgery: augmentation, reconstruction • Surgical technique: drains, plane, antibiotic use, dipping

Following determination of the quality indicators, a list of data elements to be collected by the BDR was developed, with definitions sourced from the national Metadata Online Data

Dictionary where available (Table 4).(20) Where national definitions did not exist, definitions were sought from international registries or from the published literature for review and endorsement by the steering committee. A number of data items were removed because they were considered (a) subjective - *grading of capsular contracture and ptosis* (b) poorly collected at the time of operation - *patient characteristics such as height, weight, skin type* or (c) ambiguous and liable to cause confusion - *previous breast surgery*.

Table 4 Breast Device Registry minimum dataset

Identifiers:	**Demographic Details:** Patient identifiers including contact person information **Device details:** Device batch identifiers; Manufacturer; and Distributor. **Site details:** Identifying physically separate operating theatres, via name and address **Surgeon details:** Name of primary operating surgeon
Additional factors:	**Patient history:** Reason for primary operation; Description of the operation; Previous radiotherapy **Elements of operation:** Incision site; Plane; Mastopexy; Use of mesh or Acellular Dermal Matrix; Use of fat grafting; Tissue expander intraoperative fill volume **Additional intra operative techniques**: Antiseptic rinse; Antibiotic solution; Prophylactic Antibiotics; Drains; Sleeve/funnel (Keller funnel); Nipple guards; Glove change for insertion. **Revision Operation details**: Description of operation; Capsulectomy **Complications causing or found during revision surgery:** Removal of PIP; Removal of overseas implant; Device rupture; Device deflation; Capsular contracture; Silicone extravasation; Device malposition; Skin scarring problems; Deep wound infection; Seroma/Haematoma; Breast cancer; Anaplastic large cell lymphoma.

Developing the data collection form: The BDR data could not be collected retrospectively as many of the required data elements, such as operative technique, were often not recorded

accurately enough in hospital medical records. It was decided that data should initially be captured via a paper data collection form while the data elements were being tested. Two paper forms were developed; one to capture details of the primary operation and the other for revision surgery. The form enabled patient identifiers to be collected to allow contact to be made for recording patient reported outcomes or in the event of an identified safety issue. The forms were provided to each participating site, and data were collected at the time of surgery via a short "tick and stick" process. The completed data collection forms were sent to the registry custodian monthly by overnight post for data entry. The data were then entered using a manual entry system into a database that was developed at Monash University, which also had provision to include International Classification of Disease-10 Australian Modified (ICD-10-AM) codes transmitted from hospital information systems to Monash University for the purpose of determining case ascertainment.

Follow up: The interim plan was to collect outcomes by matching patients on the registry with subsequent appearance for revision surgery. Patient reported outcome measures will be collected via individual contact at 1, 2, 5 and 10 years and patients will be asked to report any other issues related to their original surgery. Regular record linkage will be undertaken linking registry patients with routinely collected data from cancer registries, the national death registry and hospital discharge records.

Reporting framework: The reporting framework complies with the National Operating Principles for Clinical Quality Registries.(17) Aggregate reports will be available to hospital executives on institutional performance on quality indicators, with other institutions' results provided for blinded comparison. Individuals will be able to access their own results, and will be provided with individual reports. Device performance will be reported, with other devices' results used for blinded comparison. An annual report on quality indicator outcomes will also

be published and available to the public. An escalation policy will be developed in consultation with clinicians and health services.

Findings to Date

The study methodology was tested at seven pilot sites undertaking breast implant surgery between 26 March 2012 and 31 May 2015. Included were one public hospital in Victoria, one private hospital in each of New South Wales, Victoria, Tasmania, and South Australia, and one day surgery in each of South Australia and Western Australia. There was a lower rate of cosmetic surgery (45%) found in this pilot compared to the expected rate nationally (80%). This was expected given the inclusion of two day surgeries, where cosmetic operations primarily occur.

The initial step in site recruitment was identification of a clinical lead at each site and submission of an ethics application. Human Research Ethics Committees at each site provided approval for the opt out consent model. Agreement to participate was obtained from each surgeon performing implant surgery at that site. Data collection commenced once ethics approval had been obtained, and surgeons and theatre staff had received a formal orientation to the registry procedures. This meeting provided an opportunity for surgeons and theatre staff to discuss the registry with the Breast Device Registry custodian and for the team to customise the proposed data collection methodology. Feedback on the form was provided by surgeons and theatre nurses participating in the pilot as well as device supplier representatives, and *all* groups assisted in developing the final minimal dataset.

The pilot identified that having two data collection forms-one for the primary surgery and one for the revision surgery was confusing for theatre staff. This was particularly so in situations where it was unclear whether a single surgical event could be understood as primary or revision, for example, removal of a tissue expander and insertion of an implant. These forms were condensed to a single, double sided form.

A data completeness audit showed that patient demographics, mostly provided using the patient sticker, had high capture rates with the exception of email addresses, which were rarely provided (Table 5). Device and operation information were captured at over 90% completion. The section on reasons for revision had lower capture rates.

Table 5 Data items included in the minimum dataset and completeness of data capture

Data item	Completeness
Patient Demographic	
Patient Medicare number	97%
Patient address	100%
Patient phone numbers	70%
Patient email	3%
Patient DOB	100%
Patient Surname and First Name	100%
Operation	
Operation date	98%
Device	
Device master table Device in the table to select (i.e. Device is Other (-1) of NULL)	100%
Device	99%
Mesh Dermal Sheet	82%
Patient History	
Category of Operation	96%
Operation Type/Device Operation Type	99%
Previous Radiotherapy	90%
Elements of Operation	
Incision site	95%
Incision site is Other, but Incision Other is NULL	91%
Plane	90%
Concurrent Mastopexy/Reduction	83%
Concurrent Flap cover	82%
Mesh Dermal Sheet	82%
Fat grafting	76%
If Tissue Expander, Intra Operative fill volume is NULL	88%
Intraoperative Techniques	
Operations with Intraoperative Techniques	94%
Revision details	
Revision type	83%
Capsulectomy	86%
Reason for Revision	83%
Removing a PIP implant	86%
Is operation removing an implant inserted overseas	79%
Device rupture	85%
Silicone extravasation found in Device rupture	80%
Device Deflation	57%
Capsular contracture	68%
Device malposition	63%
Skin scarring problems	59%

Deep wound infection	60%
Seroma/Haematoma	58%
Breast cancer	58%
Anaplastic Large Cell Lymphoma	52%

Two Victorian hospitals sent a monthly extract of demographic and treatment information including ICD-10-AM codes to the registry custodian by a secure file transfer process for all patients undergoing breast device surgery. Case ascertainment was assessed by matching data collection forms against the operating records from hospitals. From a total of 206 patients, there were six patients for whom the hospital recorded breast implant surgery but for whom no case report form was provided. The capture rate was determined to be 97%. A total of 34 (?) patients opted out, thus the opt-out rate was 1.75%.

Strengths and limitations

The strengths of this pilot were that it was the first of its type internationally to have breast surgeons, cosmetic surgeons, and plastic and reconstructive surgeons contributing data, and that it has become the model registry for several other collaborating countries. Preliminary evaluation at seven sites has determined that both the governance process and data capture tools are acceptable.

The main limitation is the need to improve rates of completion of the data collection form. Feedback from hospital staff and Steering Committee members regarding the low rates of completion for the reason for revision details included: these details are within the last section of the double sided collection form (form fatigue), or that the clinician completing the form may not be the surgeon and may not know the answer to the question, and/or interpretation issues. The low collection rates of email addresses will prevent the registry from using this as a way to capture outcome data.

Lessons from this pilot will inform national roll out. Surgeons participating in the study have suggested that a tablet computer in the operating theatre might improve data capture rates and data accuracy. An electronic data collection application that can be accessed by any device

will be developed, which will have in-built validation rules (such as mandatory fields), and adaptive responses such that only questions relevant to that operation will be posed. It is expected to improve data completeness, accuracy and ease of collection. As part of this database, there is scope for the registry to use GS1 compatible barcode scanning to retrieve information related to device characteristics captured in the registry (shell, fill, shape) which can reduce the burden on data entry personnel. We are exploring digital interfaces for follow up of patients. Currently available patients reported outcome measures(21) will need to be shortened for use by the registry. A web enabled database capable of collecting patient data electronically will be used, and will send a survey link by text message to mobile phones. From this pilot it was determined that case ascertainment audits with each individual hospital was deemed too costly and resource intensive. Matching registry records with state-wide databases is currently being explored. Sales data reflecting the total number of implants released by manufacturers may also be used as the denominator.

The registry is a quality and safety initiative that extends a range of benefits to a number of stakeholders. Systematic and complete capture of data managed by registry experts and analysed by statisticians using appropriate risk adjustments will become a pivotal part of a feedback loop to both implanters (clinicians) and manufacturers of the devices. It was estimated from data provided by industry (commercial-in-confidence) that an Australian registry would need to recruit approximately 300 implanting sites to obtain population coverage. The work toward ensuring a near 100% data completeness and case ascertainment rates is now paramount as we begin to develop the reports that will be benchmarked and used to improve quality of care. Following the success of the pilot study described in this paper the Australian Government committed funding over a three year period in order to expand the registry to a national scale. The Australian Breast Device Registry is a Commonwealth

Government initiative tracking the outcomes and quality of all breast device surgery performed across Australia.

Collaboration

Opportunities for a collaborative network of breast device registries are being pursued internationally through the International Collaboration of Breast Registry Activities (ICOBRA).(22) We are sharing the methodology internationally, which can be accessed by joining ICOBRA. Work is currently being undertaken to harmonise an internationally agreed upon core minimum dataset and data definitions which will be collected by all contributing breast implant registries. This will enable amplification of the dataset to provide greater evidence of the safety and quality of care provided for patients receiving breast implants worldwide.

Further details

Funding declaration – This pilot study was funded by the Australian Society of Plastic Surgeons and the Australasian Foundation for Plastic Surgery.

Contributorship statement – SE, RC, JM contributed to the concept and design of the study. SE, RC, EE, CCMM, CMM, RB, MP, IH contributed to the acquisition, analysis and interpretation of the data. SE and RC wrote the first draft of the protocol. SE, RC, JM, EE, CCMM revised the protocol for important intellectual content. All authors have read and approved the final version of the manuscript to be published.

Competing interests – We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests. While an Industry representative body, Medical Technology Association of Australia are a member of the Steering Committee of this project, all work involved in this paper has been undertaken independently of Industry involvement.

Ethics approval – Ethics approval for this project was obtained from the Alfred Hospital Ethics Committee.

Acknowledgements: We gratefully acknowledge the surgeons who provided feedback from pilot sites and the stakeholder groups who provided input on the development of the pilot registry; device manufacturers and distributors, product insurers, medical indemnity insurers, Federal and State Governments including representatives from the TGA and Medicare. Also collaborating colleagues internationally through the International Collaboration of Breast Registry Activities (ICOBRA) who have surveyed, committed to, and adopted our minimum dataset in the data collection forms and data definitions.

References

1. United States Food and Drug Administration. Medical Devices Washington: U.S. Department of Health and Human Services; 2013 [Available from: http://www.fda.gov/MedicalDevices/default.htm.
2. Australian Institute of Health and Welfare. Australian Hospital Statistics 2009-10. Canberra: Australian Governement, 2011.
3. Australian Institute of Health and Welfare. Australian Hospital Statistics 2012-2013. Health services series no. 54. Canberra: AIHW, 2013.
4. McLaughlin JK, Lipworth L, Murphy DK, Walker PS. The Safety of Silicone Gel–Filled Breast Implants: A Review of the Epidemiologic Evidence. Annals of Plastic Surgery. 2007;59(5):569-80.
5. Bernstein DE. The Breast Implant Fiasco. California Law Review. 1999;87(2):Article 4.
6. Nicholson JJ 3rd, Fau-Hill SL, Frondoza CG, Rose NR. Silicone gel and octamethylcyclotetrasiloxane (D4) enhances antibody production to bovine serum albumin in mice. Journal of Biomedical Materials Research. 1996;31(3):345-53.
7. Naim JO, Iippolito Km, Lanzafame RJ, van Oss CJ. Induction of type II collagen arthritis in the DA rat using silicone gel as adjuvant. Journal of Autoimmunity. 1995;8(5):751-61.
8. Hill SL, Landavere MG, Rose NR. The adjuvant effect of silicone gel and silicone elastomer particles in rats. Current Topics in Microbiology & Immunology.210:123-37.
9. Watson R. Europe is updating rules on medical devices after implant fiasco. British Medical Journal. 2012;344(e766).
10. O'Dowd A. Europe plans to strengthen surveillance system for medical devices, MPs are told. British Medical Journal. 2012;344(e4179).
11. Jeeves AE, Cooter RD. Transforming Australia's Breast Implant Registry. Medical Journal Australia. 2012;196(4):232-4.
12. Therapeutic Goods Administration. PIP breast implants - TGA update Canberra: Australian Government; 2013 [Available from: http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-130211.htm.
13. Center for Devices and Radiological Health, United States Food and Drug Administration. Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants: Preliminary FDA Findings and Analyses: U.S. Food and Drug Administration; 2011 [Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm.
14. Pan SY, Lavigne E, Holowaty E, Villeneuve P, Xie L, Morrison H, et al. Canadian breast implant cohort: extended follow-up of cancer incidence. International Journal of Cancer. 2012;131(7):1148-57.
15. Jeeves AE, Cooter RD. Transforming Australia's Breast Implant Registry. The Medical journal of Australia. 2012;196(4):232-4.
16. Australian Government. Australian Government Response to Senate Community Affairs Reference Committee Report on The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants. July 2013. http://www.health.gov.au/internet/main/publishing.nsf/Content/RPGD-BORP-Respons-PIP-breast-implants. Accessed 28/4/2017.
17. Care ACoSaQiH. Framework for Australian clinical quality registries. 2008.
18. Tu JV, Willison DJ, Silver FL, et al. Impracticability of informed consent in the registry of the Canadian Stroke Network. New England Journal of Medicine. 2004;350(14):1414-21.

19. Centre of Research Excellence in Patient Safety Department of Epidemiology and Preventive Medicine Monash University. Measuring Quality in Private Hospitals. Australian Centre for Health Research, 2008.

20. Metadata Online Registry http://meteor.aihw.gov.au/content/index.phtml/itemId/181162. Accessed 28/4/2017.

21. Pusic AL, Chen CM, Cano S, Klassen A, McCarthy C, Collins ED, et al. Measuring Quality of Life in Cosmetic and Reconstructive Breast Surgery: A Systematic Review of Patient-Reported Outcomes Instruments. Plastic and Reconstructive Surgery. 2007;120(4):823-37 10.1097/01.prs.0000278162.82906.81.

22. Cooter RD, Barker S, Carroll SM, Evans GR, von Fritschen U, Hoflehner H, et al. International importance of robust breast device registries. Plastic and reconstructive surgery. 2015;135(2):330-6.

BMJ Open

The pilot for the Australian Breast Device Registry (ABDR), a national opt-out clinical quality registry for breast device surgery

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-017778.R1
Article Type:	Cohort profile
Date Submitted by the Author:	15-Aug-2017
Complete List of Authors:	Hopper, Ingrid; Monash University, Epidemiology and Preventive Medicine Best, Renee; Monash University, Epidemiology and Preventive Medicine McNeil, John; Monash University, Epidemiology & Preventive Medicine Mulvany, Catherine; Monash University, Epidemiology & Preventive Medicine Moore, Colin; Monash University, Epidemiology & Preventive Medicine Elder, Elisabeth; Monash University, Epidemiology & Preventive Medicine Pase, Marie; Monash University, Epidemiology & Preventive Medicine Cooter, Rodney; Monash University, Epidemiology & Preventive Medicine Evans, Sue; Department of Epidemiology and Preventive Me, Monash University
Primary Subject Heading:	Public health
Secondary Subject Heading:	Surgery, Epidemiology, Health services research, Research methods
Keywords:	breast implant registry, clinical quality registry, breast implant surgery, breast reconstruction, breast cancer, anaplastic large cell lymphoma

Cohort profile: The pilot for the Australian Breast Device Registry (ABDR), a national opt-out clinical quality registry for breast device surgery

Running head: Piloting the Australian Breast Device Registry

Authors names and qualifications:

Ingrid Hopper (MBBS PhD)[1], Renee L. Best[1] (BSc(Hons)), John J. McNeil[1] (MBBS, PhD), Catherine M. Mulvany[1] (BA/BBus.), Colin CM Moore (MBBS, FRACS)[2,3,] Elisabeth Elder (FRACS, PhD)[4,5], Marie Pase (BASc, GDipComSc)[1], Rodney D. Cooter[1,6,7#] (MD, FRACS), Sue M. Evans[1#] (BN, PhD).

[#] Joint senior authors

Affiliations:

[1]Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine (SPHPM), Monash University. [2] Australian Centre for Cosmetic Surgery, 4 Young Street, Neutral Bay, NSW, 2089, Australia. [3] Australasian College of Cosmetic Surgery, PO Box 36, Parramatta NSW 2124, Australia. [4] Breast Surgeons of Australia and New Zealand (BreastSurgANZ) 1207 PO BOX Randwick 2031, Australia. [5] Westmead Breast Cancer Institute, Westmead Hospital, NSW 2145, Australia. [6] Australian Society of Plastic Surgeons, Suite 503, Level 5, 69 Christie Street St Leonards NSW 2065, Australia. [7] Australasian Foundation for Plastic Surgery. Located at: Suite 503, Level 5, 69 Christie Street, St Leonards NSW 2065, Australia

Corresponding author:

Dr Ingrid Hopper

Department of Epidemiology & Preventive Medicine, Monash University

553 St Kilda Road

Melbourne VIC Australia 3004

Telephone: (03) 9903 0569

Email: Ingrid.hopper@monash.edu

Word count: 2990

Abstract

Purpose: To establish a pilot clinical quality registry to monitor the quality of care and device performance for breast device surgery in Australia.

Participants: All patients having breast device surgery from contributing hospitals in Australia.

A literature review was performed which identified quality indicators for breast device surgery.

Findings to date: A pilot clinical quality registry was established in 2011 to capture prospective data on breast device surgery. An interim Steering Committee and Management Committee were established to provide clinical governance, and guide quality indicator selection. The registry's minimum dataset was formulated in consultation with stakeholder groups; potential quality indicators were assessed in terms of (a) importance and relevance (b) usability (c) feasibility to collect and (d) scientific validity. Data collection is by a two-sided paper based form with manual data entry. Seven sites were recruited, including one public hospital, four private hospitals and two day surgeries. Patients were recruited and opt out consent used.

Future plans: The pilot breast device registry provides high quality population based data. It provides a model for developing a national clinical quality registry for breast devices; its minimum dataset and quality indicators reflect the opinions of the broad range of stakeholders. It is easily scalable, and has formed the basis for other international surgical groups establishing similar registries.

Registration: Not applicable

Keywords: Breast implant registry, clinical quality registry, breast implant surgery, breast cancer, anaplastic large cell lymphoma

Strengths and limitations of this study

- We outline the approach taken to establish a clinical quality registry for breast device surgery, including the establishment of governance, a minimum dataset, quality indicators, data completeness and reporting framework. This will assist other researchers developing their own clinical quality registry.
- This is the first opt out clinical quality registry for breast device surgery to have breast surgeons, cosmetic surgeons, and plastic and reconstructive surgeons contributing data. This model has become the model registry for several other collaborating countries.
- The lack of a nationally recognised ethics approval process in Australia is a major impediment for national roll out.

Introduction

Breast devices, incorporating breast implants and breast tissue expanders, are implanted under the breast tissue or chest muscle to form or improve the shape of a breast.[1] The majority of individuals undergoing surgery are young women. The Australian Institute of Health and Welfare determined that 27,600 breast devices were implanted during the 12 month period between July 2014 and June 2015,[2] a 24% increase in primary breast implant procedures from the previous year previously.

Approximately 80% of devices are implanted for cosmetic purposes, about 17% of surgeries are performed to reconstruct the breast post mastectomy and 3% to correct congenital anomalies.[2] Implants are not considered to be lifetime devices, and it is estimated that at least 30% of annual implant procedures in Australia are revisions of previous implants.[2] As these are 'known' or expected complications, there is no requirement from the Australian regulator, the Therapeutic Goods Administration (TGA), for clinicians to report or record these revision operations as an adverse effect or incident. This represents a lost opportunity to gather data which can inform either short or long term device safety, as an increased rate of adverse events (such as rupture) may indicate a problem with the breast device or with the surgical technique used for implanting it.

Breast implants have been associated with a number of high profile health scares in the past. In the 1980s it was suggested that 'silicone' breast implants were linked to cancer, connective tissue disease, offspring defects, and neurologic disease.[3] Over 12,000 individual law suits were filed against breast implant manufacturer Dow Corning[4] leading to compensation payments totalling US $3.2 billion. Lack of objective scientific data on clinical outcomes related to silicone implants allowed anecdotal impressions to gain traction, strengthening in 1996 when laboratory studies suggested silicone gel could provoke an immune response in animals[5-7] and leading to the formation of several breast implant

registries. Although epidemiological evidence has since proven these concerns to be unfounded, breast implant safety has remained controversial.[3 8-10]

The well-publicised Poly Implant Prothèse (PIP) crisis brought these issue to prominence again.[11] In 2010, the French manufacturer of these implants was found to be substituting approved medical grade silicone with unapproved silicone gel. In response, regulatory bodies recalled the unsold implants, and several countries including France, Germany and Sweden recommended a program of explantation. Also reported the same year was emerging evidence suggesting an association between breast implants (both silicone and saline filled) and anaplastic large cell lymphoma (ALCL),[12] and a cohort study of polyurethane coated breast implants suggested a link to breast cancer.[13]

These issues highlighted the urgent need for well-designed breast device registries. The existing registries failed to answer any questions arising out of the PIP crisis, and indeed it was extrapolated that only 3.4% of known PIP implants were captured in the Australian registry at the time.[10] An Australian Senate Inquiry into the PIP implants crisis recommended the establishment of a national opt-out registry for breast device surgery.[14] We describe the development of this pilot national clinical quality registry (CQR) for breast devices in Australia and here we report the governance and operation of this registry and some findings to date.

Cohort description

A pilot Breast Device Registry (BDR) was established in 2011 in Australia with the objectives of providing early identification of device adverse events at the earliest time point, benchmarking performance of clinicians implanting breast devices, providing risk mitigation for manufacturers, allowing immediate responses to safety concerns, patient tracking (by providing a central repository to allow device recall) and to facilitate research towards

improving patient safety. The new registry was named the Breast Device Registry (BDR), to describe the inclusion of tissue expanders.

1. Meetings with stakeholders

In March 2012 a stakeholder meeting was held to discuss governance arrangements and implementation methodology. In principle support was given by all members (Table 1).

Table 1: Stakeholder groups engaged throughout the development of the BDR

Clinical groups	Australian Society of Plastic Surgeons Breast Surgeons of Australia and New Zealand Australian College of Cosmetic Surgeons
Government	Therapeutic Goods Administration Department of Health
Industry	Medical Technology Association of Australia
Insurers	Medical Indemnity Industry Association of Australia
Consumers	Consumer Health Forum
Academia	Epidemiologists from Monash University

Steering Committee - The BDR governance model was developed in accordance with the Operating Principles for Australian Clinical Quality Registries,[15] which had been endorsed by Australian Health Ministers in 2010. A Steering Committee was established to identify a minimum dataset, determine methodology for data collection and to form a collaboration with stakeholders, agree on a funding model and to develop a governance platform, including a national Steering Committee. The Steering Committee membership comprised clinical governing bodies including those representing plastic surgeons, breast surgeons and cosmetic surgeons, Federal and State Governments including the regulatory sector (TGA), the governing body of the device manufacturers and distributors, insurers of devices (product) and surgeons, policy drivers (Medicare) and academics with expertise in epidemiology and clinical registries.

2. Infrastructural requirements

Funding – Seed funding was provided by the Australasian Foundation for Plastic Surgery, a not-for-profit organisation that supports quality health outcomes for everyone involved with plastic surgery.

Ethics committee approval - Ethics approval was obtained from the Human Research Ethics Committees of the Alfred Hospital, Melbourne, to operate the BDR. Ethics approval was also required from each pilot site.

Consent requirements - The BDR used an opt out consent model, a key element to large population capture.[16] All patients receiving surgery involving a breast device at the particular institution were included in the registry. Patients could choose to opt out and remove their data from the registry. On receipt of a completed data collection form, the registry posted an explanatory statement to the patient at the address listed on the form. The explanatory statement used 'plain language' and provided clear details of the process for opting out, including the free call telephone number and email address. The patient had two weeks from sending the second statement to opt out, then their details were included in the registry. Opt out could occur later, in which case patient details were removed from the database. A total of 34 patients opted out, thus the opt-out rate was 1.75%.

Finding centres to participate – Hospitals were approached in which Monash University had established registries previously. The initial step in site recruitment was identification of a clinical lead, then submission for ethics approval. Ethics Committees at each site provided approval. Agreement to participate was obtained from each surgeon performing implant surgery at that site. The study methodology was tested at seven pilot sites undertaking breast implant surgery between 26 March 2012 and 31 May 2015. Included were one public hospital in Victoria, one private hospital in each of New South Wales, Victoria,

Tasmania, and South Australia, and one day surgery in each of South Australia and Western Australia. There was a lower rate of cosmetic surgery (45%) found in this pilot compared to the expected rate nationally (80%), which was expected given the inclusion of two day surgeries, where cosmetic operations primarily occur.

3. Registry development issues

Inclusion criteria - Any person undergoing surgery involving the insertion or removal of a breast implant or breast tissue expander, reposition of an existing device, or surgery on a breast with a device already inserted, at a participating site was eligible for inclusion in the registry, provided that their surgeon had agreed to contribute data to the registry. Patients' eligibility was definitively determined through reference to a list of relevant ICD-10 AM codes (Table 2).

Procedures are listed on table 2.

Table 2 The ICD-10 AM codes as per the ABDR Data Extract and Transfer Instructions are:

Breast Surgery ICD-10 AM codes	
45524-00	Augmentation mammoplasty, unilateral
45528-00	Augmentation mammoplasty, bilateral
45527-00	Augmentation mammoplasty, following mastectomy, unilateral
45527-01	Augmentation mammoplasty, following mastectomy, bilateral
45539-00	Reconstruction of breast with insertion of tissue expander
45530-02	Reconstruction of breast using flap
45548-02	Adjustment of breast tissue expander Relocation of breast tissue expander
45548-01	Removal of breast tissue expander
45542-00	Removal of breast tissue expander and insertion of permanent prosthesis
45548-00	Removal of breast prosthesis Includes capsulotomy Excision of fibrous capsule Excludes that with replacement (capsulectomy)
45552-00	Replacement of breast prosthesis Includes: capsulotomy Excision of fibrous capsule Formation of new pocket

Developing quality indicators - A literature review identified potential quality indicators relating to breast surgery against which the registry might report and the Steering Committee was asked to provide suggestions for possible reporting by the registry. Quality indicators thus identified formed a full ('maximum') list of proposed indicators. This list was discussed with the clinical specialty groups and each indicator then assessed against the following criteria (a) importance and relevance to clinicians (b) usability (c) feasibility to collect, and (d) scientific validity.[17] Table 3 lists the final quality indicators that were selected for collection and evaluation through the pilot project.

Table 3 Quality indicators selected to be tested by the Breast Device Registry

Outcome measures	Structural indicators	Predictor variables
• Rate of symptomatic revision • Rate of symptomatic revision due to Infection • Rate of symptomatic revision due to capsular contracture • Risk adjusted mortality rate	• Site type (public / private) • Site procedure volumes	• Device selection: brand, design characteristics e.g. shell, fill, texture • Indication for surgery: augmentation, reconstruction • Surgical technique: drains, plane, antibiotic use, dipping

Developing the minimum dataset - Following determination of the quality indicators, a list of data elements to be collected by the BDR was developed, with definitions sourced from the national Metadata Online Data Dictionary where available (Table 4).[18] Where national definitions did not exist, definitions were sought from international registries or from

the published literature for review and endorsement by the steering committee. A number of data items were removed because they were considered (a) subjective - *grading of capsular contracture and ptosis* (b) poorly collected at the time of operation - *patient characteristics such as height, weight, skin type* or (c) ambiguous and liable to cause confusion - *previous breast surgery*. All stakeholder groups assisted in developing the final minimal dataset.

Table 4 Breast Device Registry minimum dataset

Identifiers:	**Demographic Details:** Patient identifiers including contact person information **Device details:** Device batch identifiers; Manufacturer; and Distributor. **Site details:** Identifying physically separate operating theatres, via name and address **Surgeon details:** Name of primary operating surgeon
Additional factors:	**Patient history:** Reason for primary operation; Description of the operation; Previous radiotherapy **Elements of operation:** Incision site; Plane; Mastopexy; Use of mesh or Acellular Dermal Matrix; Use of fat grafting; Tissue expander intraoperative fill volume **Additional intra operative techniques**: Antiseptic rinse; Antibiotic solution; Prophylactic Antibiotics; Drains; Sleeve/funnel (Keller funnel); Nipple guards; Glove change for insertion. **Revision Operation details**: Description of operation; Capsulectomy **Complications causing or found during revision surgery:** Removal of PIP; Removal of overseas implant; Device rupture; Device deflation; Capsular contracture; Silicone extravasation; Device malposition; Skin scarring problems; Deep wound infection; Seroma/Haematoma; Breast cancer; Anaplastic large cell lymphoma.

Developing the data collection form: Data were collected at the time of surgery via a short "tick and stick" process. Retrospective data collection was not possible as many of the required data elements, such as operative technique, were poorly documented in hospital medical records. Patient identifiers were collected for future contact for patient reported outcomes, or in the event of a safety issue. Data were initially captured via a paper data collection form while the data elements were being tested. Two paper forms were developed; one for primary and one for revision surgery. The pilot identified that having two data collection forms was confusing for theatre staff. This was particularly so in situations where it was unclear whether a single surgical event could be understood as primary or revision, for example, removal of a tissue expander and insertion of an implant. These forms were condensed to a single, double sided form.

Commentary on the form was provided by device supplier representatives, as well as surgeons and theatre nurses participating in the pilot. The latter occurred during a formal orientation to the registry procedures, which allowed surgeons and theatre staff to discuss the registry with the BDR custodian and for the team to customise the proposed data collection methodology. The completed data collection forms were sent to the registry custodian monthly by overnight post for data entry. The data were then entered using a manual entry system into a database that was developed at Monash University.

Data completeness - For this pilot, data were not imputed if missing, and a data element was considered complete if data were entered into the data field. A data completeness audit showed that patient demographics, mostly provided using the patient sticker, had high capture rates with the exception of email addresses, which were rarely provided (Table 5). The low collection rates of email addresses will prevent the registry from using this as a way to capture outcome data unless strategies can be implemented in clinical information systems to improve this situation. Device and operation information were

captured at over 90% completion. The section recording reasons for revision had lower capture rates. Feedback from hospital staff and Steering Committee members regarding the low rates of completion for the reason for revision details included: these details are within the last section of the double sided collection form (form fatigue), or that the clinician completing the form may not be the surgeon and may not know the answer to the question, and/or interpretation issues. Reconciliation against medical records was not possible as much of the data on the BDR data collection form were not duplicated in the medical record.

Surgeons suggested a tablet computer be used in the operating theatre to facilitate data capture and potentially improve completeness rates and data accuracy. An electronic data collection application that can be accessed by any device is under development, which will have in-built validation rules (such as mandatory fields), and adaptive responses such that only questions relevant to that operation will be posed. It is expected to improve data completeness, accuracy and ease of collection. As part of this database, there is scope for the registry to use barcode scanning which is in accordance with GS1 data standards to retrieve information related to device characteristics captured in the registry (shell, fill, shape) which can reduce the burden on data entry personnel. GS1 data standards provide unique, unambiguous product identifiers.[19]

Case ascertainment - Two Victorian hospitals sent a monthly extract of demographic and treatment information including ICD-10-AM codes to the registry custodian by a secure file transfer process for all patients undergoing breast device surgery. Case ascertainment was assessed by matching data collection forms against the operating records from hospitals. From a total of 206 patients, there were six patients for whom the hospital recorded breast implant surgery but for whom no case report form was provided, thus the capture rate was determined to be 97%. From this pilot it was determined that case ascertainment audits with each individual hospital was deemed too costly and resource intensive. Matching registry

records with state-wide databases is currently being explored. Sales data reflecting the total number of implants released by manufacturers may also be used as the denominator. The work toward ensuring a near 100% data completeness and case ascertainment rates is now paramount as we begin to develop the reports that will be benchmarked and used to improve quality of care.

Table 5 Data items included in the minimum dataset and completeness of data capture

Data item	Completeness
Patient Demographic	
Patient Medicare number	97%
Patient address	100%
Patient phone numbers	70%
Patient email	3%
Patient DOB	100%
Patient Surname and First Name	100%
Operation	
Operation date	98%
Device	
Device master table Device in the table to select (i.e. Device is Other (-1) of NULL)	100%
Device	99%
Mesh Dermal Sheet	82%
Patient History	
Category of Operation	96%
Operation Type/Device Operation Type	99%
Previous Radiotherapy	90%
Elements of Operation	
Incision site	95%
Incision site is Other, but Incision Other is NULL	91%
Plane	90%
Concurrent Mastopexy/Reduction	83%
Concurrent Flap cover	82%
Mesh Dermal Sheet	82%
Fat grafting	76%
If Tissue Expander, Intra Operative fill volume is NULL	88%
Intraoperative Techniques	
Operations with Intraoperative Techniques	94%
Revision details	
Revision type	83%
Capsulectomy	86%

Reason for Revision	83%
Removing a PIP implant	86%
Is operation removing an implant inserted overseas	79%
Device rupture	85%
Silicone extravasation found in Device rupture	80%
Device Deflation	57%
Capsular contracture	68%
Device malposition	63%
Skin scarring problems	59%
Deep wound infection	60%
Seroma/Haematoma	58%
Breast cancer	58%
Anaplastic Large Cell Lymphoma	52%

4. Outcome measures

Reporting framework - Systematic and complete capture of data managed by registry experts and analysed by statisticians using appropriate risk adjustments are an essential part of the feedback loop to both implanters (clinicians) and manufacturers of the devices. The reporting framework is designed to comply with the National Operating Principles for Clinical Quality Registries.[15] Aggregate reports will be available to hospital executives on institutional performance on quality indicators, with other institutions' results provided for blinded comparison. Individual surgeons will be able to access their own results, and will be provided with individual reports. Device performance will be reported, with other devices' results used for blinded comparison, and will be available to industry. An annual report on quality indicator outcomes will also be published and available to the public. An escalation policy will be developed in consultation with clinicians and health services.

Device performance -Complication rates relating to specific devices will be monitored as time series and as a static display each six months. A surveillance system will trigger a signal of possible excess complication rates for a certain device, and a plan for subsequent follow up of any such trigger. In the first instance, it is likely that a difference of

2 standard deviations from the expected revision rate will trigger a review of the data. .However, a comprehensive action plan to decide upon the rate of revision due to failure reportable to the TGA will be developed in consultation with biostatisticians.

Institution and clinician performance - It is expected that the respective colleges will manage clinician performance concerns, either the Royal Australasian College of Surgeons (RACS) or the Australasian College of Cosmetic Surgery (ACCS). Each College has policies and processes for managing performance issues, including mentoring and disciplinary action. Details of the communication and action plan for devices, hospitals and clinicians will be based on a risk assessment from the registry data.

Follow up - Patient reported outcome measures will be collected via individual contact at 1, 2, 5 and 10 years. Currently available patients reported outcome measures[20] have been shortened for use by the registry, and will be collected using a web enabled database capable of collecting patient data electronically, which sends a secure survey link by text message to mobile phones. Regular record linkage is planned to link registry patients with routinely collected data from cancer registries including the breast quality audit, the national death registry and hospital discharge records.

Collaboration - Opportunities for a collaborative network of breast device registries are being pursued internationally through the International Collaboration of Breast Registry Activities (ICOBRA).[21] We are sharing the methodology internationally, which can be accessed by joining ICOBRA. Work is currently being undertaken to harmonise an internationally agreed upon core minimum dataset and data definitions which will be collected by all contributing breast implant registries. This will enable amplification of the dataset to provide greater evidence of the safety and quality of care provided for patients receiving breast implants worldwide.

Strengths and limitations

The strengths of this pilot were that it was the first of its type internationally to have breast surgeons, cosmetic surgeons, and plastic and reconstructive surgeons contributing data, and that it has become the model registry for several other collaborating countries. Preliminary evaluation at seven sites has determined that both the governance process and data capture tools are acceptable.

The lack of a nationally recognised ethics approval process in Australia is a major impediment to national roll out of this important government supported safety initiative. Substantial time delays and financial impost are associated with such ethics hurdles[22], giving individual institutions the means to obstruct the path to better patient safety. This hampers Australia's capacity as an international leader in registry science compared with other countries in which medical ethical approval is obtained nationally, such as the Netherlands and Sweden.[23] It is imperative that a nationally recognised ethics approval for clinical quality registries is developed for Australia.[24]

Conclusion

The pilot BDR provided high quality population based data and a model for developing a national clinical quality registry for breast devices. Its minimum dataset and quality indicators reflect the opinions of the broad range of stakeholders. It is easily scalable, and has formed the basis for other international surgical groups establishing similar registries. It was estimated from data provided by industry (commercial-in-confidence) that an Australian registry would need to recruit approximately 300 implanting sites to obtain population coverage. In 2015, a report of the Independent Review of Medicines and Medical Devices Regulation made 58 recommendations including that all high-risk implantable devices be

included in a registry to perform post-marketing monitoring of adverse events. This, supported by the success of the pilot study, acted as an impetus for the Australian Government committing funding over a three year period in order to expand the registry to a national scale. The Australian Breast Device Registry is a Commonwealth Government initiative tracking the outcomes and quality of all breast device surgery performed across Australia.

Further details

Funding declaration – This pilot study was funded by the Australian Society of Plastic Surgeons and the Australasian Foundation for Plastic Surgery.

Contributorship statement – SE, RC, JM contributed to the concept and design of the study. SE, RC, EE, CCMM, CMM, RB, MP, IH contributed to the acquisition, analysis and interpretation of the data. SE and RC wrote the first draft of the protocol. SE, RC, JM, EE, CCMM revised the protocol for important intellectual content. All authors have read and approved the final version of the manuscript to be published.

Competing interests – We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests. While an Industry representative body, Medical Technology Association of Australia are a member of the Steering Committee of this project, all work involved in this paper has been undertaken independently of Industry involvement.

Ethics approval – Ethics approval for this project was obtained from the Alfred Hospital Ethics Committee.

Acknowledgements - We gratefully acknowledge the surgeons who provided feedback from pilot sites and the stakeholder groups who provided input on the development of the pilot registry; device manufacturers and distributors, product insurers, medical indemnity insurers, Federal and State Governments including representatives from the TGA and Medicare. Also collaborating colleagues internationally through the International Collaboration of Breast Registry Activities (ICOBRA) who have surveyed, committed to, and adopted our minimum dataset in the data collection forms and data definitions. Also Arul Earnest for assistance with drafting.

References

1. United States Food and Drug Administration. Medical Devices Washington: U.S. Department of Health and Human Services; 2013 [Available from: http://www.fda.gov/MedicalDevices/default.htm.]
2. Australian Institute of Health and Welfare 2016. Admitted patient care 2014–15: Australian hospital statistics. Health services series no. 68. Cat. no. HSE 172. Canberra: AIHW. .
3. McLaughlin JK, Lipworth L, Murphy DK, et al. The Safety of Silicone Gel–Filled Breast Implants: A Review of the Epidemiologic Evidence. Annals of Plastic Surgery 2007;**59**(5):569-80.
4. Bernstein DE. The Breast Implant Fiasco. California Law Review 1999;**87**(2):Article 4.
5. Nicholson JJ 3rd, Fau-Hill SL, Frondoza CG, et al. Silicone gel and octamethylcyclotetrasiloxane (D4) enhances antibody production to bovine serum albumin in mice. Journal of Biomedical Materials Research 1996;**31**(3):345-53.
6. Naim JO, Iippolito Km, Lanzafame RJ, et al. Induction of type II collagen arthritis in the DA rat using silicone gel as adjuvant. Journal of Autoimmunity 1995;**8**(5):751-61.
7. Hill SL, Landavere MG, Rose NR. The adjuvant effect of silicone gel and silicone elastomer particles in rats. Current Topics in Microbiology & Immunology;**210**:123-37.
8. Watson R. Europe is updating rules on medical devices after implant fiasco. British Medical Journal 2012;**344**(e766).
9. O'Dowd A. Europe plans to strengthen surveillance system for medical devices, MPs are told. British Medical Journal 2012;**344**(e4179).
10. Jeeves AE, Cooter RD. Transforming Australia's Breast Implant Registry. The Medical Journal of Australia 2012;**196**(4):232-4.
11. Therapeutic Goods Administration. PIP breast implants - TGA update Canberra: Australian Government; 2013 [Available from: http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-130211.htm.
12. Center for Devices and Radiological Health, United States Food and Drug Administration. Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants: Preliminary FDA Findings and Analyses: U.S. Food and Drug Administration; 2011 [Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProstheticsBreastImplants/ucm239996.htm.]
13. Pan SY, Lavigne E, Holowaty E, et al. Canadian breast implant cohort: extended follow-up of cancer incidence. International Journal of Cancer 2012;**131**(7):1148-57.
14. Australian Government. Australian Government Response to Senate Community Affairs Reference Committee Report on The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants. July 2013. http://www.health.gov.au/internet/main/publishing.nsf/Content/RPGD-BORP-Respons-PIP-breast-implants. Accessed 28/4/2017.
15. Australian Commission on Safety and Quality in Health Care. Framework for Australian clinical quality registries. Sydney. ACSQHC, March 2014
16. Tu JV, Willison DJ, Silver FL, et al. Impracticability of informed consent in the registry of the Canadian Stroke Network. New England Journal of Medicine 2004;**350**(14):1414-21.
17. Centre of Research Excellence in Patient Safety Department of Epidemiology and Preventive Medicine Monash University. Measuring Quality in Private Hospitals: Australian Centre for Health Research, 2008.

18. Metadata Online Registry http://meteor.aihw.gov.au/content/index.phtml/itemId/181162. Accessed 28/4/2017.
19. Buyargan N, Jayaraman R, Rardin R.L., et al. A Novel GS1 Data Standard Adoption Roadmap for Healthcare Providers International Journal of Healthcare Information Systems and Informatics 2011;**6**(4):42-59.
20. Pusic AL, Chen CM, Cano S, et al. Measuring Quality of Life in Cosmetic and Reconstructive Breast Surgery: A Systematic Review of Patient-Reported Outcomes Instruments. Plastic and Reconstructive Surgery 2007;**120**(4):823-37 10.1097/01.prs.0000278162.82906.81.
21. Cooter RD, Barker S, Carroll SM, et al. International importance of robust breast device registries. Plastic and Reconstructive Surgery 2015;**135**(2):330-6.
22. Brown WA, Smith BR, Boglis M, et al. Streamlining ethics review for multisite quality and safety initiatives: national bariatric surgery registry experience. The Medical Journal of Australia 2016;**205**(5):200-1.
23. Ludvigsson JF, Haberg SE, Knudsen GP, et al. Ethical aspects of registry-based research in the Nordic countries. Clinical epidemiology 2015;**7**:491-508.
24. Evans SM, Zalcberg JR. Enough is enough ... a call to action to improve ethical and governance review processes in Australia. Internal Medicine Journal 2016;**46**(12):1362-64.