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AUSTRALIAN Breast Device REGISTRY

Knowledge based sharing in health

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Project Lead, ABDR

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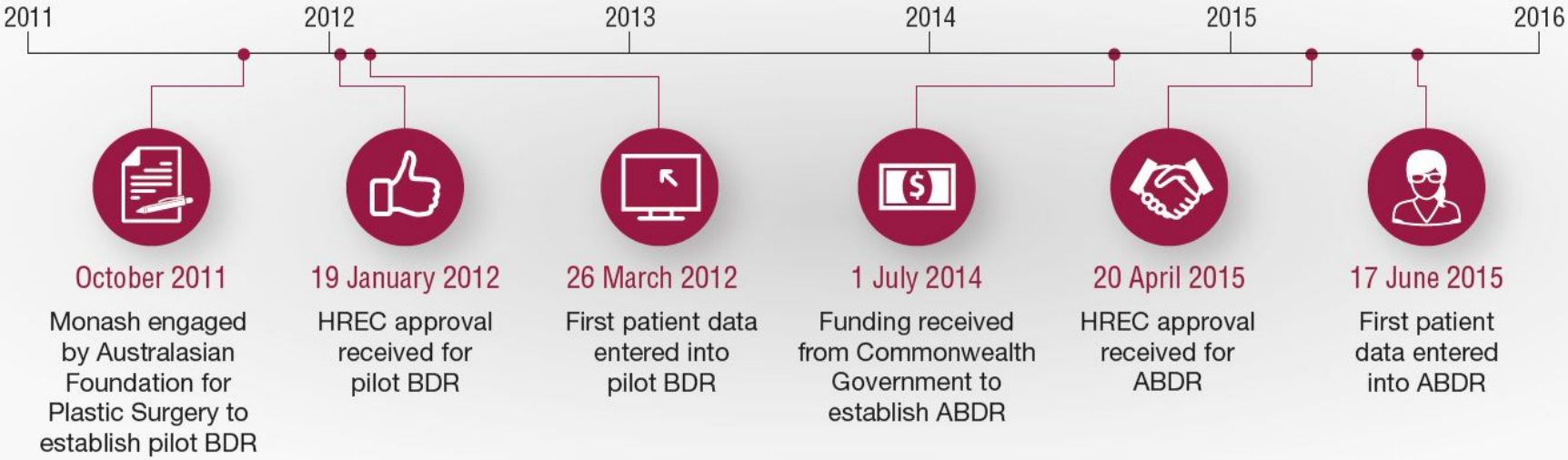
SCIENCE tells us what we CAN do.
GUIDELINES what we SHOULD do.
REGISTRIES what we are ACTUALLY doing!

Reference: Ralph Brindis, MD, MPH,FACC, Past CMO & Chair,
ACC National Cardiovascular Registry

About ABDR

- Commonwealth funded, clinical quality registry
- Established on recommendation by Australian Senate enquiry following PIP crisis (2010)

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



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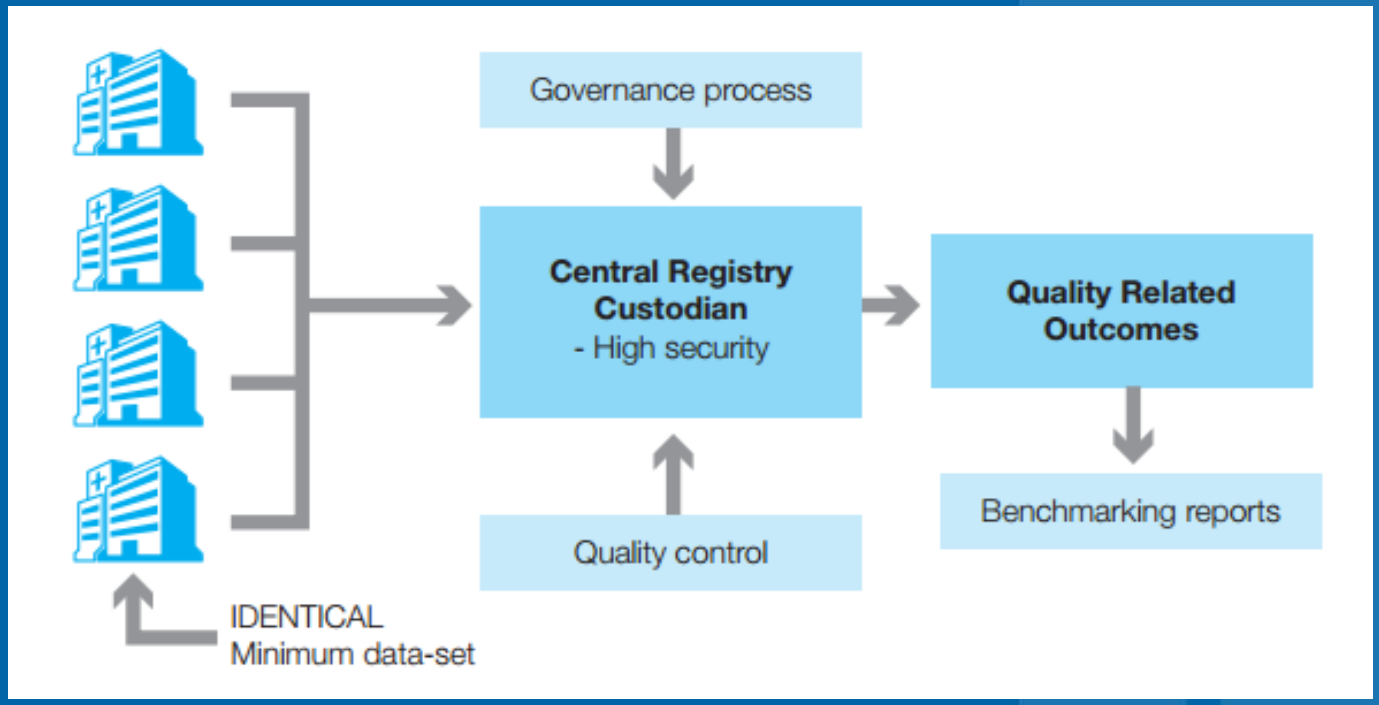
Basic architecture of the ABDR



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Stakeholders

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Clinical Leads:



ABDR Project Team

Project Lead:	Dr Ingrid Hopper
Research Fellows:	Dr Emily Parker, Dr Husna Begum
ABDR Coordinator:	Catherine Mulvany
Database Coord:	Marie Pase
Communications:	Trish Nichols
Research Officers:	Vanessa Fox, Alice Noone, Nicole Ng, Sarah Barrington-Smith

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Key aims of ABDR

- Track outcomes by patient, site, provider
- Create accountability loop for providers
- Drive system improvement
- Support evidence-based care

Public Good
Improve patient outcomes

Private Good
Private hospitals,
Private insurers,
Device Manufacturers

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ABDR will provide real world evidence of device safety and help answer questions about…

- In vivo lifespan of devices
- Influence of Tissue Expander on outcome
- Influence on Dermal Mesh on outcome
- Cosmetic vs Reconstruction
- Impact of surface coatings
- Anaplastic Large Cell Lymphoma
- Complications
- Patient satisfaction
- Surgeon performance
- Institution performance
- Cosmetic tourism

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Scope of the ABDR

Approximately 20,000 surgeries per year

ABDR tasked with capturing 95% of procedures including implant, revision and explant

~ 300 sites (public, private, day surgeries)

~ 400 surgeons from three craft groups

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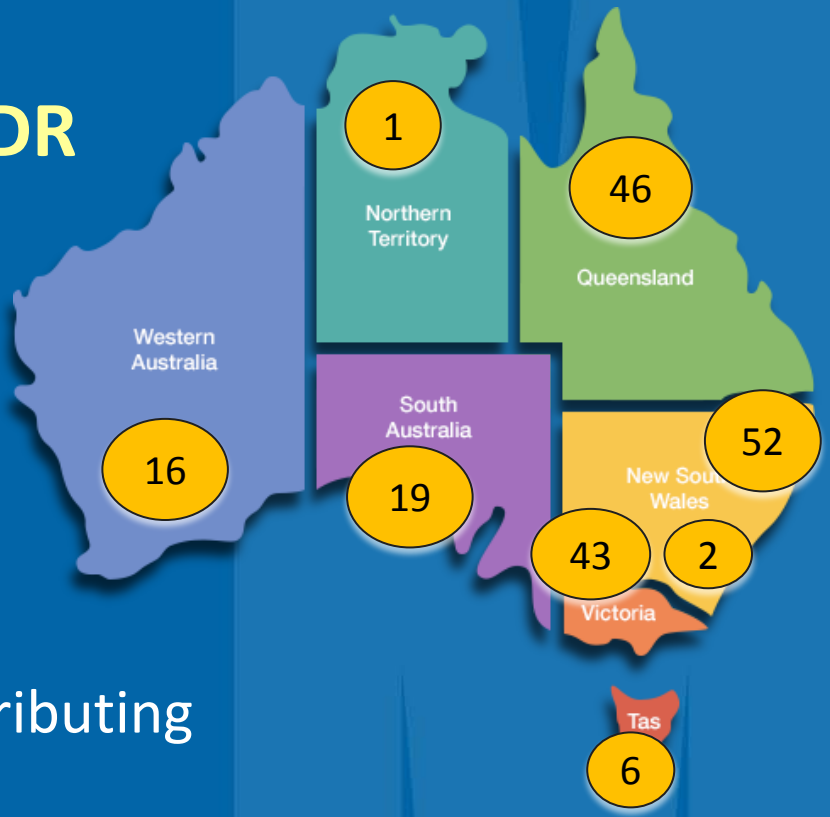
Progress to date on the ABDR

As at 25th May 2017



Sites

185 sites contributing

46 sites approved but not yet contributing

Surgeons

324 surgeons contributing

54 surgeons approved but not yet contributing

Key elements of methodology

- National
- Includes all clinician groups
- Opt out model
- Small minimum dataset
- Validating case ascertainment
- Auditing of accuracy

Data Collection and patient follow up process

Figure 3: ABDR data collection and patient follow up process

Consulting room
- display poster
- provide patients with a patient leaflet

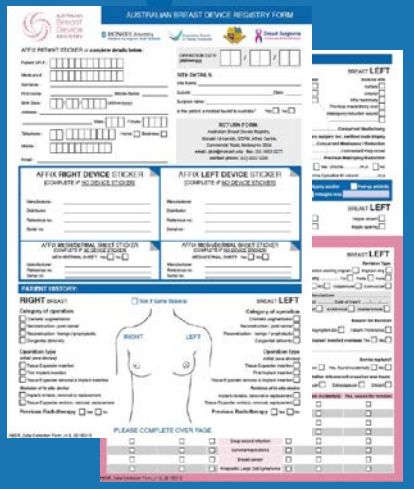
Theatre
- complete data collection form
- batch forms and send to Monash

Monash
- data entered into database
- patient sent an explanatory statement

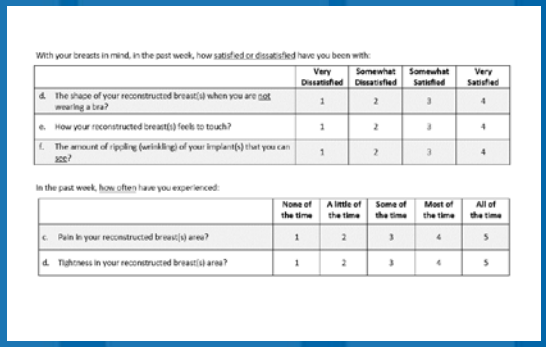
Monash
- patient follow-up at 1, 2, 5,10 years (BREAST-Q IS)

Consult

Theatre



Monash



With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

		Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
d.	The shape of your reconstructed breast(s) when you are not wearing a bra?	1	2	3	4
e.	How your reconstructed breast(s) feels to touch?	1	2	3	4
f.	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
c.	Pain in your reconstructed breast(s) area?	1	2	3	4	5
d.	Tightness in your reconstructed breast(s) area?	1	2	3	4	5

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ABDR Data Collection Form (DCF)

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 # :

Citizen, Jamie UR: 03156681
100 Metropolitan Drive Melbourne VIC 3000
Tel: 9876543210 Work: DOB: 8/08/1988
Ref: No Referral

Ref Date:
a Pty Ltd
: 345675
BUPA

Te Business:

Mobile :

Email :

Patient Details

OPERATION DATE: (dd/mm/yy) 01 / 09 / 15

SITE DETAILS

Site Name:

Suburb:

Surgeon name:

Is this patient a me

Operation & Site Details

RETURN FORM:
Australian Breast Device Registry,
Monash University, DEPM, Alfred Centre,
Commercial Road, Melbourne 3004
email: abdr@monash.edu **fax:** (03) 9903 0277
contact phone: (03) 9903 0205

AFFIX **RIGHT DEVICE** STICKER

Patient Name:
Surgeon Name:
Address:
Phone: ( )
Date of Implant:
Left ☐
Right ☑

MENTOR
375 cc
Mentor Medical Systems B.V.
Zernikedreef 2
2333 CL Leiden
The Netherlands
+31 71 7513600
www.mentorwwllc.com
REF 324-5375
LOT 6846218
SN 6846218-063

AFFIX **MESH/DERMAL SHEET** STICKER
[COMPLETE IF NO DEVICE STICKER]
MESH/DERMAL SHEET: Yes ☐ No ☐

Manufacturer:
Reference no:
Serial no:

Device Sticker

Patient Name:
Surgeon Name:
Left ☐
Right ☐
MENTOR
Systems B.V.
Zernikedreef 2
2333 CL Leiden
The Netherlands
+31 71 7513600
www.mentorwwllc.com

AFFIX **MESH/DERMAL SHEET** STICKER
[COMPLETE IF NO DEVICE STICKER]
MESH/DERMAL SHEET: Yes ☐ No ☐

Manufacturer:
Reference no:
Serial no:

PATIENT HISTORY:

Patient History

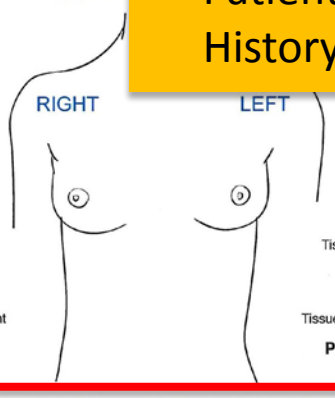
RIGHT BREAST

Tick if

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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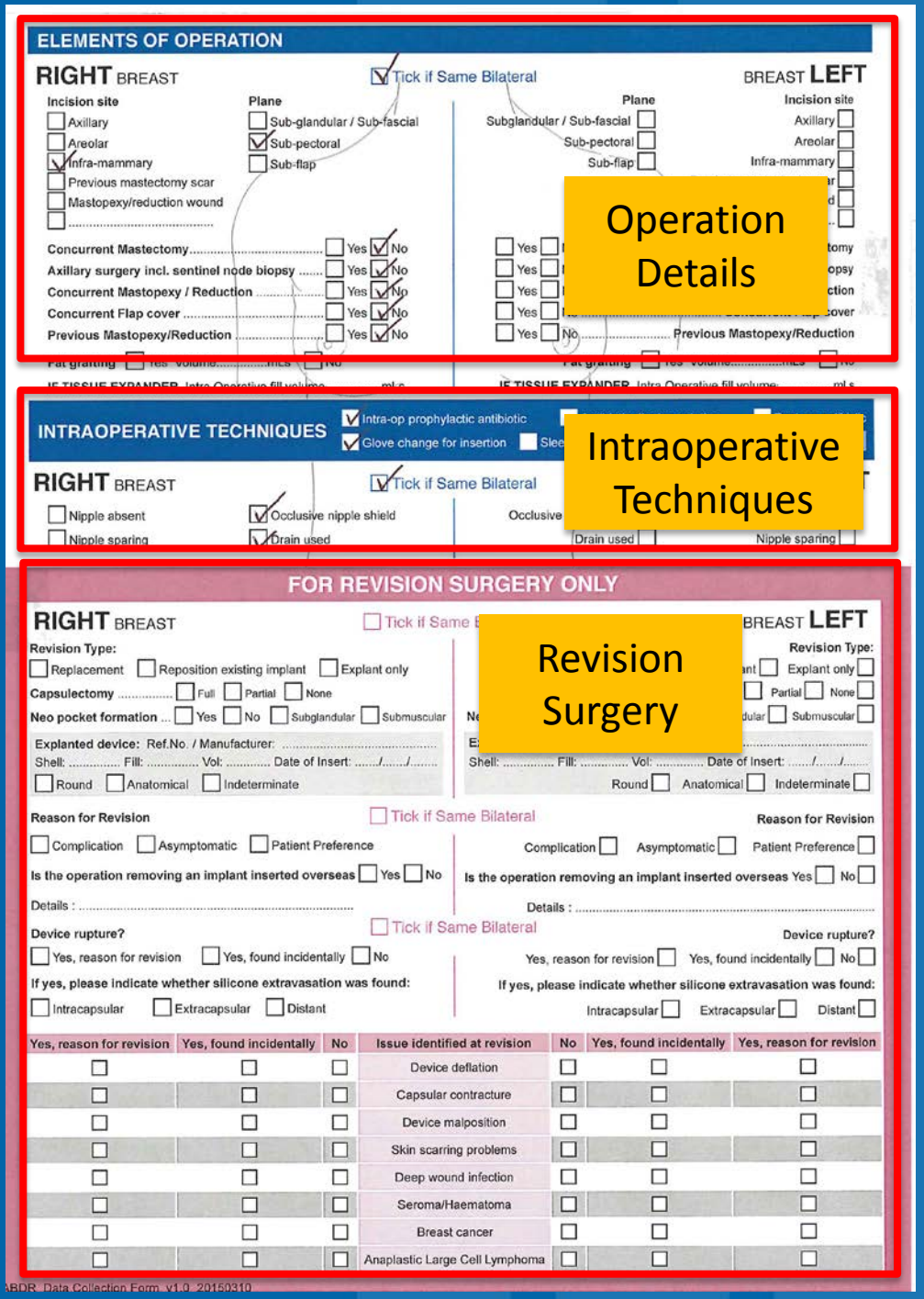

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Requirements of opt out approach to consent

It is imperative that patients are aware:

1. their data will go to the ABDR
2. they may opt out at any time, including prior to their surgery
3. they may elect to receive communication via email (default is post)

Patients must receive a Patient Leaflet prior to surgery

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Participation is voluntary. What's in it for me?

Stakeholders	Benefits
Patients	Product recall, Electronic identification
Surgeons	Product recall, Implant failure rate, Benchmarking
Hospital	Maintenance of certification, Government accreditation
Industry	Product recall, Market share
Insurance	Product recall, Implant failure rate
Government	Patient safety, Regulatory instrument

Permission to display the ABDR logo

Accrue CPD/CME points (approved by RACS, ACCS, ANMF)

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icobra™

International Collaboration of Breast Registry Activities

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Challenges

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Challenges

- Ongoing governance approvals
- Data Completeness
- Database
- Follow up

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Follow up

- Aim is to understand medium to long term outcomes with breast device surgery from a patient perspective

- Anticipated to be followed up 1 year, 2 years, 5 years and 10 years post-procedure

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Patient Reported Outcome Measures (PROMs)

1. Acceptability of Patient Reported Outcome Measures (PROMs)

2. Patient Reported Outcome Measures (PROMs) for women with breast implants – A pilot Study

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BREAST-Q Implant Surveillance (BREAST-Q IS)

BREAST-Q Implant Surveillance (BREAST-Q IS)

AUGMENTATION ITEMS

With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. The shape of your breasts when you are not wearing a bra?	1	2	3	4
b. How your breasts feels 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

RECONSTRUCTION ITEMS

With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. The shape of your reconstructed breast(s) when you are not wearing a bra?	1	2	3	4
b. How your reconstructed breast(s) feels 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
d. Pain in your reconstructed breast(s) area?	1	2	3	4	5
e. Tightness in your reconstructed breast(s) area?	1	2	3	4	5

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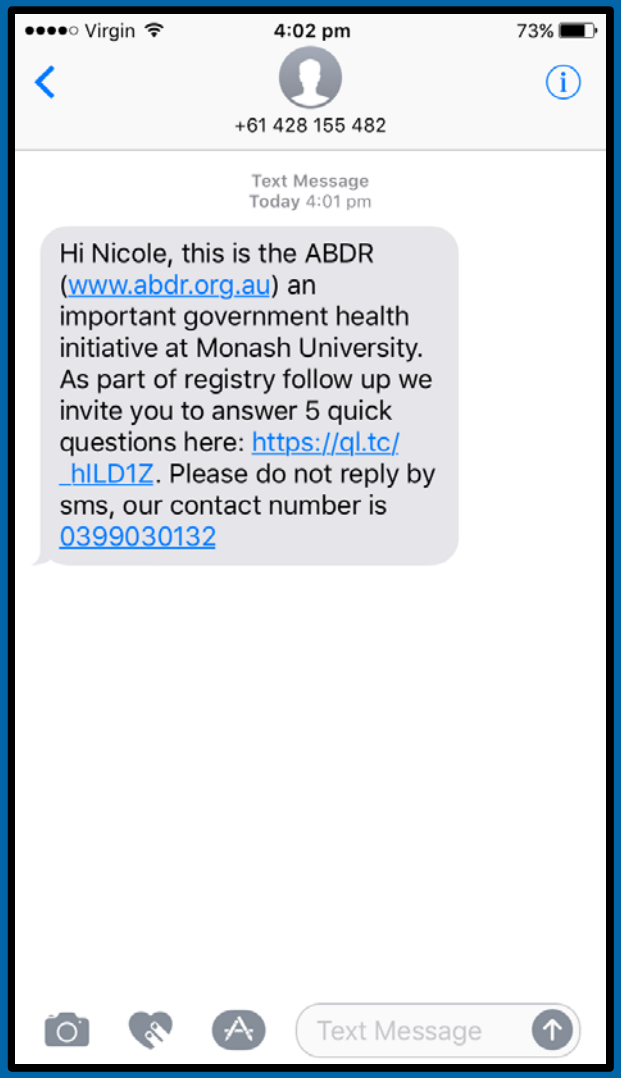
Current Text Message



Proposed Text Messages

Hi, this is the ABDR (www.abdr.org.au) an important government health initiative at Monash University, in association with (Insert Surgeon Name). As part of registry follow up we invite you to answer 5 quick questions here: (link). Please do not reply by sms, our contact number is 0399030132.

ABDR reporting

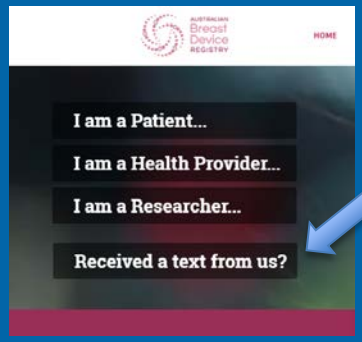
2016 Annual Report

- Data cut encompassing all procedure data up to 31/12/16
- Currently being analysed by Registry Sciences Unit biostatisticians
- ABDR Steering committee, societies and stakeholder review: August 2017
- Publication: September 2017

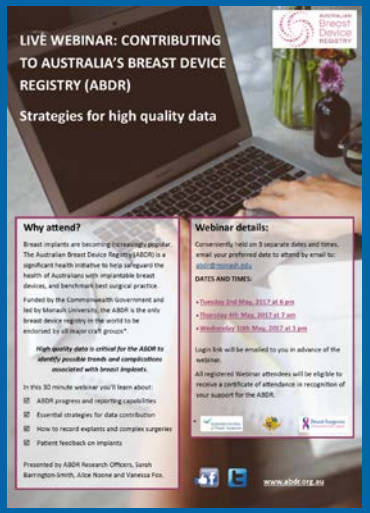
Site Reports

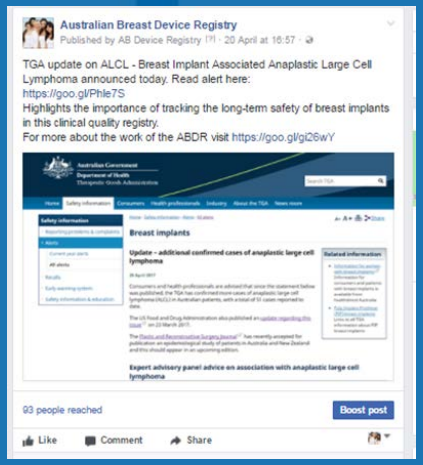
- Template will be a cut down version of the annual report
- Site reports will be piloted at 10 sites
- National rollout after pilot report feedback

Communications Snapshot



- Website development
- ABDR Newsletter 3.04.2017
- May Webinars
- In house researcher engagement
- SPHPM e-news – PRATO, PROMS
- ABDR Social Media
- In-service & presentations
- Media Outreach progress
- Consumer network engagement
- Reclaim Your Curves, Saferbreast Implants Website
- Inclusion of ABDR logo on 14 Point Plan video





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Ongoing projects and collaborations

- Exploring possibilities for direct data capture
- Capturing cosmetic tourism patients
- Pilot in New Zealand
- Potential linkages with cancer registries
- ICOBRA – harmonization, data pooling, data amplification

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ICOBRA, Prato Summit. In summary, it was AGREED

- High risk devices should all have registries.
- Breast device registries should be supported by all parties.
- BDR are to be designed to detect adverse events early and guide superior treatment protocols and implants.
- Opt out systems are known to be superior.
- A core spine dataset should be internationally agreed upon for breast implant registries
- Core spine data points should have agreed definitions internationally.
- The Delphi method will be used to obtain optimal core data points and quality indicators.
- PRO-s can be used as a screening method for early detection of implant adverse events.
- PRO systems for breast device patients should be uniform internationally.
- GS-1 should be mandatory for manufacturers to provide for all breast devices.
- GS-1 should be part of the registry.
- GS-1 should be optimized to import all implant specific characteristics to a registry.

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Knowledge based sharing and the ABDR

- Population level data collection for the purpose of tracking device safety and driving systems improvement

- A key element is knowledge sharing amongst a broad range of stakeholders including surgeons, hospitals, patients, industry, regulators and international collaborators.

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Breast
Device
REGISTRY

Thank you

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ABDR Email: abdr@monash.edu
ABDR Website: www.abdr.org.au
ABDR twitter: @BreastDeviceReg

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Questions?