



Knowledge based sharing in health

Ingrid Hopper *MBBS BMedSc PhD FRACP*

Project Lead, ABDR

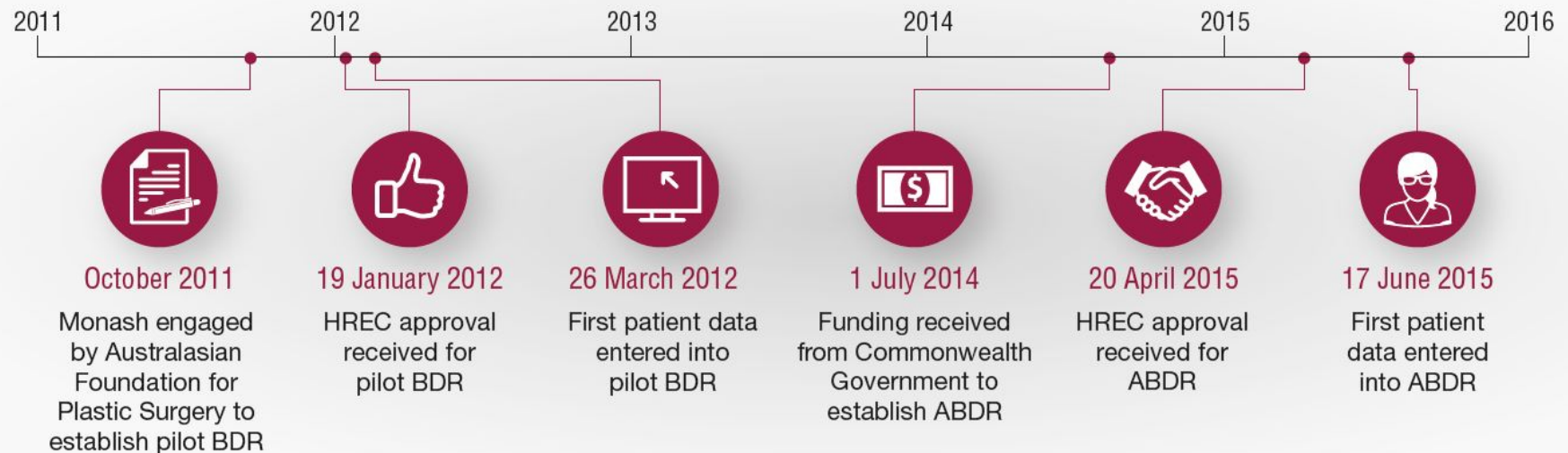
SCIENCE tells us what we CAN do.
GUIDELINES what we SHOULD do.
REGISTRIES what we are ACTUALLY doing!

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

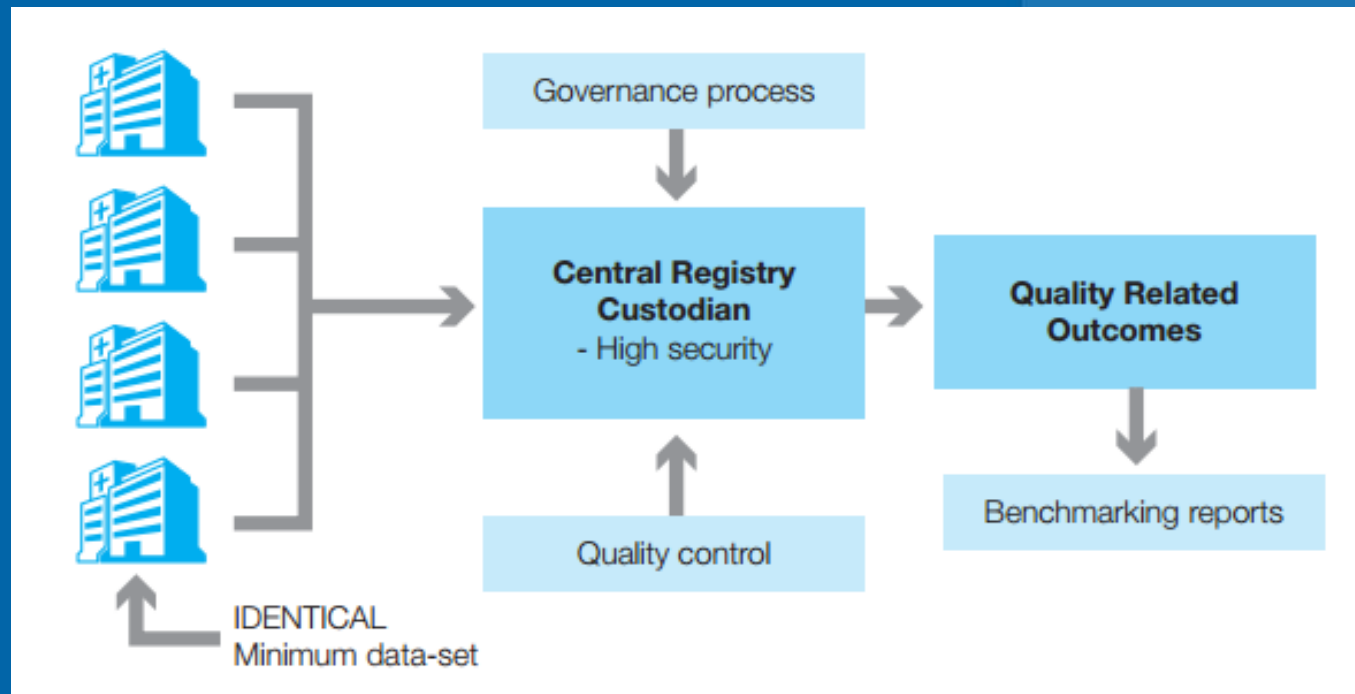
About ABDR

- 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



Basic architecture of the ABDR



Stakeholders



Australian Government
Department of Health



Australian Government
Department of Health
Therapeutic Goods Administration



**Australian Society
of Plastic Surgeons**



BreastSurgANZ



**Consumers
Health Forum
of Australia**



MONASH University
Medicine, Nursing and Health Sciences



Medical Technology
ASSOCIATION OF AUSTRALIA

**AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE**

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

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

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

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

Progress to date on the ABDR

As at 25th May 2017

Sites

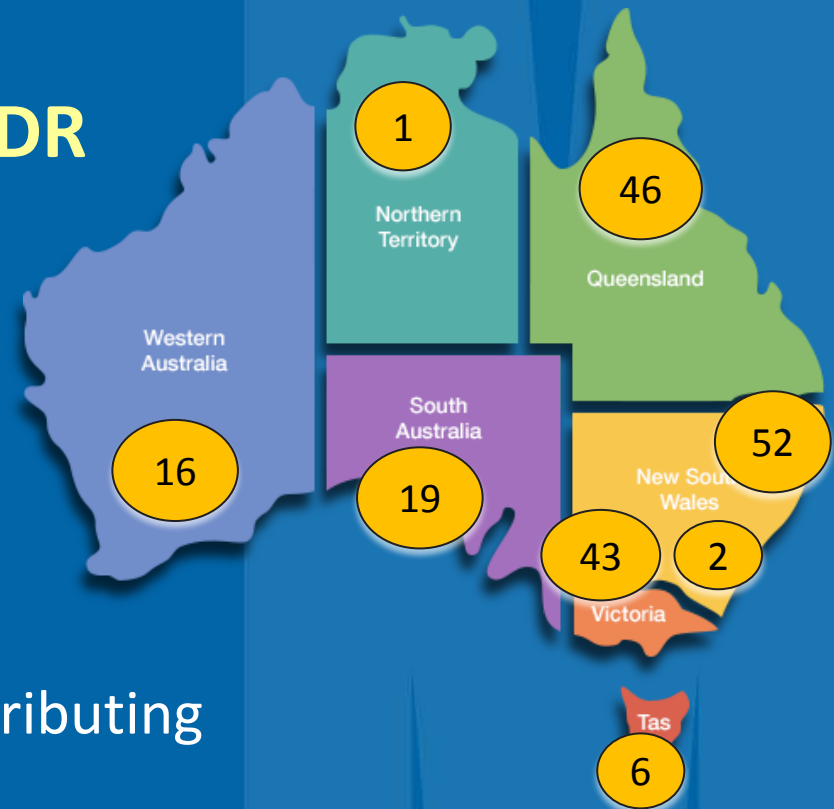
185 sites contributing

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



Consult

Theatre

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)

Australian Breast Device Registry

The Australian Breast Device Registry (ABDR) is a Commonwealth Government initiative... Monash University's Breast of Public Health and Preventive Medicine is leading in partnership with the Australian Department of Health, the Australian College of Cosmetic Surgery (ACCS) and Breast Surgeons of Australia (BSA) to establish the ABDR.

The Registry will capture data on all Australian patients undergoing breast device surgery... Your surgeon contributing to the ABDR on your behalf will go into the Registry. The Registry will collect information such as the reason for your surgery, the type of procedure, size of device and whether your experience was complicated.

Placing surgery with a breast implant or device requires it all contribute to our understanding of the long term safety of implanted breast devices and help to improve patient safety.

To help understand the impact of long-term outcomes associated with breast device surgery, we may contact you 1, 2, 5 and 10 years post procedure to obtain any issues arising from the surgery.

Your privacy is of utmost importance to us. Your data will be handled in accordance with the Australian Privacy Principles and stored in a secure and safe database. You will not be individually identified in any report arising from the Registry.

It is important to note that participation in the Registry is **NOT** compulsory for you, the patient. The data provided to you at the practice will be collected to ensure you have the best possible outcome for your procedure in the Registry.

If you would like to register, you should inform your surgeon about the Registry for your surgery please contact the ABDR Coordinator on:

1800-066-722 or abdr@monash.edu or (03) 8000-0266

or contact the website: www.abdr.gov.au

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

Australian Breast Device Registry Form

PATIENT INFORMATION

First name: [] Last name: [] Date of birth: [] Sex: []

SURGERY DETAILS

Procedure: [] Date of surgery: [] Surgeon: []

DEVICE INFORMATION

Device name: [] Device type: [] Device size: []

PATIENT SATISFACTION

How satisfied are you with the results of your surgery? []

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 (spilling/leaking) 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

Australian Breast Device Registry

Explanatory Statement

Why the public should not register a response only performed by the local health service is required to be placed for the response.

1. To ensure that this information is kept with the patient's personal data, rather than in a separate database, it is important to ensure that the patient's personal data is kept with the patient's personal data.

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10. To ensure that the patient's personal data is kept with the patient's personal data, it is important to ensure that the patient's personal data is kept with the patient's personal data.



ELEMENTS OF OPERATION

RIGHT BREAST

Incision site

- ☐ Axillary
☐ Areolar
☒ Infra-mammary
☐ Previous mastectomy scar
☐ Mastopexy/reduction wound

Plane

- ☐ Sub-glandular / Sub-fascial
☒ Sub-pectoral
☐ Sub-flap

☒ Tick if Same Bilateral

Plane

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

BREAST LEFT

Incision site

- ☐ Axillary
☐ Areolar
☐ Infra-mammary
☐ Previous mastectomy scar
☐ Mastopexy/reduction wound

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

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

Operation
Details

INTRAOPERATIVE TECHNIQUES

☒ Intra-op prophylactic antibiotic

☒ Glove change for insertion ☐ Sleeve

Intraoperative
Techniques

RIGHT BREAST

☐ Nipple absent

☐ Nipple sparing

☒ Occlusive nipple shield

☒ Drain used

☒ Tick if Same Bilateral

Occlusive

Drain used

Nipple sparing

FOR REVISION SURGERY ONLY

RIGHT BREAST

☐ Tick if Same Bilateral

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

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

☐ Tick if Same Bilateral

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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Device deflation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Capsular contracture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Device malposition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Skin scarring problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Deep wound infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Seroma/Haematoma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Breast cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Anaplastic Large Cell Lymphoma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

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

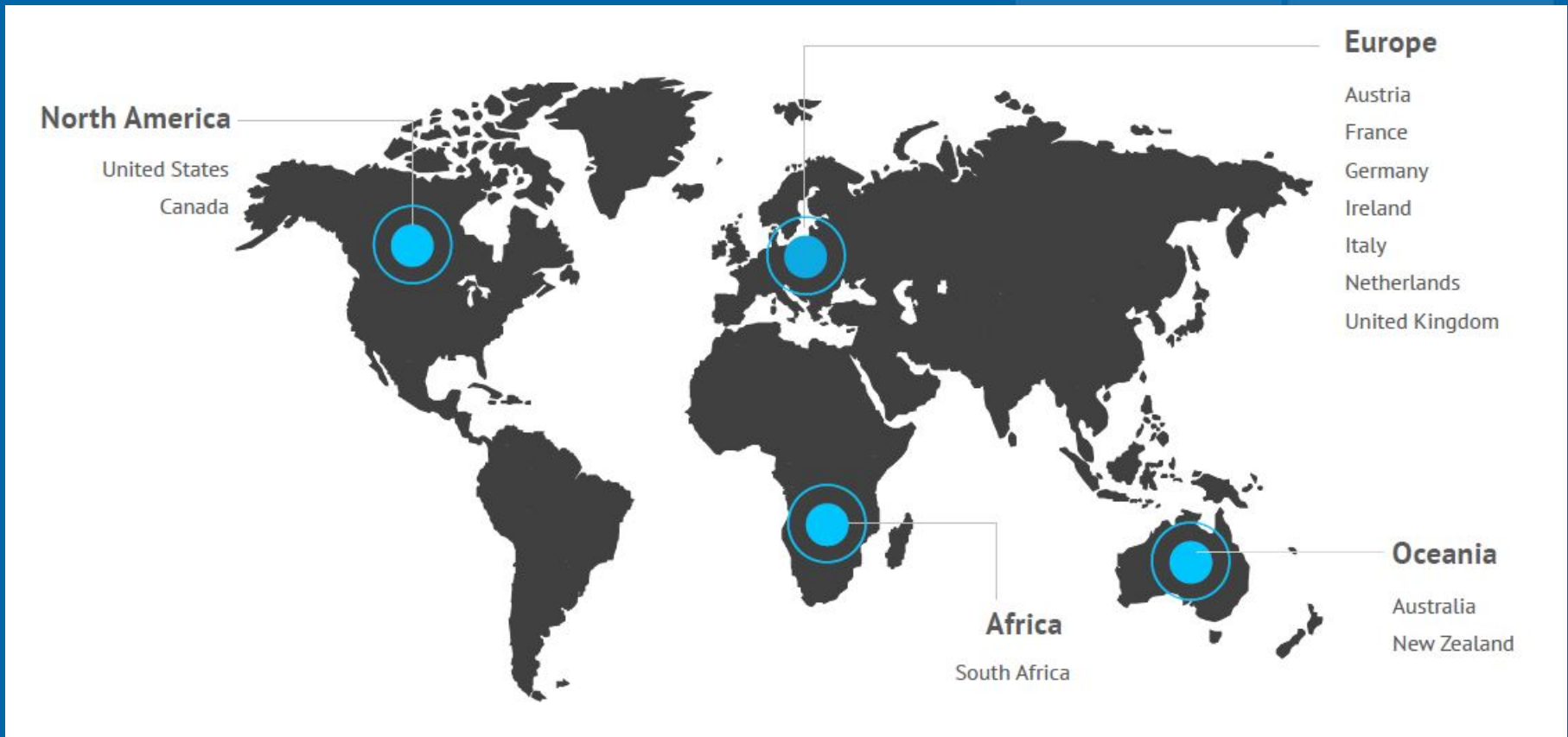
Stakeholders	Benefits
Patients	Product recall, Electronic identification
Surgeons	Product recall, Implant failure rate, Benchmarking
Hospital	Maintenance of certification, Government accreditation
Industry	Product recall, Market share
Insurance	Product recall, Implant failure rate
Government	Patient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



Permission to display the ABDR logo

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

International Collaboration of Breast Registry Activities





Challenges



Challenges

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

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

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

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 <u>not</u> 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 <u>see</u> ?	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

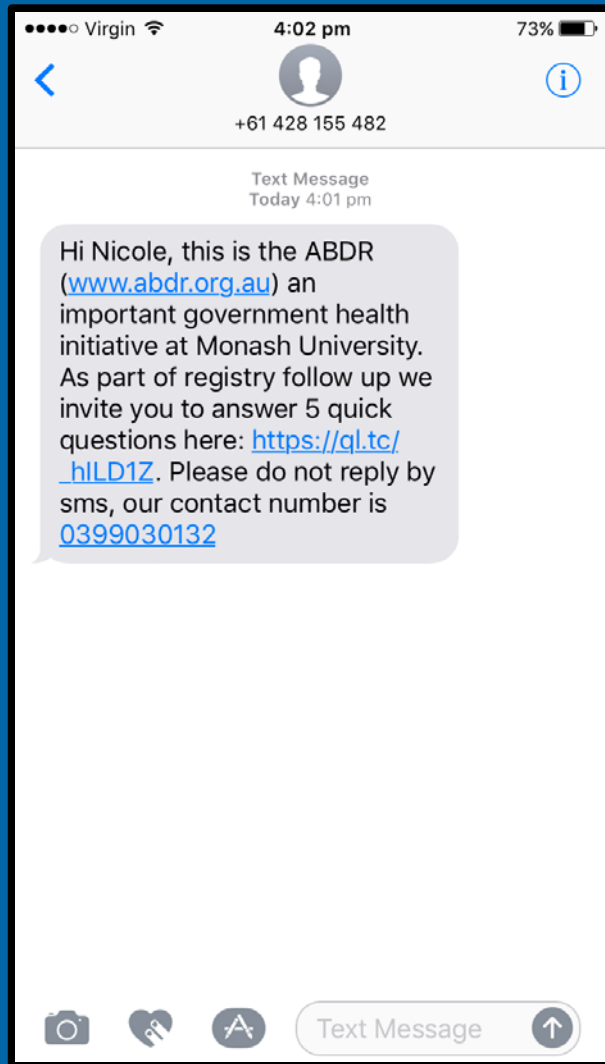
With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. The shape of your reconstructed breast(s) when you are <u>not</u> 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 <u>see</u> ?	1	2	3	4

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d. Pain 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.



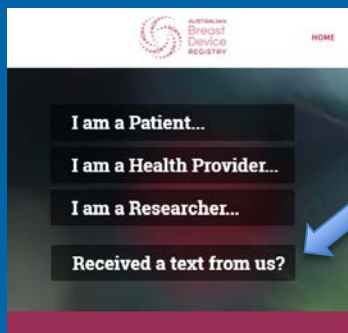
ABDR reporting

2016 Annual Report

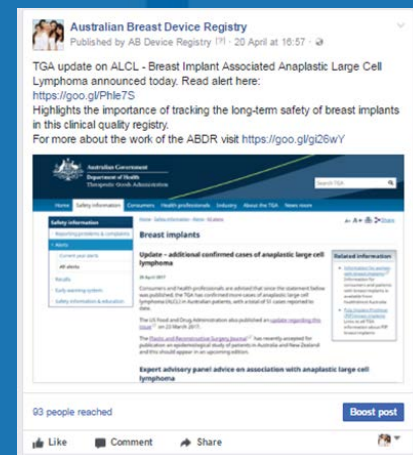
- Data cut encompassing all procedure data up to 31/12/16
- Currently being analysed by Registry Sciences Unit biostatisticians
- ABDR Steering committee, societies and stakeholder review: August 2017
- Publication: September 2017

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



- 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



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



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.

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.



AUSTRALIAN
Breast
Device
REGISTRY

Thank you

ABDR Phone: 03 99030205

ABDR Email: abdr@monash.edu

ABDR Website: www.abdr.org.au

ABDR twitter: @BreastDeviceReg



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Questions?