MONASH University

# AUSTRALIAN BREAST DEVICE REGISTRY

# 2016 REPORT

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The Australian Breast Device Registry is supported by funding from the Australian Government Department of Health.


**Data Period:** The data contained in this document were extracted from the ABDR on 28 April 2017 and pertains to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2016. As the registry does not capture data in real time, there can be a lag between occurrence of an event and capture in the ABDR.

# FOREWORD

It is with great pleasure that we, the Clinical Leads at the Australian Breast Device Registry (ABDR), present the ABDR's 2016 Annual Report.

Led by the Department of Epidemiology and Preventive Medicine, Monash University, and funded by the Australian Government Department of Health, the ABDR collaborates with peak Australian surgical societies with interests in breast device monitoring and safety: the Australian Society of Plastic Surgeons (ASPS); the Australasian College of Cosmetic Surgery (ACCS); and Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ). Combined, these societies successfully foster engagement with plastic and reconstructive surgeons, general (breast) surgeons, cosmetic surgeons and affiliated theatre and practice staff around Australia.

The ASPS, ACCS and BreastSurgANZ form part of a wider ABDR governance committee that represents the clinical and policy interests of the clinical and scientific community, consumers, government and industry. This collaborative governance structure, coupled with a broad outreach to practising clinicians, has laid the foundations for a clinical quality registry of world-leading standards. The objective of the ABDR is to curate quality data to monitor device safety and patient outcomes. To this end, this 2016 Annual report provides a significant milestone in the development of the ABDR.

This first report includes patient and outcome data encompassing 216 public and private hospitals in Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria, and Western Australia. Data in this report showcase the early progress of the ABDR and the commitment of clinical stakeholders to patient safety and best practice.

We would like to acknowledge and thank fellow members of the ABDR Steering and Management Committees, who have substantial clinical commitments.

We also acknowledge the work of the current ABDR Project Team; Professor John McNeil, Dr Ingrid Hopper, Dr Emily Parker, Ms Catherine Mulvany, Dr Husna Begum, Ms Vanessa Fox, Ms Alice Noone, Ms Sarah Barrington-Smith, Ms Marie Pase, Ms Trisha Nichols, Dr Nicole Ng, Ms Tu Nguyen, Ms Masuma Hoque, Ms Ying Khu, Ms Vera Boomaerts and Associate Professor Sue Evans; and all past team members who have provided invaluable input and helped shape the ABDR into the ground-breaking resource it has become. Analytical and Statistical support was provided by Monash University Registry Sciences Unit (Associate Professor Susannah Ahern, Associate Professor Arul Earnest and Ms Breanna Pellegrini).

We gratefully acknowledge the contribution of lead clinical staff from hospitals and day surgeries enrolled in the ABDR, and their patients who have also agreed to participate. This report would not have been possible without the support of surgeons, theatre staff, consulting room staff and the many thousands of Australians undergoing these procedures.

**Professor Rodney Cooter** MD, FRACS, ASPS

**Associate Professor Colin Moore** FRACS, ACCS

**Associate Professor Elisabeth Elder** PhD, FRACS, BreastSurgANZ

The Australian Breast Device Registry demonstrates successful collaboration between the three peak surgical societies with interest in breast device monitoring and safety. Patient safety is our number one priority.

Australian Society *of* Plastic Surgeons

Breast Surgeons of Australia & New Zealand

ARTISTRY INTEGRITY EXCELLENCE A.C.C.S. AUSTRALASIAN COLLEGE OF COSMETIC SURGERY

MONASH University

# EXECUTIVE SUMMARY

Each year approximately 20,000 Australians undergo implantation of a breast device; a breast implant or breast tissue expander; equating to over 40,000 breast devices inserted nationally. The primary roles of the ABDR are to monitor the long term safety and performance of implanted breast devices and to improve patient outcomes.

The ABDR was established in 2015 with funding from the Australian Government Department of Health, and superseded the previous Australian Society of Plastic Surgeons' Breast Implant Registry and the pilot Breast Device Registry funded by the Australasian Foundation for Plastic Surgery (Figure 1). As a Clinical Quality Registry, the ABDR has been established in accordance with the Australian Commission on Safety and Quality in Healthcare's Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008) and Framework for Australian Clinical Quality Registries (2014). The ABDR uses an opt-out approach to consent and received Ethics approval from the Alfred Hospital Human Research Ethics Committee (HREC) in April 2015 and further ethics approval from 15 HRECs nationally.

**The focus of the registry is to:**

- collect data, at a population level, that includes all patients having breast device procedures, all breast devices, all surgeons performing these procedures, in all locations across Australia;
- study the safety and quality of breast device surgery longitudinally by collecting data from patients at the time of revision surgery, and at one, two, five and ten years thereafter; and
- develop datasets that are useful to clinicians, government, industry and academics, including data about device failures, complications, and revision rates.

The registry aims to identify health risks associated with breast device implantation, and to inform strategies and make clinical recommendations for appropriate monitoring and replacement of breast devices. The goal is to foster continuous improvement in patient care and outcomes across the entire Australian health system. The registry encourages surgeons, as the primary contact for patients in the event of a device recall, to register for a Healthcare Provider Identifier in the My Health Record system (previously known as the Personally-Controlled Electronic Health Record, PCEHR). The registry also participates in the International Collaboration of Breast Registry Activities (ICOBRA) which serves to harmonise and amplify data with international collaborators.

The ABDR is a relatively new registry capturing breast device procedure data provided by engaged sites and surgeons. It is important to note that the ABDR does not yet have population coverage and hence the data contained in this first annual report cannot be understood to reflect the broader Australian population. As the registry matures and case ascertainment increases, the data reported to the registry will reflect national trends.

"As a consumer, the ABDR provides the peace of mind that an independent, accurate mechanism for tracking breast devices and arising complications exists. I would encourage anyone considering surgery involving a breast device, to talk with your surgeon about the ABDR."

**Cindy Schultz Ferguson**
**Consumers Health Forum of Australia**

# 2016 KEY FINDINGS AND HIGHLIGHTS

- A collaborative governance structure coupled with a broad outreach to practising clinicians has laid the foundations for a breast device clinical quality registry of world-leading standards.
- There has been a steady increase in the number of sites, surgeons and patients participating in the ABDR since inception. At 31 December 2016:
  - 216 (67%) of the identified 321 sites were participating in the ABDR, with 168 (78%) of these actively contributing data;
  - 338 (61%) of the identified 552 surgeons were participating in the ABDR, with 303 (90%) of these actively contributing data;
  - 13,019 patients had allowed the ABDR to retain their data (opt out rate less than 1%).
- The majority of breast device surgery takes place in the private setting; private overnight (71%), private same day (26%), public (2%); with the greatest number of participating sites seen across New South Wales, Queensland and Victoria (74% of total).
- The registry analysed data from 14,303 procedures in 13,019 patients – 85% of procedures were bilateral, resulting in data capture of 26,505 primary and revision procedures at an individual breast level.
- Of the 26,505 breast level procedures, 72% were for reasons of cosmetic augmentation, 21% for breast reconstruction (post cancer or benign/risk-reducing), 3% to correct developmental deformity and 4% were not stated.
- The median age of patients undergoing cosmetic augmentation was 33 years (IQR: 26-41 years), breast reconstruction 50 years (IQR: 42-58 years), and correction of developmental deformity 26 years (IQR: 21-34 years).
- Acellular Dermal Matrix, or an alternative, was used with 2% of breast implants and with 22% of tissue expanders.
- Capsular contracture, device malposition and device rupture were the most common issues identified at breast implant revision.
- Based on 17,987 primary implant breasts, as at 31 December 2016, 2.2% of primary breast implants were revised within one year of their initial insertion, and 3.5% within two years of their initial insertion.
- Identified challenges include variable levels of completeness of data submitted by participating surgeons. The ABDR has developed several strategies to address this issue.
- A Clinical Quality Committee has been established to review issues of clinical quality and develop policies for monitoring quality of care.

# BACKGROUND

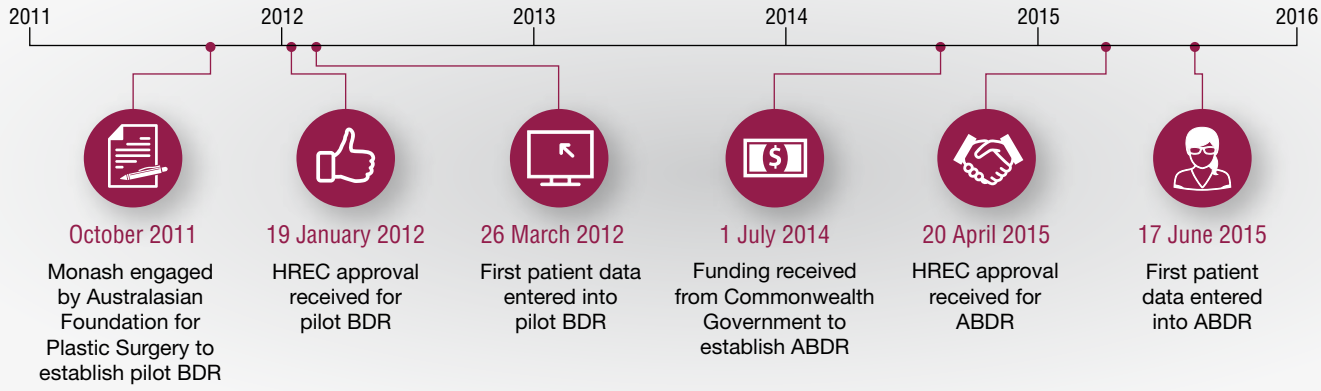
## Rationale for registry

It is estimated that over 20,000 Australians are having breast implants inserted annually (1). An estimated 1 million implants are inserted annually worldwide (2). Breast implants are used predominantly for cosmetic augmentation in healthy patients, but also for reconstruction following breast cancer and risk-reducing mastectomy, as well as to correct developmental deformity. Tissue expanders are used in preparation for breast implants, usually post-mastectomy. Breast implant usage worldwide is rising, with increased per capita income, expanding upper-middle class populations in poorer countries, more aesthetically conscious populations and higher uptake of risk-reducing mastectomy for mitigation of cancer risk (3).

Breast implants are classified as high-risk devices by the Therapeutic Goods Administration (TGA) in Australia, as well as other governing bodies worldwide including the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA). A number of high profile health scares have been associated with breast implants since they were first used in the 1960s, including the Dow Corning crisis through 1980s and 1990s (4), in which silicone implants were thought to be associated with health problems including breast cancer, rheumatological and neurological conditions. More recently in 2010 there was the Poly Implant Prosthèse (PIP) incident, in which non-medical grade silicone gel was used by the manufacturer and there were fears that they were associated with a higher rupture rate overseas (5). In Australia, attempts were made to trace PIP patients using the opt-in Breast Implant Registry (BIR), established in 1998 by the Australian Society of Plastic Surgeons (ASPS). For a small fee, patients could opt to have their data recorded in the BIR, so they could be contacted in the event of concerns regarding their breast implants. However, the BIR captured only 3.4% of the PIP implant population (7, 8).

In response to the PIP incident, in 2012 the Australian Senate commissioned an inquiry, 'The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prosthèse (PIP) breast implants' which examined the Government's regulation of medical devices. This report recommended that the Department of Health 'establish an opt-out Breast Implant Registry as a priority' (6). The opt-out model of consent was selected following the previous failure of the opt-in model. The opt-out model of consent describes the process whereby health facilities that have approved the collection of registry data through both ethics and governance processes, send patient data to the ABDR which are then automatically entered into the registry, and patients have the option to withdraw their consent and their data, or 'opt-out' if they desire.

**Figure 1: Timeline for development of the pilot BDR and ABDR**



Following the Senate Inquiry, Monash University, in collaboration and with funding provided by the Australasian Foundation for Plastic Surgery Limited (AFPS), established a pilot Breast Device Registry (BDR) which incorporated an opt-out approach to consent with no cost to patients. The pilot BDR was rolled out to seven sites across Australia including public hospitals, private overnight hospitals and private same day hospitals. Plastic and reconstructive surgeons and general/breast surgeons at these sites were invited to contribute.

The methodology was demonstrated to be successful and in May 2013 the Australian Government announced it would provide funds to support a national rollout of the pilot BDR. Monash University, through the Department of Epidemiology and Preventive Medicine, successfully tendered and commenced work on the Australian Breast Device Registry (ABDR) in July 2014 (Figure 1).

Under the terms of Monash University's contract to deliver the ABDR, the scope of the registry was broadened to involve all clinical specialties undertaking breast device surgery in Australia; so for the first time, cosmetic surgeons were invited to contribute with plastic and reconstructive surgeons and general/breast surgeons.

The BIR formally ended on 6 May 2015 by decision of the AFPS Council. The ABDR has now superseded both the pilot BDR and the BIR (Table 1).

Further information about the structure and operation of the ABDR is available online at **abdr.org.au**

**Table 1: Characteristics of past and current Australian breast device registries**

| | Breast Implant Registry | Pilot Breast Device Registry | Australian Breast Device Registry |
|---|---|---|---|
| Funded by | Patient / ASPS | AFPS / Health | Health (Commonwealth) |
| Surgeons contributing | Plastic | Plastic, General | Plastic, General, Cosmetic |
| Participation | Voluntary | Invited | Encouraged* |
| Patient consent | Opt-in | Opt-out | Opt-out |
| Cost to patient | $25 | Nil | Nil |
| Year commenced | 1998 | 2012 | 2015 |
| Year ended | 2015 | 2015 | Ongoing |

* Patients are informed about the ABDR by their surgeon and advised that they may opt-out of participating if desired.
AFPS – Australasian Foundation for Plastic Surgery / ASPS – Australian Society of Plastic Surgeons

Further information about the structure and operation of the ABDR is available online at **abdr.org.au**

## Registry governance

The ABDR is governed in accordance with The Australian Commission on Safety and Quality in Health Care's (ACSQHC) 'Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008)' and 'Framework for Australian Clinical Quality Registries (2014)'. This provides assurance to all key stakeholders that registry data and its supporting systems satisfy security, technical and operating standards.

Overall running of the ABDR is governed by the Steering Committee, while day-to-day operations are overseen by the Management Committee.

The ABDR Steering Committee meets three times per year to approve any major operational changes and to resolve matters relating to project operations, clinical quality and safety, data access, and reporting and publications. The Steering Committee is ultimately responsible for the financial viability of the registry, the project's strategic direction and delivery of contractual obligations.

The Steering Committee includes two representatives of the data custodian (Professor John McNeil and Doctor Ingrid Hopper, Department Epidemiology and Preventive Medicine, Monash University (DEPM)), and one representative from each of the following organisations:

- Australian Government Department of Health (as observer only)
- Australian Commission on Safety and Quality in Healthcare (ACSQHC)
- Therapeutic Goods Administration (TGA)
- Australian Society of Plastic Surgeons (ASPS)
- Australasian College of Cosmetic Surgery (ACCS)
- Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ)
- Consumers Health Forum of Australia (CHF)
- Medical Technology Association of Australia (MTAA)

The ABDR Management Committee meets monthly to oversee the day-to-day management of the registry to monitor recruitment progress, ensure key milestones are met, and address problems as they arise. Current membership includes the Chair of the Steering Committee, a representative from each of the three clinical specialty groups, the ABDR Project Lead, and the ABDR Coordinator.

Membership of the ABDR Management Committee comprises:

- Professor John McNeil, Chair, Head of School of Public Health and Preventive Medicine, Monash University
- Professor Rodney Cooter, Clinical Lead, ASPS
- Associate Professor Colin Moore, Clinical Lead, ACCS
- Associate Professor Elisabeth Elder, Clinical Lead, BreastSurgANZ
- Dr Ingrid Hopper, Head of Drug and Device Registries, DEPM, Monash University
- Ms Catherine Mulvany, Project Coordinator, DEPM, Monash University

In the future, the registry expects to put in place a Technical Reference Group to provide a channel for further engagement with Industry partners, and to develop a College Working Group through which surgeons from each speciality may contribute to the ABDR. Both these groups will report to and receive reports from the Steering Committee.

## Registry collaborators

Australia has led the way by establishing the International Collaboration of Breast Registry Activities (ICOBRA) and sharing the ABDR's expertise in order to monitor breast devices across the world. At the heart of the ICOBRA concept is the core ethic and commitment to improving patient outcomes. Contributing countries and organisations are working towards an agreed global minimum data set, comprising standardised, epidemiologically sound data points that reflect global best practice. In this way, the ICOBRA network is helping to set standards for the international benchmarking of clinical quality registry outcomes.

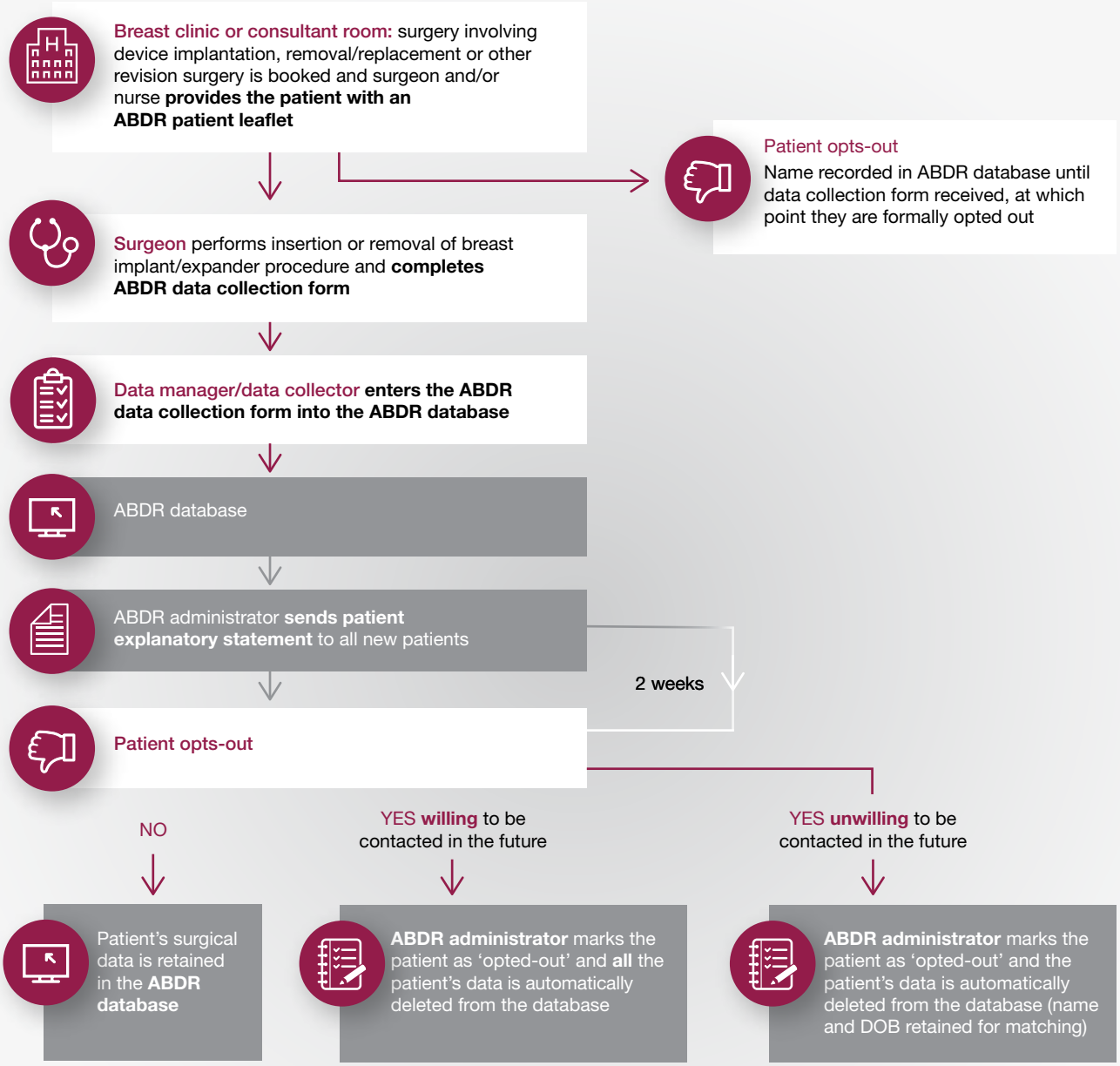
icobra™

Collaborative governance, coupled with broad outreach to practising clinicians and health service providers, has laid the foundations for a clinical quality registry of world-leading standards.

Less than 1% of patients choose to opt out of the ABDR.

## Registry methodology

Figure 2: Data collection methodology of the ABDR




### Quality control process

The ABDR coordinator will request an extract of relevant ICD procedure codes from each participating site on a monthly or quarterly basis. This data extract will be used to assess whether the registry is capturing all relevant surgeries taking place at the site.

Site coordinators and clinical leaders will be advised of the percentage of cases for which data collection was missed and, where necessary, ABDR representatives will work with site staff to improve the capture rate.

The ABDR utilises the methodology outlined in the ACSQHC Operating Principles and Technical Standards for Australian Clinical Quality Registries document, dated November 2008. The methodology was formulated and tested during the pilot BDR. Essential features included the opt-out approach to consent, and zero cost to the patient. The registry obtained formal ethics approval for this methodology (Figures 2 and 3) from the Alfred Hospital HREC on 20 April 2015, and from 15 HRECs across all Australian jurisdictions.

## Surgeon and site recruitment

The ABDR has been endorsed by ASPS, ACCS and BreastSurgANZ, and they encourage their members to participate.

Surgeons sign a 'Surgeon Participation Agreement' in which they agree to abide by the methodology of the ABDR, including making all patients aware that their data will be forwarded to the ABDR. Highlighted benefits to surgeons contributing to the ABDR include the ability to track patients and devices inserted, the capacity to compare practice against peers in a protected environment, the award of Continuous Medical Education (CME) points for participating in the registry, and the capacity to include a logo demonstrating that they are contributing to the ABDR on their website.

The ABDR initially recruited eligible sites identified by the Department of Health as reported by Medicare Benefits Scheme codes. The ABDR obtains ethics and governance approval for each site prior to commencing data collection. The benefits of participation for sites include the ability to track patients and devices; the award of Continuous Professional Development (CPD) points for staff assisting in the collection of data; and through site reporting, evidence towards quality improvement measures and patient safety activities which can be used for site accreditation against the national standards.

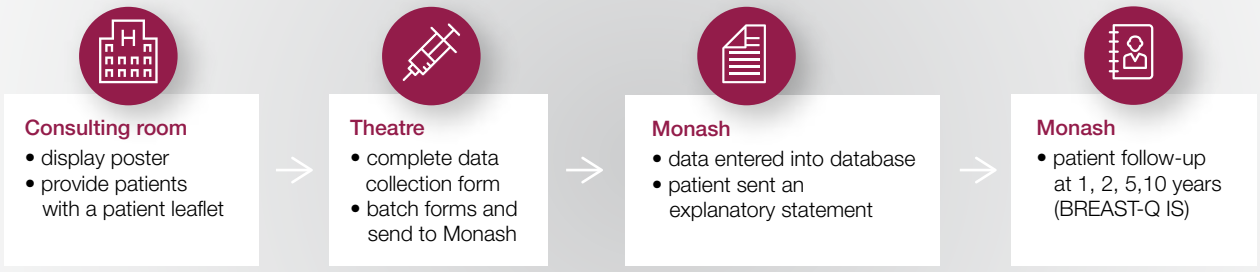
## Registry reporting

This report is the first report to be published by the ABDR and encompasses data from the pilot study, beginning March 2012, up until 31 December 2016. The data analysed in this report was extracted from the ABDR on 28 April 2017. As the registry does not capture data in real time, there can be a lag between occurrence of an event and capture in the ABDR.

The ABDR also publishes a quarterly newsletter. This is distributed by email to internal and external stakeholders including hospital administrators, surgeons and their consulting room staff and theatre staff.

Additional reporting will commence in the near future, and will include surgeon and site level reports.

**Figure 3: ABDR data collection and patient follow up process**



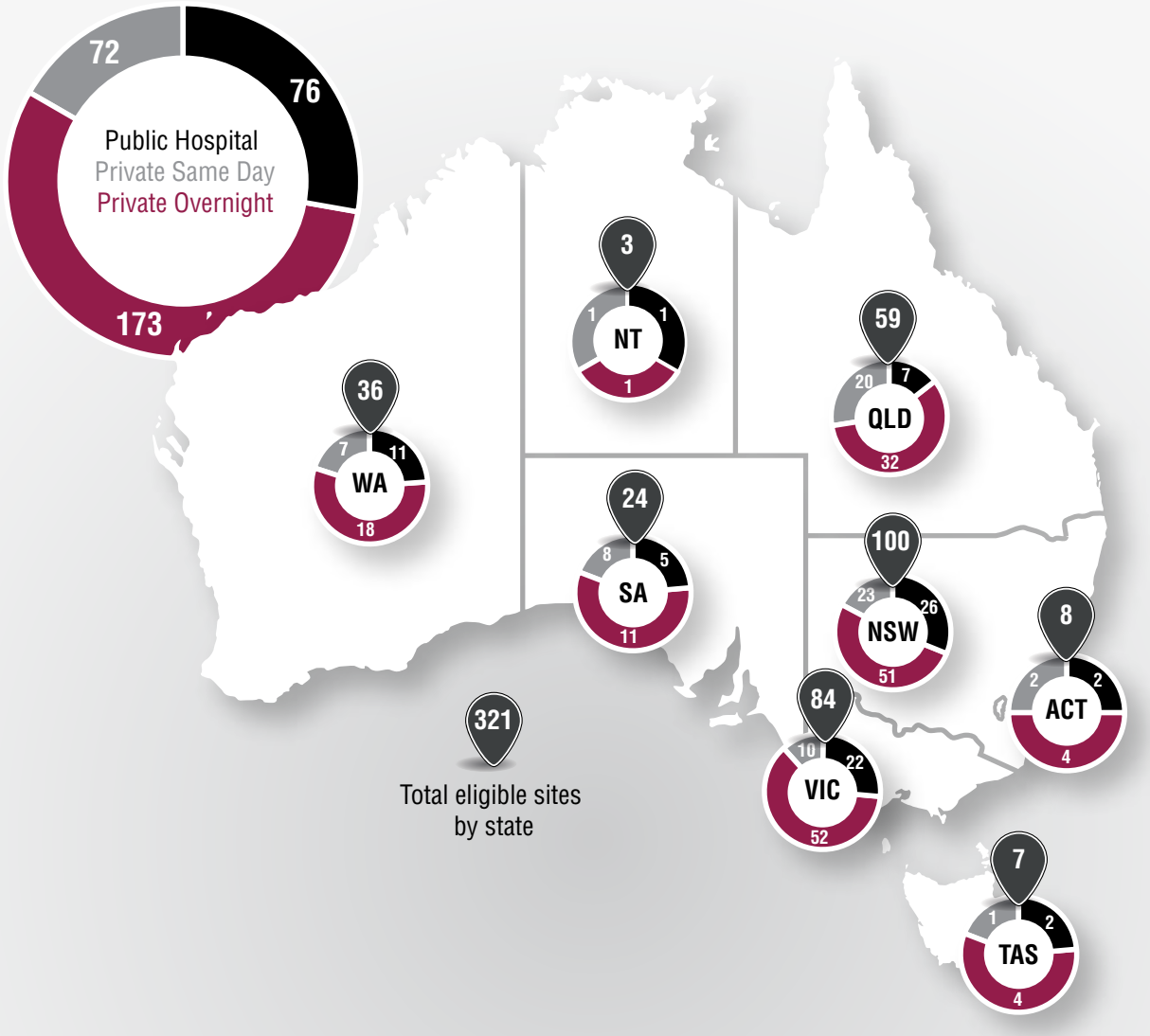
# REGISTRY PARTICIPATION

## Site participation

The process of engaging sites is ongoing with the aim to have data contributed by all eligible sites and surgeons Australia wide. An **eligible** site is defined as a site undertaking breast device surgery as identified by ICD-10-AM[1] code data provided by the Australian Government Department of Health (26 Oct 2015). Additional sites have been identified using search engines and networking websites and as reported by surgeons. The number and classification of eligible sites per state are shown in Figure 4. The total number of currently eligible sites is estimated at 321. Approximately 76% of these sites are located in New South Wales, Queensland and Victoria. Private Overnight sites represent the greatest number of sites across all states.

The number of eligible sites nationally is a fluid number, and the ABDR continually monitors and tracks both new sites and sites which have ceased undertaking breast device surgery. At this point in time, an additional 78 sites have been identified that do not currently undertake breast device surgery but have capacity to do so in the future. The ABDR maintains communication with these sites to monitor any changes that occur.

Figure 4: Number of sites eligible for ABDR participation




1. Australian modification of the *International statistical classification of diseases and health related problems, 10th revision* (ICD-10-AM)

A **participating** site is defined as any site that has committed to contribute data to the ABDR (implemented) or is represented by a surgeon that contributes data to the ABDR. As of 31 December 2016, 67% (216) of eligible sites were participating in the ABDR (Table 2).

New South Wales, Queensland and Victoria have the greatest number of participating sites (74%), reflecting the higher concentration of providers in these states (Table 2 and Figure 5). Data have been collected predominantly from private overnight facilities (62%) and private same day facilities (23%) (Figure 6).
Of the 216 participating sites, 168 are actively contributing data. The remaining 48 have received ethics and governance approval but have either not contributed data in the reporting period or are considered a low device site.

## Timeline of site participation

There has been a steady increase in the number of sites participating and contributing data to the ABDR since its inception in April 2015 (Figure 7). Prior to this date, a pilot study was conducted involving seven sites, four of which were recruited by April 2012 and a further three by September 2013. The national rollout of the ABDR commenced in 2015 and the number of sites contributing has since increased rapidly.

**Table 2: Site engagement by state**

| State | Number of eligible sites | Participating sites | | Sites in progress | Engagement of eligible sites* |
|---|---|---|---|---|---|
| | | Implemented sites | Sites represented by surgeons contributing | | |
| **NSW** | 100 | 30 | 25 | 45 | 55% |
| **VIC** | 84 | 39 | 16 | 29 | 65% |
| **QLD** | 59 | 37 | 13 | 9 | 85% |
| **WA** | 36 | 14 | 4 | 18 | 50% |
| **SA** | 24 | 23 | 0 | 1 | 96% |
| **ACT** | 8 | 5 | 1 | 2 | 75% |
| **TAS** | 7 | 7 | 0 | 0 | 100% |
| **NT** | 3 | 2 | 0 | 1 | 67% |
| | **321** | **157** | **59** | **105** | **67%** |

Notes: * Engagement of eligible sites is the percentage of eligible sites that are also participating sites ('implemented' and 'sites represented by surgeons contributing').

**Figure 5: Site participation by state** (n=216)

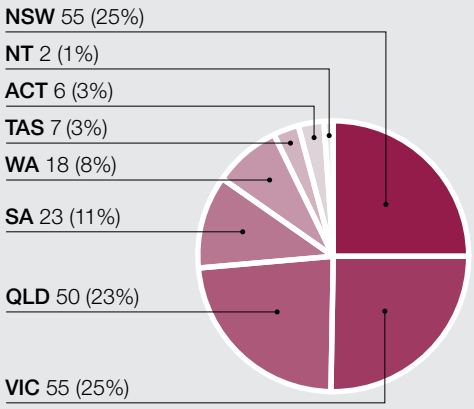



**Figure 6: Site participation by site type** (n=216)

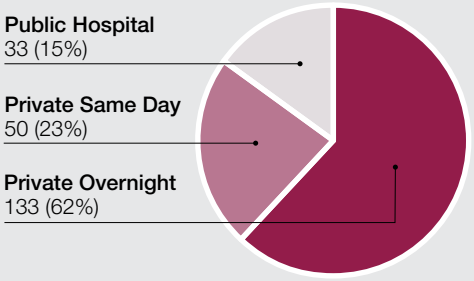
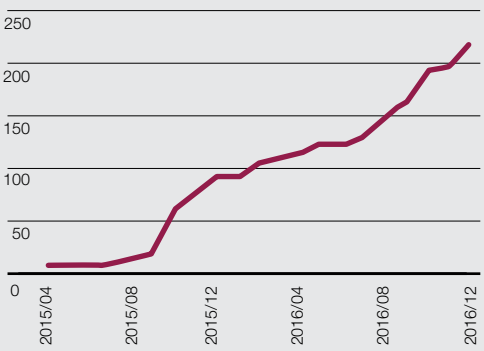



**Figure 7: Cumulative participating ABDR sites** (n=216)



## Surgeon participation

Surgeons eligible to participate in the ABDR are identified through the ASPS, ACCS and BreastSurgANZ. Each society supports the ABDR and provides an up to date list of surgeons who have reported breast device work. Surgeons are also identified through site contacts at hospitals who undertake breast device procedures, and further confirmed through internet search engines and networking sites. A total of 552 surgeons were identified as undertaking breast device procedures at 31 December 2016 (Table 3).

An additional 60 surgeons were identified not currently undertaking breast device procedures but have capacity to do so in the future. The ABDR communicates with these 'no device' surgeons regularly to confirm their status.

A wide-ranging group of clinicians participate in the ABDR. At 31 December 2016, 338 individual surgeons were participating in the ABDR; 238 plastic surgeons, 62 general/breast surgeons and 38 cosmetic surgeons. Participating surgeons are predominantly from New South Wales, Victoria, and Queensland (Figure 8). Plastic surgeons are the largest participating group, comprising 71% of participating surgeons (Figure 9), however the ABDR continues to strive to increase participation rates amongst surgeons from all three groups.

Of the 338 participating surgeons, 303 currently contribute data on a regular basis with the remaining 35 surgeons awaiting final ethics or governance approval for their operating sites.

**Figure 8: Surgeon participation by state** (n=338)

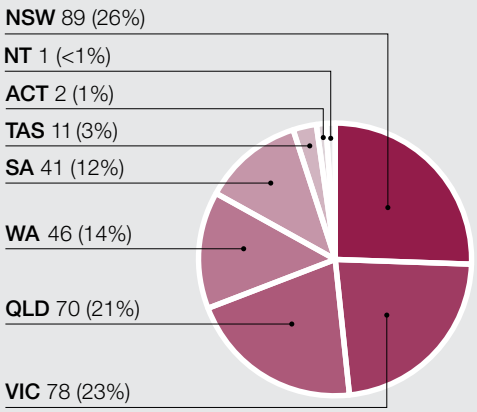



**Figure 9: Surgeon participation by craft group** (n=338)

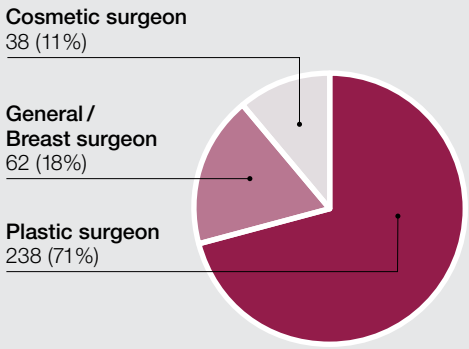


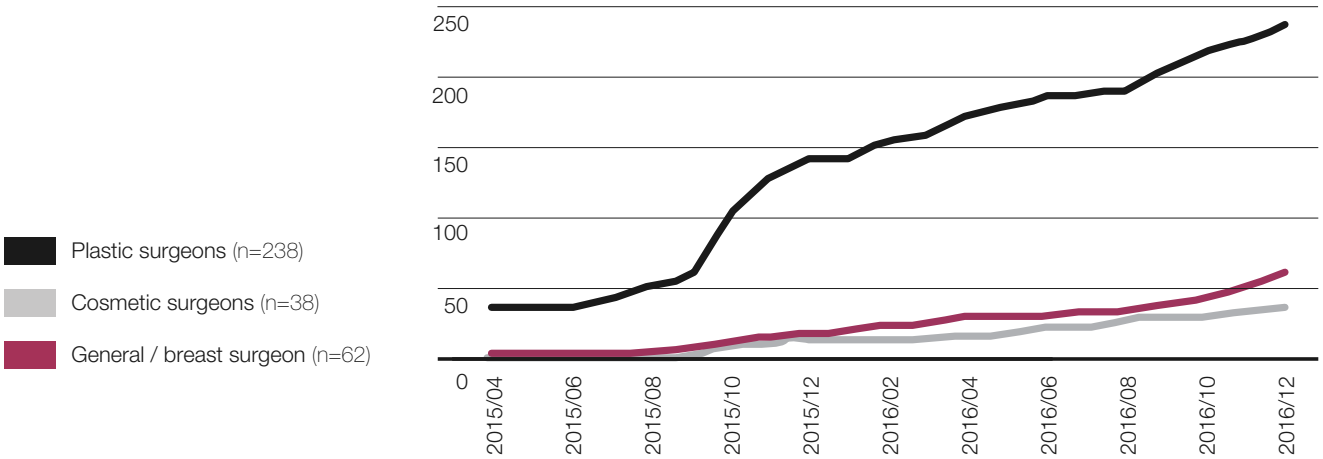

**Table 3: Number of surgeons eligible for ABDR participation**

| State | Plastic surgeon | General / breast surgeon | Cosmetic surgeon | Total |
|---|---|---|---|---|
| NSW | 99 | 39 | 29 | 167 |
| VIC | 108 | 46 | 6 | 160 |
| QLD | 59 | 23 | 18 | 100 |
| WA | 34 | 20 | 4 | 58 |
| SA | 29 | 14 | 2 | 45 |
| ACT | 3 | 4 | 0 | 7 |
| TAS | 11 | 1 | 0 | 12 |
| NT | 2 | 1 | 0 | 3 |
| **TOTAL** | | | | **552** |

### Timeline of surgeon participation

Figure 10 shows the timeline for recruitment of surgeons into the pilot BDR and ABDR. Prior to April 2015, the pilot study included accredited sites with plastic surgeons and general/breast surgeons only. In late 2014 the registry became an initiative of the Australian Government Department of Health and the scope was broadened to include all medical professionals performing breast device surgery. Surgeons belonging to the Australasian College of Cosmetic Surgery began participating in October 2015.

**Figure 10: Cumulative participating ABDR surgeons by craft group** (n=338)

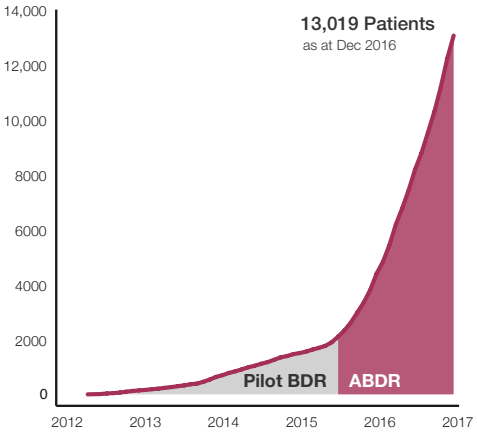



## Patient recruitment

The ABDR is currently seeking a reliable data source against which to confirm the number of breast device procedures being performed each year in a timely and cost effective manner. These data will then be compared with the ADBR data to provide an estimate of the coverage of the registry at a population level.

At the time of reporting, 13,019 patients were participating in the ABDR, and the accumulation rate reflects a steady rise over the last six months of the reporting period (Figure 11). The opt-out rate was extremely low, at less than 1%. A patient is considered to be participating in the ABDR from the date of their earliest ABDR recorded surgery. Due to the lag of data transfer from the surgeon to the ABDR, additional patients may have had surgery in this timeframe but are yet to be included in the database. Data from patients who chose to opt-out and patients who did not have a procedure date listed are not included in the reported figures.

**Figure 11: Number of patient registrations** (2012–2016)



## Patient characteristics

### Reason for procedure

The analysis in this section provides a description of those procedures captured by the ABDR since national roll-out and includes the preceding pilot (2012-2016). As the participation of surgeons, sites and patients evolves, the registry data will better reflect the breast device activity within the Australian population.

At the end of 2016, the 13,019 patients captured in the ABDR database had a total of 14,303 procedures recorded, representing 26,505 procedures at the individual breast level. Patients were assigned to cohorts based on the reason for their first procedure recorded in the ABDR database (Table 4). Where the operation was bilateral but different procedures were undertaken on each breast, a three-tier hierarchy of reason beginning with reconstruction (post cancer or benign/risk-reducing), followed by developmental deformity and then cosmetic augmentation was used to classify the reason for procedure. For example, a bilateral procedure where one side underwent post cancer reconstruction and the other side cosmetic augmentation would be classified as a reconstruction procedure based on this hierarchy of reason.

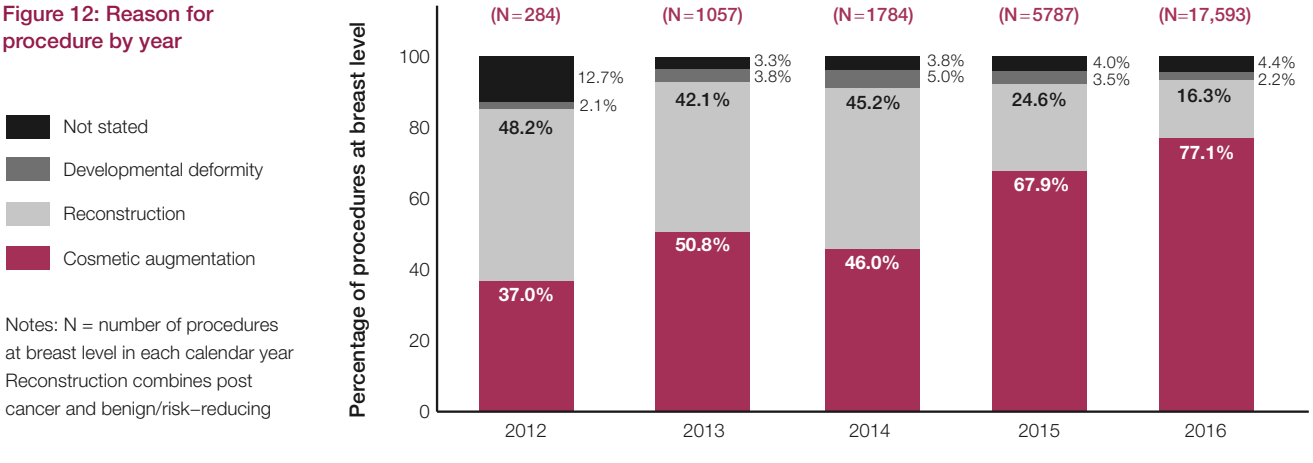
Patients underwent breast surgery for a number of reasons. Of the 13,019 patients in the ABDR, 72% underwent surgery for the reason of cosmetic breast augmentation, 21% underwent surgery for breast reconstruction (post cancer or benign/risk-reducing), 3% to correct developmental deformity and 4% for reasons that were not stated. The proportion of reconstructive surgery for this report was higher in the first few years (2012-2014) due to the pilot BDR enrolling more surgeons performing this work. As participation in the registry has evolved greatly in the last two years, the capture of procedures by the ABDR appears to be approaching a more accurate reflection of what is expected within the wider Australian population. Figure 12 shows this change in procedure cohort capture by year as the national roll-out has progressed, with a higher capture of cosmetic augmentations as surgeon recruitment increased.

**Table 4: Reason for procedure** (2012–2016)

| Reason for procedure | Patients | | Procedures | | Procedures at breast level | |
|---|---|---|---|---|---|---|
| | N | (%) | N | (%) | N | (%) |
| Cosmetic augmentation | 9319 | (71.6%) | 9554 | (66.8%) | 18,965 | (71.5%) |
| Reconstruction | 2719 | (20.9%) | 3679 | (25.7%) | 5685 | (21.5%) |
| Developmental deformity | 410 | (3.1%) | 443 | (3.1%) | 720 | (2.7%) |
| Not stated | 571 | (4.4%) | 627 | (4.4%) | 1135 | (4.3%) |
| **TOTAL** | **13,019** | **(100%)** | **14,303** | **(100%)** | **26,505** | **(100%)** |

Notes: Procedure numbers are higher than patient numbers due to multiple procedures occurring in some patients. Each procedure was performed either unilaterally or bilaterally. Reconstruction includes post cancer and benign/risk-reducing.

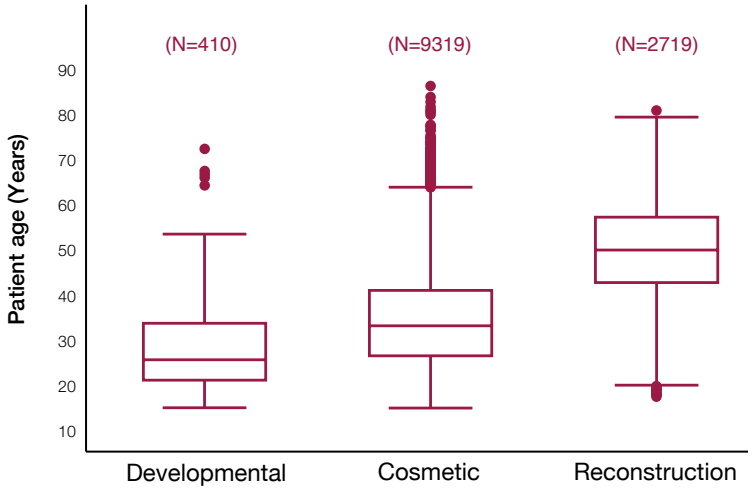
**Figure 12: Reason for procedure by year**



## Patient age at first procedure captured by ABDR

The median age of patients undergoing surgery due to developmental deformity was younger than patients undergoing cosmetic augmentation or reconstruction (Figure 13). The median age was 26 years for surgery for developmental deformity (Interquartile range: 21-34 years) compared with 33 years for cosmetic augmentation (Interquartile range: 26-41 years) and 50 years for reconstructive surgery (Interquartile range: 42-58 years).

**Figure 13: Patient age distribution by reason for procedure** (2012–2016)




Notes: N = number of patients
Reconstruction combines post cancer and benign/risk–reducing

| Patient age | Developmental | Cosmetic | Reconstruction |
|---|---|---|---|
| **N** | **410** | **9319** | **2719** |
| **Mean** (standard deviation) | 28.5 (9.8) | 34.8 (10.8) | 49.9 (11.2) |
| **Median** (interquartile range) | 25.6 (20.8 34.0) | 33.2 (26.2, 41.3) | 49.9 (42.4, 57.5) |

For interpretation of the above box plot, the box region indicates the interquartile range (IQR), and the horizontal line inside the box region indicates the median age. The ends of the whiskers indicate the most extreme values within (75th percentile + 1.5*IQR) and (25th percentile – 1.5*IQR). The round markers represent extreme values outside of the whiskers.

Of the 13,019 patients in the ABDR, 72% underwent surgery for the reason of cosmetic breast augmentation, 21% underwent surgery for breast reconstruction (post cancer or benign/risk-reducing), 3% to correct developmental deformity and 4% for reasons that were not stated.

## Type and frequency of procedures

There were 14,303 surgical procedures involving breast devices recorded by the ABDR since 2012. During the period from 2012 to 2016, 85% of procedures were performed bilaterally and 15% were performed unilaterally.

The proportion of bilateral procedures increased since the inception of the registry, reflecting the increased number of cosmetic augmentations captured in the registry, which are undertaken primarily by plastic and cosmetic surgeons (Figure 14).

The reasons for these unilateral and bilateral procedures are detailed in Tables 5 and 6. The most common reason to undergo a unilateral procedure was reconstruction post-cancer (67%), and the most common bilateral procedure was cosmetic augmentation (76%). Procedure numbers relate to data captured by the ABDR between 2012 and 2016 and *'Not stated'* numbers are a result of incomplete fields on the data collection form.

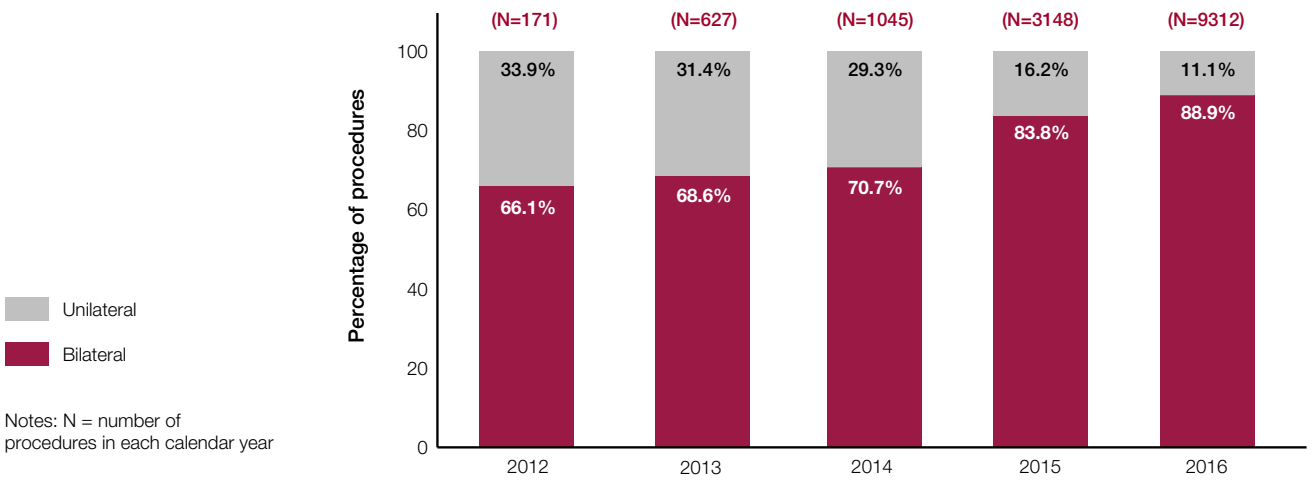
**Table 5: Type and frequency of unilateral procedures** (2012 – 2016)

| Reason for unilateral procedures | N | (%) |
|---|---|---|
| Reconstruction post cancer | 1409 | (67.1%) |
| Cosmetic augmentation | 291 | (13.8%) |
| Reconstruction benign/risk-reducing | 153 | (7.3%) |
| Developmental deformity | 109 | (6.6%) |
| Not stated | 139 | (5.2%) |
| **TOTAL** | **2101** | **(100%)** |

**Table 6: Type and frequency of bilateral procedures** (2012–2016)

| Reason for bilateral procedures | N | (%) |
|---|---|---|
| Cosmetic augmentation – both sides | 9256 | (75.9%) |
| Reconstruction post cancer – both sides | 846 | (6.9%) |
| Reconstruction benign/risk-reducing one side and reconstruction post cancer the other side | 581 | (4.8%) |
| Reconstruction benign/risk-reducing both sides | 579 | (4.7%) |
| Not stated – both sides | 488 | (4.0%) |
| Developmental deformity – both sides | 275 | (2.2%) |
| Cosmetic augmentation one side and reconstruction post cancer the other side | 92 | (0.8%) |
| Developmental deformity one side and cosmetic augmentation the other side | 58 | (0.5%) |
| Other combinations | 27 | (0.2%) |
| **TOTAL** | **12,202** | **(100%)** |

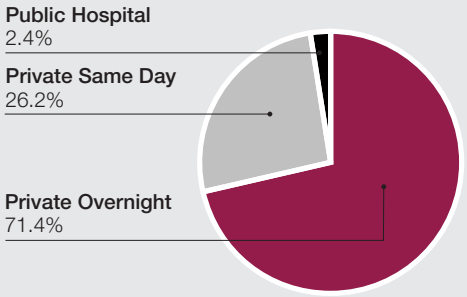
**Figure 14: Unilateral and bilateral procedures by year**



## Procedure site characteristics

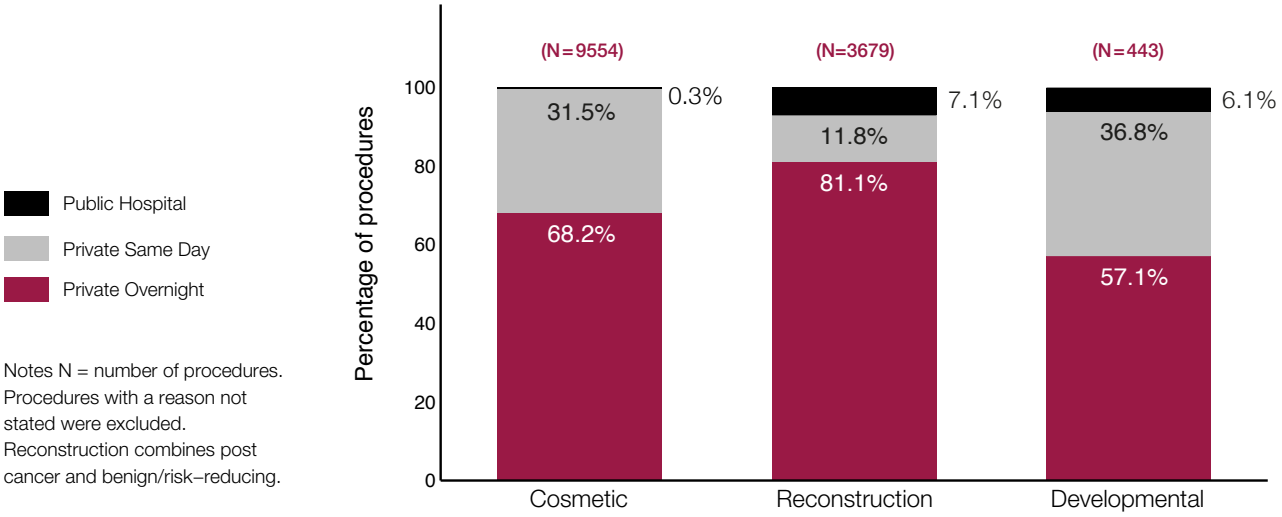
The majority of procedures were performed in the private healthcare setting, with only 2% performed in the public setting (Figure 15). The majority of patients attended a private overnight hospital rather than a same day facility. Procedures at public hospitals were infrequent, however were higher for breast reconstruction and developmental procedures compared to augmentation procedures (Figure 16). Reconstruction procedures were more likely to require an overnight admission in a private hospital, 81% compared with only 12% with a same day admission. Whereas a higher proportion of cosmetic and developmental procedures resulted in a same day admission within the private hospital setting, 37% for developmental procedures and 32% of cosmetic procedures.

**Figure 15: Procedures performed by site type** (2012-2016)




N = 14,303 procedures as at Dec 2016

**Figure 16: Reason for procedure by site type** (2012–2016)



## Intra-operative techniques

The ABDR collects data on intra-operative techniques used by contributing surgeons to identify current practice in surgical techniques, and to determine their effect on patient outcomes. More than one intra-operative technique can be used and recorded per procedure. The fields collected have differed during the pilot and national rollout as described in Table 7. In procedures recorded during the pilot, 87% of surgeons administered prophylactic antibiotics, 74% used an antiseptic rinse and 66% of surgeons changed gloves before inserting the device (Table 7). In procedures recorded since the national rollout, 70% of surgeons administered both intra-operative and post-operative antibiotics, 74% used an antiseptic rinse and 56% changed gloves before inserting the device (Table 7). In future, site-specific data will allow centres of excellence to be identified, and best-practice in breast device surgery determined, which can assist in formulating guidelines to support best-practice.

**Table 7: Intra-operative techniques** (2012–2016)

| **Intra-operative techniques** | **Pilot** (2012 – 2015) | | **ABDR** (2015 – 2016) | |
|---|---|---|---|---|
| | **N** | **(%)** | **N** | **(%)** |
| Administered prophylactic antibiotics | 2262 | (87.1%) | NC | NC |
| Intra-op prophylactic antibiotic only | NC | NC | 1566 | (13.4%) |
| Post-op antibiotic only | NC | NC | 323 | (2.8%) |
| Both intra-op and post antibiotics | NC | NC | 8132 | (69.5%) |
| Antiseptic rinse | 1909 | (73.5%) | 8611 | (73.6%) |
| Glove change for insertion | 1719 | (66.2%) | 6555 | (56.0%) |
| Antibiotic dipping solution | 943 | (36.3%) | 5979 | (51.1%) |
| Sleeve/funnel | 97 | (3.7%) | 2271 | (19.4%) |
| Not stated | 153 | (5.9%) | 1237 | (10.6%) |
| **TOTAL procedures** | **N = 2598** | | **N = 11,705** | |

Notes: More than one intra-operative technique can be used and recorded per procedure. NC – Not collected.

## Characteristics of device insertions

The vast majority of inserted breast implants (75%) and all inserted tissue expanders had a textured device shell. Silicone was the most common device fill for breast implants (98%) whereas saline was the most common for tissue expanders (91%). Round implants had slightly higher uptake than anatomical shaped implants (56% vs 44%), whereas all tissue expanders inserted were anatomical shape (Table 8). Acellular Dermal Matrix (ADM) or a similar alternative product were used with 2% of inserted breast implants and 22% of tissue expanders, most commonly in breast reconstruction procedures (Table 9).

**Table 8: Characteristics of device insertions** (2012–2016)

| Characteristics of device insertions | | Breast implants | | Tissue expanders | |
|---|---|---|---|---|---|
| | | N | (%) | N | (%) |
| **Device shell** | Textured | 13,632 | (75.5%) | 1707 | (100.0%) |
| | Smooth | 3387 | (18.8%) | 0 | (0.0%) |
| | Polyurethane | 1022 | (5.6%) | 0 | (0.0%) |
| | Not stated | 9 | (0.1%) | 0 | (0.0%) |
| **Device fill** | Silicone | 17,786 | (98.5%) | 0 | (0.0%) |
| | Saline | 242 | (1.3%) | 1560 | (91.4%) |
| | Silicone/Saline | 13 | (0.1%) | 28* | (1.6%) |
| | Other | 0 | (0.0%) | 119** | (7.0%) |
| | Not stated | 9 | (0.1%) | 0 | (0.0%) |
| **Device shape** | Round | 10,092 | (55.9%) | 0 | (0.0%) |
| | Anatomical | 7949 | (44.0%) | 1707 | (100.0%) |
| | Not stated | 9 | (0.1%) | 0 | (0.0%) |
| **TOTAL devices** | | **18,050** | | **1707** | |

Notes: *Device fill 'Silicone/Saline' have been classified as tissue expanders for this report. As they are a permanent expander,they will be reclassified as an implant for future reports.
** Device fill 'Other' category includes 'airXpander' tissue expanders with a carbon dioxide fill.

**Table 9: ADM usage in device insertions by reason for procedure** (2012-2016)

| Reason for procedure | ADM usage in breast implant insertions | | | | ADM usage in tissue expander insertions | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | | No | | Yes | | No | |
| | N | (%) | N | (%) | N | (%) | N | (%) |
| Reconstruction post cancer | 208 | (11.0%) | 1680 | (89.0%) | 234 | (21.2%) | 869 | (78.8%) |
| Reconstruction benign/risk-reducing | 172 | (20.3%) | 674 | (79.7%) | 123 | (23.4%) | 402 | (76.6%) |
| Cosmetic | 12 | (0.1%) | 14,636 | (99.9%) | 1 | (11.1%) | 8 | (88.9%) |
| Developmental | 0 | (0.0%) | 535 | (100.0%) | 0 | (0.0%) | 40 | (100.0%) |
| Not stated | 0 | (0.0%) | 133 | (100.0%) | 12 | (40.0%) | 18 | (60.0%) |
| **TOTAL** | **392** | **(2.2%)** | **17,658** | **(97.8%)** | **370** | **(21.7%)** | **1337** | **(78.3%)** |

## Primary implant breasts

In the period from 2012 to 2016, there were 17,987 initial breast implants captured by the ABDR. This cohort of breasts is classified as *Primary implant breasts*. Amongst this cohort of breasts, 97.8% of breast implant devices remained in situ, and 2.2% (392 breasts) progressed to at least one revision following their initial implant (Table 10).

A total of 420 breast implant revisions were recorded in this cohort of primary breasts, as some breasts had undergone multiple revision procedures (369 had one revision, 18 had two revisions, and five had three revisions, resulting in 420 breast implant revisions), as seen in Table 10. A revision procedure in this case included removal or repositioning of the breast implant or breast implant-to-breast implant replacement. Replacement of a breast implant was the most common type of implant revision surgery, comprising 81% of implant revisions in primary breasts (Table 11). Only 7% of revisions in primary implant breasts involved explant of a breast implant (without replacement), and 8% involved repositioning the existing implant (Table 11).

**Table 10: Number of procedures by primary implant breasts** (2012-2016)

| Number primary implant breasts with | N | (%) |
|---|---|---|
| A primary breast implant inserted and *in situ* | 17,595 | (97.8%) |
| A primary breast implant inserted and 1 revision | 369 | (2.1%) |
| A primary breast implant inserted and 2 revisions | 18 | (0.1%) |
| A primary breast implant inserted and 3 revisions | 5 | (0.0%) |
| **TOTAL primary implant breasts** | **17,987** | **(100%)** |

Notes: 17,595 primary breast implants remained in situ and a total of 392 primary implant breasts progressed to have at least one revision following their initial implant insertion. Some breasts had multiple revisions which resulted in the record of 420 implant revision procedures in primary implant breasts (369 x 1 revision, 18 x 2 revisions, 5 x 3 revisions = 420). Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

**Table 11: Revision type for implant revisions in primary implant breasts** (2012-2016)

| Revision type | N | (%) |
|---|---|---|
| Replacement of the breast implant | 339 | (80.7%) |
| Explant of the breast implant | 31 | (7.4%) |
| Reposition of the existing breast implant | 34 | (8.1%) |
| Not stated | 16 | (3.8%) |
| **TOTAL breast implant revisions in primary implant breasts** | **420** | **(100%)** |

Notes: Some breasts had multiple revision procedures, so these 420 implant revisions were recorded for 392 primary implant breasts. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

## Revision incidence rates for primary implant breasts

Revision incidence rates can be analysed by calculating the time between the insertion of the primary breast implant and the first subsequent implant revision procedure. Those primary breasts with an implant inserted soon after March 2012 when the pilot began are observed for longer time periods than those with a primary implant inserted later in the observation period. Survival analysis techniques (i.e. Nelson-Aalen method) estimate the probability of revision at each time point following the initial implant insertion based on the number at risk of revision and the number of revisions recorded at that time point. The number at risk denotes the number of breasts that have been followed up at that particular time point.

Based on 17,987 primary implant breasts, Nelson-Aalen cumulative revision incidence rates are reported in Figures 17, 18 and 19. Crude revision incidence rates are presented with no adjustment for risk factors. Future reports will aim to account for potential confounders based on an initial set of risk factors to be deemed clinically important by the Steering Committee. Subsequently a statistical risk adjustment modelling exercise will be undertaken using the list of risk adjustment factors.

A low revision incidence rate is shown in Figure 17, with 2.2% of primary breast implants revised for the first time within the first year after primary implant insertion. At two years after primary implant insertion, 3.5% had been revised (Figure 17). Revision incidence rates are reported for cosmetic, reconstruction and developmental cohorts in Figure 18. For cosmetic implants, 1.3% had been revised at one year after primary implant insertion and 2.3% at two years (Figure 18). For implants used to correct developmental deformity, 3.6% had been revised at one year and 6.3% at two years after primary implant insertion (Figure 18).

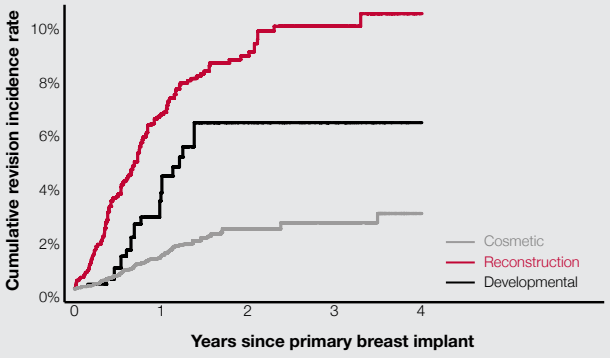
For reconstruction primary implants, 6.6% had been revised at one year and 8.8% at two years after initial insertion (Figure 18). Figure 19 provides revision incidence rates for the reconstruction cohorts with either a direct implant inserted or an implant inserted using a two-stage process (whereby a tissue expander is inserted and then removed prior to the insertion of a breast implant). For the primary reconstruction breasts captured by the ABDR with direct implants, 6.9% had been revised at one year post implant insertion, and 11% at two years (Figure 19). Of the two-stage reconstruction implants, 6.4% had been revised at one year and 7.9% at two years after primary implant (Figure 19).

Figure 17


**Number at risk**

| 17,987 | 8308 | 1796 | 916 | 216 |
|---|---|---|---|---|

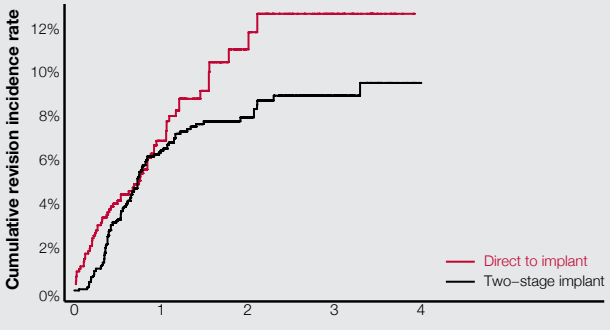
Figure 18




**Number at risk**

| | | | | | |
|---|---|---|---|---|---|
| 14,627 | 6343 | 995 | 559 | 124 | Cosmetic |
| 2692 | 1584 | 673 | 297 | 86 | Reconstruction |
| 535 | 321 | 122 | 58 | 6 | Developmental |

Figure 19




**Number at risk**

| | | | | | |
|---|---|---|---|---|---|
| 872 | 464 | 128 | 58 | 9 | Direct |
| 1820 | 1120 | 545 | 239 | 77 | Two–stage |

### Figure 17: Cumulative revision incidence rates of primary breast implants as at 31 December 2016

| | Number implanted | Number revised | Cumulative revision incidence rates at years since primary implant (95% CI) | | | |
|---|---|---|---|---|---|---|
| | | | 1 Year | 2 Years | 3 Years | 4 Years |
| **All primary implant breasts** | 17,987 | 392 | 2.2% (2.0, 2.5) | 3.5% (3.2, 4.0) | 4.1% (3.6, 4.7) | 4.4% (3.8, 5.3) |

Notes: Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

### Figure 18: Cumulative revision incidence rates of primary breast implants by reason for procedure as at 31 December 2016

| Reason for procedure | Number implanted | Number revised | Cumulative revision incidence rates at years since primary implant (95% CI) | | | |
|---|---|---|---|---|---|---|
| | | | 1 Year | 2 Years | 3 Years | 4 Years |
| **Cosmetic** | 14,627 | 181 | 1.3% (1.1, 1.5) | 2.3% (1.9, 2.7) | 2.5% (2.0, 3.1) | 2.8% (2.1, 3.8) |
| **Reconstruction** | 2692 | 187 | 6.6% (5.6, 7.7) | 8.8% (7.5, 10.2) | 8.9% (7.4, 10.8) | 10.3% (8.7, 12.4) |
| **Developmental** | 535 | 22 | 3.6% (2.2, 6.0) | 6.3% (4.1, 9.6) | 6.3% (4.1, 9.6) | 6.3% (4.1, 9.6) |

Notes: Reconstruction combines both cancer and benign/risk-reducing.
Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

### Figure 19: Cumulative revision incidence rates of primary reconstruction breast implants by implant process as at 31 December 2016

| Reconstruction implant process | Number implanted | Number revised | Cumulative revision incidence rates at years since primary implant (95% CI) | | | |
|---|---|---|---|---|---|---|
| | | | 1 Year | 2 Years | 3 Years | 4 Years |
| **Direct to implant** | 872 | 66 | 6.9% (5.2, 9.1) | 11% (8.4, 14.6) | 12.7% (9.4, 17.1) | 12.7% (9.4, 17.1) |
| **Two-stage implant** | 1820 | 121 | 6.4% (5.3, 7.8) | 7.9% (6.6, 9.6) | 8.9% (7.4, 10.8) | 9.5% (7.6, 11.8) |

Notes: Reconstruction combines both cancer and benign/risk-reducing.
Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

## Revision reasons and issues for primary implant breasts

Of the 420 breast implant revision procedures captured by the ABDR in the cohort of primary implant breasts (including cosmetic augmentation, developmental deformity and reconstruction groups), the most common reason for revision was due to a complication, accounting for 61% of implant revisions in primary breasts (Table 12). Other reasons included patient preference and asymptomatic revisions (25%, Table 12).

Table 13 reports a list of issues identified at implant revision in the cohort of primary implant breasts captured by the ABDR. These issues were identified either as a reason for the revision or found incidentally during the revision procedure, and more than one issue can be stated. From 2012 to 2016, device malposition was the most common issue identified in implant revision procedures for primary breasts (33%), followed by capsular contracture (28%), deep wound infections (6%) and seroma/haematoma (6%, Table 13).

**Table 12: Reason for revision in primary implant breasts** (2012-2016)

| Reason for revision | N | (%) |
|---|---|---|
| Complication | 256 | (61.0%) |
| Patient preference / Asymptomatic | 105 | (25.0%) |
| Not stated | 59 | (14.0%) |
| **TOTAL breast implant revisions in primary implant breasts** | **420** | **(100%)** |

Notes: Some breasts had multiple revision procedures, so these 420 implant revisions were recorded for 392 primary breasts. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

**Table 13: Issues identified at revision of primary implant breasts** (2012-2016)

| Issues identified at revision of primary implant breast | N | (%) |
|---|---|---|
| Device malposition | 137 | (32.6%) |
| Capsular contracture | 116 | (27.6%) |
| Deep wound infection | 27 | (6.4%) |
| Seroma/Haematoma | 26 | (6.2%) |
| Skin scarring problems | 16 | (3.8%) |
| Device rupture | 7 | (1.7%) |
| Device deflation | 5 | (1.2%) |
| Breast cancer | 1 | (0.2%) |
| ALCL* | 1 | (0.2%) |

Notes: Listed in order of frequency are issues identified during 420 breast implant revisions in 392 primary breasts, multiple issues can be recorded per revision. Data completeness for issues identified at revision range from 65% to 84% (see Table 22). Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR. *One case of ALCL was reported to the registry for which the ABDR also captured the primary insert data.

## Legacy implant breasts

From 2012 to 2016, there were 5076 breasts with breast implant revisions captured by the ABDR with no record of the initial insertion of the implanted device. Reasons for this may include that the initial procedure occurred prior to commencement of the ABDR, before the site joined the registry or overseas. The starting point of the breast implant journey for this cohort is therefore unknown, and these breasts are categorised as *Legacy implant breasts*. From this cohort of legacy implant breasts, 96% had one implant revision procedure captured by the ABDR, and 4% had multiple implant revisions captured (Table 14).

**Table 14: Number of procedures by legacy implant breasts** (2012-2016)

| Number of legacy implant breasts with: | N | (%) |
|---|---|---|
| 1 implant revision procedure captured by the ABDR | 4883 | (96.2%) |
| 2 implant revision procedures captured by the ABDR | 174 | (3.4%) |
| 3 implant revision procedures captured by the ABDR | 17 | (0.3%) |
| 4 implant revision procedures captured by the ABDR | 2 | (0.0%) |
| **TOTAL legacy implant breasts** | **5076** | **(100%)** |

Notes: 5076 legacy implant breasts had one or more revision procedures recorded. Since some breasts had multiple revisions captured this resulted in the record of 5290 implant revisions in legacy breasts (4883 x 1 revision, 174 x 2 revisions, 17 x 3 revisions, 2 x 4 revisions = 5290 revisions). Legacy implant breasts are defined as breasts with implant revisions captured by the ABDR with no record of the initial insertion of the implanted device.

A total of 5290 implant revision procedures were recorded in the ABDR for the cohort of legacy implant breasts due to some breasts having multiple revision procedures (4883 had one revision, 174 had two revisions, 17 had three revisions and three had four revisions, resulting in 5290 breast implant revisions), as seen in Table 14. A revision procedure in this case included repositioning or removal of the breast implant or breast implant-to-breast implant replacement. Replacement of a breast implant was the most common type of implant revision surgery, comprising 85% of revisions in legacy implant breasts (Table 15). Five per cent of revisions in legacy implant breasts involved explant of a breast implant (without replacement), and only 1% involved reposition of the existing implant (Table 15).

**Table 15: Revision type for implant revisions in legacy implant breasts** (2012-2016)

| Revision type | N | (%) |
|---|---|---|
| Replacement of the breast implant | 4491 | (84.9%) |
| Explant of the breast implant | 249 | (4.7%) |
| Reposition of the existing breast implant | 75 | (1.4%) |
| Not stated | 475 | (9.0%) |
| **TOTAL breast implant revisions in legacy implant breasts** | **5290** | **(100%)** |

Notes: Some breasts had multiple revision procedures, so these 5290 implant revisions were recorded for 5076 legacy breasts. Legacy implant breasts are defined as breasts with implant revisions captured by the ABDR with no record of the initial insertion of the implanted device.

## Revision reasons and issues for legacy implant breasts

Of the 5290 breast implant revision procedures captured by the ABDR in the cohort of legacy implant breasts, the most common reason for revision was due to a complication, accounting for 62% of implant revisions in legacy breasts (Table 16). Other reasons included patient preference and asymptomatic revisions (23%, Table 16).

Table 17 reports a list of complication issues identified at implant revision in the cohort of legacy implant breasts captured by the ABDR. These issues were identified either as a reason for the revision or found incidentally during the revision procedure, and more than one issue can be stated. From 2012 to 2016, capsular contracture was the most common issue identified in implant revision procedures for legacy breasts (39%), followed by device malposition (22%) and device rupture (19%, Table 17).

**Table 16: Reason for revision in legacy implant breasts** (2012-2016)

| Reason for revision | N | (%) |
|---|---|---|
| Complication | 3274 | (61.9%) |
| Patient preference / Asymptomatic | 1196 | (22.6%) |
| Not stated | 820 | (15.5%) |
| **TOTAL breast implant revisions in legacy implant breasts** | **5290** | **(100%)** |

Notes: Some breasts had multiple revision procedures, so these 5290 implant revisions were recorded for 5076 legacy breasts. Legacy implant breasts are defined as breasts with implant revisions captured by the ABDR with no record of the initial insertion of the implanted device.

**Table 17: Issues identified at revision of legacy implant breasts** (2012-2016)

| Issues identified at revision of legacy implant breasts | N | (%) |
|---|---|---|
| Capsular contracture | 2060 | (38.9%) |
| Device malposition | 1163 | (22.0%) |
| Device rupture | 1004 | (19.0%) |
| Device deflation | 492 | (9.3%) |
| Skin scarring problems | 187 | (3.5%) |
| Seroma/Haematoma | 130 | (2.5%) |
| Deep wound infection | 54 | (1.0%) |
| Breast cancer | 28 | (0.5%) |
| ALCL* | 8 | (0.2%) |

Notes: Listed in order of frequency are issues identified during 5290 breast implant revisions in 5076 legacy breasts, multiple issues can be recorded per revision. Data completeness for issues identified at revision range from 65% to 84% (see Table 22). Legacy implant breasts are defined as breasts with implant revisions captured by the ABDR with no record of the initial insertion of the implanted device. *Eight cases of ALCL were reported to the registry for which the ABDR did not capture the primary insert data.

## Anaplastic Large Cell Lymphoma

The least common but potentially most serious complication was Anaplastic Large Cell Lymphoma (ALCL). Nine cases of ALCL were recorded in the registry as an identified issue at implant revision (Tables 13 and 17). Recent studies have pointed to a link between ALCL and textured breast implants (9). Current estimates on incidence are based on spontaneous case reports, and interpreting such data is limited because it has not been systematically collected.

A joint task force for Breast Implant Associated (BIA) ALCL convened by clinicians and researchers from Australia and New Zealand supports international recommendations for recognising and managing BIA-ALCL (10). At December 2016 there were 46 cases of BIA-ALCL identified in Australia (11), and a retrospective review of all cases was undertaken (12). The nine cases reported to the ABDR since its inception are a subset of the 46 cases reported to the TGA since 2007. These data will be housed in the ABDR following completion of the retrospective review, and the ABDR will be the primary point of contact for notification of BIA-ALCL cases in the future.

## Primary tissue expander breasts

In the period from 2012 to 2016, there were 1692 breasts with primary tissue expander insertion captured by the ABDR. This cohort of breasts is labelled *Primary tissue expander breasts*. Amongst this cohort, 43% of breasts had the tissue expander device *in situ*, 55% had a tissue expander-to-breast implant exchange, and 27 breasts (1.6%) had progressed to at least one tissue expander revision procedure following the initial insertion (Table 18).

A total of 28 tissue expander revision procedures were recorded in this group, with one breast undergoing two revision procedures, as seen in Table 18. A revision procedure in this case included repositioning or removal of the tissue expander or tissue expander-to-tissue expander replacement[2]. Tissue expander replacement (exchange of one tissue expander for another tissue expander) was the most common revision procedure (54%) recorded in primary tissue expander breasts, and 36% were explant of the tissue expander (Table 19).

**Table 18: Number of procedures by primary tissue expander breasts** (2012-2016)

| Number of primary tissue expander breasts with: | N | (%) |
|---|---|---|
| A primary tissue expander inserted and *in situ* | 737 | (43.6%) |
| A primary tissue expander inserted and then exchanged for a breast implant | 928 | (54.8%) |
| A primary tissue expander inserted and 1 revision | 26 | (1.5%) |
| A primary tissue expander inserted and 2 revisions | 1 | (0.1%) |
| **TOTAL primary tissue expander breasts** | **1692** | **(100%)** |

Notes: Of the 1692 primary tissue expander breasts, 27 breasts progressed to requiring at least one revision procedure of their inserted tissue expander. One of these breasts had two revisions which resulted in the record of 28 tissue expander revisions in primary tissue expander breasts. Primary tissue expander breasts are defined as those for which the initial insertion of a tissue expander has been captured by the ABDR.

**Table 19: Revision type for tissue expander revisions in primary tissue expander breasts** (2012-2016)

| Revision type | N | (%) |
|---|---|---|
| Tissue expander-to-tissue expander replacement | 15 | (53.6%) |
| Explant of the tissue expander | 10 | (35.7%) |
| Reposition of the existing tissue expander | 0 | (0.0%) |
| Not stated | 3 | (10.7%) |
| **TOTAL tissue expander revisions in primary tissue expander breasts** | **28** | **(100%)** |

Notes: One breast had multiple revisions, so these 28 tissue expander revisions were recorded for 27 primary tissue expander breasts. Primary tissue expander breasts are defined as those for which the initial insertion of a tissue expander has been captured by the ABDR.

2. Note that tissue expander-to-breast implant exchange is not considered revision surgery

## Legacy tissue expander breasts

From 2012 to 2016, there were 1230 breasts with tissue expander revisions and tissue expander-to-breast implant exchanges captured by the ABDR, with no record of the initial insertion of the tissue expander device. Reasons for this may include that the initial procedure occurred prior to commencement of the ABDR, before the site joined the registry or overseas. The starting point of the tissue expander journey for this cohort is therefore unknown, and these breasts are classified as *Legacy tissue expander breasts*.

Amongst this cohort of breasts, 94% had a tissue expander-to-breast implant exchange captured by the ABDR and 6% had one tissue expander revision recorded (Table 20). No legacy breasts had more than one tissue expander revision procedure recorded[3]. A revision procedure in this case includes repositioning or removal of the tissue expander or tissue expander-to-tissue expander replacement. Of the 76 tissue expander revisions in legacy breasts, tissue expander-to-tissue expander replacement was the most common revision procedure (61%), and 22% involved explant of the tissue expander (Table 21).

**Table 20: Number of procedures by legacy tissue expander breasts** (2012-2016)

| Number of legacy tissue expander breasts with: | N | (%) |
|---|---|---|
| Tissue expander removal before a breast implant exchange | 1154 | (93.8%) |
| One tissue expander revision procedure captured by ABDR | 76 | (6.2%) |
| **TOTAL legacy tissue expander breasts** | **1230** | **(100%)** |

Notes: No legacy breasts had more than one tissue expander revision procedure recorded. Legacy tissue expander breasts are defined as breasts with tissue expander revisions captured by the ABDR with no record of the initial insertion of the tissue expander device.

**Table 21: Revision type for tissue expander revisions in legacy tissue expander breasts** (2012-2016)

| Revision type | N | (%) |
|---|---|---|
| Tissue expander-to-tissue expander replacement | 46 | (60.5%) |
| Explant of the tissue expander | 17 | (22.4%) |
| Reposition of the existing tissue expander | 1 | (1.3%) |
| Not stated | 12 | (15.8%) |
| **TOTAL tissue expander revisions in legacy tissue expander breasts** | **76** | **(100%)** |

Notes: These 76 tissue expander revision procedures were recorded for 76 legacy breasts. Legacy tissue expander breasts are defined as breasts with tissue expander revisions captured by the ABDR with no record of the initial insertion of the tissue expander device.

3. Note that tissue expander-to-breast implant exchange is not considered revision surgery

# REGISTRY OUTCOMES

As a Clinical Quality Registry, one purpose of the ABDR is to drive quality improvement in breast device surgery through reporting risk-adjusted outcomes in line with specified clinical quality indicators. A Clinical Quality Committee has been established with the aim of providing a framework for the development of clinical quality indicators and a process for the ABDR to report on quality of care; to set performance benchmarks for sites and surgeons; and to measure outcomes for patient safety. Specifically, the Clinical Quality Committee is working to develop quality indicators reflecting structure, process and outcomes of breast device surgery.

According to the Donabedian model, which provides a conceptual framework for examining health services and evaluating the quality of health care, information can be drawn from three categories: 'structure', 'process' and 'outcome' (13).

Structural indicators describe the type and amount of resources, facilities, and the impact of various organisational structures at a site level. Process indicators measure the effectiveness of various surgical intraoperative techniques for individual patient procedures, for example anti-infective strategies (14). Outcome indicators assess the state of patient health and wellbeing following care, and are based on complication rates, as captured through further surgery, or patient satisfaction within a set timeframe of surgery. Outcome indicators can be determined through registry activities, can be patient reported, or captured from data linkages with other data sets like the National Death Index (NDI) or Admitted Episodes Datasets.

The Clinical Quality Committee will also advise on risk adjustment, which is the process of statistically accounting for differences in patient case mix that influence health care outcomes (15), to ensure the outcomes are not unduly influenced by conditions beyond the clinicians' control. Examples of some risk adjustment factors may include patient demographic factors (i.e. age, BMI), or pre-existing medical conditions (i.e. cancer).

# REGISTRY QUALITY ASSURANCE

## Data completeness

The ABDR is designed to collect information about surgical procedures involving a breast implant or tissue expander, and Acellular Dermal Matrix (ADM), or similar product if used. The current data collection process entails:

1. Surgeon performs procedure for insertion, revision or removal of breast implant/tissue expander and completes ABDR Data Collection Form (DCF) (Appendix 1);
2. The surgeon or operating theatre staff return the completed DCF to the ABDR;
3. ABDR staff enter the data from the DCF into the ABDR database.

A summary of the completeness of data elements captured within the ABDR database for the 14,303 procedures from 13,019 patients, as of 31 December 2016 is presented in Table 22.

Intuitive checks (validation rules) have been built into the ABDR database, however data entry is currently completed manually from paper DCFs forwarded by participating sites. There are several problems associated with a paper-based system for data entry, including incomplete fields on the DCF, difficulties in reading/interpreting the handwritten text, and manual data entry leading to double-handling of data with potential to introduce transcription errors.

Direct data collection using a web portal or mobile device (smartphone or tablet) system is considered a priority to optimise the quality of the data entered. Adaptive pathways can be incorporated to capture data specific to the procedure being performed, as opposed to the entire DCF including non-relevant tick boxes. Development of direct-entry capacity requires substantial investment of resources, and is currently being investigated.

Further strategies to improve data completeness have been explored. As an immediate strategy to improve the quality of the ABDR dataset, it has been resolved to regularly notify participating sites about the completeness of the data they provide. Data completeness is regularly discussed during site visits, and a log kept with details of suggested improvements from surgeons and operating theatre staff.

An audit program will also be undertaken to evaluate factors contributing to incomplete data (particularly the ‘Revision’ section of the DCF). Interviews with surgeons and operating theatre staff will be conducted to better understand:

- whether the layout and format of the existing paper-based form can be improved (i.e. if the flow is logical for data entry, if optional data items that do not have to be completed on every procedure have been clearly specified in the form);
- which data items are particularly difficult to collect;
- which sites require further training; and
- whether there are other factors at play in the operating theatre environment which may contribute to incomplete data.

**Table 22: Data completeness** (2012–2016)

| | (%) Complete* |
|---|---|
| **Patient demographic** | **N = 13,019** |
| Name | (100%) |
| Surname | (100%) |
| Medicare number | (91.7%) |
| Date of birth | (100%) |
| Address | (98.0%) |
| Telephone | (75.5%) |
| Email | (10.3%) |
| **Procedure** | **N = 14,303** |
| Date of operation | (100%) |
| Hospital | (100%) |
| UR number | (100%) |
| Name of surgeon | (100%) |
| Intra operative techniques | (90.3%) |
| **Patient history (Breast level)** | **N = 26,505** |
| Reason of operation | (95.7%) |
| Procedure performed (primary or revision) | (96.5%) |
| Previous radiotherapy (if reason of operation = Reconstruction) | (90.8%) |
| **Element of operation (Breast level)** | **N = 26,505** |
| Side of breast | (100%) |
| Incision site | (92.5%) |
| Plane of implantation | (87.7%) |
| Concurrent mastectomy^ | (71.5%) |
| Axillary surgery^ | (71.0%) |
| Concurrent mastopexy | (85.5%) |
| Concurrent flap cover | (84.3%) |
| Previous mastopexy/reduction^ | (71.0%) |
| Fat grafting | (74.4%) |
| Fat grafting volume (if Fat grafting = Yes)^ | (87.7%) |
| Intra operative fill volume (if Tissue Expander) | (66.2%) |
| **Device implants characteristics (Breast level)** | **N = 24,758** |
| Device ID | (99.9%) |
| ADM used | (63.8%) |
| ADM ID (if ADM used) | (70.4%) |

| | (%) Complete* |
|---|---|
| **Revision surgery (Breast level)** | **N = 5814** |
| Revision type | (91.3%) |
| Capsulectomy | (81.1%) |
| Neo-pocket formation^ | (59.4%) |
| Neo-pocket formation details^ | (72.9%) |
| Reason for revision | (84.3%) |
| Is the operation removing an implant inserted overseas | (79.4%) |
| Breast cancer identified at revision | (66.6%) |
| **Issue identified at revision:** | |
| Device rupture | (84.2%) |
| Device deflation | (67.3%) |
| Capsular contracture | (73.2%) |
| Device malposition | (69.5%) |
| Skin scarring problems | (67.0%) |
| Deep wound infection | (67.1%) |
| Seroma/Haematorma | (66.9%) |
| Anaplastic Large Cell Lymphoma | (64.7%) |
| **Explanted device characteristics (Breast level)** Type of revision surgery: replacement and explant only | **N = 5261** |
| Device details supplied = Yes | (52.8%) |
| Device ID^ | (13.3%) |
| **If Device ID = Other:** | **N = (2376)** |
| Manufacturer | (77.7%) |
| Shape^ | (81.4%) |
| Shell^ | (44.3%) |
| Fill^ | (55.2%) |
| Volume^ | (83.2%) |
| Date of insert^ | (63.6%) |

Notes: * NULL, Not known or Not stated data entries were classified as incomplete.

^The ABDR DCF underwent a number of changes during the pilot period. Data elements were added and removed and the format of the DCF has changed. As a result, newly added data elements such as fat grafting volume, neo pocket formation and explant device details have low completion rates.

# FUTURE INITIATIVES

## Infrastructure development

The existing ABDR database was originally built to cater for the pilot study. With the increasing size of the registry, a major expansion of the database with increased functionality is required. Stage one of the database upgrade will be implemented in 2018 with additional staged functionality assessments and upgrades planned on an ongoing basis.

In April 2016, a Customer Relationship Management (CRM) system was implemented to assist registry staff to manage details of sites and surgeons contributing data to the ABDR, and to record names of sites and surgeons eligible to contribute. This is considered a short-term undertaking as it is expected that the planned database upgrade will incorporate CRM functionality.

The current website (abdr.org.au) was developed in early 2016 to provide a *'one-stop'* accessible interface between the ABDR and stakeholders, including contributing surgeons and staff, Australian consumers and researchers. The website, which is continually evolving as a communications tool, supports recruitment and retention of health providers participating in the ABDR, and strategies to increase public awareness of the registry in Australia and around the world.

## Patient Reported Outcome Measures (PROMs) and clinical indicators

Work is ongoing to assess the suitability of a PROM designed to assess device performance for use in breast registries. A five question survey called the Breast-Q Implant Surveillance tool (Breast-Q IS) has been developed by the BREAST-Q team at Memorial Sloan-Kettering Hospital, in New York, led by Professor Andrea Pusic. Semi-structured interviews of recipients of breast devices will be used to explore the acceptability and feasibility of the five questions, and methods of contacting participants on the ABDR. Acceptability to surgeons will also be examined. A pilot study will be conducted prior to use across the ABDR for follow up at one, two, five and 10 years.

A project is being undertaken to develop a set of indicators to enable assessment and reporting of quality of care for recipients of breast devices. Candidate quality indicators will be identified through a targeted search of the medical literature. A panel will be invited to participate in a modified Delphi process, consisting of stakeholders including surgeons from all craft groups, the Therapeutic Goods Administration, a nurse, biostatistician and consumer representative. The objective of a modified Delphi process is to achieve consensus among a panel of experts bringing a range of perspectives. It involves multiple rounds with each round consisting of an online survey, feedback of the results from this survey to the panel members, and a teleconference discussion of the survey results. This process ensures a structured communication between the panel members which then allows them to deal with a complex problem (16). Results of this research will assist in the development of a defined list of quality of care indicators for the management of breast device surgery internationally.

## Data linkages and collaborations

State, national and international data linkages will be explored in 2018 to maximise the value of the ABDR dataset. We expect to commence work on combining a portion of the ABDR and Dutch Breast Implant Registry (DBIR) de-identified datasets with the aim of studying the feasibility of combining datasets and examining differences between countries with regard to breast devices. The newly formed Lymphoma and Related Diseases Registry (LaRDR) will automatically notify any cases of BIA-ALCL that are reported. The ABDR was invited to take part in the Therapeutic Goods Administration Breast Implants and ALCL expert panel convened in November 2016. The ABDR is collaborating with researchers on the joint ANZ Taskforce on BIA-ALCL, with the ABDR being the central reporting site for BIA-ALCL cases in Australia. These works will enable important health information about patients to be linked and create a 'whole picture' of patient data related to their breast device experience.

The ABDR is preparing for two world-firsts in breast device research: a PROMs study into patient wellbeing and establishing international clinical indicators that measure quality of care.

# REGISTRY PERSONNEL

## Steering Committee representatives

| | |
|---|---|
| Australian Society of Plastic Surgeons (ASPS) | plasticsurgery.org.au |
| Australasian College of Cosmetic Surgery (ACCS) | accs.org.au |
| Breast Surgeons of Australia and New Zealand (BreastSurgANZ) | breastsurganz.com |
| Therapeutic Goods Administration (TGA) | tga.gov.au |
| Department of Health (Health) | health.gov.au |
| Medical Technology Association of Australia (MTAA) | mtaa.org.au |
| Consumers Health Forum of Australia (CHF) | chf.org.au |
| Australian Commission on Safety and Quality in Health Care (ACSQHC) | safetyandquality.gov.au |

## Clinical Leads

| | |
|---|---|
| **Professor Rod Cooter** | Australian Society of Plastic Surgeons (ASPS) |
| **Associate Professor Colin Moore** | Australasian College of Cosmetic Surgeons (ACCS) |
| **Associate Professor Elisabeth Elder** | Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ) |

## ABDR Staff

| | |
|---|---|
| **Professor John McNeil** | Head of School of Public Health and Preventive Medicine, Department of Epidemiology and Preventive Medicine |
| **Dr Ingrid Hopper** | Head of Drug and Device Registries, School of Public Health and Preventive Medicine, ABDR Project Lead and ABDR Data Custodian |
| **Associate Professor Sue Evans** | ABDR Data Custodian (2012–2016) |
| **Catherine Mulvany** | ABDR Project Coordinator |
| **Dr Emily Parker** | Research Fellow |
| **Dr Husna Begum** | Research Fellow |
| **Vanessa Fox** | Research Officer |
| **Alice Noone** | Research Officer |
| **Sarah Barrington-Smith** | Research Officer |
| **Dr Nicole Ng** | Research Officer |
| **Marie Pase** | Database Coordinator |
| **Trisha Nichols** | Communications Officer |
| **Tu Nguyen** | Research Assistant |
| **Dr Masuma Hoque** | Research Assistant |
| **Vera Boomaerts** | Research Assistant |
| **Ying Khu** | Research Assistant |

## International Collaborators

| | |
|---|---|
| **Andrea Pusic** | United States |
| **Andy Crosbie** | United Kingdom |
| **Birgit Stark** | Sweden |
| **Charles Randquist** | Sweden |
| **Charles Verheyden** | United States |
| **Claude Le Louarn** | France |
| **Danica Marinac-Dabic** | United States |
| **David B Lumenta** | Austria |
| **Graeme Perks** | United Kingdom |
| **Gregory R D Evans** | United States |
| **Hinne Rakhorst** | Netherlands |
| **Howard Klein** | New Zealand |
| **Irene M J Mathijssen** | Netherlands |
| **Marc A M Mureau** | Netherlands |
| **Pauline Spronk** | Netherlands |
| **Sean M Carroll** | Ireland |
| **Stephen Mulgrew** | United Kingdom |
| **Uwe von Fritschen** | Germany |

# GLOSSARY

| | |
|---|---|
| **ABDR** | Australian Breast Device Registry |
| **ACCS** | Australasian College of Cosmetic Surgery |
| **ADM** | Acellular Dermal Matrix |
| **ASPS** | Australian Society of Plastic Surgeons |
| **AFPS** | Australasian Foundation for Plastic Surgery |
| **BIA-ALCL** | Breast-implant-associated Anaplastic Large Cell Lymphoma |
| **Breast-Q IS** | Breast-Q Implant Surveillance tool |
| **BreastSurgANZ** | Breast Surgeons of Australia and New Zealand Inc. |
| **Contributing site** | Any site that is currently contributing data to the ABDR |
| **DBIR** | Dutch Breast Implant Registry |
| **DCF** | Data Collection Form |
| **Eligible site** | A site undertaking breast device surgery as identified by ICD-10-AM code data |
| **HREC** | Human Research Ethics Committee |
| **ICD-10-AM** | Australian modification of the International statistical classification of diseases and health related problems, 10th revision |
| **ICOBRA** | International Collaboration of Breast Registry Activities |
| **IQR (Interquartile range)** | Quartiles divide a rank-ordered dataset into four equal parts. The values that divide each part are called the first, second and third quartiles. First, second and third quartiles correspond to the observation at the 25th, 50th and 75th percentiles, respectively. The observation from the 25th percentile to the 75th percentile is referred as the interquartile range. An observation at the 50th percentile corresponds to the median value in the dataset. |
| **Legacy implant breast** | A breast for which an implant revision procedure is recorded with no ABDR capture of the initial implant insertion for that breast. |
| **Legacy tissue expander breast** | A breast for which a tissue expander revision procedure is recorded with no ABDR capture of the initial tissue expander insertion for that breast |
| **Primary implant breast** | A breast for which the initial insertion of a breast implant has been captured by the ABDR |
| **Primary tissue expander breast** | A breast for which the initial insertion of a tissue expander has been captured by the ABDR |
| **Primary surgery** | A procedure involving insertion of an initial (first) breast device captured by the ABDR |
| **Revision surgery** | A procedure involving replacement, removal or reposition of an existing breast device captured by the ABDR |

# LIST OF FIGURES



# LIST OF TABLES

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# APPENDIX 1– DATA COLLECTION FORM

AUSTRALIAN Breast Device REGISTRY

## AUSTRALIAN BREAST DEVICE REGISTRY FORM

MONASH University Medicine, Nursing and Health Sciences

Australian Society of Plastic Surgeons

Breast Surgeons of Australia & New Zealand

AFFIX **PATIENT** STICKER or complete details below:

Patient UR # :

Medicare # :

Surname :

First name: Middle Name:

Birth Date: / / (dd/mm/yyyy)

Address :

State: P/code:

Telephone : - Home: Business:

Mobile :

Email :

**OPERATION DATE: (dd/mm/yy)** / /

**SITE DETAILS:**

Site Name:

Suburb: State:

Surgeon name:

Is this patient a medical tourist to Australia? Yes No

**RETURN FORM:**

Australian Breast Device Registry,
Monash University, DEPM,
553 St Kilda Road, Melbourne 3004
**email:** abdr@monash.edu **fax:** (03) 9903 0277
**contact phone:** (03) 9903 0205

### AFFIX **RIGHT DEVICE** STICKER

[COMPLETE IF NO DEVICE STICKER]

Manufacturer:

Distributor:

Reference no:

Serial no:

### AFFIX **LEFT DEVICE** STICKER

[COMPLETE IF NO DEVICE STICKER]

Manufacturer:

Distributor:

Reference no:

Serial no:

### AFFIX **MESH/DERMAL SHEET** STICKER

[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes No

Manufacturer:

Reference no:

Serial no:

### AFFIX **MESH/DERMAL SHEET** STICKER

[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes No

Manufacturer:

Reference no:

Serial no:

## PATIENT HISTORY:

### **RIGHT** BREAST

Tick if Same Bilateral

### BREAST **LEFT**

**Category of operation**

- Cosmetic augmentation
- Reconstruction - post cancer
- Reconstruction - benign / prophylactic
- Congenital deformity

**Operation type**

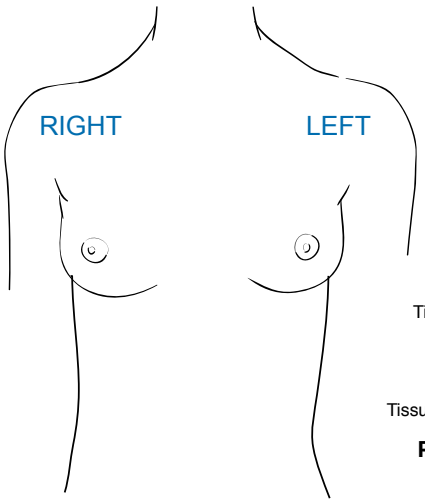
***Initial (new device)***

- Tissue Expander insertion
- First Implant insertion
- Tissue Expander removal & Implant insertion

***Revision of in situ device***

- Implant revision, removal or replacement
- Tissue Expander revision, removal, replacement

**Previous Radiotherapy** Yes No




**Category of operation**

- Cosmetic augmentation
- Reconstruction - post cancer
- Reconstruction - benign / prophylactic
- Congenital deformity

**Operation type**

***Initial (new device)***

- Tissue Expander insertion
- First Implant insertion
- Tissue Expander removal & Implant insertion

***Revision of in situ device***

- Implant revision, removal or replacement
- Tissue Expander revision, removal, replacement

**Previous Radiotherapy** Yes No

PLEASE COMPLETE OVER PAGE

## ELEMENTS OF OPERATION

### RIGHT BREAST

☐ Tick if Same Bilateral

**Incision site**
- ☐ Axillary
- ☐ Areolar
- ☐ Infra-mammary
- ☐ Previous mastectomy scar
- ☐ Mastopexy/reduction wound
- ☐ .....

**Plane**
- ☐ Sub-glandular / Sub-fascial
- ☐ Sub-pectoral
- ☐ Sub-flap

**Concurrent Mastectomy**..... ☐ Yes ☐ No
**Axillary surgery incl. sentinel node biopsy** ..... ☐ Yes ☐ No
**Concurrent Mastopexy / Reduction** ..... ☐ Yes ☐ No
**Concurrent Flap cover** ..... ☐ Yes ☐ No
**Previous Mastopexy/Reduction** ..... ☐ Yes ☐ No

**Fat grafting** ☐ Yes Volume.....mLs ☐ No

**IF TISSUE EXPANDER,** Intra Operative fill volume: .....mLs

### BREAST LEFT

**Plane**
- Subglandular / Sub-fascial ☐
- Sub-pectoral ☐
- Sub-flap ☐

**Incision site**
- Axillary ☐
- Areolar ☐
- Infra-mammary ☐
- Previous mastectomy scar ☐
- Mastopexy/reduction wound ☐
- ..... ☐

☐ Yes ☐ No ..... **Concurrent Mastectomy**
☐ Yes ☐ No ..... **Axillary surgery incl. sentinel node biopsy**
☐ Yes ☐ No ..... **Concurrent Mastopexy / Reduction**
☐ Yes ☐ No ..... **Concurrent Flap cover**
☐ Yes ☐ No ..... **Previous Mastopexy/Reduction**

**Fat grafting** ☐ Yes Volume.....mLs ☐ No

**IF TISSUE EXPANDER,** Intra Operative fill volume: .....mLs

## INTRAOPERATIVE TECHNIQUES

☐ Intra-op prophylactic antibiotic ☐ Antibiotic dipping solution ☐ Post-op antibiotic
☐ Glove change for insertion ☐ Sleeve/funnel ☐ Antiseptic rinse .....

### RIGHT BREAST

☐ Tick if Same Bilateral

- ☐ Nipple absent
- ☐ Nipple sparing
- ☐ Occlusive nipple shield
- ☐ Drain used

### BREAST LEFT

- Occlusive nipple shield ☐
- Drain used ☐
- Nipple absent ☐
- Nipple sparing ☐

## FOR REVISION SURGERY ONLY

### RIGHT BREAST

☐ Tick if Same Bilateral

**Revision Type:**
☐ Replacement ☐ Reposition existing implant ☐ Explant only

**Capsulectomy** ..... ☐ Full ☐ Partial ☐ None

**Neo pocket formation** ... ☐ Yes ☐ No ☐ Subglandular ☐ Submuscular

**Explanted device:** Ref.No. / Manufacturer: .....
Shell: ..... Fill: ..... Vol: ..... Date of Insert: ...../...../.....
☐ Round ☐ Anatomical ☐ Indeterminate

**Reason for Revision**
☐ Complication ☐ Asymptomatic ☐ Patient Preference

**Is the operation removing an implant inserted overseas** ☐ Yes ☐ No

Details : .....

☐ Tick if Same Bilateral

**Device rupture?**
☐ Yes, reason for revision ☐ Yes, found incidentally ☐ No

**If yes, please indicate whether silicone extravasation was found:**
☐ Intracapsular ☐ Extracapsular ☐ Distant

### BREAST LEFT

**Revision Type:**
Replacement ☐ Reposition existing implant ☐ Explant only ☐

**Capsulectomy** ..... Full ☐ Partial ☐ None ☐

**Neo pocket formation** ... Yes ☐ No ☐ Subglandular ☐ Submuscular ☐

**Explanted device:** Ref.No. / Manufacturer: .....
Shell: ..... Fill: ..... Vol: ..... Date of Insert: ...../...../.....
Round ☐ Anatomical ☐ Indeterminate ☐

**Reason for Revision**
Complication ☐ Asymptomatic ☐ Patient Preference ☐

**Is the operation removing an implant inserted overseas** Yes ☐ No ☐

Details : .....

**Device rupture?**
Yes, reason for revision ☐ Yes, found incidentally ☐ No ☐

**If yes, please indicate whether silicone extravasation was found:**
Intracapsular ☐ Extracapsular ☐ Distant ☐

| Yes, reason for revision | Yes, found incidentally | No | Issue identified at revision | No | Yes, found incidentally | Yes, reason for revision |
|---|---|---|---|---|---|---|
| ☐ | ☐ | ☐ | Device deflation | ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ | Capsular contracture | ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ | Device malposition | ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ | Skin scarring problems | ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ | Deep wound infection | ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ | Seroma/Haematoma | ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ | Breast cancer | ☐ | ☐ | ☐ |
| ☐ | ☐ | ☐ | Anaplastic Large Cell Lymphoma | ☐ | ☐ | ☐ |

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# APPENDIX 2 – LIST OF PARTICIPATING SITES

as at December 2016

| | |
|---|---|
| ACT | Calvary Bruce Private Hospital |
| ACT | Calvary Bruce Public Hospital |
| ACT | Calvary John James Hospital |
| ACT | Canberra Private Hospital |
| ACT | National Capital Private Hospital |
| NSW | Aesthetic Day Surgery |
| NSW | Auburn Hospital |
| NSW | Bondi Junction Private Hospital |
| NSW | Brisbane Waters Private Hospital |
| NSW | Campbelltown Private Hospital |
| NSW | Castle Hill Day Surgery |
| NSW | Charlestown Private Hospital |
| NSW | Crows Nest Day Surgery |
| NSW | East Sydney Private Hospital |
| NSW | Gosford Private Hospital |
| NSW | Holroyd Private Hospital |
| NSW | Hospital for Specialist Surgery |
| NSW | Hunter Valley Private Hospital |
| NSW | Lingard Private Hospital |
| NSW | Macquarie University Hospital |
| NSW | Maitland Private Hospital |
| NSW | Mount Druitt Hospital |
| NSW | Nepean Private Hospital |
| NSW | Prince of Wales Private Hospital |
| NSW | Shellharbour Private Hospital |
| NSW | St George Hospital |
| NSW | St Luke's Private Hospital |
| NSW | Surry Hills Day Hospital |
| NSW | Sydney Southwest Private Hospital |
| NSW | Sydney Surgical Centre |
| NSW | The Cosmetic and Restorative Surgery Clinic |
| NSW | Waratah Private Hospital |
| NSW | Westmead Hospital |
| NSW | Wollongong Day Surgery |
| NT | Darwin Day Surgery |
| NT | Darwin Private Hospital |
| QLD | Brisbane Private Hospital |
| QLD | Canossa Private Hospital |
| QLD | Chermside Day Hospital |
| QLD | Friendly Society Private Hospital |
| QLD | Gold Coast Private Hospital |
| QLD | Gold Coast Surgical Hospital |
| QLD | Ipswich Day Hospital |
| QLD | Kawana Private Hospital |
| QLD | Mater Hospital Brisbane |
| QLD | Mater Hospital Pimlico |
| QLD | Mater Private Hospital Brisbane |
| QLD | Mater Women's and Children's Hospital Hyde Park |
| QLD | Mercy Health Gladstone – Mater Misericordiae Hospital Gladstone |
| QLD | Mercy Health Mackay – Mater Misericordiae Hospital Mackay |
| QLD | Mercy Health Rockhampton – Mater Misericordiae Hospital Rockhampton |
| QLD | Miami Day Hospital |
| QLD | Montserrat – Gaythorne Day Hospital |
| QLD | Montserrat – North Lakes Day Hospital |
| QLD | Pacific Day Surgery |
| QLD | Pacific Private Day Hospital |
| QLD | Princess Alexandra Hospital |
| QLD | Royal Brisbane and Women's Hospital |
| QLD | South Bank Day Hospital |
| QLD | Southport Day Hospital |
| QLD | Spring Hill Specialist Day Hospital |
| QLD | St Andrew's Toowoomba Hospital |
| QLD | St Vincent's Private Hospital – Holy Spirit Northside |
| QLD | St Vincent's Private Hospital – Toowoomba |
| QLD | St Vincent's Private Hospital – Brisbane |
| QLD | Sunshine Coast Day Surgery |
| QLD | Toowoomba Surgicentre |
| QLD | UnitingCare – St Andrew's War Memorial Hospital |
| QLD | UnitingCare – St Stephen's Hospital |
| QLD | UnitingCare – The Sunshine Coast Private Hospital |
| QLD | UnitingCare – The Wesley Hospital |
| SA | Adelaide Day Surgery |
| SA | Ashford Hospital |
| SA | Brighton Day Surgery |
| SA | Burnside War Memorial Hospital |
| SA | Calvary North Adelaide Hospital |
| SA | Calvary Wakefield Hospital |

| | |
|---|---|
| SA | Calvary Wakefield Surgicentre |
| SA | Flinders Medical Centre |
| SA | Flinders Private Hospital |
| SA | Glenelg Community Hospital |
| SA | Hamilton House Day Surgery |
| SA | Noarlunga Hospital |
| SA | North Adelaide Day Surgery |
| SA | Norwood Day Surgery |
| SA | Parkside Cosmetic Surgery |
| SA | Royal Adelaide Hospital |
| SA | St Andrew's Hospital (SA) |
| SA | Stirling Hospital |
| SA | The Memorial Hospital |
| SA | The Queen Elizabeth Hospital |
| SA | Waverley House Plastic Surgery Centre |
| SA | Western Hospital (SA) |
| TAS | Calvary Health Care Tasmania St John's Campus |
| TAS | Calvary Health Care Tasmania St Vincent's Campus |
| TAS | Hobart Private Hospital |
| TAS | Launceston General Hospital |
| TAS | North Tas Day Hospital |
| TAS | Royal Hobart Hospital |
| VIC | Austin Hospital |
| VIC | Bellbird Private Hospital |
| VIC | Bendigo Day Surgery |
| VIC | Cabrini Hospital – Brighton |
| VIC | Cabrini Hospital – Malvern |
| VIC | Casey Hospital |
| VIC | Corymbia House |
| VIC | Cotham Private Hospital |
| VIC | Dandenong Hospital |
| VIC | Eastlink Surgical & Specialist Centre |
| VIC | Epworth Cliveden |
| VIC | Epworth Eastern |
| VIC | Epworth Freemasons |
| VIC | Epworth Geelong |
| VIC | Epworth Hawthorn |
| VIC | Epworth Richmond |
| VIC | Holmesglen Private Hospital |
| VIC | John Fawkner Private Hospital |
| VIC | Knox Private Hospital |
| VIC | Linley Clinic |
| VIC | Maroondah Hospital |
| VIC | Maryvale Private Hospital |
| VIC | Melbourne Private Hospital |
| VIC | Moorabbin Hospital |
| VIC | Repatriation Hospital (The Surgery Centre) |
| VIC | SJOG Ballarat |
| VIC | SJOG Bendigo |
| VIC | SJOG Berwick |
| VIC | SJOG Geelong |
| VIC | SJOG Warrnambool |
| VIC | Stonnington Day Surgery |
| VIC | The Alfred Hospital |
| VIC | The Bays Hospital |
| VIC | The Royal Women's Hospital |
| VIC | Western Private Hospital |
| VIC | Windsor Private Hospital |
| VIC | Wyndham Clinic Private Hospital |
| WA | Bethesda Hospital |
| WA | Bunbury Day Surgery |
| WA | Cambridge Day Surgery |
| WA | Colin Street Day Surgery |
| WA | Concept Fertility Centre and Day Hospital |
| WA | Royal Perth Hospital |
| WA | SJOG Bunbury |
| WA | SJOG Geraldton |
| WA | SJOG Mt Lawley |
| WA | SJOG Murdoch |
| WA | SJOG Subiaco |
| WA | SJOG Wembley Day Surgery |
| WA | Subiaco Private Hospital |
| WA | Waikiki Private Hospital |

Seven additional sites, not listed in the above table, have approval to submit data to the ABDR but are not currently performing device work.

MONASH
University

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