MONASH University

AUSTRALIAN BREAST DEVICE REGISTRY

2017 REPORT

AUSTRALIAN Breast Device REGISTRY

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Data Period

The data contained in this document were extracted from the ABDR on 30 April 2018 and pertains to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 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 Australian Breast Device Registry is supported by funding from the Australian Government Department of Health.

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FOREWORD

It is our pleasure to introduce the Australian Breast Device Registry (ABDR) 2017 Annual Report.

The ABDR has made great strides in a relatively short space of time. What started as a small 'proof of concept' pilot in 2012 has become a successful clinical quality registry recording data on over 25,000 patients receiving breast device surgery. Now, through the ABDR, Australia is becoming one of the world leaders in breast device registry science.

Data in this report highlight the ongoing progress of the ABDR and the commitment of clinical stakeholders to patient safety and best practice. We are excited to see the growing list of contributing surgeons and hospitals across all states and territories. In this annual report we see the beginning of long-term outcomes with different procedures, and as the registry dataset matures, we will have information about the performance of specific devices. High quality, validated data are essential for this, and the ABDR worked hard in 2017 on a focused campaign to improve the quality of the data reported by clinicians.

An important role of the registry is to provide feedback to surgeons to enable them to assess their individual performance, with the intent of targeting improvement in healthcare delivery. During 2017 the ABDR team worked with a diverse team of clinicians and collaborators, both Australian and international, to agree on a set of clinical quality indicators which can be used to assess outcomes in breast device surgery. Clinician involvement ensures that these measures are relevant and meaningful, and will provide real opportunities for quality improvement. We expect to see the start of clinician-level reporting in 2018.

Another significant initiative undertaken in 2017 included pilot studies on the BREAST-Q Implant Surveillance module, a patient reported outcome measure developed in association with the BREAST-Q team. This brief 5-question survey is administered innovatively by text message, and was selected as one of the clinical quality indicators. We hope that it will enable early detection of problems with breast devices, as well as provide insights on patients' perspectives on the results of their surgery.

We have also seen strengthening of our international collaborations, with a successful meeting at Monash Prato campus in Italy of the International Collaboration of Breast Registry Activities (ICOBRA), and substantial work towards an internationally harmonised dataset to identify potential device safety issues earlier. We are also very proud to see our associated research output.

We would like to take this opportunity to thank all those involved in this annual report, and acknowledge the work of the ABDR Project Team towards national rollout of the registry, and a body of work that strengthens the potential of the ABDR to answer the most pressing clinical questions in breast device surgery. The ABDR is grateful for the initial support of the Australasian Foundation for Plastic Surgery and the continued support of the Commonwealth Department of Health which provides funding for the activities of the registry. We also gratefully acknowledge the contribution of surgeons, theatre staff, consulting room staff and hospital administrators, without whom the ABDR would not have made such a successful start and without whom it could not continue to function.

Finally, our biggest thanks go to the patients who allow us to retain their data. They recognise the personal value of participating in this important safety and quality initiative for their own health, but also the opportunity to contribute to the broader knowledge base that will support individuals undergoing this surgery in the future.

Australian Society *of* Plastic Surgeons

Breast Surgeons of Australia & New Zealand

Professor Rodney Cooter, MD, FRACS, ASPS

Associate Professor Colin Moore, FRACS, ACCS

Associate Professor Elisabeth Elder, PhD, FRACS, BreastSurgANZ

ACKNOWLEDGEMENTS

The ABDR was initially funded by the Australasian Foundation for Plastic Surgery and receives ongoing funding from the Commonwealth Department of Health with in-kind support from Monash University. The registry is operated by the Department of Epidemiology and Preventive Medicine, Monash University, and is endorsed by major surgical societies in Australia.

We gratefully acknowledge the contributions made by the ABDR steering committee, ABDR clinical quality committee, and ABDR management committee. We acknowledge the leadership of Professor John McNeil who is the chair of the steering committee, and Dr Ingrid Hopper who is project lead and data custodian. We would like to acknowledge the contributions of the ABDR project team (Full list on page 43) and the Registry Sciences Unit (RSU) including Associate Professor Susannah Ahern, Associate Professor Arul Earnest and Breanna Pellegrini.

We also gratefully acknowledge the dedication of the steering committee members, including the clinical leads Professor Rodney Cooter representing Australian Society of Plastic Surgeons (ASPS), Associate Professor Elisabeth Elder, Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ) and Associate Professor Colin Moore, Australasian College of Cosmetic Surgery (ACCS). Also Pamela Carter, Therapeutic Goods Administration (TGA), Cindy Schultz Ferguson, Consumers Health Forum of Australia (CHF), Andrea Kunca, Medical Technology Association of Australia (MTAA), Suzanna Henderson, Australian Commission on Safety and Quality in Healthcare (ACSQHC) and Michelle Hillard, Australian Government Department of Health (as observer only).

Dr Ingrid Hopper is supported by a National Health and Medical Research Council Fellowship which provides salary support to contribute to initiatives such as the ABDR.

This work would not have been possible without the ongoing efforts of the many doctors, nurses and other hospital staff who contribute data to the ABDR, including surgeons who act as Principal Investigator for their site. We would like to thank them for their commitment. We would also like to thank the patients who allow the ABDR to retain their data and recognise the importance of the ABDR.

This report was subject to critical review prior to publication. We thank the members of the committee who were involved in the review meeting and subsequent draft review, including individuals representing Monash University (ABDR and RSU), the three surgical societies (ACCS, ASPS, BreastSurgANZ), TGA, CHF and Australian Government Department of Health.

We also acknowledge our international collaborators through the International Collaboration of Breast Registry Activities (ICOBRA), including Babette Becherer, Andy Crosbie, Howard Klein, David Lumenta, Danica Marinac-Dabic, Marc Mureau, Graeme Perks, Andrea Pusic, Hinne Rakhorst, Pauline Spronk, Birgit Stark and Uwe von Fritschen.

Our goal is to foster continuous improvement in patient care and outcomes across the entire Australian health system.

EXECUTIVE SUMMARY

The ABDR was established in 2015 with the primary goal of monitoring the long-term safety and performance of implanted breast devices and to improve patient outcomes. It is funded by the Australian Government Department of Health, and has 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.

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 17 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 at various time-points in each patient's journey - surgical data at initial implant and/or future revision of a breast device, and patient reported data at one, two, five and ten years following the initial surgery ; 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 devices and the associated surgery, 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 is a founding member of the International Collaboration of Breast Registry Activities (ICOBRA) which serves to harmonise and amplify data with international collaborators.

The ABDR is currently in the process of determining case ascertainment rates. While we hope that the data from the registry will reflect national trends, it is not yet confirmed that we have population coverage. As the registry matures and case capture increases, the data reported to the registry will reflect national trends.

Key findings and highlights from the 2017 Annual Report.

- This report contains the most comprehensive dataset of breast device registry activity to date and represents surgeons and sites from all Australian states and territories.
- The national rollout of the registry is well underway with an increase in participation of sites (242), surgeons (430), and patients (25,386) since the end of 2016.
- The procedures captured in the 2017 calendar year (13,388) increased by 41% compared to the 2016 calendar year procedures (9,520) reflecting the increase in site and surgeon participation in the registry.
- Data from reconstruction surgery is further broken down and analysed in the categories of 'risk reducing' and 'post-cancer' cohorts separately, made possible by the increase in the number of procedures captured by the ABDR in 2017.
- The Patient Reported Outcome Measure (PROMs) pilot study was completed, and the PROMs national rollout was commenced.
- An initiative was undertaken to improve data completeness by sites and surgeons. Sites were notified of data completeness rates and additional training was provided during site visits resulting in an increase in the accuracy and rate of data capture in the data collection forms.

We are excited to see the growing list of contributing surgeons and hospitals across all states and territories.

INTRODUCTION

The ABDR is a clinical quality registry, established in 2015 following an Australian Senate enquiry into problems with Poly Implant Prosthèse breast devices (1). The ABDR was established to enhance the long term safety and performance monitoring of implanted breast devices and improve patient outcomes.

Now in its third year of operation, the ABDR reports on breast implants, tissue expanders and acellular dermal/synthetic matrices for use in breast augmentation, breast reconstruction, correction of developmental deformity, and on explantation of breast devices. Recording the full patient journey including revision and explantation is imperative to track device performance. Clinicians contribute data from public and private hospitals across all states and territories of Australia. In 2017 the ABDR commenced collection of patient reported outcome measures (PROMs).

The design and implementation of the ABDR complies with 'Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008)' which was developed by the Australian Commission on Quality and Safety in Health Care (ACQSHC), in collaboration with the states and territories, and expert registry groups. The Australian Health Ministers' Advisory Council (AHMAC) endorsed the framework in 2014. This provides assurance to all key stakeholders that the registry satisfies minimum security, technical and operating standards.

Alfred Hospital Ethics Committee approved the ABDR on 20 April 2015, followed in subsequent years by a further 17 HRECs from across all Australian jurisdictions.

Registry governance

The ABDR governance has been described in detail in the previous annual report (2). ABDR conforms to the ACQSHC National Operating Principles for Clinical Quality Registries.

In 2017 the ABDR updated terms of reference for the Steering and Clinical Quality Committees to reflect a clearer distinction between the committees in relation to monitoring safety and quality and to incorporate a statement outlining the responsibilities of Steering Committee members. The stakeholder groups represented within the Steering Committee did not change in 2017, although there were some personnel changes.

Steering committee

The Steering Committee (SC) comprises representatives from stakeholder groups and the Monash University Department of Epidemiology and Preventive Medicine. It meets three times per year to oversee the registry's strategic direction, delivery of contractual obligations and overall financial viability.

In 2017 the SC welcomed Associate Professor Susannah Ahern of the Monash Registry Sciences Unit as a permanent member.

Clinical quality committee

The Clinical Quality Committee (CQC) was convened for the first time in 2017, and met three times. Membership included clinical leads and project lead. The CQC was active in reviewing data quality, reviewing the minimum dataset, and guiding development of data definitions, clinical quality indicators and risk adjustment factors. The committee also provided guidance towards developing surgeon reports.

Management committee

The Management Committee continued to meet monthly throughout 2017, to oversee day-to-day operations of the registry, set long-term priorities, and ensure key milestones were met, particularly in regards to the ongoing national roll out of the ABDR. Membership included clinical leads, the project lead and the head of Monash SPHPM. Clinical leads were responsible for updating their society/college on progress with the ABDR rollout.

Surgeon and site recruitment

The ABDR has been endorsed by ASPS, ACCS and BreastSurgANZ, and they support and 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.

There are many benefits to surgeons contributing to the ABDR. These include the ability to track patients, and breast devices that have been inserted. We are working towards outcomes benchmarking, so that these data can be used to inform sites and surgeons about their own outcomes, which can be used to support continuous service improvement and for site accreditation against the national standards, ensuring patients receive the highest quality care. Participation in the registry can be used for the award of Continuous Medical Education (CME). Contributors are also encouraged to use a logo demonstrating that they are contributing to the ABDR on their website or in their practice.

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.

Registry reporting

This is the second report published by the ABDR and incorporates data for surgeries taking place between the start of the pilot project (March 2012) and 31 December 2017. These data were extracted from the ABDR database on 30 April 2018, to account for the known lag between a surgical intervention occurring and its subsequent capture in the ABDR.

Surgeon-level reporting will commence in 2018, with site-level reporting expected to follow soon after.

The ABDR publishes three e-newsletters annually to report on progress with the registry and with breast registry science in general. Newsletters are emailed to a variety of stakeholders, including surgeons, consulting room and theatre staff, hospital administrators, funders, and industry representatives.

REGISTRY PARTICIPATION

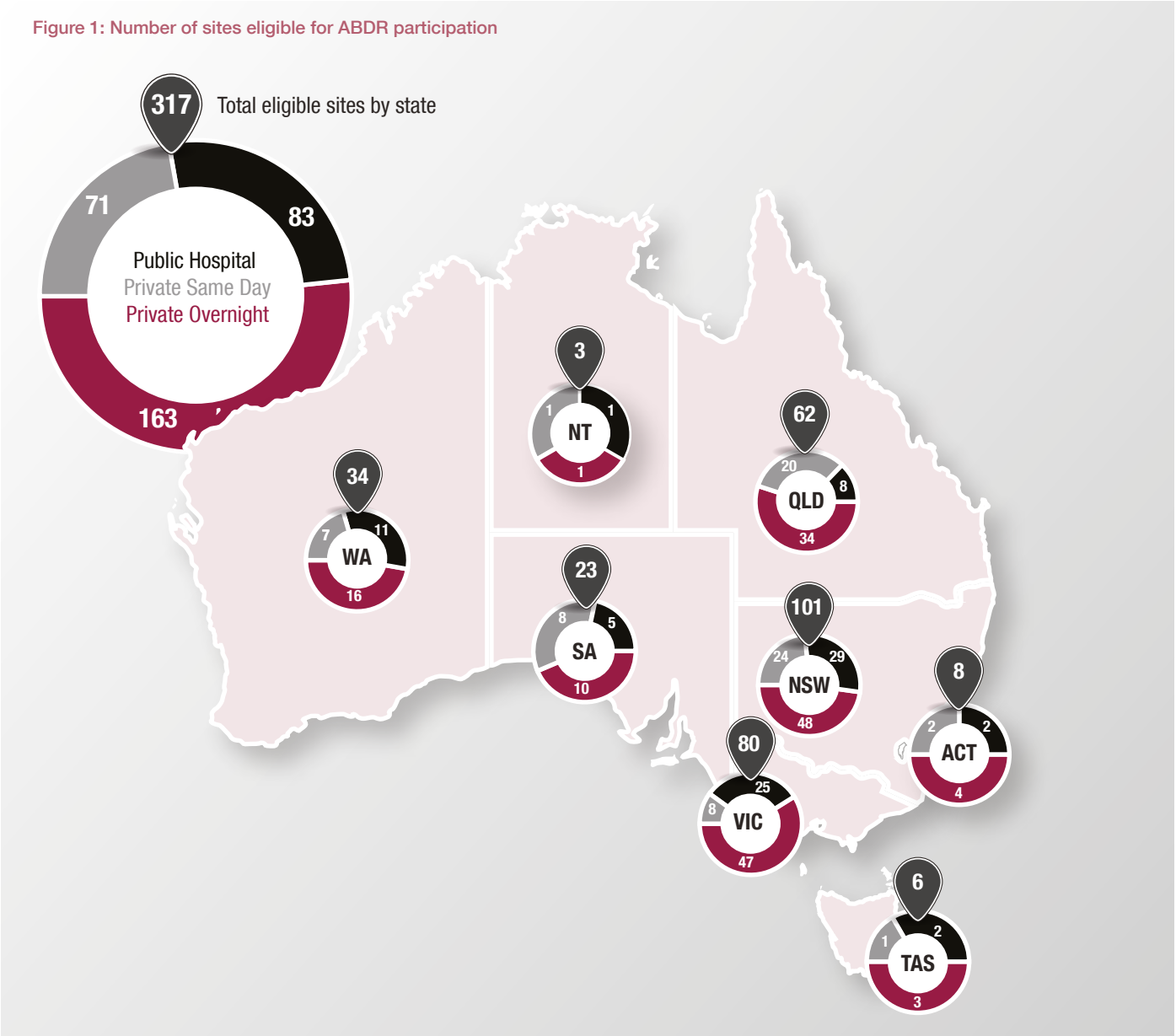
Site participation

The ABDR continues to engage eligible sites Australia-wide to contribute data to the registry. An **eligible** site is defined as a site currently undertaking breast device surgery as identified by ICD-10-AM[1] coding data provided by the Australian Government Department of Health (data provided Oct 2015) or as reported by external sources (internet search, surgeons or site staff).

The number and classification of eligible sites per state are shown in Figure 1. The total number of currently eligible sites is estimated at 317, decreasing by 4 from 2016 due to sites ceasing breast device surgery or closing down. Approximately 77% of eligible sites are located in New South Wales, Queensland and Victoria and 51% of eligible sites are Private Overnight sites.

The list of eligible sites is dynamic and updated regularly based on information obtained from surgeons and site staff, and information gleaned from internet search engines and websites.

Figure 1: Number of sites eligible for ABDR participation



The ABDR maintains a 'watch list' of sites identified as having the potential to undertake occasional breast device surgeries or commence a regular list. The ABDR team update these lists regularly based on information obtained from surgeons and site staff.

1. International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (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 2017, 73% (231) of eligible sites were participating in the ABDR (Table 1). The total number of participating sites throughout 2017 was 242, including 11 sites that by the end of 2017 were classified as closed or no device sites.

New South Wales, Queensland and Victoria continue to have the greatest number of participating sites (76%), reflecting the higher concentration of providers in these states (Table 1 and Figure 2). Data have been collected predominantly from private overnight facilities (55%) and private same day facilities (23%) (Figure 3). Of the 242 participating sites, 229 are actively contributing data. The remaining 13 have received ethics and governance approval but have either not contributed data in the reporting period or are considered to not routinely perform breast device surgery.

Table 1: Site engagement by state at 31st December 2017

State/ Territory	Number of closed sites	Number of sites not performing device surgery	Number of eligible sites	Participating sites		Sites in progress	Engagement of eligible sites *
				Implemented sites	Sites represented by surgeons contributing		
NSW	2	41	101	45	21	35	65%
VIC	3	19	80	50	9	21	74%
QLD	2	11	62	35	16	11	82%
WA	0	11	34	14	5	15	56%
SA	0	7	23	21	0	2	91%
ACT	0	0	8	5	1	2	75%
TAS	0	1	6	6	0	0	100%
NT	0	4	3	3	0	0	100%
TOTAL	**7**	**94**	**317**	**179**	**52**	**86**	**73%**

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

Figure 2: Site participation by state (n=242)

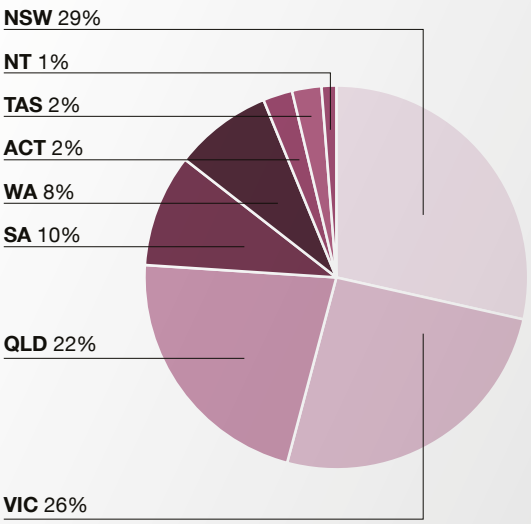
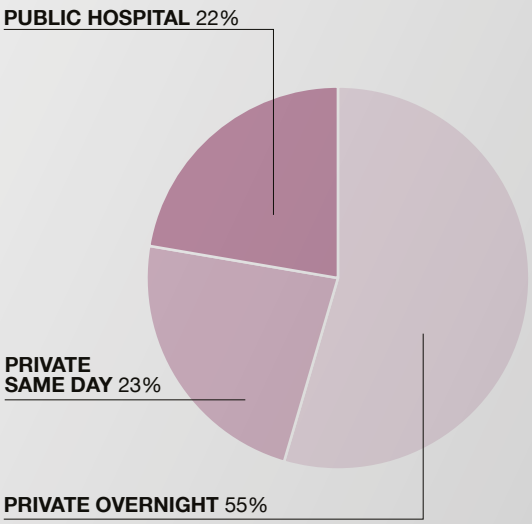


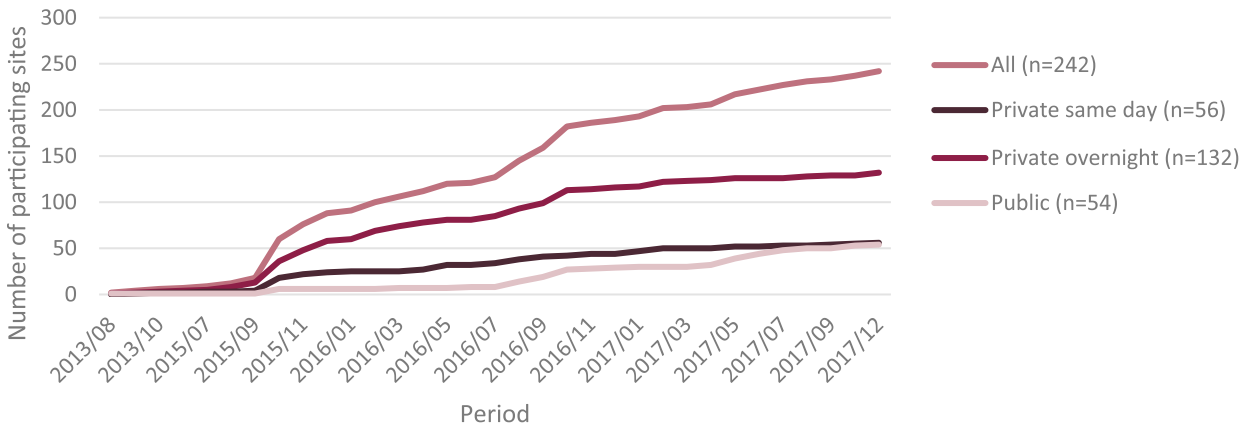
Figure 3: Site participation by site type (n=242)



Timeline of site participation

The number of participating sites continues to increase steadily since inception of the ABDR in April 2015 (Figure 4) after a pilot study was conducted involving seven sites. At the end of 2017, a total of 242 sites were participating.

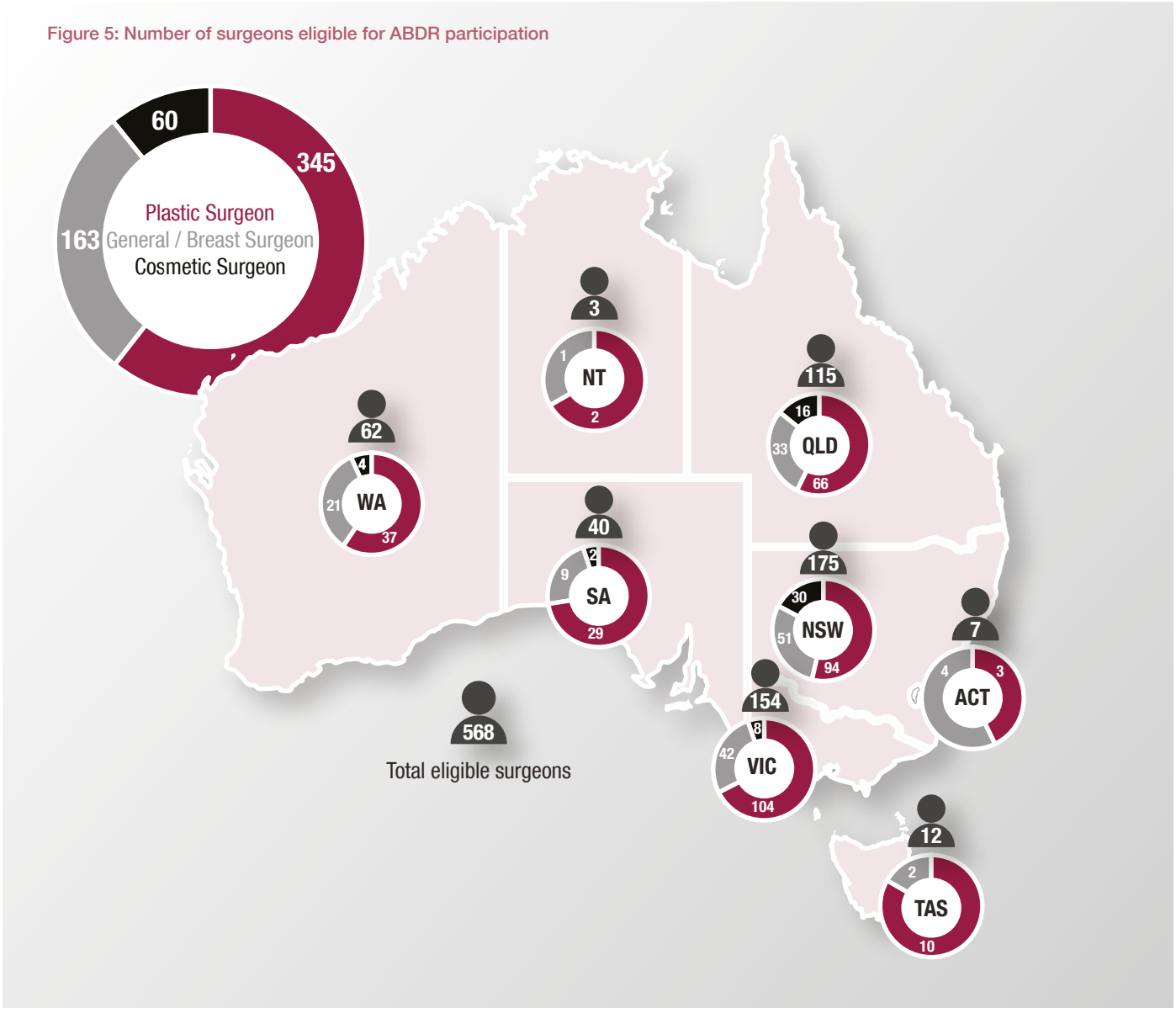
Figure 4: Cumulative participating ABDR sites by site type (n=242)



Surgeon participation

Surgeons eligible to participate in the ABDR were initially 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 where breast device procedures are undertaken, and further confirmed through internet search engines and networking sites. At 31 December 2017, a total of 568 surgeons were identified as undertaking breast device procedures (Figure 5). An additional 84 surgeons were identified not currently undertaking breast device procedures but having capacity to do so in the future. The ABDR communicates with these 'no device' surgeons regularly to confirm their status. The objective of the ABDR is to have all surgeons who insert or explant breast devices participate in the registry.

Figure 5: Number of surgeons eligible for ABDR participation



Note: The number of participating surgeons includes surgeons that contributed data to the ABDR but are now retired. These surgeons are not included in figures for 'surgeons eligible for participation' (Figure 5) resulting in a greater number of surgeons participating than eligible in some states.

A wide-ranging group of clinicians participate in the ABDR. At 31 December 2017, 430 individual surgeons were participating in the ABDR including 295 plastic surgeons, 93 general/breast surgeons and 42 cosmetic surgeons. Participating surgeons are principally from New South Wales, Victoria, and Queensland (Figure 6). Plastic surgeons are the largest participating group, comprising 68% of participating surgeons (Figure 7)

Of the 430 participating surgeons, 395 currently contribute data on a regular basis with the remaining 35 surgeons awaiting final ethics or governance approval for their operating sites.

Figure 6: Surgeon participation by state (n=430)

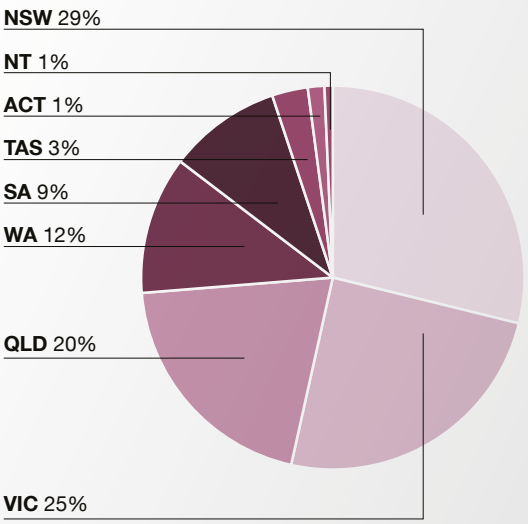
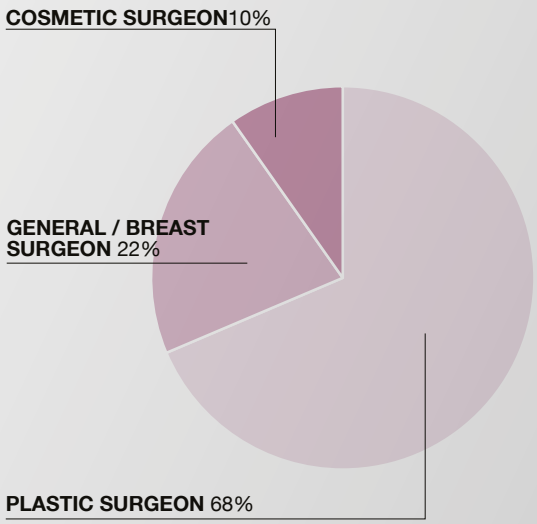


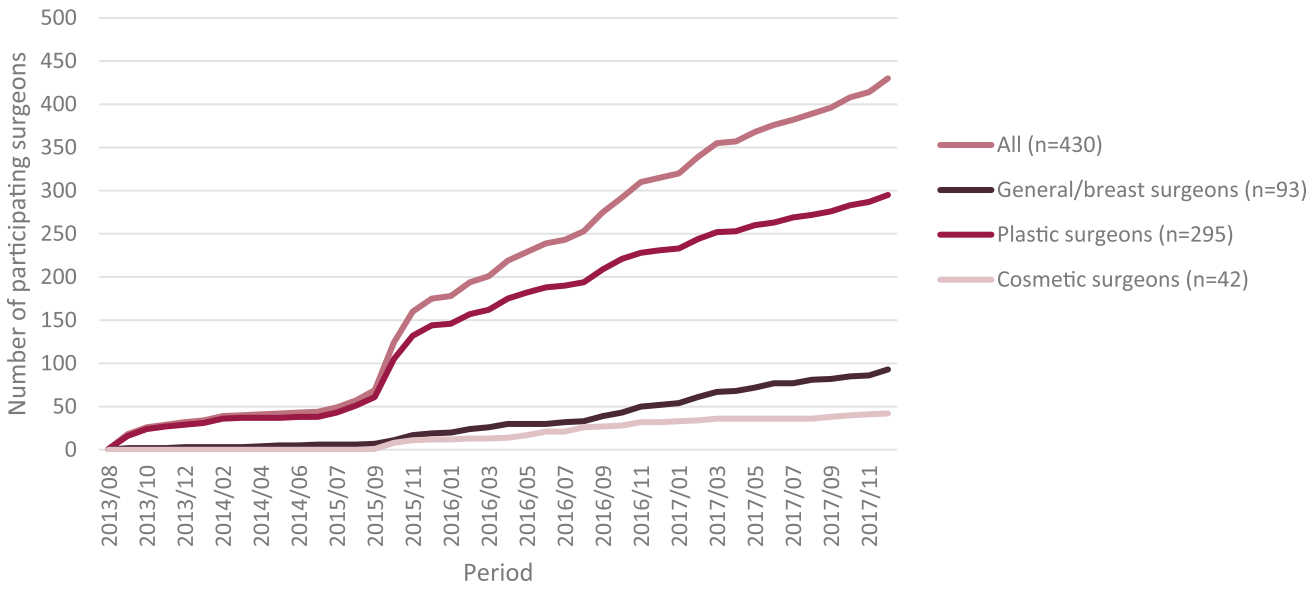
Figure 7: Surgeon participation by craft group (n = 430)



Timeline of surgeon participation

Figure 8 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 8: Cumulative participating ABDR surgeons by craft group (n=430)

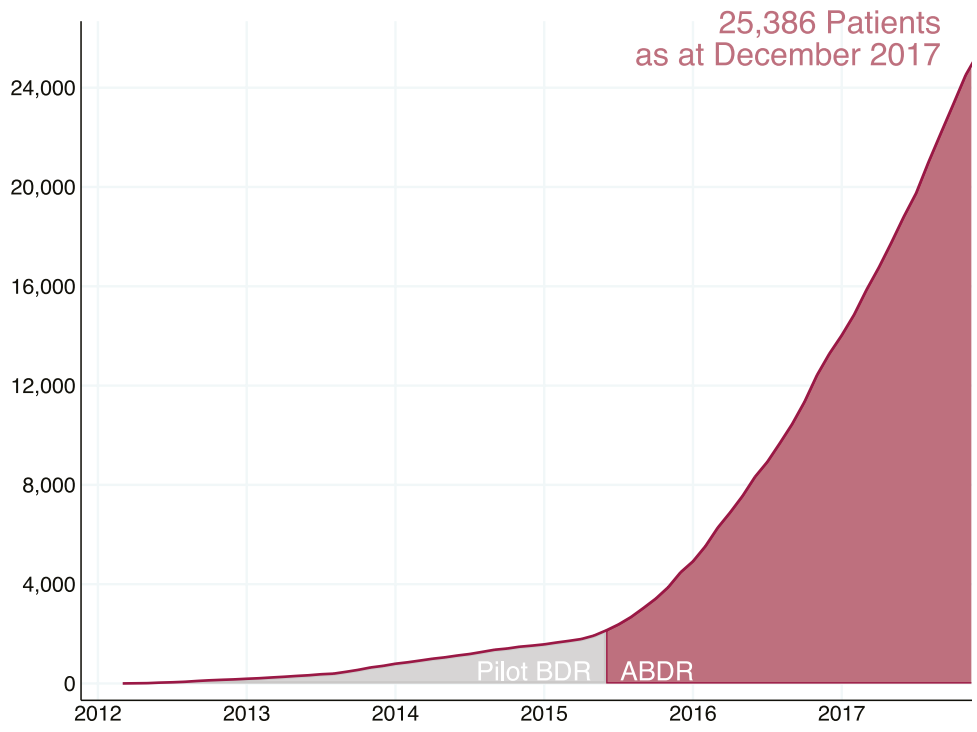


Patient recruitment

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.

As at December 2017, 25,386 patients were participating in the ABDR, an addition of 12,367 in 2017, and the accumulation rate reflects a steady rise over the last two years of the reporting period (Figure 9). The patient opt-out rate was 0.99%. 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 are not included in the reported figures.

Figure 9: Number of patient registrations (2012-2017)

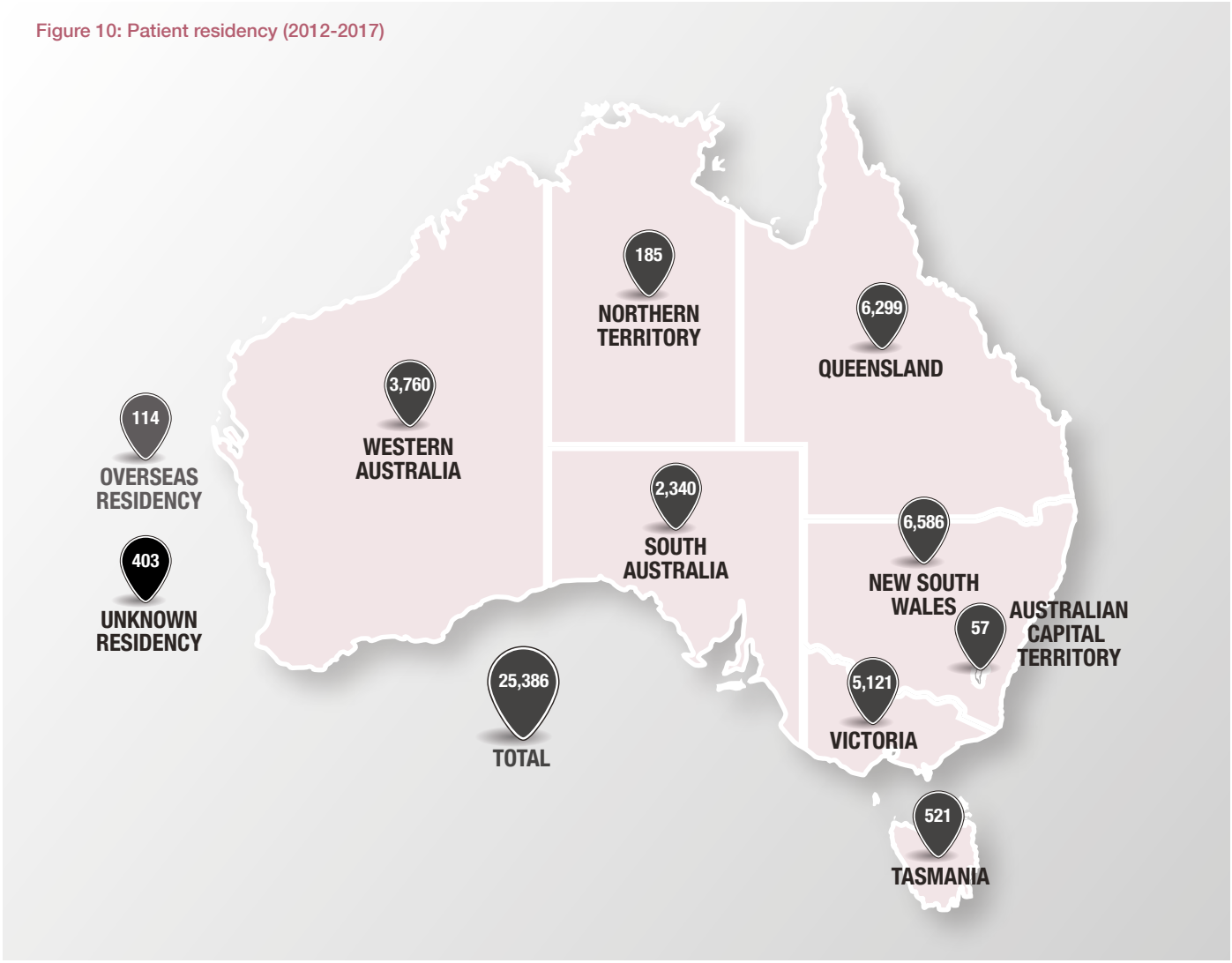


REGISTRY OUTPUTS

Patient cohort, age and residency

As at December 2017, 25,386 patients were enrolled in the ABDR database. Patients predominately were residents in New South Wales (26%), Queensland (25%), Victoria (20%) and Western Australia (15%, Figure 10).

Figure 10: Patient residency (2012-2017)



Notes: Patients with unknown residency are those who have elected email as the form of correspondence.

Patients were assigned to cohorts based on the reason for their first procedure as indicated on the Data Collection Form submitted by surgeons and subsequently recorded in the ABDR database (Table 2). Where the first operation was bilateral but different procedures were undertaken on each breast, a four-tier hierarchy of reason beginning with post-cancer reconstruction, followed by risk reducing reconstruction, developmental deformity and then cosmetic augmentation was used to classify the patients into cohorts. For example, a patient with a bilateral procedure with post-cancer reconstruction on one side, and cosmetic augmentation on the other side would be classified into the post-cancer reconstruction cohort based on this hierarchy of reason for procedure.

Of the 25,386 patients in the ABDR, 75% entered the registry as cosmetic augmentation patients, 15% as post-cancer reconstruction patients, 4% as risk reducing reconstruction patients, 2% to correct for developmental deformity and 4% entered the registry for reasons that were not stated and therefore could not be assigned to a patient cohort.

Table 2: Patient cohort (2012-2017)

Patient cohort	N	(%)
Cosmetic augmentation	19,014	(74.9%)
Post-cancer reconstruction	3,795	(14.9%)
Risk reducing reconstruction	969	(3.8%)
Developmental deformity	643	(2.5%)
Not stated	965	(3.8%)
TOTAL	**25,386**	**(100%)**

Notes: Patients were assigned to cohorts based on the reason for their first procedure recorded in the ABDR.

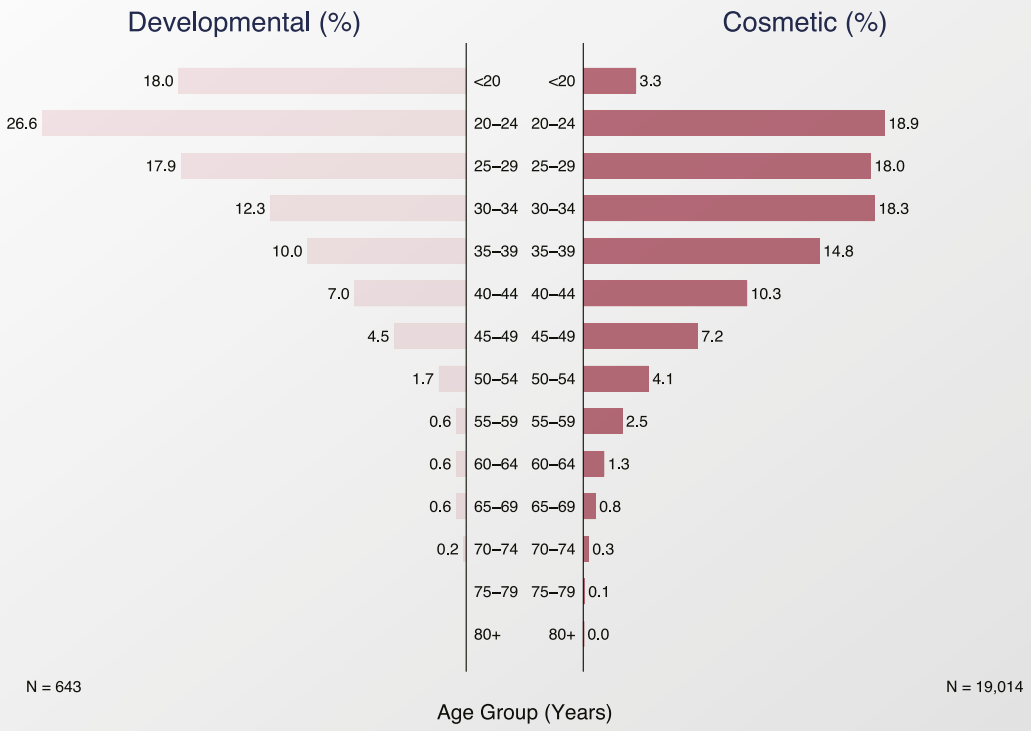
The age distribution of patients when first registered by the ABDR differs by patient cohort (Figure 11). Patients who entered the registry for developmental deformity and cosmetic augmentation were younger than those patients who entered for reconstruction (both post-cancer and risk reducing cohorts). The median patient age for the developmental deformity cohort was 26 years compared with 33 years for the cosmetic augmentation cohort, 42 years for risk reducing reconstruction patients and 51 years for post-cancer reconstruction patients (Table 3).

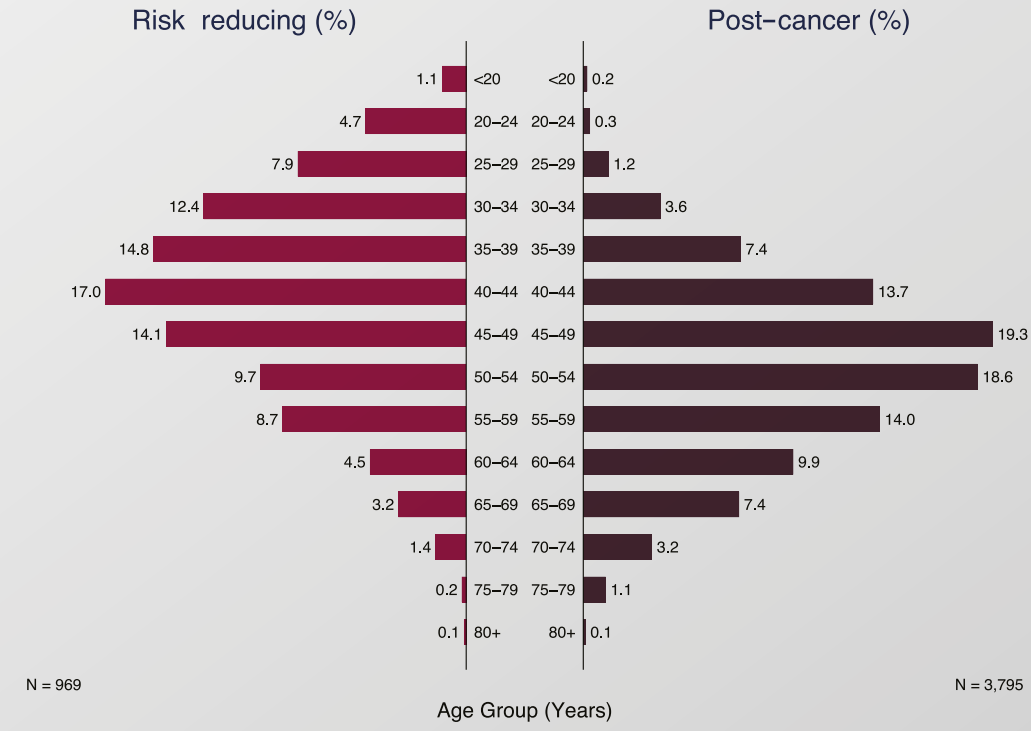
Table 3: Patient age by patient cohort (2012-2017)

Patient age	Developmental deformity	Cosmetic augmentation	Risk reducing reconstruction	Post-cancer reconstruction
N	643	19,014	969	3,795
Mean age (SD)	29.1 (10.1)	34.4 (10.8)	43.3 (12.1)	51.6 (10.5)
Median (IQR)	26.3 (21.3, 35.3)	32.7 (25.8, 40.7)	42.4 (34.5, 51.8)	51.1 (44.6, 58.8)

Notes: SD – Standard Deviation. 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 range from the observation at the 25th percentile to the observation at the 75th percentile is referred to as the IQR. An observation at the 50th percentile corresponds to the median value.

Figure 11: Patient age distribution by patient cohort (2012-2017)





Type and frequency of procedures

A total of 13,388 surgical procedures involving breast devices were recorded by the ABDR in 2017 (Figure 12). This is a 41% increase from the 9,520 procedures recorded by ABDR in 2016. Of the procedures performed in 2017, 88% (11,723) were performed bilaterally and 12% (1,665) were performed unilaterally. The reasons for the unilateral and bilateral procedures performed are detailed in Tables 4 and 5. In 2017, the most common reason to undergo a unilateral procedure was post-cancer reconstruction (67%, Table 4), and the most common bilateral procedure was cosmetic augmentation (82%, Table 5).

Figure 12: Number of procedures recorded in ABDR (2012-2017)

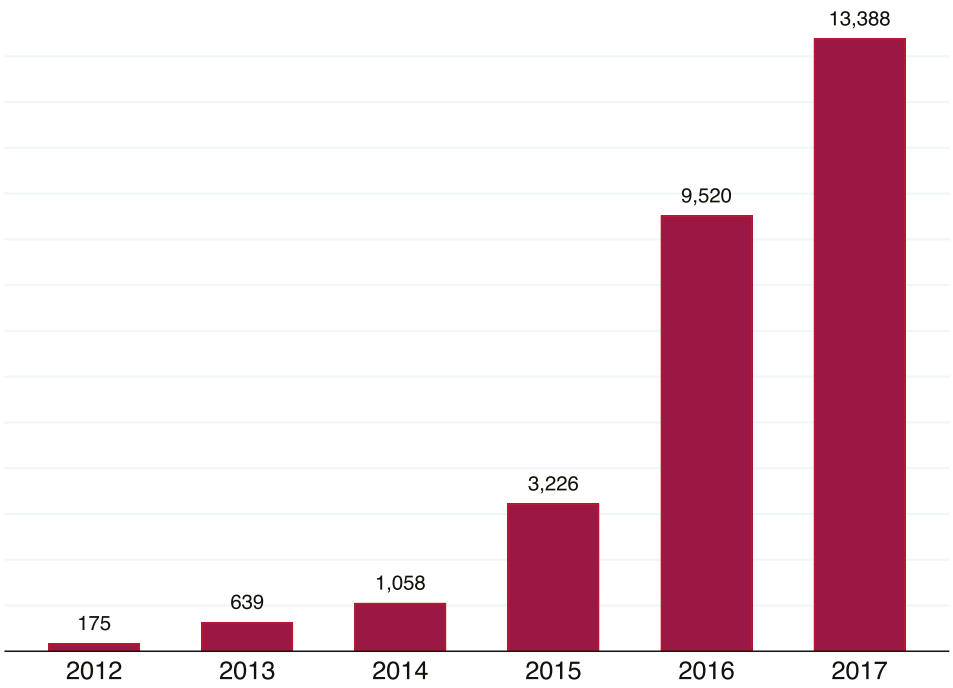


Table 4: Unilateral procedure type

Reason for unilateral procedures	TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
	N	(%)	N	(%)	N	(%)
Post-cancer reconstruction	2,584	(67.3%)	675	(62.2%)	1,115	(67.0%)
Cosmetic augmentation	537	(14.0%)	188	(17.3%)	236	(14.2%)
Risk reducing reconstruction	275	(7.2%)	86	(7.9%)	118	(7.1%)
Developmental deformity	192	(5.0%)	53	(4.9%)	83	(5.0%)
Reason not stated	252	(6.6%)	84	(7.7%)	113	(6.8%)
TOTAL	**3,840**	**(100%)**	**1,086**	**(100%)**	**1,665**	**(100%)**

Table 5: Bilateral procedure type

Reasons for bilateral procedures	TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
	N	(%)	N	(%)	N	(%)
Cosmetic augmentation - both sides	19,081	(79.0%)	6,807	(80.7%)	9,614	(82.0%)
Post-cancer reconstruction - both sides	1,455	(6.0%)	413	(4.9%)	589	(5.0%)
Risk reducing reconstruction one side & post-cancer reconstruction the other side	1054	(4.4%)	329	(3.9%)	454	(3.9%)
Risk reducing reconstruction - both sides	992	(4.1%)	343	(4.1%)	398	(3.4%)
Developmental deformity - both sides	443	(1.8%)	162	(1.9%)	150	(1.3%)
Post-cancer reconstruction one side & cosmetic augmentation the other side	166	(0.7%)	49	(0.6%)	69	(0.6%)
Developmental deformity one side & cosmetic augmentation the other side	80	(0.3%)	22	(0.3%)	21	(0.2%)
Other combinations	34	(0.1%)	15	(0.2%)	16	(0.1%)
Reason not stated - both sides	861	(3.6%)	294	(3.5%)	412	(3.5%)
TOTAL	**24,166**	**(100%)**	**8,434**	**(100%)**	**11,723**	**(100%)**

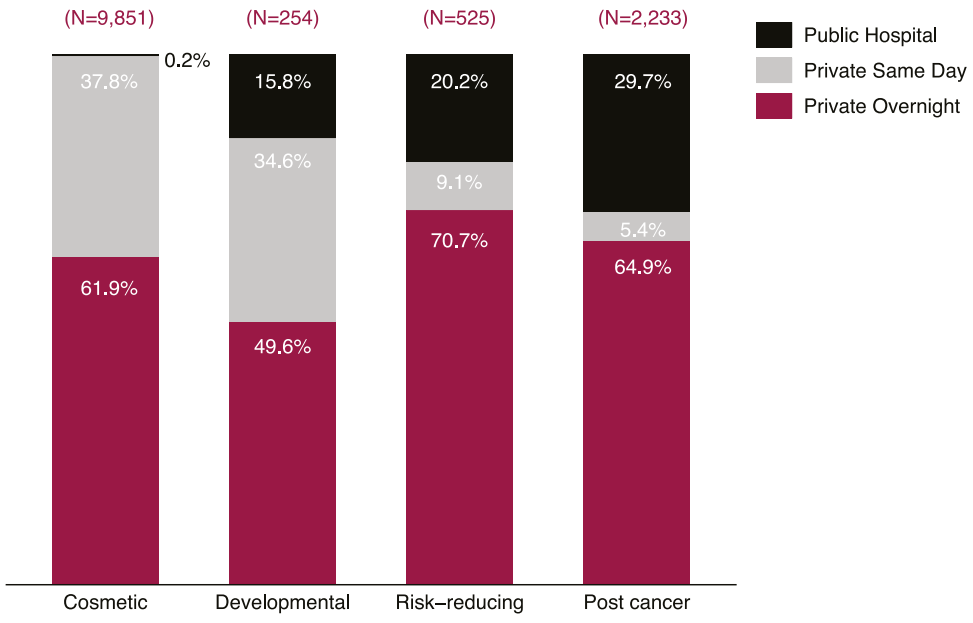
Procedure site characteristics

The majority of procedures captured by ABDR were performed in the private healthcare setting (Table 6). Almost two-thirds of procedures in 2017 were reported in private overnight hospitals (63%) compared with same day private facility (31%, Table 6). Procedures captured at public hospitals were infrequent, although higher in 2017 (6%) compared to 2016 (3%, Table 6). Reconstruction procedures in 2017 were most likely to occur in a private overnight facility (risk reducing 71%; post-cancer 65%) followed by public facilities (risk reducing 20%; post-cancer 30%) and then private same day facilities (risk reducing 9%; post-cancer 5%) (Figure 13). Whereas a higher proportion of cosmetic and developmental procedures in 2017 occurred in private same day facilities and fewer in public facilities (Figure 13).

Table 6: Procedures reported by site type

Site Type	TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
	N	(%)	N	(%)	N	(%)
Private Overnight	18,083	(64.6%)	6,457	(67.8%)	8,380	(62.6%)
Private Same Day	8,674	(31.0%)	2,806	(29.5%)	4,122	(30.8%)
Public Hospital	1,249	(4.5%)	257	(2.7%)	886	(6.6%)
TOTAL	**28,006**	**(100%)**	**9,520**	**(100%)**	**13,388**	**(100%)**

Figure 13: 2017 Site type by reason for procedure



Note: N = number of procedures in 2017. Procedures with a reason not stated were excluded.

Intraoperative techniques

The ABDR collects data on intraoperative techniques used by contributing surgeons to identify current practice in surgical techniques, and to determine their association with patient outcomes. More than one intraoperative technique can be used and recorded per procedure. In procedures recorded in 2017 compared to 2016, there was similar use of intraoperative and post-operative antibiotics, antiseptic rinse and antibiotic dipping solution (Table 7). Usage of surgeon glove change and sleeve/funnel was more common during 2017 procedures compared to 2016 procedures (Table 7).

Table 7: Intraoperative techniques (2016 and 2017)

Intraoperative techniques	TOTAL ABDR (2012-2017) N = 28,006		ABDR 2016 N = 9,520		ABDR 2017 N = 13,388	
	N	(%)	N	(%)	N	(%)
Intraoperative prophylactic antibiotics only	3,357	(12.0%)	1,269	(13.3%)	1,935	(14.5%)
Post-op antibiotics only	540	(1.9%)	207	(2.2%)	221	(1.7%)
Both intra-op and post-operative antibiotics*	20,549	(73.4%)	6,710	(70.5%)	9,728	(72.7%)
Antiseptic rinse	21,363	(76.3%)	7,049	(74.0%)	10,620	(79.3%)
Glove change for insertion	17,564	(62.7%)	5,467	(57.4%)	9,088	(67.9%)
Antibiotic dipping solution	14,213	(50.7%)	4,923	(51.7%)	7,153	(53.4%)
Sleeve/funnel	6,566	(23.4%)	1,889	(19.8%)	4,106	(30.7%)
Not stated	2,489	(8.9%)	940	(9.9%)	1,061	(7.9%)

Notes: More than one intraoperative technique can be used and recorded per procedure.
*Includes procedures where the pilot data collection form field "Administered prophylactic antibiotics" was selected.

Characteristics of devices

The ABDR captures information about breast devices used during procedures in Australia. Information is collected about breast implants, tissue expanders and also acellular dermal/synthetic matrix. Table 8a and 8b provide device shell, fill and shape characteristics for breast implants and tissue expanders inserted during an insertion procedure or a replacement revision procedure. Of the breast implants inserted during 2017, 74% had a textured device shell, 21% had a smooth shell and 5% a polyurethane shell (Table 8a). In 2017, the TGA advised the removal of polyurethane implants from the market (3), reflected by the low percentage of use captured by the ABDR.

Almost all inserted and replaced tissue expanders had a textured device shell (Table 8b). Silicone was the most common device fill for breast implants (99% in 2017, Table 8a) whereas saline was the most common device fill for tissue expanders (88% in 2017, Table 8b). Round implants had higher uptake than anatomical shaped implants (63% vs 37% in 2017, Table 8a), whereas almost all tissue expanders inserted and replaced were anatomical shape (Table 8b). Refer to Appendix 3 for a more detailed breakdown of device characteristics.

Table 8a: Device characteristics – Breast implants

Device characteristics BREAST IMPLANTS		TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
		N	(%)	N	(%)	N	(%)
Device Shell	Textured	35,744	(74.7%)	12,153	(72.8%)	17,238	(74.5%)
	Smooth	9,380	(19.6%)	3,401	(20.4%)	4,814	(20.8%)
	Polyurethane	2,700	(5.6%)	1,139	(6.8%)	1,086	(4.7%)
	Not stated	26	(0.1%)	8	(<0.1%)	0	(0.0%)
Device Fill	Silicone	47,199	(98.6%)	16,433	(98.4%)	22,895	(98.9%)
	Saline	509	(1.1%)	223	(1.3%)	185	(0.8%)
	Silicone/Saline*	116	(0.2%)	37	(0.2%)	58	(0.3%)
	Not stated	26	(0.1%)	8	(<0.1%)	0	(0.0%)
Device Shape	Round	28,859	(60.3%)	9,889	(59.2%)	14,658	(63.4%)
	Anatomical	18,965	(39.6%)	6,804	(40.7%)	8,480	(36.6%)
	Not stated	26	(0.1%)	8	(<0.1%)	0	(0.0%)

Notes: Device characteristics are reported for all new devices captured during an insertion procedure or a replacement revision procedure.
*Device fill 'Silicone/Saline' category comprises permanent expanders which have been classified as breast implants.

Table 8b: Device characteristics – Tissue expanders

Device characteristics TISSUE EXPANDERS		TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
		N	(%)	N	(%)	N	(%)
Device Shell	Textured	3,036	(99.8%)	879	(100.0%)	1,234	(99.6%)
	Smooth	5	(0.2%)	0	(0.0%)	5	(0.4%)
Device Fill	Saline	2,754	(90.6%)	763	(86.8%)	1,087	(87.7%)
	Carbon dioxide	287	(9.4%)	116	(13.2%)	152	(12.3%)
Device Shape	Round	10	(0.3%)	7	(0.8%)	3	(0.2%)
	Anatomical	3,031	(99.7%)	872	(99.2%)	1,236	(99.8%)

Notes: Device characteristics are reported for all new devices captured during an insertion procedure or a replacement revision procedure.

The ABDR reports when acellular dermal/synthetic matrices are used in conjunction with a breast implant device or tissue expander device. Acellular dermal/synthetic matrices are most commonly used during reconstructive surgery. Table 9 reports acellular dermal/synthetic matrix usage for post-cancer reconstruction and risk reducing reconstruction cohorts. Of the post-cancer reconstruction cohort in 2017, acellular dermal/synthetic matrix usage was seen in 47% of direct-to-implant insertions, 3% of two-stage implant insertions and 9% of breast implant revisions (Table 9). Of the risk reducing cohort in 2017, acellular dermal/synthetic matrix usage was seen in 38% of direct-to-implant insertions, 2% of two-stage insertions and 7% of breast implant revisions (Table 9). Acellular dermal/synthetic matrix usage was also seen with 27% of inserted tissue expanders for post-cancer reconstruction (26% for risk reducing reconstruction, Table 9).

Table 9: Acellular Dermal/Synthetic Matrix usage

ADM# Usage		TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
Cohort	**Procedure**	**N**	**(% with ADM#)**	**N**	**(% with ADM#)**	**N**	**(% with ADM#)**
BREAST IMPLANTS							
Post-cancer	Insert | Direct-to-implant	1,026	(40.4%)	327	(40.4%)	495	(46.5%)
	Insert | Two-stage	2,313	(2.5%)	629	(1.7%)	881	(2.8%)
	Revision	1,333	(7.5%)	380	(6.3%)	589	(8.8%)
Risk reducing	Insert | Direct-to-implant	830	(38.2%)	246	(41.9%)	411	(38.0%)
	Insert | Two-stage	742	(2.7%)	260	(2.3%)	278	(2.2%)
	Revision	872	(6.8%)	320	(6.6%)	334	(6.6%)
TISSUE EXPANDER							
Post-cancer	Insert	1,919	(23.7%)	507	(28.2%)	789	(26.9%)
	Revision	136	(5.9%)	41	(2.4%)	68	(1.5%)
Risk reducing	Insert	859	(24.6%)	279	(32.3%)	336	(25.9%)
	Revision	27	(7.4%)	3	(0.0%)	18	(5.6%)

Note: # ADM includes acellular dermal and synthetic matrices

Primary implant breasts

In the period from 2012 to 2017 there were 37,583 initial breast implants captured by the ABDR. This cohort of breasts is classified as "Primary implant breasts". Amongst this cohort of breasts, 97% of breast implant devices remained *in situ*, and 2.7% (1,023 breasts) progressed to at least one revision following their initial implant (Table 10).

A total of 1,105 breast implant revisions were recorded in this cohort of primary breasts, as some breasts had undergone multiple revision procedures (956 had one revision, 53 had two revisions, 13 had three revisions and one had four revisions, resulting in 1,105 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.

Table 10: Number of procedures by primary implant breasts (2012-2017)

Number of primary implant breasts with:	**N**	**(%)**
A primary breast implant inserted & in situ	36,550	(97.3%)
A primary breast implant (permanent expander*) inserted & planned replacement within 12 months	10	(<0.1%)
A primary breast implant inserted & 1 revision	956	(2.5%)
A primary breast implant inserted & 2 revisions	53	(0.1%)
A primary breast implant inserted & 3 revisions	13	(<0.1%)
A primary breast implant inserted & 4 revisions	1	(<0.1%)
TOTAL primary implant breasts	**37,583**	**(100%)**

Notes: 36,550 primary breast implants remained in situ, 10 (permanent expanders) had a planned replacement within 12 months and a total of 1,023 primary implant breasts progressed to have at least one unplanned revision following their initial implant insertion. Some breasts had multiple revisions which resulted in the record of 1,105 implant revision procedures in primary implant breasts (956 x 1 revision, 53 x 2 revisions, 13 x 3 revisions, 1 x 4 revisions = 1,105 revisions). Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

*Permanent expanders have been classified as breast implants. The 10 cases listed as 'planned replacement' reflect exchange of a permanent expander to a breast implant within 12 months in the absence of any revision or complication data.

Revision incidence rates for primary implant breasts as at 31 December 2017

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. A revision procedure in this case included removal or repositioning of the breast implant or breast implant-to-breast implant replacement. 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 (4)) 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.

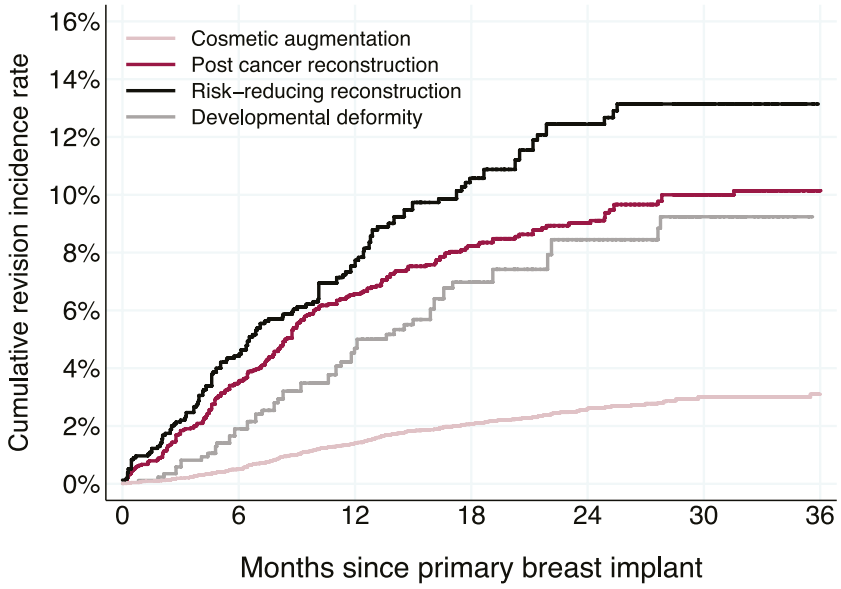
Based on 37,583 primary implant breasts, Nelson-Aalen cumulative revision incidence rates are reported in Figures 14-17. Crude revision incidence rates are presented in all figures with no adjustment for risk factors. A statistical risk adjustment modelling exercise is currently in progress. Once finalised, future reports will aim to account for potential confounders.

Revision incidence rates are reported for cosmetic, post-cancer reconstruction, risk reducing reconstruction and developmental cohorts in Figure 14. These are reported by breast cohort, in recognition of the different complexity of the procedures. Revision rates will be tracked over time for all cohorts. Revision incidence includes all revisions and explants recorded due to complications, patient preference, asymptomatic and reasons not stated. Of the primary breast implants inserted for cosmetic augmentation, 1.4% had been revised at one year after primary implant insertion and 2.6% at two years (Figure 14). Of the primary implants used to correct developmental deformity, 4.7% had been revised at one year and 8.5% at two years after primary implant insertion (Figure 14).

Of the reconstruction primary implant groups, 6.6% had been revised at one year and 9.0% at two years after initial post-cancer reconstruction implant whereas 7.5% had been revised at one year and 12.5% at two years after initial risk reducing reconstruction implant (Figure 14). Figure 15a and 15b provide 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. Note: Revision incidence rate is calculated from the time of breast implant insertion). For the primary post-cancer reconstruction breasts captured by the ABDR with direct implants, 7.4% had been revised at one year post implant insertion, and 9.4% at two years (Figure 15a). Whereas revision rates were slightly lower for two-stage post-cancer reconstruction implants, 6.2% had been revised at one year and 8.8% at two years after primary implant (Figure 15a). For the primary risk reducing reconstruction breasts, revision incidence at one year after primary implant was 7.5% for direct implants and 7.6% for two-stage implants (Figure 15b). At two years after primary implant for risk reducing reconstruction, 14.7% of direct implants were revised and 10.4% of two-stage implants were revised.

Figures 14-15b provide insight for overall revision incidence, whereas Figure 16 provides revision incidence for revisions due to complications and Figure 17 provides revision incidence for revisions due to patient preference (including asymptomatic revisions). When interpreting Figure 16 and 17 please note that data completeness (on the paper data collection form) for the reason for revision was 85% for revisions reported in 2016 and 93% for revisions reported in 2017 (Table 16). Revisions due to complications had a lower incidence of 1.5% at two years after primary implant for the cosmetic cohort compared to a complication revision incidence of around 6.0% at two years for the other three cohorts (Pearson's chi-squared p-value <0.001) (Figure 16). Revisions due to patient preference had an incidence rate of 0.9% at two years after primary implant for the cosmetic cohort, compared to 1.7% for the developmental deformity cohort, 2.0% for post-cancer reconstruction and 4.5% for risk reducing reconstruction (Figure 17).

Figure 14: Revision incidence for primary breast implants by cohort



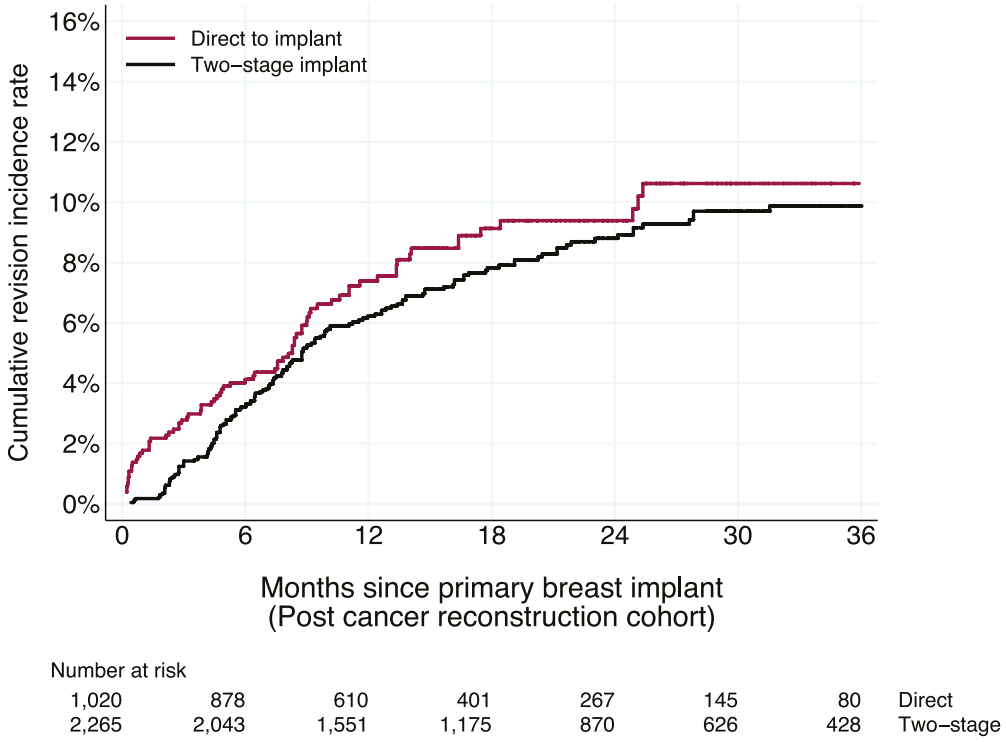
Number at risk

31,660	28,596	19,730	12,582	6,900	2,625	1,025	Cosmetic
3,285	2,921	2,161	1,576	1,137	771	508	Post cancer
1,559	1,377	995	690	467	270	175	Risk–reducing
859	810	635	486	336	202	131	Developmental

Reason for procedure	Number implanted	Number revised	Cumulative revision incidence rates at months since primary implant (95% CI)		
			12 Months	24 Months	36 Months
Cosmetic augmentation	31,660	559	1.4% (1.3, 1.6)	2.6% (2.4, 2.9)	3.1% (2.8, 3.5)
Post-cancer reconstruction	3,285	247	6.6% (5.7, 7.6)	9.0% (7.9, 10.3)	10.1% (8.9, 11.6)
Risk reducing reconstruction	1,559	145	7.5% (6.2, 9.2)	12.5% (10.5, 14.8)	13.1% (11.0, 15.7)
Developmental deformity	859	62	4.7% (3.4, 6.5)	8.5% (6.4, 11.1)	9.2% (7.0, 12.2)

Notes: Revision incidence includes all revisions recorded due to complications, patient preference and reasons not stated calculated as at 31 December 2017. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR. A total of 220 primary breasts with 'not stated' reason for primary procedure are not presented here.

Figure 15a: Revision incidence for primary breast implants - Post-cancer reconstruction cohort



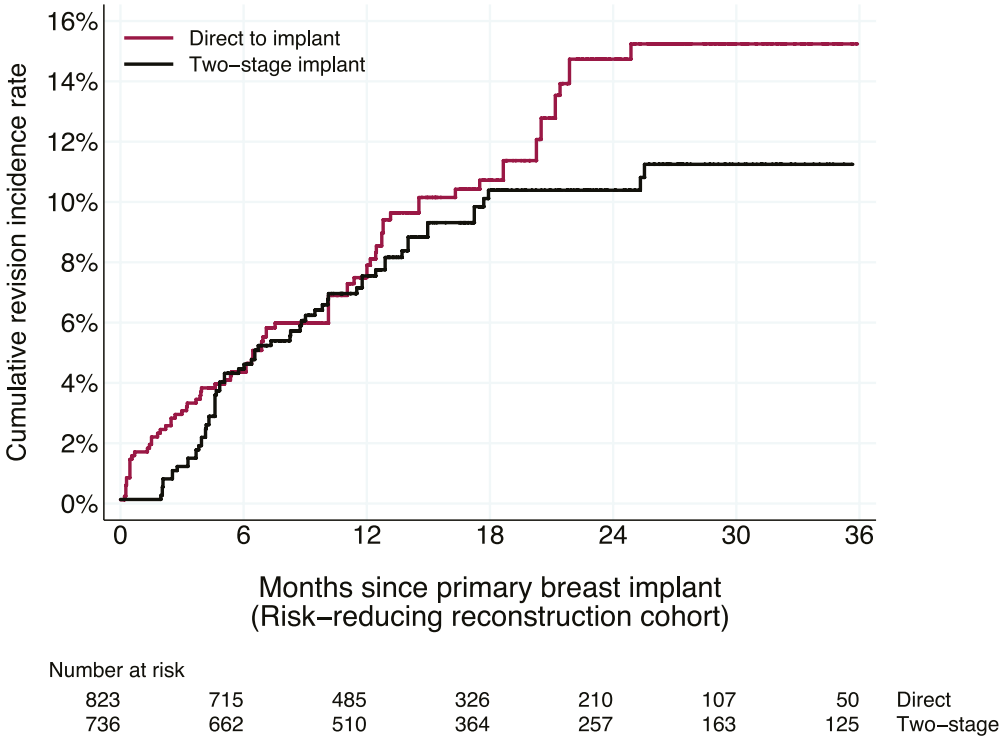
Number at risk

1,020	878	610	401	267	145	80	Direct
2,265	2,043	1,551	1,175	870	626	428	Two–stage

Reconstruction implant process	Number implanted	Number revised	Cumulative revision incidence rates at months since primary implant (95% CI)		
			12 Months	24 Months	36 Months
Post-cancer cohort					
Direct-to-implant	1,020	79	7.4% (5.8, 9.5)	9.4% (7.4, 11.9)	10.6% (8.3, 13.6)
Two-stage implant	2,265	168	6.2% (5.2, 7.4)	8.8% (7.5, 10.3)	9.9% (8.4, 11.6)

Notes: Revision incidence includes all revisions recorded due to complications, patient preference and reasons not stated calculated as at 31 December 2017. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

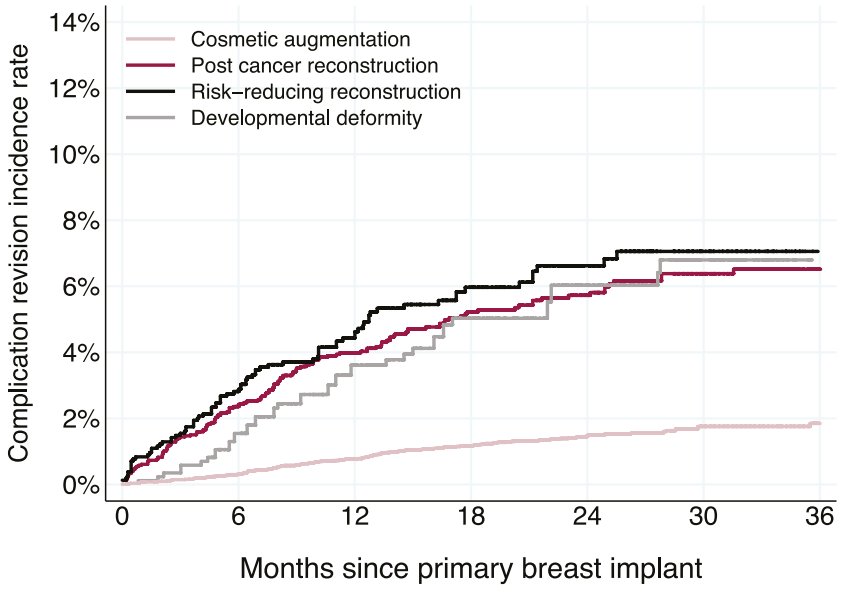
Figure 15b: Revision incidence for primary breast implants – Risk reducing reconstruction cohort



Reconstruction implant process	Number implanted	Number revised	Cumulative revision incidence rates at months since primary implant (95% CI)		
			12 Months	24 Months	36 Months
Risk reducing cohort					
Direct-to-implant	823	80	7.5% (5.7, 9.8)	14.7% (11.6, 18.8)	15.2% (12.0, 19.4)
Two-stage implant	736	65	7.6% (5.7, 10.0)	10.4% (8.1, 13.4)	11.3% (8.7, 14.6)

Notes: Revision incidence includes all revisions recorded due to complications, patient preference and reasons not stated calculated as at 31 December 2017. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR.

Figure 16: Complication revision incidence for primary breast implants by cohort



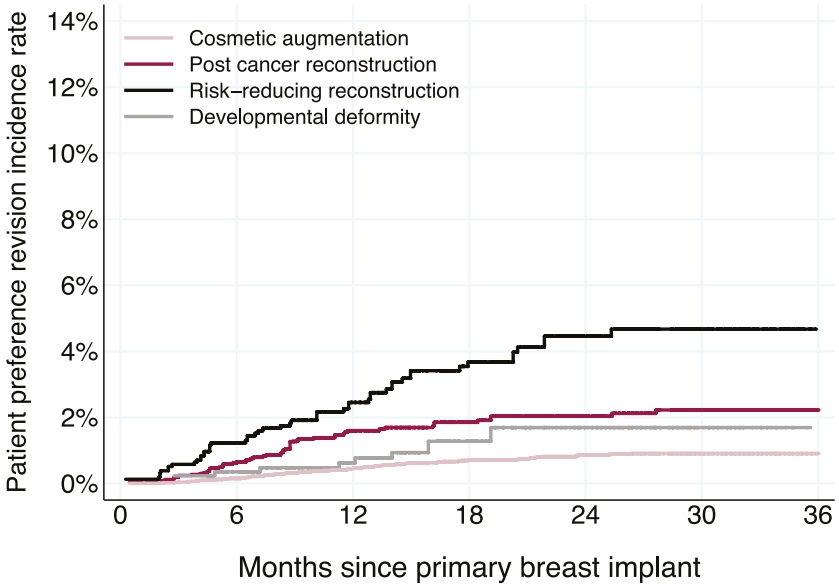
Number at risk

31,660	28,657	19,882	12,732	7,001	2,669	1,044	Cosmetic
3,285	2,957	2,228	1,629	1,183	806	536	Post cancer
1,559	1,399	1,034	734	504	287	184	Risk–reducing
859	813	641	496	347	205	132	Developmental

Reason for procedure	Number implanted	Number revised	Cumulative complication revision incidence rates at months since primary implant (95% CI)		
			12 Months	24 Months	36 Months
Cosmetic augmentation	31,660	325	0.8% (0.7, 0.9)	1.5% (1.3, 1.7)	1.9% (1.6, 2.2)
Post-cancer reconstruction	3,285	160	4.0% (3.3, 4.8)	5.7% (4.9, 6.8)	6.5% (5.5, 7.7)
Risk reducing reconstruction	1,559	83	4.4% (3.5, 5.7)	6.6% (5.3, 8.3)	7.1% (5.6, 8.9)
Developmental deformity	859	43	3.6% (2.5, 5.2)	6.0% (4.4, 8.3)	6.8% (4.9, 9.4)

Notes: Revision incidence includes only those revisions recorded for complication reasons calculated as at 31 December 2017. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR. A total of 220 primary breasts with 'not stated' reason for primary procedure are not presented here.

Figure 17: Patient preference revision incidence for primary breast implants by cohort



Number at risk

31,660	28,703	19,962	12,811	7,064	2,714	1,059	Cosmetic
3,285	3,010	2,286	1,703	1,235	851	564	Post cancer
1,559	1,423	1,057	758	520	299	198	Risk–reducing
859	823	661	519	371	222	145	Developmental

Reason for procedure	Number implanted	Number revised	Cumulative patient preference revision incidence rates at months since primary implant (95% CI)		
			12 Months	24 Months	36 Months
Cosmetic augmentation	31,660	180	0.5% (0.4, 0.6)	0.9% (0.7, 1.0)	0.9% (0.8, 1.1)
Post-cancer reconstruction	3,285	57	1.6% (1.2, 2.1)	2.0% (1.6, 2.7)	2.2% (1.7, 2.9)
Risk reducing reconstruction	1,559	52	2.5% (1.8, 3.4)	4.5% (3.3, 6.0)	4.7% (3.5, 6.3)
Developmental deformity	859	13	0.6% (0.3, 1.5)	1.7% (0.9, 3.1)	1.7% (0.9, 3.1)

Notes: Revision incidence includes only those revisions recorded for patient preference reasons calculated as at 31 December 2017. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR. A total of 220 primary breasts with 'not stated' reason for primary procedure are not presented here.

Revision reasons and issues for primary implant breasts

Table 11 reports a list of issues identified at implant revisions 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 2017, device malposition was the most common issue identified in implant revision procedures for primary breasts (31%), followed by capsular contracture (28%), skin scarring problems (6%) and seroma/haematoma (6%). This breakdown is likely to change over time as the registry matures.

Table 11: Issues identified at revision of primary implant breasts (2012-2017)

Issues identified at revision of primary implant breast	N	(%)
Device malposition	347	(31.4%)
Capsular contracture	313	(28.3%)
Skin scarring problems	69	(6.2%)
Seroma/Haematoma	68	(6.2%)
Deep wound infection	63	(5.7%)
Device rupture	28	(2.5%)
Device deflation	18	(1.6%)
Breast cancer	3	(0.3%)
Anaplastic Large Cell Lymphoma (ALCL)*	2	(0.2%)

Notes: Listed in order of frequency are issues identified during 1,105 breast implant revisions in 1,023 primary breasts, multiple issues can be recorded per revision. Issues identified include both those noted as 'reason for revision' and 'found incidentally'. Primary implant breasts are defined as those for which the initial insertion of a breast implant has been captured by the ABDR. *Two cases of ALCL were reported to the registry for which the ABDR also captured the primary insert data.

Legacy implant breasts

From 2012 to 2017, there were 9,578 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 or before the site joined the registry or the implants were inserted 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, 95% had one implant revision procedure captured by the ABDR, and 5% had multiple implant revisions captured (Table 12).

Table 12: Number of procedures by legacy implant breasts (2012-2017)

Number of legacy implant breasts with:	N	(%)
1 implant revision procedure captured by the ABDR	9,092	(94.9%)
2 implant revision procedures captured by the ABDR	435	(4.5%)
3 implant revision procedures captured by the ABDR	38	(0.4%)
4 implant revision procedures captured by the ABDR	10	(0.1%)
5 implant revision procedures captured by the ABDR	3	(<0.1%)
TOTAL legacy implant breasts	**9,578**	**(100%)**

Notes: 9,578 legacy implant breasts had one or more revision procedures recorded. Since some breasts had multiple revisions captured this resulted in the record of 10,131 implant revisions in legacy breasts (9,092 x 1 revision, 435 x 2 revisions, 38 x 3 revisions, 10 x 4 revisions, 3 x 5 revisions = 10,131 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 10,131 implant revision procedures were recorded in the ABDR for the cohort of legacy implant breasts due to some breasts having multiple revision procedures (9,092 had one revision, 435 had two revisions, 38 had three revisions, 10 had four revisions and three had five revisions, Table 12). A revision procedure in this case included repositioning or removal of the breast implant or breast implant-to-breast implant replacement.

Table 13 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 2017, capsular contracture was the most common issue identified in implant revision procedures for legacy breasts (42%), followed by device malposition (23%) and device rupture (21%, Table 13). This breakdown may change over time as the registry matures.

Table 13: Issues identified at revision of legacy implant breasts (2012-2017)

Complications identified at revision of legacy implant breasts	N	(%)
Capsular contracture	4,274	(42.2%)
Device malposition	2,373	(23.4%)
Device rupture	2,093	(20.7%)
Device deflation	1,013	(10.0%)
Skin scarring problems	385	(3.8%)
Seroma/Haematoma	314	(3.1%)
Deep wound infection	104	(1.0%)
Breast cancer	54	(0.5%)
Anaplastic Large Cell Lymphoma (ALCL)*	17	(0.2%)

Notes: Listed in order of frequency are issues identified during 10,131 breast implant revisions in 9,578 legacy breasts, multiple issues can be recorded per revision. 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 17 cases of ALCL were reported to the registry for which the ABDR did not capture the primary insert data.

Breast implant associated - anaplastic large cell lymphoma

Potentially the most serious complication but fortunately the least common is Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL). A total of 19 cases of BIA-ALCL were recorded in the registry as an identified issue at implant revision (Tables 11 and 13). This is an additional 10 cases on top of the nine previously reported in the ABDR 2016 Report. Recent studies have pointed to a link between ALCL and textured breast implants (5). Current incidence estimates 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 (6). At April 2018 there were 72 cases of BIA-ALCL identified in Australia and New Zealand (7), and a retrospective review of all cases was undertaken (8). The 19 cases reported to the ABDR since its inception are a subset of the 72 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 a key point of contact for notification of BIA-ALCL cases in the future.

Primary tissue expander breasts

In the period from 2012 to 2017, there were 2,887 breasts with primary tissue expander insertion captured by the ABDR. This cohort of breasts is labelled “Primary tissue expander breasts”. Amongst this cohort, 40% of breasts had the tissue expander device in situ, 58% had a tissue expander-to-breast implant exchange, and 73 breasts (2.5%) had progressed to at least one tissue expander revision procedure following the initial insertion (Table 14).

A total of 75 tissue expander revision procedures were recorded in this group, with two breasts undergoing two revision procedures, as seen in Table 14. A revision procedure in this case included repositioning or removal of the tissue expander or tissue expander-to-tissue expander replacement. Tissue expander-to-breast implant exchange is not considered revision surgery.

Table 14: Number of procedures by primary tissue expander breasts (2012-2017)

Number of primary tissue expander breasts with:	**N**	**(%)**
A primary tissue expander inserted & in situ	1,152	(39.9%)
A primary tissue expander inserted & then exchanged for a breast implant	1,662	(57.6%)
A primary tissue expander inserted & 1 revision	71	(2.5%)
A primary tissue expander inserted & 2 revisions	2	(<0.1%)
TOTAL primary tissue expander breasts	**2,887**	**(100%)**

Notes: Of the 2,887 primary tissue expander breasts, 73 breasts progressed to requiring at least one revision procedure of their inserted tissue expander. Two of these breasts had two revisions which resulted in the record of 75 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.

Legacy tissue expander breasts

From 2012 to 2017, there were 1,812 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 or before the site joined the registry. 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, 93% had a tissue expander-to-breast implant exchange captured by the ABDR and 7% had at least one tissue expander revision recorded (Table 15). Some legacy tissue expander breasts had multiple revisions, resulting in a total of 131 tissue expander revisions captured by the ABDR (119 breasts had one revision, three breasts had two revisions and two breasts had three revisions, Table 15). A revision procedure in this case includes repositioning or removal of the tissue expander or tissue expander-to-tissue expander replacement.

Table 15: Number of procedures by legacy tissue expander breasts (2012-2017)

Number of legacy tissue expander breasts with:	**N**	**(%)**
Tissue expander removal before a breast implant exchange	1,688	(93.2%)
1 tissue expander revision procedure captured by ABDR	119	(6.6%)
2 tissue expander revision procedures captured by ABDR	3	(0.1%)
3 tissue expander revision procedures captured by ABDR	2	(0.1%)
TOTAL legacy tissue expander breasts	**1,812**	**(100%)**

Notes: 1,688 legacy breasts underwent a tissue expander removal before a breast implant exchange and 124 legacy breasts had at least one tissue expander revision procedure recorded (119 x 1 revision, 3 x 2 revisions, 2 x 3 revisions = 131 revisions). 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.

REGISTRY OUTCOMES

Device outcome tracking

ABDR monitors the performance of individual breast devices. Work is underway with Monash biostatisticians on statistical models to identify devices with higher than expected revision rates. These models are based on Bayesian change-point modelling of risk-adjusted survival time (9) and the risk-adjusted sequential probability ratio test (10).

Clinical quality indicators

An important 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 quality indicator measures the quality of healthcare with little inter- and intra-observer variability so that outcomes can be compared between professionals and institutions (11). To allow for a fair comparison of quality indicators and account for factors beyond the control of the surgeon, risk adjustment must be performed. This process statistically accounts for differences in patient case-mix that influences health care outcomes (12). Work was undertaken in 2017 to determine clinical quality indicators and risk adjustment factors in breast device surgery which can be used by the ABDR for benchmarking reports. This work was done in conjunction with ICOBRA.

A total of 12 candidate quality indicators and risk adjustment factors were identified, and a scoping review of the literature suggested that most of the evidence was from retrospective studies with Level III evidence. Consensus on the final list was obtained using a modified Delphi approach (13), with the participation of 17 panel members and involved a series of online surveys, and teleconferences. The panel included representatives from surgical speciality groups including breast and general surgeons, plastic and reconstructive surgeons, cosmetic surgeons, a breast-care nurse, a consumer, a devices regulator (Therapeutic Goods Administration) and a biostatistician. Countries with functioning breast device registries were represented (Australia, Netherlands, Sweden).

Three of the proposed 12 quality indicators were endorsed by the panel: preoperative intravenous antibiotics, reoperation due to a complication, and patient reported outcome measures (PROMs). Nine of the 12 risk adjustment factors were endorsed: indication for surgery, age, BMI, smoking, diabetes, use of acellular dermal/synthetic matrices, radiation therapy, chemotherapy, and immunosuppressive therapy.

The Clinical Quality Committee will review the data on outcomes using the clinical quality indicators, and refine the model using risk adjustment factors. Reporting on clinical quality indicators will commence in due course.

REGISTRY QUALITY ASSURANCE

Data completeness

The ABDR is designed to collect information about surgical procedures involving breast implants, tissue expanders and acellular dermal/synthetic matrices 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 (Appendix 1);
2. The surgeon or operating theatre staff return the completed data collection form to the ABDR;
3. ABDR staff enter the data from the data collection form into the ABDR database.

A summary of the completeness of data elements captured within the ABDR database for the 9,520 procedures in 2016 and the 13,388 procedures in 2017 is presented in Table 16.

Table 16: Data completeness (2016 and 2017)

	% Complete* for procedures in 2016	% Complete* for procedures in 2017
PATIENT DEMOGRAPHICS	**N = 9,110**	**N = 12,795**
Name	100%	100%
Surname	100%	100%
Medicare number	91.0%	88.1%
Date of birth	100%	100%
Address	100%	100%
Telephone	80.8%	81.1%
Email	11.6%	9.6%
PROCEDURE	**N = 9,520**	**N = 13,388**
Date of operation	100%	100%
Hospital	100%	100%
UR number	100%	100%
Name of surgeon	100%	100%
Intraoperative Techniques	90.1%	92.1%
PATIENT HISTORY (Breast level)	**N = 17,954**	**N = 25,111**
Reason for operation	96.2%	96.2%
Procedure performed (primary or revision)	99.7%	100%
Previous radiotherapy (if reason of operation=Reconstruction)	90.5%	90.1%
ELEMENTS OF OPERATION (Breast level)	**N = 17,954**	**N = 25,111**
Side of breast	100%	100%
Incision site	91.7%	93.6%
Plane	87.7%	89.2%
Concurrent mastectomy^	86.1%	94.1%
Axillary surgery^	85.6%	93.9%
Concurrent mastopexy/reduction	87.1%	94.4%
Concurrent flap cover	86.2%	93.8%
Previous mastopexy/reduction^	85.6%	93.8%
Fat grafting	75.4%	89.7%
Fat grafting volume (if fat grafting=yes)^	96.5%	98.6%
Intraoperative fill volume (if tissue expander)	69.3%	67.2%

	% Complete* for procedures in 2016	% Complete* for procedures in 2017
DEVICES USED (Breast level)	**N = 17,580**	**N = 24,377**
Device ID	100%	100%
ADM# used	68.9%	99.2%
ADM# ID (if ADM# used=yes)	100%	100%
REVISION SURGERY (Breast level)	**N = 3,732**	**N = 5,383**
Revision type	100%	100%
Capsulectomy	80.3%	85.2%
Neo pocket formation^	68.8%	73.7%
Neo pocket formation details^ (if Neo pocket formation=yes)	80.2%	82.6%
Reason for revision	85.6%	92.7%
Is the operation removing an implant inserted overseas^	79.6%	84.0%
Breast cancer identified at revision	73.6%	91.6%
Issue identified at revision:		
Device rupture	85.3%	92.5%
Device deflation	74.2%	91.1%
Device contracture	77.8%	92.5%
Device malposition	74.8%	91.7%
Skin scarring problems	73.7%	91.5%
Deep wound infection	73.7%	91.6%
Seroma/Haematoma	73.8%	91.8%
Anaplastic Large Cell Lymphoma	72.9%	91.5%
EXPLANTED DEVICE (Breast level) Type of revision surgery: replacement and explant only	**N = 3,652**	**N = 5,238**
Device details supplied = Yes	60.0%	77.7%
Device Id^ (if device details supplied=yes)	12.6%	17.9%
If Device ID = Other:	N = 1,885	N = 3,343
Manufacturer^	78.8%	77.5%
Shape^	85.5%	87.2%
Shell^	44.8%	51.0%
Fill^	54.9%	54.4%
Volume^	84.4%	86.1%
Date of insert^	62.2%	65.5%

Notes:
* If the entry was NULL, Not known or Not stated the data were classified as incomplete.
\# ADM includes acellular dermal and synthetic matrices.
^ The ABDR data collection forms underwent a number of changes during the pilot period. Data elements were added and removed and the format of the data collection form has changed. As a result, newly added data elements such as fat grafting volume, neo pocket formation and explant device details had low completion rates.

Data completeness (cont…)

Intuitive checks (validation rules) have been built into the ABDR database, however data entry is currently completed manually from paper data collection forms forwarded by participating sites. There are several limitations with a paper-based system for data entry, which may include incomplete fields on the data collection form, challenging handwriting, 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 data collection form including non-relevant tick boxes. The Monash School of Public Health and Preventive Medicine is currently investing in an adaptable database that will minimise manual data entry.

When comparing the data completeness for procedures in 2016 and 2017, there has been a noticeable improvement in the 'Elements of Operation' and 'Revision' sections. The strategies used were:

- Reviewing incoming forms and promptly following up with missing key data fields.
- Imputing missing data (examples: if no mesh/dermal sheet sticker then impute 'No', if only yes ticked to questions impute 'No' to the unanswered questions, use prior patient data collection form to impute device journey or category of operation, if only one side, usually the right breast data is ticked and the form indicates a bilateral procedure, then the same values are imputed for the left side.
- Following up with sites and/or surgeons on up to three occasions for missing key data fields.
- Conducting in-service education at sites on how to complete the forms.

Further strategies to improve data completeness include regularly notifying 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.

PATIENT REPORTED OUTCOME MEASURES (PROMs)

ABDR data collection includes Patient Reported Outcome Measures (PROMs). The ABDR aims to follow up patients and collect PROMs at one, two, five and ten years. The PROM tool selected is the BREAST-Q Implant Surveillance (BREAST-Q IS) (Appendix 4) which asks five questions on satisfaction (shape, feel and rippling) and symptoms (pain and tightness) after breast implant surgery. These five questions were selected from the BREAST-Q by Professor Andrea Pusic at Harvard University and her team, creators of the BREAST-Q (14), in consultation with the ABDR Steering Committee. The questions that were chosen were those most discriminating for poor outcomes, and most sensitive to device issues including capsular contracture and leaking devices.

We sought patient and clinician views on the BREAST-Q IS through interviews and surveys from 20 patients and 10 surgeons in a qualitative study conducted between October 2016 and June 2017. The majority of patients and surgeons found the BREAST-Q IS to be an acceptable tool, and feasible to complete in a registry setting.

The PROMs pilot study commenced in March 2017 and was completed in June 2017. We aimed to further test the feasibility of the BREAST-Q IS, and refine our contact methodology before undertaking national roll out of the PROM to all ABDR patients. In total, 200 patients who had primary breast implant surgery in the previous 10-15 months were contacted, including 120 who had received breast augmentation and 80 who had received breast reconstruction. The total completion rate was 70% for the BREAST-Q IS survey, including 64% of the patients who had received breast augmentation, and 78% of the patients who had received breast reconstruction completing the survey. Minor modifications were made to improve the survey. The pilot study results indicated that text message with a web link to the survey was a very effective method of contacting patients. This was supplemented by phone calls, letters and email if required. The ABDR will distribute the follow up survey via text message to mobile phone numbers, which is a time efficient and cost effective contact method.

Outcomes from the PROMs pilot study were applied to the PROMs national rollout. The ABDR PROMs rollout commenced in October 2017 after receiving ethics approval from a number of sites to follow up their patients. Ethics committees from Calvary ACT, Epworth, Menzies and St John of God approved the follow up in October 2017 and by December 2017 a further three ethics committees (Calvary Adelaide, Royal Brisbane and Bellberry) approved the PROMs follow up.

From October 2017 to December 2017 a total of 513 patients who had received breast augmentation were contacted, and 121 who had received breast reconstruction were contacted. Of these, 250 (49%) patients with breast augmentation and 91 (75%) patients with breast reconstruction completed the follow up. Mobile phone numbers again proved to have high completion rates. This and the likelihood that the mobile phone numbers remain constant despite changes in residence underscores the importance of including patients' mobile numbers in the data collection form.

ABDR continues to work on acquiring ethics approval from more sites to commence further follow up. PROMs results will be published in due course. Validation of the PROMs tool will be undertaken in conjunction with the BREAST-Q team. It is expected that PROMs will be used as a clinical quality indicator in the future, and surgeons will be able to access their own aggregate PROMs results to compare to a national average.

FUTURE INITIATIVES

Infrastructure development

The existing ABDR database will undergo a number of modifications to decrease manual workflow and incorporate the PROMs data. The School of Public Health and Preventive Medicine is currently sourcing an adaptive database model to be implemented for registries at the end of 2018.

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.

Surgeon reporting

The ABDR plans to deliver a surgeon activity report to the surgeons who have contributed data. The report will provide the total number of patients with a breakdown by patient cohort (augmentation, reconstruction, developmental); a total number of data collection forms by site with a breakdown by year and operation type; and a data completeness summary of key data fields to provide feedback to the surgeon on areas to improve when completing a data collection form. The report will cover the period from the surgeon's earliest data collection form to the 31st December 2017. The report and a cover letter will be mailed to the surgeon's primary consult room.

ICD-10 case ascertainment/ site reporting

The ABDR is currently collecting data (ABDR data collection forms) from 202 active sites across all states in Australia, representing the top 80% of sites contributing data (by volume). Work is underway to ascertain the data capture rates across these sites. The pilot study will include 46 sites which contribute to the top 80% of all breast device procedures in 2017. ICD-10-AM data will be requested from each individual site, and the data received from sites compared to the number of data collection forms received by the ABDR in order to calculate data capture rates. In order to streamline the data collection processes, data will also be sought from state Departments of Health to standardise data collection and minimise manual data collection from individual sites. Through these methods, we will identify sites with low data capture rates and collaborate with the site to identify factors contributing to the low rates as part of a quality improvement process. The ABDR will undertake the first round of site reporting in 2018 providing sites with activity data including the number of primary and revision procedures, data capture rates and intraoperative technique use.

International minimum data set and data definitions

The ABDR, in collaboration with ICOBRA, aims to identify an internationally agreed minimum core set of data points, along with data definitions, to be collected by all breast device registries worldwide. Data points from six countries (Australia, Austria, Netherlands, Sweden, United Kingdom, United States) were collated and reviewed. Data points collected in more than one third of the six registries went through a consensus process to identify the core data set (mandatory for all registries to collect internationally) and the optional data set.

Consensus on data points was achieved using a modified Delphi approach with the participation of expert panel members representing a wide range of stakeholders. The panel was international and multi-disciplinary, with representatives from registries from six countries (Australia, Austria, Netherlands, Sweden, United Kingdom, United States), other specialists in breast device surgery (breast surgeons, plastic surgeons, and cosmetic surgeons and a breast-care nurse), two consumer representatives to confirm that the dataset would identify outcomes that were important for them, national regulators to help maximize the utility of the data and ensure the work aligned with other international registries, biostatisticians to ensure the statistical rigor of the methodology, and was chaired by a registry science expert.

The modified Delphi approach comprised online surveys and video teleconferences, and resulted in a total of 32 (59 including sub-points) data points being classified as the core global data set and 16 data points as the optional dataset for registries to collect internationally. Currently the ABDR is in the process of finalising the data definitions for these data points and plans to pilot the new data collection form with the core data points.

Collaborations

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.

GLOSSARY

ABDR	Australian Breast Device Registry
ACCS	Australasian College of Cosmetic Surgery
ADM	Acellular Dermal Matrix (including synthetic matrices)
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 module
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
Direct-to-implant	A breast reconstruction procedure whereby an implant is inserted at the time of the mastectomy
Eligible site	A site undertaking breast device surgery as identified by ICD-10-AM* code data
HREC	Human Research Ethics Committee
ICD-10-AM	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification
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
Two-stage implant	A breast reconstruction procedure whereby the initial device insertion is a Tissue Expander, which is exchanged to a Breast Implant in a subsequent procedure

REGISTRY PERSONNEL

Steering committee representatives

Australian Society of Plastic Surgeons (ASPS) – www.plasticsurgery.org.au

Australasian College of Cosmetic Surgery (ACCS) – www.accs.org.au

Breast Surgeons of Australia and New Zealand (BreastSurgANZ) – www.breastsurganz.com

Therapeutic Goods Administration (TGA) – www.tga.gov.au

Department of Health (Health) – www.health.gov.au

Medical Technology Association of Australia (MTAA) – www.mtaa.org.au

Consumers Health Forum of Australia (CHF) – https://chf.org.au/

Australian Commission on Safety and Quality in Health Care (ACSQHC) – www.safetyandquality.gov.au

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LIST OF FIGURES

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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

Category of operation

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

Operation type

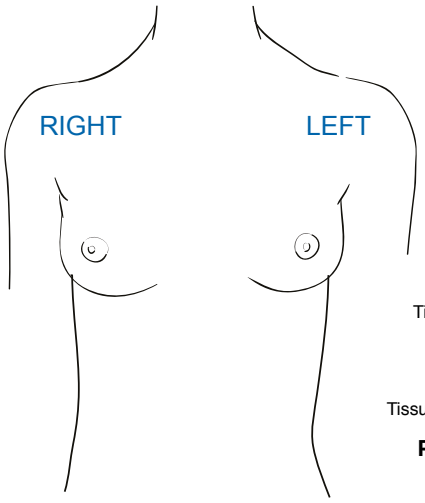
Initial (new device)

- ☐ 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



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

PLEASE COMPLETE OVER PAGE

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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

☐ Tick if Same Bilateral

☐ Complication ☐ Asymptomatic ☐ Patient Preference

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

Details : .....

Device rupture?

☐ Tick if Same Bilateral

☐ 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 2017

State	Site Name
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	Bankstown-Lidcombe Hospital
NSW	Bondi Junction Private Hospital
NSW	Brisbane Waters Private Hospital
NSW	Calvary Mater Newcastle
NSW	Campbelltown Private Hospital
NSW	Charlestown Private Hospital
NSW	Concord Repatriation General 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	Liverpool Hospital
NSW	Macquarie St Day Surgery
NSW	Macquarie University Hospital
NSW	Maitland Private Hospital
NSW	Mater Hospital, North Sydney
NSW	Mount Druitt Hospital
NSW	Nepean Hospital
NSW	Nepean Private Hospital
NSW	North Shore Specialist Day Hospital
NSW	Norwest Private Hospital
NSW	Pittwater Day Surgery
NSW	Prince of Wales Hospital
NSW	Prince of Wales Private Hospital
NSW	Royal Hospital for Women, Sydney
NSW	San Day Surgery Hornsby
NSW	St George Hospital
NSW	St Luke's Private Hospital
NSW	St Vincent's Private Community Hospital Griffith
NSW	St Vincent's Hospital, Sydney
NSW	St Vincent's Private Hospital, Sydney
NSW	Surry Hills Day Hospital
NSW	Sydney Adventist Hospital
NSW	Sydney Children's Hospital (Inc Royal Alexandra Hospital for Children)
NSW	Sydney Day Hospital
NSW	Sydney Surgical Centre

State	Site Name
NSW	The Tweed Hospital
NSW	Waratah Private Hospital
NSW	Westmead Hospital
NSW	Wollongong Day Surgery
NT	Darwin Day Surgery
NT	Darwin Private Hospital
NT	Royal Darwin Hospital
QLD	Brisbane Private Hospital
QLD	Canossa Private Hospital
QLD	Chermside Day Hospital
QLD	Gold Coast Private Hospital
QLD	Gold Coast University 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	Precision Cosmetic Surgery
QLD	Princess Alexandra Hospital
QLD	Robina Hospital
QLD	Royal Brisbane and Women's Hospital
QLD	South Bank Day Hospital
QLD	Southport Day Hospital (The Cosmetic Institute)
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, Brisbane
QLD	Sunshine Coast Day Surgery
QLD	Toowoomba Surgicentre
QLD	UnitingCare - Buderim Private Hospital
QLD	UnitingCare - St Andrew's War Memorial Hospital
QLD	UnitingCare - St Stephen's Hospital
QLD	UnitingCare - The Wesley Hospital
SA	Adelaide Day Surgery
SA	Ashford Hospital

State	Site Name
SA	Burnside Hospital (War Memorial)
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	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)
SA	Women's and Children's 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	Austin TSC (Repatriation) Hospital
VIC	Bellbird Private Hospital
VIC	Bendigo Day Surgery
VIC	Bendigo Hospital
VIC	Box Hill Hospital
VIC	Cabrini Hospital – Brighton
VIC	Cabrini Hospital – Malvern
VIC	Casey Hospital
VIC	Corymbia House
VIC	Cotham Private Hospital
VIC	Dandenong Hospital
VIC	Epworth Cliveden
VIC	Epworth Eastern (Box Hill)
VIC	Epworth Freemasons
VIC	Epworth Geelong
VIC	Epworth Hawthorn
VIC	Epworth Richmond
VIC	Footscray Hospital
VIC	Frankston Hospital
VIC	Holmesglen Private Hospital
VIC	John Fawkner Private Hospital

State	Site Name
VIC	Knox Private Hospital
VIC	Maroondah Hospital
VIC	Maryvale Private Hospital
VIC	Melbourne Private Hospital
VIC	Moorabbin Hospital
VIC	Northpark Private Hospital
VIC	Peter MacCallum Cancer Centre
VIC	Ringwood Private Hospital
VIC	SJOG Ballarat
VIC	SJOG Bendigo
VIC	SJOG Berwick
VIC	SJOG Geelong
VIC	SJOG Warrnambool
VIC	St Kilda Day Hospital
VIC	Stonnington Day Surgery
VIC	Sunshine Hospital
VIC	The Alfred Hospital
VIC	The Bays Hospital
VIC	The Royal Melbourne Hospital
VIC	The Royal Women's Hospital
VIC	The Valley Private Hospital
VIC	University Hospital Geelong
VIC	Victorian Cosmetic Institute Day Surgery(VCI)
VIC	Warrnambool Base Hospital
VIC	Western Private Hospital
VIC	Williamstown 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	SJOG Bunbury
WA	SJOG Midland Public and Private Hospital
WA	SJOG Mt Lawley
WA	SJOG Murdoch
WA	SJOG Subiaco
WA	SJOG Wembley Day Surgery
WA	Subiaco Private Hospital
WA	Waikiki Private Hospital
WA	West Leederville Private Hospital

APPENDIX 3 – DETAILED DEVICE CHARACTERISTICS

Device characteristics	TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
	N	(%)	N	(%)	N	(%)
BREAST IMPLANTS (Shell | Fill | Shape)						
Textured | Silicone | Anatomical	16,904	(35.3%)	5,982	(35.8%)	7,645	(33.0%)
Textured | Silicone | Round	18,699	(39.1%)	6,126	(36.7%)	9,529	(41.2%)
Textured | Saline | Anatomical	7	(<0.1%)	1	(<0.1%)	0	(0.0%)
Textured | Saline | Round	18	(<0.1%)	7	(<0.1%)	6	(<0.1%)
Textured | Silicone/Saline* | Anatomical	113	(0.2%)	37	(0.2%)	55	(0.2%)
Textured | Silicone/Saline* | Round	3	(<0.1%)	0	(0.0%)	3	(<0.1%)
Smooth | Saline | Round	484	(1.0%)	215	(1.3%)	179	(0.8%)
Smooth | Silicone | Round	8,896	(18.6%)	3,186	(19.1%)	4,635	(20.0%)
Polyurethane | Silicone | Anatomical	1,941	(4.1%)	784	(4.7%)	780	(3.4%)
Polyurethane | Silicone | Round	759	(1.6%)	355	(2.1%)	306	(1.3%)
Not stated	26	(0.1%)	8	(<0.1%)	0	(0.0%)
TOTAL	**47,850**	**(100%)**	**16,701**	**(100%)**	**23,138**	**(100%)**
TISSUE EXPANDERS (Shell | Fill | Shape)						
Textured | Saline | Anatomical	2,742	(90.2%)	756	(86.0%)	1,082	(87.3%)
Textured | Saline | Round	7	(0.2%)	7	(0.8%)	0	(0.0%)
Textured | Carbon Dioxide | Anatomical	287	(9.4%)	116	(13.2%)	152	(12.3%)
Smooth | Saline | Anatomical	2	(0.1%)	0	(0.0%)	2	(0.2%)
Smooth | Saline | Round	3	(0.1%)	0	(0.0%)	3	(0.2%)
Not stated	0	(0.0%)	0	(0.0%)	0	(0.0%)
TOTAL	**3,041**	**(100%)**	**879**	**(100%)**	**1,239**	**(100%)**

Notes: Device characteristics are reported for all new devices captured during an insertion procedure or a replacement revision procedure.
*Device fill 'Silicone/Saline' category comprises permanent expanders which have been classified as breast implants.

APPENDIX 4 – BREAST Q IMPLANT SURVEILLANCE

BREAST-Q IS AUGMENTATION ITEMS

Answer these questions thinking of the breast you are least satisfied with.

Please state which breast you are least satisfied with:

No Difference ◯ Right Breast ◯ Left Breast ◯

In the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How do you look in the mirror unclothed?	1	2	3	4
b. How your breast(s) feel(s) to touch?	1	2	3	4
c. The amount of rippling (wrinkling) of your implant(s) that you can see?	1	2	3	4

In the past week, how often have you experienced:

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. Pain in your breast area?	1	2	3	4	5
b. Tightness in your breast area?	1	2	3	4	5

Would you like to add any comments?

BREAST-Q IS RECONSTRUCTION ITEMS

If you have had implant surgery of both breasts, answer these questions thinking of the breast you are least satisfied with.

Please state which breast you are least satisfied with:

No Difference ◯ Right Breast ◯ Left Breast ◯

In the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How do you look in the mirror unclothed?	1	2	3	4
b. How your breast(s) feel(s) to touch?	1	2	3	4
c. The amount of rippling (wrinkling) of your implant(s) that you can see?	1	2	3	4

In the past week, how often have you experienced:

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. Pain in your reconstructed breast(s) area?	1	2	3	4	5
b. Tightness in your reconstructed breast(s) area?	1	2	3	4	5

Would you like to add any comments?

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