Data Provision Notice

Breast and Cosmetic Implant Registry (England)

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Contents

Version History

Version	**Changes**	**Date**
4.0	Published	29/01/2019
5.0	Content moved into new template; details for NHS and independent providers combined into one DPN.	19.10.2023

Background

The Health and Social Care Act 2012 (the Act) gives NHS England statutory powers, under section 259(1)(a), to require data from health or social care bodies, or organisations that provide publicly funded health or adult social care in England, where it has been directed to establish an information system by the Secretary of State for Health and Social Care.

The data, as specified by NHS England in this published Data Provision Notice, is required to support a direction from the Secretary of State for Health and Social Care to NHS England. Therefore, organisations that are in scope of the notice are legally required, under section 259(5) of the Act, to provide the data in the form and manner specified below.

Purpose

NHS England has developed the Breast and Cosmetic Implant Registry (BCIR), to capture the details of all breast implant procedures completed in England by both the NHS and private providers. The Department of Health and Social Care directed NHS Digital (now part of NHS England) to carry out this work in response to Recommendation 21 of the Keogh Review of the Regulation of Cosmetic Interventions. See link: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf

The primary purpose of the BCIR is to record the details of any patient, who has had breast implant surgery, so that they can be traced in the event of a product recall or other safety concern relating to a specific type of implant. Should an implant recall arise, an agreed process will be followed.

The secondary purpose of the BCIR is to provide an ‘early warning system’. Data from the registry will inform an outlier process through the identification of any trends and complications related to specific implants.

NHS England will publish reports on the total numbers and types of implants, procedures and outcomes. These reports will only contain aggregated information (that is, data that has been grouped or combined) so that no individual patient will be identifiable.

Benefits

The main benefit of the BCIR is to improve patient safety by providing the ability to accurately track and trace patients in the event of a product recall following breast implant surgery in England. NHS England will not be able to trace overseas patients. Furthermore, the BCIR can also be used to monitor outcomes which fall below an expected level and report any such outliers to the Medicines and Healthcare products Regulatory Agency (MHRA) and providers as necessary.

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 England to attempt to trace the patients’ current address using records held on the NHS Spine.

NHS England will then inform the relevant organisations that carried out the surgery, of the affected patients to be contacted, providing up-to-date address details where available, so that they can be advised of the appropriate steps to be taken to ensure their safety.

Legal basis for collection, analysis, publication and dissemination

NHS England has been directed by Secretary of State for Health and Social Care under section 254 of the Health and Social Care Act 2012; to establish and operate a system for the collection and analysis of the information specified for this service. A copy of the Direction is published here: https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/breast-and-cosmetic-implant-registry-2018.

Breast implant registry NHS Providers

This information is required by NHS England under section 259(1)(a) of the Health and Social Care Act 2012.

Providers are required under section 259(1)(a) to comply with the requirement and **must** provide information to NHS England in the form, manner and period specified in this Data Provision Notice.

Breast implant registry private providers

This information is required by NHS England under section 259(1)(b) of the Health and Social Care Act 2012. All Independent Sector providers (private providers), performing privately funded breast and/or cosmetic surgery, in England are requested to provide information to NHS Digital in the form, manner and period specified in this Data Provision Notice.

However, under section 259(2)(b), where Independent Sector providers are performing NHS funded care, providers are required under section 259(1)(a) to comply with the requirement and **must** provide information to NHS England in the form, manner and period specified in this Data Provision Notice.

In line with section 259(5) of the Act, all organisations in scope, in England, must comply with the requirement and provide information, where stated, to NHS England in the form, manner and period specified in this Data Provision Notice.

The Breast and Cosmetic Implant Registry Direction (No 2) 2018 removed the requirement for patient consent to be given for their record to be included in the BCIR.

A patient information leaflet is available on the BCIR web page.

This Notice is issued in accordance with the procedure published as part of NHS England duty under section 259(8).

Persons consulted

Following receipt of a direction to establish a system to collect Breast and Cosmetic Implant Registry, NHS England has, as required under section 258 of the Health and Social Care Act 2012, consulted with the following persons:

- Department of Health and Social Care
- Association of Breast Surgeons

- British Association of Aesthetic Plastic Surgeons
- British Association of Plastic, Reconstructive and Aesthetic Surgeons
- Medicines and Healthcare products Regulatory Agency
- Patient representatives
- Private Healthcare Information Network
- Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group
- Royal College of Surgeons of England

Scope of the collection

Under section 259(1)(a) of the Health and Social Care Act 2012, this Notice is served in accordance with the procedure published as part of the NHS England duty under section 259(8) on the following persons:

- NHS Trusts that provide specialist breast implant surgery including NHS funded and non-NHS funded patients.

Under section 259(1)(b) of the Health and Social Care Act 2012, this Notice is served in accordance with the procedure published as part of the NHS England duty under section 259(8) on the following persons:

- Independent Sector Service Providers in England that provide specialist breast implant surgery for NHS funded patients must submit data to the registry.
- Independent Sector Service Providers in England are requested to provide information to the registry of patients whose care is non-NHS funded.

Under section 259(5) of the Health and Social Care Act 2012 the organisation types specified above must comply with the Form, Manner and Period requirements below.

Form of the collection

A list of the data items to be collected for the registry can be found in the document Data Collection Items and Paper Data Collection Form on the BCIR webpage.

For certain data items, the NHS data dictionary has been referenced (for example, gender).

The following patient identifiable information is included in the collection:

- NHS Number (mandatory where available)
- First name (optional, mandatory if NHS Number not provided)
- Surname (optional, mandatory if NHS Number not provided)
- Gender (optional, mandatory if NHS Number not provided)
- Date of birth (mandatory)
- Post code (optional, mandatory if NHS Number not provided)

Manner of the collection

Data will be submitted by providers using the NHS England secure online platform, currently this is the Clinical Audit Platform (CAP). During the autumn of 2023 the collection will migrate to the Medical Device and Outcome Registry (MDOR) platform.

A link to the CAP is available here: Breast and Cosmetic Implant Registry - NHS Digital

Information on the MDOR platform will be published in due course.

Surgeons and administrative staff submitting data to MDOR, will be required to register to use the system by creating an account with NHS England and completing and submitting a registration form which needs to be signed off by the designated approver for the hospital providing the care.

The CAP registration process form can be found under Documents on the BCIR webpage: Breast and Cosmetic Implant Registry - NHS Digital

An operational guidance note is also available under Documents, on the webpage, to help providers submit data onto the registry:

https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry/clinical-audit-platform-operational-guidance

There is also the BCIR Data Collection form, which is a paper data collection, available under Documents, for providers to record the required information, in the unlikely event of the MDOR system not being available. When the system is available, it is suggested that data is captured electronically on MDOR, as close to the point of care delivery as possible. Local processes should be agreed as to how the data collection is to be completed.

Period of the collection

The BCIR was launched on 10th October 2016 and is an ongoing collection; this must be updated whenever patients have breast implants or tissue expanders implanted, exchanged, replaced or removed. Providers will need to develop local processes as to when and how data is entered into the system, but NHS England has advised in the support documents that it is best practice to submit the data as close to the surgery as possible.

NHS England has a statutory obligation to keep collections under review on an ongoing basis. As such, the BCIR is to be reviewed continuously post launch to ensure:

- That it remains fit for purpose
- To assess data quality
- That it maintains alignment with clinical safety
- That it is aligned to policy requirements
- That corrections are made in light of any errors highlighted by stakeholders.

A revised Data Provision Notice will be issued following any amendments to the data set required for the registry as a result of any review.

Data quality

- The quality of the data being entered into the registry is reviewed continuously. The first annual report was published in November 2018 and a report has been published in each following year. From 2022 the report included a dashboard, allowing users to drill into the data for a particular hospital or region. Both the report and dashboard are available from the Reports section of the website: https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry#reporting
- Work is ongoing to inform providers of the need to improve the quality of the data entered and all supporting materials/documentation have been and will be updated accordingly.

Burden of the collection

Steps taken by NHS England to minimise the burden of collection

NHS England has a statutory duty under section 253(2) of the Act to seek to minimise the burden it imposes on others. In seeking to meet these obligations in relation to this collection, NHS England has:

- consulted on the data requirements of the registry with the BCIR Stakeholder Group and identified what information is mandatory and non-mandatory.
- undertaken detailed testing of the initial dataset by surgical teams, which has resulted in the dataset being reduced. It is recognised that there is no existing standard clinical system, recording all the required details. It is proposed that a file upload system will be developed to enable those that may have existing databases to upload data in place of manual data entry.

In addition, in support of its obligation under 265(3) of the Act, NHS England has an assessment process to validate and challenge the level of burden incurred through introducing new information standards, collections and extractions.

This process is carried out by the Data Standards Assurance Service (DSAS) which assures burden assessment evidence as part of the overarching Data Alliance Partnership Board (DAPB) approval process. The DAPB, acting under authority of the Secretary of State, oversees the assurance, approval and publication of information standards and data collections for the health and social care system in England.

Assessed costs

The associated burden of the data collection is:

Burden on providers	£645,000	Year 1 costs (including set up costs) (estimated in 2016/17) [1]

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[1] A new burden assessment is scheduled for 2023-24 as part of the migration to the Outcome Registries Platform

Burden on providers	£379,000	Year 2 and ongoing annual costs