Breast and Cosmetic Implant Registry
Clinical Audit Platform: Operational Guidance
Published June 2019
<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment History</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>11/10/2016</td>
<td>Minor amendments to text</td>
</tr>
<tr>
<td>1.1</td>
<td>28/12/2016</td>
<td>Amended wording to Type of Operation, Risk Reduction renamed to Infection Control</td>
</tr>
<tr>
<td>1.2</td>
<td>23/03/2017</td>
<td>Web links updated and information relating to MESH manufactures and products</td>
</tr>
<tr>
<td>1.3</td>
<td>26/08/2018</td>
<td>New data item of manufacturer of explanted device and change of labels</td>
</tr>
<tr>
<td>1.4</td>
<td>02/01/2019</td>
<td>Updated to reflect removal of patient consent</td>
</tr>
<tr>
<td>1.5</td>
<td>03/06/2019</td>
<td>Updated to reflect inclusion of surgeries in Scotland</td>
</tr>
</tbody>
</table>
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1 INTRODUCTION

1.1 Purpose

The purpose of this document is to provide a guide for users entering breast implant data into the Clinical Audit Platform (CAP) for the purposes of the Breast and Cosmetic Implant Registry (BCIR). CAP is accessible from the following link: https://clinicalaudit.hscic.gov.uk/bir

CAP is the data collection tool owned and supported by NHS Digital. The tool is currently used for a variety of audits and data collections. Further information about CAP is available from https://digital.nhs.uk/services/clinical-audit-platform

To use CAP, you must create a Single Sign On account with NHS Digital and register to submit data for the BCIR. This can be done following the steps on the form BCIR Registration Form and Documents

This guidance document provides an overview of the CAP screens and the data fields required for completion.

1.2 Scope

Data should be submitted to the registry whenever patients undergo surgery for primary cosmetic breast augmentation, breast reconstruction using a tissue expander or implant, or the replacement, removal or reposition of an implant.

Each time a patient has one of these surgical procedures a new surgery record must be created.

1.3 Related Documents

The following have been put together to provide you with additional support and are available on the webpage: www.digital.nhs.uk/bcir

- Patient Information Leaflet
- Clinical Audit Platform: Operational Guidance for Breast Implant Registry
- Frequently Asked Questions for healthcare providers
- Frequently Asked Questions for patients
- Paper data collection form for use locally prior to submission to CAP
- Data Collection Items

1.4 How CAP is structured

The Clinical Audit Platform consists of separate tabs, each of which contains a different screen where you will enter data pertaining to a distinct aspect of the record. These tabs include:

- Patient details
- Surgery details
• Implant device details
• Operation details
• Revision details including replacement, reposition and removal
• Complications
• Infection control techniques during surgery
• Implant mesh details

Where a data item is mandatory you will see required next to the item. The icon next to a data item means there is information to clarify what is required, which can be viewed by hovering over the icon.

2 CREATING A PATIENT RECORD

To submit data you will need to open CAP using this link: https://clinicalaudit.hscic.gov.uk/bir

You must use the username that you registered with and your own password. Please note that you should not attempt to sign in to CAP using another user’s credentials. This constitutes a breach of information governance guidelines.

When you have signed in, you will see along the top of the screen a banner with links to various parts of the portal – see the below screenshot:

Figure 1: Areas of the Breast Implant Registry

Breast Implant Registry

Add / Search for Patient Record

REPORTING

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For technical problems and login queries, please contact NHS Digital on:
0300 303 5678
enquiries@nhsdigital.nhs.uk

2.1 Adding a new Patient record

Click on Add/Search for Patient Record: See Figure 2

Until January 2019, patient consent was required for records to be added to the BCIR. This is no longer required following agreement with the Department of Health and Social Care.

The consent form has been removed from our website but will still be held in local records for patients that had surgery before 14 January 2019.

You will be presented with a screen asking you whether or not consent has been obtained from the patient to submit their information to the registry; this should be completed for surgeries before 14 January 2019. For surgeries that take place after 14 January 2019 you should select NO.
For patients having surgery before 14 January 2019, if there is no evidence of the relevant consent form in the patient’s records, you should select **NO** and the data should not be submitted.

**Figure 2: Start data submission by adding patient record**

**Breast Implant Registry**

Where available, the NHS or CHI number **should** be recorded along with the date of birth as a minimum. **If the patient is under 18 years of age, an alert will appear on screen to ask if the date of birth is correct.** If the NHS or CHI number is not available, select ‘NO’. This is most likely for overseas and private patients. It is important to ensure the patient details are accurate to allow the patient to be traced in the event of a recall.

When the NHS number and date of birth are known also enter the demographic details.

### 2.2 Patient Details

When you have completed the first screen you will be asked for further patient details (see Figure 3).

If an NHS or CHI number is not available, when you enter NO, you will be asked to complete the patient’s first name, surname/family name, date of birth, gender and postcode – these **must** be recorded.

**Figure 3: Patient demographics where NHS or CHI number not available**

*Add / Search for Patient Record*
In both of the above scenarios when you click submit, you are taken to a screen which will already be populated with the information you have entered. Enter the remaining data, the final question to answer is if the patient is a ‘medical tourist’, i.e. they are a citizen of another country who has come to this country for surgery. If you answer YES, you will be able to select the relevant country from the drop down list.

For patients from overseas, who do not have a UK postcode you can use a pseudo postcode. Type in: ZZ99 3WZ.

**Figure 4: Patient demographics**

NHS Number: 8824791646

CHI Number:

Date of birth: 01/01/1990

Firstname:

Surname:

Gender: Female

Postcode:

Is the Patient a Medical Tourist? Yes

If yes, Country of Residance:

Once the patient details are submitted you will see on the screen a Record Tree:

![Record Tree](image)

**Note:**

Once you have submitted the patient record if you realise that you have entered an incorrect NHS or CHI number you **cannot** edit it, you will need to delete the record and re-enter the information and submit it.

If you know that a patient has had surgery before at your hospital and has been submitted onto the registry, look at the patient extract by selecting the report function and check if an NHS or CHI number has been added. (NHS Digital search for missing NHS numbers on a regular basis and add them to the registry, this will make it easier to find the patient. If there is no NHS number to find your patient you must enter details exactly as they were before, take care with the spelling and dates of birth)
3 ADDING A SURGERY RECORD

Once the patient record has been created you are now able to add the details of the operation that has taken place and the implant that has been inserted. Click on Add Surgery.

Depending on the Category of Operation entered, further data items will be required or will be “greyed out”.

**Figure 5: Identify the type of surgery being undertaken**

**Warning**

NB: If you change the Laterality or Category of Operation half way through data entry, the new validation rules will be applied. Data will be removed if no longer applicable and cells greyed out. If data is still relevant it will remain in the User Interface.

**Warning**

Where a patient has an *Explant*, select “Different procedures on each breast” in the laterality field so that you can enter specific information for each breast.

**Note:** If a patient has completely different types of procedures during one operating session you should enter them as 2 separate surgeries on the same day.

For example, a patient may have a reconstruction on the left breast and a primary cosmetic augmentation on the right breast to obtain symmetry. In these instances, the Record Tree will show both records with date and the type of operation.
3.1 Device tab

The device screen is essential to enable the recall process in the event of an implant failure and should be completed for Left and Right as appropriate.

Mandatory items are:

- Device Manufacturer (selected from a drop-down list)
- Device Identifier (DI)
- Serial number
- Catalogue Reference number (if the DI is not available)
- Lot number (if the DI is not available)

The DI consists of a GTIN (the first 14 digits underneath the barcode and is prefixed with (01). Examples of two manufacturers’ labels are shown below in figure 8 and the items you will be using for your data entry. In the DI field enter the 14 digits. Along with this you must enter the serial number.

If you are unable to identify the 14-digit Device Identifier you will have to enter the
- Serial number
- Catalogue Reference number (if the DI is not available)
- Lot number (if the DI is not available)

Sometimes the manufacturer label only records a serial or Lot number in these cases repeat whichever one you have in both fields.

When you have finished entering data click **Next** at the bottom of the screen.

**Figure 6: Details of device (implant used)**
Figure 7: Example implant labels for manufacturer
3.2 Operation tab

This provides information on where the surgery was performed, the Consultant responsible for the patient’s care, the surgeon who performed the operation, the operation date, and the American Society of Anaesthesiologist Grade (ASA).

Figure 8: Operation details

Surgery

Mandatory items are as follows:

- Site code and name: this is the hospital where surgery took place. A separate list will drop down when you click in the site code and name box, allowing you to select the relevant site by entering the site code in the search box.

- Responsible consultant GMC Number: The General Medical Council registration number for the surgeon responsible for the surgery. When a surgeon is registered to practice medicine in the United Kingdom, their details will appear on the "General Medical Council List of Registered Medical Practitioners". (http://www.gmc-uk.org/doctors/register/LRMP.asp) The GMC code must be 7 digits.

- Operating Surgeon GMC Number: The General Medical Council registration number for the surgeon carrying out the operation. When a surgeon is registered to practice medicine in the United Kingdom, their details will appear on the "General Medical Council List of Registered Medical Practitioners". (http://www.gmc-uk.org/doctors/register/LRMP.asp) The GMC code must be 7 digits.

- Operation Date: The date that the operation took place.

- The ASA Classification before Operation is as follows:

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A normal healthy patient.</td>
</tr>
<tr>
<td>2</td>
<td>A patient with mild systemic disease.</td>
</tr>
<tr>
<td>3</td>
<td>A patient with severe systemic disease, that limits function, but is not incapacitating.</td>
</tr>
<tr>
<td>4</td>
<td>A patient with severe systemic disease that is a constant threat to life.</td>
</tr>
<tr>
<td>5</td>
<td>A moribund patient who is not expected to survive without the operation.</td>
</tr>
</tbody>
</table>

When you have finished entering data, click **Next** at the bottom of the screen.
3.3 Surgery tab

The following picture (Figure 9) shows the data items for surgery. Depending on the laterality (side of operation) selected some of the data items will be greyed out.

**Figure 9: Surgery details**

![Surgery details](image)

Peri-operative antibiotics include pre-op/intra-operative and post-op
Remember

If a tissue expander was used (as indicated in ‘Type of Operation’), you should have already entered the device number on the device tab as this is essential for any recall process.

NOTE

Each time a patient has a surgical procedure a surgery record MUST be created.

For example, if a primary breast augmentation has been carried out, but 3 months later the implants are replaced, repositioned or explanted. The patient’s NHS Number or patient identifiers can be used to search for the patient and the Record tree will appear.

Click on Add Surgery and enter the details for the replacement, reposition or removal. The Record Tree will display the dates of various surgeries.

3.4 Revision tab

For all procedures involving an implant replacement, reposition or removal, in addition to the operation and surgery tabs you will need to complete the Revision tab. The data items required will differ depending on the type of revision and the laterality of the operation as shown in figures 11-13.

On the revision tab you will be asked to identify the ‘reason for revision’, e.g. if the revision is due to patient preference (i.e. the patient has requested it or the revision has been performed due to a complication).

If an implant has been removed you will also be asked to identify, if possible, the manufacturer of that implant.

If Complication has been selected, once you have entered the revision details, you should select the complications screen. If patient preference is selected, when the surgery was performed, it may have identified some complications and therefore you may need to enter data on the complication screen.
3.4.1 Implant Replacement

Figure 10: Replacing an implant

3.4.2. Procedure to Reposition Implant

Figure 11: Repositioning implant
### 3.4.3 Procedure to remove an Implant (Explant)

**Figure 12: Removing implant surgery**

When a replacement, reposition or explant takes place the next section **Complications** will need to be completed.

#### 3.4.4 Complications tab

The information required here is what may be discovered during a revision procedure. It is important to complete this in the event of a revision being performed, as it will help to identify outliers as part of an early warning system (e.g. implants with a higher than average rupture rate).

**REMEMBER**

If you select Yes reason for revision or Yes found incidentally when answering the question about Anaplastic Large Cell Lymphoma, ask the clinical team to notify the MHRA via the Yellow Card system.
Figure 13: Complications identified during revision

Select **Next** to advance to the next section of the registry.
Table 1: Complications identified may be:

<table>
<thead>
<tr>
<th>Complication</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicone extravasation found</td>
<td>Silicone found in the cavity outside of the implant</td>
</tr>
<tr>
<td>Device rupture / deflation</td>
<td>Implant has ruptured</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td>Scar tissue inside the body around the implant</td>
</tr>
<tr>
<td>Device Malposition</td>
<td>Implant has moved from original placement</td>
</tr>
<tr>
<td>Deep wound infection</td>
<td>Infection identified during revision</td>
</tr>
<tr>
<td>Seroma or Haematoma</td>
<td>Some bleeding occurred and collection of blood around the implant</td>
</tr>
<tr>
<td>Histology Sent</td>
<td>Biopsy taken during revision and sent for histology</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>Malignancy identified during revision</td>
</tr>
<tr>
<td>Anaplastic Large Cell Lymphoma</td>
<td>Anaplastic large cell lymphoma (ALCL) is a rare type of non-Hodgkin lymphoma (NHL)</td>
</tr>
</tbody>
</table>

**NOTE**

In this section, the item ‘Histology Sent’ relates to a biopsy being sent for histological investigation as part of the revision – not if histology was taken when the initial reconstruction was performed.

### 3.5 Infection Control Tab

For all categories of operation you can submit data on the infection control techniques that were used during the surgical procedure. Responses to these questions are Yes, No or Unknown.

**Figure 14: Infection Control techniques**
When you select **Next**, you will be moved to the final screen, Mesh.

**NOTE**

At any point during your submission, once you have entered all the mandatory data, instead of clicking on NEXT you can click on the MESH tab and click SUBMIT.

### 3.6 Mesh Tab

This will be relevant if the surgical procedure is for a reconstruction or a Revision/Replacement where a surgical mesh is used.

The drop-down list for the manufacturer will show the product name and the manufacturer.

**Figure 15 Data Items for MESH**

<table>
<thead>
<tr>
<th>Data Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laterality</td>
<td>Same bilateral</td>
</tr>
<tr>
<td>Category Of Operation</td>
<td>Reconstruction</td>
</tr>
<tr>
<td>Left Mesh Or Dermal Sheet</td>
<td>-- Please Select --</td>
</tr>
<tr>
<td>Left Mesh Manufacturer</td>
<td>-- Please Select --</td>
</tr>
<tr>
<td>Left Mesh Device Identifier</td>
<td></td>
</tr>
<tr>
<td>LEFT Mesh Catalogue Reference Number</td>
<td></td>
</tr>
<tr>
<td>LEFT Mesh Serial Number</td>
<td></td>
</tr>
<tr>
<td>LEFT Mesh Lot Number</td>
<td></td>
</tr>
<tr>
<td>Right Mesh Or Dermal Sheet</td>
<td>-- Please Select --</td>
</tr>
<tr>
<td>Right Mesh Manufacturer</td>
<td>-- Please Select --</td>
</tr>
<tr>
<td>Right Mesh Device Identifier</td>
<td></td>
</tr>
<tr>
<td>RIGHT Mesh Catalogue Reference Number</td>
<td></td>
</tr>
<tr>
<td>RIGHT Mesh Serial Number</td>
<td></td>
</tr>
<tr>
<td>RIGHT Mesh Lot Number</td>
<td></td>
</tr>
</tbody>
</table>

When you click submit if any mandatory data is missing a warning message will appear. You can go back to the relevant section and enter the data.
4 REPORTING

Within CAP it is possible to run a report by clicking on the ‘Reporting’ link in the banner at the top of the page. You can then select ‘Extract’.

There are currently two reports that can be extracted (see Figure 16).

Figure 16: Extracting Reports

<table>
<thead>
<tr>
<th>Extract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
</tr>
<tr>
<td>Surgery</td>
</tr>
</tbody>
</table>

4.1 Patient extract

When selecting ‘Patient’, you will then need to identify the dates that you are searching for – remember to select the month, day and year. By selecting export you will be able to open or save the csv spreadsheet.

This report will show you all the patients that have been created and edited using the site code that you are registered against.

Surgeons that are registered to use CAP will be able to view all patients wherever they have performed the surgery as the records and report are linked to their GMC code.

4.2 Surgery extract

By selecting ‘Surgery’, this will provide you with patient information and surgical details.

This report will show you all records of surgeries that have been created and edited using the site code that you are registered against. Surgeons that are registered to use CAP will be able to view all patients wherever they have performed the surgery, as the records and extracts are linked to their GMC code.

NOTE

If you can’t see the patient on the surgery extract you have probably only entered a patient record.

Figure 17 and Table 2 illustrates what you can view in the extracts.
Figure 17: Reports that can be viewed

```
Start
   ↓
Type of Extract
   ↓
Surgery Extract
   ↓
Is user a surgeon?
   ↓
YES
   | Records for patients undergoing surgery in the selected date range that were created/updated by the surgeon or have the surgeon’s GMC CODE assigned to the (associated) surgery record
   ↓
NO
   | Records for patients undergoing surgery in the selected date range that were created/updated by the user or underwent surgery at the users’ organisation

Patient Extract
   ↓
Is user a surgeon?
   ↓
YES
   | Patient extract shows patient records created or updated by the surgeon or patient records with an associated surgery record where their GMC code is present in the associated surgery record, that were created/updated in the selected date range
   ↓
NO
   | Patient extract shows patient records created/updated by the user or undergoing surgery at the users’ organisation, that were created/updated in the selected date range
```

### Table 2 Data Extracts

| Filters          | From date, To date                                                                 | Patient extract - filters on date record created/updated  
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Surgery extract - filters on date of surgery (in surgery record)</td>
</tr>
<tr>
<td>Criteria</td>
<td>Displays a list records as detailed in table below</td>
<td>Surgeon - records they personally created/updated, and/or their GMC code has been assigned to the associated surgery record</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-clinical staff - records where the user (or another user registered at their organisation) created/updated the record and/or their organisation is the surgical organisation (in the surgery record)</td>
</tr>
<tr>
<td>Output</td>
<td>CSV only</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Extract</th>
<th>Consultant</th>
<th>User Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient</td>
<td>Non-Consultant</td>
</tr>
<tr>
<td>Patient</td>
<td>Patient records that were; *created/updated in selected date range AND *created/updated by that consultant OR *the surgeon’s GMC code appears in the associated surgery record</td>
<td>Patient records that were; *created/updated in selected date range AND *the user (or another user registered at their organisation) created/updated the Patient record OR *the surgery took place at the users' organisation (if the patient has an associated surgery record)</td>
</tr>
<tr>
<td>Surgery</td>
<td>Surgery records where; *the date of surgery is within the selected date range AND *the surgeon created/updated the surgery record OR *the surgeon's GMC code appears in the record</td>
<td>Surgery records where; *the date of surgery is within the selected date range AND *the user (or another user registered at their organisation) created/updated the surgery record OR *the surgery took place at the users' organisation</td>
</tr>
</tbody>
</table>
5 LOGGING OUT OF CAP

Once you have finished adding and editing BCIR records within CAP, select ‘Sign Out’ from the top right of the browser screen (see Figure 19). It is important to do this to ensure that no one else can gain unauthorised access to your account.

Figure 18: CAP home screen with ‘Sign Out’ highlighted

Breast Implant Registry

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