Australian Breast Device Registry (ABDR) Patient Reported Outcome Measure (PROM) Pilot Study

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Research Officer, Australian Breast Device Registry
About ABDR

- Commonwealth funded, clinical quality registry
- Established on recommendation by Australian Senate enquiry following Poly Implant Prosthese (PIP) crisis (2010)
Progress to date on the ABDR
As of August 2017

392 Surgeons
240 Sites
17,671 patients
<1% opted out
Estimated 20,000 surgeries a year
ABDR Data Collection Form (DCF)
### Operation Details

**Elements of Operation**

<table>
<thead>
<tr>
<th>Right Breast</th>
<th>Left Breast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision site</td>
<td>Plane</td>
</tr>
<tr>
<td>Axillary</td>
<td>Sub-pectoral/Sub-fascial</td>
</tr>
<tr>
<td>Axillary</td>
<td>Sub-pectoral</td>
</tr>
<tr>
<td>Inframammary</td>
<td>Sub-pectoral/Sub-fascial</td>
</tr>
<tr>
<td>Previous mastectomy scar</td>
<td>Sub-pectoral</td>
</tr>
<tr>
<td>Mastectomy/Reduction wound</td>
<td></td>
</tr>
</tbody>
</table>

- Concurrent Mastectomy: [ ] Yes [ ] No
- Concurrent Axillary surgery incl. sentinel node biopsy: [ ] Yes [ ] No
- Concurrent Mastectomy / Reduction: [ ] Yes [ ] No
- Concurrent Flap cover: [ ] Yes [ ] No
- Previous Mastectomy/Reduction: [ ] Yes [ ] No

### Intraoperative Techniques

**Intraoperative Techniques**

<table>
<thead>
<tr>
<th>Right Breast</th>
<th>Left Breast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nipple absent</td>
<td>Occlusive nipple shield</td>
</tr>
<tr>
<td>Nipple sparing</td>
<td>Occlusive nipple shield</td>
</tr>
<tr>
<td>Nipple retractor</td>
<td>Occlusive nipple shield</td>
</tr>
</tbody>
</table>

### Revision Surgery

**For Revision Surgery Only**

<table>
<thead>
<tr>
<th>Right Breast</th>
<th>Left Breast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision Type:</td>
<td>Revision Type:</td>
</tr>
<tr>
<td>Replacement</td>
<td></td>
</tr>
<tr>
<td>Capsulectomy</td>
<td>Fat</td>
</tr>
<tr>
<td>Neo-pocket formation</td>
<td>Yes</td>
</tr>
<tr>
<td>Explanted device: Ref. No.</td>
<td>Date Inserted</td>
</tr>
<tr>
<td>Shell:</td>
<td>Anatomical</td>
</tr>
<tr>
<td>Fill:</td>
<td></td>
</tr>
</tbody>
</table>

- Reason for Revision: [ ] Yes [ ] No
- Details: 

- Device rupture? [ ] Yes, reason for revision [ ] Yes, found incidentally [ ] No
- If yes, please indicate whether silicone extravasation was found:
  - Intracapsular
  - Extracapsular
  - Distal

<table>
<thead>
<tr>
<th>Yes, reason for revision</th>
<th>Yes, found incidentally</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device infection</td>
<td>Capsular contracture</td>
<td>Device malposition</td>
</tr>
<tr>
<td>Skin scoring problems</td>
<td>Deep wound infection</td>
<td>Seroma/Healmatoma</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>Anaplastic Large Cell Lymphoma</td>
<td></td>
</tr>
</tbody>
</table>
Why do we do Patient-reported outcome measure (PROM)

- Basis for making choices about treatment
- Track safety of implants and predict rate of revision surgery
- Create realistic expectations toward surgical outcomes
- Identify problems, facilitate communication, direct appropriate treatment of underappreciated symptoms
- Reassure patients with implants about their safety and improve patient care
Patient Reported Outcome Measure (PROM) for ABDR

1. A Patient Reported Outcome Measure for the Australian Breast Device Registry – an acceptability and feasibility study.

2. Patient Reported Outcome Measure (PROM) for women with breast implants – A pilot Study
Development of BREAST-Q Implant Surveillance (IS)

Questions were selected from 88-question BREAST-Q

5 questions most predictive of performance of devices were selected

3 questions selected from “Physical Well-Being” domain

2 questions selected from “Satisfaction with Breasts” domain
## AUGMENTATION ITEMS

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Very Dissatisfied</th>
<th>Somewhat Dissatisfied</th>
<th>Somewhat Satisfied</th>
<th>Very Satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. The shape of your breasts when you are not wearing a bra?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>b. How your breasts feel to touch?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>c. The amount of rippling (wrinkling) of your implant(s) that you can see?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

In the past week, how often have you experienced:

<table>
<thead>
<tr>
<th>Item</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Pain in your breast area?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>b. Tightness in your breast area?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

## RECONSTRUCTION ITEMS

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Very Dissatisfied</th>
<th>Somewhat Dissatisfied</th>
<th>Somewhat Satisfied</th>
<th>Very Satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. The shape of your reconstructed breast(s) when you are not wearing a bra?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>b. How your reconstructed breast(s) feels to touch?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>c. The amount of rippling (wrinkling) of your implant(s) that you can see?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

In the past week, how often have you experienced:

<table>
<thead>
<tr>
<th>Item</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>d. Pain in your reconstructed breast(s) area?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>e. Tightness in your reconstructed breast(s) area?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
PROM for ABDR – An acceptability and feasibility study

**Aim:** To examine the acceptability and feasibility of a PROM for the ABDR

**Participants:**
- 21 recipients (10 implant based reconstruction and 11 breast augmentation)
- 10 surgeons (five plastic, two cosmetic and three breast surgeons)
Key Findings:

- Overall support for using BREAST-Q Implant Surveillance (BREAST-Q IS) as a PROM Tool.
- Majority supported receiving follow up from ABDR with email as a preferred method of follow up.
- Recipients find areas on restriction of movement, barrier to intimacy and support to be important while some surgeons are more concerned about the subjective nature of the answers which might affect surgical outcome and carry reputational risks.
‘it is good that the questionnaire is brief—much more likely you will get responses as it would take minimal time to read and answer questions’ (ID04_Recon)

‘essential, very straightforward and good balance’ (ID05_Surg)

‘This is an extremely subjective process what women feel about the shape of their breast and their breast might not change shape at all. I mean she might be happy at year one and not happy at year three. Maybe they lost some weight, maybe the partner made some disappointing comment about it, all these kind of stuff and there is that kind of noise that I think you are going to get’ (ID08_Surg)
**Aim:** To pilot test our PROM Tool for monitoring breast implant devices in registry patients with breast implants by utilising different methods of follow up including text messaging, phone call, email and mail.

- 200 registry patients who fit our selection criteria were randomly selected from the ABDR database.
Selection Criteria:
- Primary device insertion was 10 to 15 months prior to commencement of study
- 18+ years old
- Has mobile number recorded in the database
- Primary device surgery was performed at a site that follows Alfred and Monash Ethics approvals
### Number of Patients Selected in Various Age Groups

<table>
<thead>
<tr>
<th>Patient Cohort</th>
<th>20-30 years</th>
<th>31-40 years</th>
<th>41-50 years</th>
<th>51+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosmetic</td>
<td>42</td>
<td>25</td>
<td>32</td>
<td>21</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>8</td>
<td>24</td>
<td>23</td>
<td>25</td>
</tr>
</tbody>
</table>

We try to have even numbers across the 2 cohorts in different age groups so we can see if our method of follow up is preferred by a particular age group.
Patients Engagement Process

Flow Chart 2: Patients engagement process

1. **Text Messaging – Individual weblink**
   - Completed follow up through web link
   - No Response
   - Opt out of follow up through web link

2. **Week 1**
   - Follow up with phone call No.1
     - Yes: Opt out of follow up confirmed
     - No: Follow up with phone call No.2
       - Follow up with phone call No.3
         - Follow up with phone call No.4
           - Email if any, otherwise mail
             - Mail

3. **Week 2**
   - Follow up with phone call No.1
     - Yes: Opt out of follow up confirmed
     - No: Follow up with phone call No.2
       - Follow up with phone call No.3
         - Follow up with phone call No.4
           - Email if any, otherwise mail
             - Mail

4. **Week 3**
   - Follow up with phone call No.1
     - Yes: Opt out of follow up confirmed
     - No: Follow up with phone call No.2
       - Follow up with phone call No.3
         - Follow up with phone call No.4
           - Email if any, otherwise mail
             - Mail

5. **Week 4**
   - Follow up with phone call No.1
     - Yes: Opt out of follow up confirmed
     - No: Follow up with phone call No.2
       - Follow up with phone call No.3
         - Follow up with phone call No.4
           - Email if any, otherwise mail
             - Mail
Why Text Message?

- Positive feedback from the acceptability and feasibility study
- 70% of our registry patients have mobile phone numbers as compared to only 10% have recorded email addresses
- BREAST-Q IS being a 5-question survey
- Mean age: Cosmetic patients - 34.8yrs
  Reconstructive patients - 49.9yrs
- According to Australia Mobile Consumer Survey, smartphone ownership is 84% in 2016 and rising

1 Deloitte Global Mobile Consumer Survey, 2016
Why QUALTRICS?

- Monash University has ongoing Qualtrics license
- Surveys can be easily designed on Qualtrics which is well presented as a web survey and optimised for smart phone web viewing.
- Other advantages include:
  + Cost effective (approx. $0.08/SMS)
  + Instant response
  + Individual unique link for tracking
  + Secure and ISO certified
### Example of Creating a Survey on QUALTRICS

#### DROP-DOWN LIST

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>The shape of your breasts when you are not wearing a bra?</td>
<td>dropdown</td>
</tr>
<tr>
<td>How your breasts feels to touch?</td>
<td>dropdown</td>
</tr>
<tr>
<td>The amount of rippling (wrinkling) of your implant(s) that you can see?</td>
<td>dropdown</td>
</tr>
</tbody>
</table>

#### SURVEY DISPLAY TYPE

**In the past week, how often have you experienced?**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain in your breast area?</td>
<td>dropdown</td>
</tr>
<tr>
<td>Tightness in your breast area?</td>
<td>dropdown</td>
</tr>
</tbody>
</table>

*Click here to edit scale points*
Creating Contact Lists on QUALTRICS

Add Contacts

- Import From a File
- Add Manually
- Import From a Survey

<table>
<thead>
<tr>
<th>Email</th>
<th>First Name</th>
<th>Last Name</th>
<th>External Data Reference</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Viewing Rows 1 - 10 of 10

Skip this step
Add Contacts
Hi Nicole, this is the ABDR (www.abdr.org.au) an important government health initiative at Monash University. As part of registry follow up we invite you to answer 5 quick questions here: https://gl.tc/h1LdiZ. Please do not reply by sms, our contact number is 0399030132.

You have been invited to participate in the Australian Breast Device Registry (ABDR) follow up pilot study. The ABDR is a Commonwealth Government initiative, managed by Monash University. The timelines for follow up were explained in the Patient Explanatory Statement sent to you by ABDR when your procedure was first recorded in the Registry.

The ABDR team has developed a 5 question BREAST-Q IS questionnaire with the aim of monitoring the safety of breast device(s) and to understand their impact on women’s health and wellbeing. We request that you take a few minutes to complete the 5 questions as accurately as possible. Your contribution will enable us to identify predictors of breast implant...
I am a Patient...

I am a Health Provider...

I am a Researcher...

Received a text from us?
With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

The shape of your breasts when you are not wearing a bra?

How your breasts feels to touch?

The amount of rippling (wringling) of your implant(s) that you can see?

In the past week, how often have you experienced?

Pain in your breast area?

Tightness in your breast area?

Any further comments?

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

The shape of your breasts when you are not wearing a bra?

How your breasts feels to touch?

The amount of rippling (wringling) of your implant(s) that you can see?

Very Dissatisfied

Somewhat Dissatisfied

Somewhat Satisfied

Very Satisfied
PROMs PILOT STUDY
(n=200)

Ineligible
(n=3)

Breast Augmentation
(n=118)
- 8 Opt off follow-up
- 36 Lost to follow-up

Completed follow-up
(n=74)

Breast Reconstruction
(n=79)
- 3 Opt off follow-up
- 1 Opt off registry
- 14 Lost to follow-up

Completed follow-up
(n=61)
Completed Follow Up
(n=135)

30% completed survey via text message in the first instance

23% completed survey via text message after a phone call follow-up
## Percentage of patients who completed follow up via text message by age group

<table>
<thead>
<tr>
<th>Patient Cohort</th>
<th>20-30 years (n=50)</th>
<th>31-40 years (n=49)</th>
<th>41-50 years (n=55)</th>
<th>51 + years (n=46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage who completed Follow Up via Text Message</td>
<td>36%</td>
<td>41%</td>
<td>27%</td>
<td>48%</td>
</tr>
</tbody>
</table>

- 11 patients clicked through the survey link but did not complete the survey
- 4 patients completed the survey through email
Results from Breast Augmentation Cohort

Breast Augmentation

<table>
<thead>
<tr>
<th>Satisfied with</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHAPE</td>
<td>50</td>
</tr>
<tr>
<td>TOUCH</td>
<td>56</td>
</tr>
<tr>
<td>RIPPLING</td>
<td>63</td>
</tr>
</tbody>
</table>

- Very Dissatisfied: 2
- Somewhat Dissatisfied: 5
- Somewhat Satisfied: 13
- Very Satisfied: 63

Breast Augmentation

<table>
<thead>
<tr>
<th>Experienced</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAIN</td>
<td>53</td>
</tr>
<tr>
<td>TIGHTNESS</td>
<td>59</td>
</tr>
</tbody>
</table>

- All of the time: 53
- Most of the time: 59
- Some of the time: 2
- A little of the time: 3
- None of the time: 0
Results from Breast Reconstruction Cohort
Key Findings

- BREAST-Q IS is a well received short survey and on average takes less than 4 minutes to complete over the phone.
- Most registry patients have forgotten what ABDR is and therefore did not complete the survey through the first text message.
- It is important that surgeons and sites fill in as many contact details as possible for patients, particularly email.
- Some registry patients would like to comment on each breasts separately.
Hi, this is the ABDR (www.abdr.org.au) an important government health initiative at Monash University, in association with (Insert Surgeon’s 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 1800-930-989.
**In Conclusion**

- Text messaging is an effective way to follow up registry patients in conjunction with phone, email and post.

- However some minor amendments need to be made to the text message to remind the patients of ABDR and highlight the importance of completing follow up

- PROM is extremely important for tracking the long term experience and performance of breast implants.
THANK YOU