Does the patient have to consent to their information being submitted to the registry?

No. In late 2018 the legal basis for the collection was amended so consent is no longer required for patients having a surgery from 14 January 2019 onwards.

Patients who had surgery prior to 14 January 2019 but had not previously consented or been added to the registry can still request to have their data added to the registry. A consent form need not be completed but hospitals may wish to keep a record of the request.

Patients who had surgery prior to 14 January 2019 and completed a consent form but have not yet been added to the registry, can still be added and their consent recorded in the registry.

Which hospitals are eligible?

All NHS trusts and independent hospitals performing breast implant surgery in England are eligible to submit data to the registry.

NHS Digital is commissioned by the Department of Health and Social Care to run the Breast and Cosmetic Implant Registry in England. Through the Health and Social Care Act 2012, a devolved administration can make a formal request to NHS Digital to collect their data.

Scotland is in the process of joining the registry. The other devolved nations are not currently in the registry.

Do hospitals have to pay a subscription to participate?

The NHS Trusts and Independent providers do not have to pay any subscription to participate and submit data.

Which surgeries are eligible?

All breast implant and explant surgery, including revisions and reconstructions, are eligible for inclusion. The main aim of the registry is to be able to trace patients in the event of a product recall or safety concern relating to a specific type of implant.

Where will the data be stored?

Data will be stored on a restricted access secure database managed by NHS Digital. Primarily data is used by NHS Digital to instigate a recall of relevant patients in the event of a product failure, and where it is identified that their implant is involved.
NHS Digital will publish reports on such things as: total numbers, procedures, types of implants, and outcomes. These reports will only contain aggregated information (i.e. data that has been grouped or combined) so no individual patient will be identifiable.

Who can register to submit data?

It is up to the hospital provider to decide who in their organisation will collect and submit the patient information onto the registry, which is hosted on NHS Digital’s Clinical Audit Platform (CAP). There can be more than one user per organisation. This may be a surgeon, theatre staff or administrative staff.

The person(s) identified to submit data will need to register to use CAP by creating a Single Sign On Account (if they have not already got one) and completing a registration form. [https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry registration form]

Surgeons only need to register once, even if they work across several hospitals. Surgeons need to register if they intend to submit data themselves, but they would also need to be registered to be able to view their patient’s data submitted by someone else.

I am already registered with a Single Sign On account with NHS Digital for other applications. Do I have to register to input data for the registry?

Yes. You will still need to complete a registration form so that we can link your e-mail address to the registry. However, if you have already created a Single Sign On (SSO) account for some other application, you don’t need to complete the SSO step again, but you must use the same email address for the registry as your Single Sign On account.

I completed a registration form and was given access to the clinical audit platform, but I can’t access it when I sign in?

If you have had confirmation that you have been given access to the clinical audit platform for the registry you have to do the Single Sign on first and assign a password.

Follow this link [Single Sign On]
Who can view data?

When each patient record is entered, they can select where the procedure was carried out by selecting the hospital from the drop-down list on CAP. The records are all linked to the surgeons GMC code.

A non-clinical person (i.e. a “non- surgeon” will only be able to view patients records that they have created/submitted and patients that have been operated on at their hospital).
Breast and Cosmetic Implant Registry
Frequently Asked Questions (FAQs) for providers

Centrally, is it possible to have someone (or several people) with reporting access to view all of our provider sites?

In the initial phase, users will only be able to view their own sites, apart from the surgeon who will be able to view all patients that they have operated on. This will be reviewed later as a possible future development. It is recognised that the senior management team for an organisation may need to have an overview of all patients undergoing surgery at their sites.

Does a Caldicott Guardian need to complete a form?

Yes. As part of the governance process the Caldicott Guardian needs to complete Part C of the CAP user registration form. The Caldicott Guardian must be the registered Caldicott Guardian listed on the National Caldicott Guardian Register.

The completed form must be sent to the enquiries team at NHS Digital enquiries@nhsdigital.nhs.uk from the Caldicott Guardian's own professional email address.

Independent hospitals within a large hospital group, e.g. Nuffield Health, BMI Healthcare, Spire, Ramsay should have the registration form completed by the group’s Caldicott Guardian.

If the Caldicott Guardian has recently changed, the organisation will need to notify the Exeter Help Desk using the appropriate form on the National Caldicott Guardian Register webpage.

How do I submit to the registry once registered?

BCIR Operational Guidance is available on our webpage: www.digital.nhs.uk

Data is manually submitted into CAP. CSV or XML file upload is not currently available.

I can’t access the clinical audit platform (CAP), what should I do?

If you have registered and have been given access to CAP but cannot sign in, check which version of Internet explorer your IT system is using. If it is Internet explorer version 8 or below you will not be able to access CAP.

Check your browser settings by clicking on a cog in top right and select “About Internet Explorer” this will confirm the operating system. You may need to ask your IT department for an upgrade. If you are using IE8 (or below) with XP you will be able to access CAP if you use the latest version of Chrome.
Use the paper data collection form and submit to CAP later once you are able to access CAP.

If you need further advice contact NHS Digital contact centre on enquiries@nhsdigital.nhs.uk or phone 0300 303 5678

**How can I check if a surgeon who works in our organisation is already registered?**

Locally you will need to ask them, but if a registration form is sent in to NHS Digital and they are already registered for the registry, that won’t matter, they will not be duplicated.

**When will data be required to be entered on the system? Will there be a cut-off date?**

This will need to be agreed locally but it is best to submit the data as close to the surgery as possible.

We have provided a paper data collection form which can be used to record the data, then passed to a designated member of staff to submit to CAP.

Deadlines will be set prior to planned publications and all registered users informed.

**Can data be submitted for a patient that had an implant before the launch of the registry in 2016?**

**Yes.** If patients that had surgery prior to the existence of the registry wish to be included, their data can be submitted by the hospital. The provider must still be in business for this to be possible, with all the patient notes still available about the implant.

Since the amendment to the legal basis in late 2018, a consent form need not be completed if a historical patient requests to have their data added to the registry. However, hospitals may wish to keep a record of the request.

**I have entered the NHS number incorrectly and when I try to edit it the field is “greyed” out**

Once the NHS number is entered and the patient record submitted you can not edit the NHS number. You will need to delete the patient record and re-enter the details.
Breast and Cosmetic Implant Registry
Frequently Asked Questions (FAQs) for providers

If you have already submitted a surgery record attached to the wrong NHS number you must delete that surgery record and re-enter.

Which numbers are required about the implant in the device section and MESH section of the Clinical Audit Platform?

You need to record the Device Identifier (DI). This is the first 14 digits underneath the barcode and is prefixed with (01). In the DI field, enter the 14 digits. You also need to provide:

- The manufacturer
- The serial number

If you cannot find the Device identifier you must complete the

- The manufacturer
- The catalogue reference number
- The serial number
- The Lot number

These can be found on the sticky label taken off the device during surgery. Please refer to section 3 of the operational guidance or further information.

BCIR Operational Guidance

The implant label does not have a serial number and Lot number what should I enter?

- The manufacturer
- The catalogue reference number
- The number on the label indicated as either the serial or Lot number record in both fields

Version 0.7 (January 2019)
One of the data items on the surgery tab asks about peri-operative antibiotics what does that mean?

If patients are given antibiotics before surgery, during surgery or post-operatively answer YES to this question.

What happens in the event of a recall?

If for patient safety reasons, there is a need to contact patients and recall them for assessment, then details from the registry will be used by NHS Digital to attempt to trace the patients’ current address using records held on the NHS Spine.

The organisation that carried out the surgery will then be provided with the patient’s current address, where available, so that the provider can contact their patients and arrange for the appropriate steps to be taken to ensure patient safety.

How can I check that patients operated at my hospital are on the registry?

Sign into CAP. Select Report then select the patient extract, select the date range from <use 16/10/2016> To <use the current date> – it will show you which patients have been submitted. Then check the surgery extract to make sure that all your patients have had their surgery details entered.

I have submitted patients onto the registry without an NHS number but now see that there is an NHS number for that patient?

NHS Digital will be updating patient records, where possible, by searching the NHS Spine. If an NHS number is found NHS Digital will add the number to the patients’ record.

How can I prevent duplicate records?

Check the patient extract in the report function. If your patient has had previous breast surgery at your hospital make sure that you search for them in CAP using the exact name, date of birth and postcode that was put in before. If you see that they now have an NHS number on their record in the extract use that in the search function to find the patient record and add their new surgery.
Can I edit a patient record if I find that I have made an error?

YES. In CAP when you search for your patient record you can then select \textit{Edit record}. This will allow you to make any necessary amendments.

I have a patient who has had 2 different types of procedures on the same day how do I enter that?

Example if a patient has an only primary cosmetic augmentation on the Left breast and a reconstruction on the Right breast they will need to be added as 2 surgeries.

The screenshot below shows how this will be displayed on the record tree in CAP.