

Data Provision Notice

Breast and Cosmetic Implant Registry Northern Ireland and Scotland

Information Asset Owner: Chris Dew

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Version History

Version	Changes	Date
1.0	Published	2021
2.0	Content moved into new template; details for Scotland combined with Northern Ireland into one DPN.	19/10/2023

Background

Section 255 of the Health and Social Care Act 2012 (the Act) enables any organisation that can meet the requirements of the Act (including a devolved authority) to request that NHS England establish and operate an information system for the collection or analysis of information described in the section 255 request.

Where it has accepted a valid section 255 request, under section 259(1)(b) of the Act, NHS England may request information from any person that holds information that NHS England considers is necessary or expedient for it to have to fulfil the section 255 request.

The data, as specified by NHS England in this published Data Provision Notice, is requested to support non-mandatory requests under section 255 of the Act from the Department of Health, Northern Ireland and from the Scottish Government 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.

Requesting organisation

Department of Health, Northern Ireland

Chief Medical Officer (CMO) Group

Castle Buildings

Stormont Estate

Belfast BT4 3SQ

Scottish Government

Healthcare Quality and Improvement Directorate

St Andrew's House

Regent Road, Edinburgh

EH1 3DG

Purpose

NHS England has developed a Breast and Cosmetic Implant Registry (BCIR) which is expected to capture the details of all breast implant procedures completed by both the NHS and private healthcare providers in England, Scotland and Northern Ireland. The Department of Health and Social Care, England 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://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf

The Direction for England is published: <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>

The primary purpose of the BCIR is to record the details of any patient, who has had breast implant surgery for any reason, so that they can be traced in the event of a product recall or

other safety concern relating to a specific type of implant. As a secondary purpose, the BCIR will also allow the identification of possible trends and complications relating to specific implants which could be used as an early warning of a potential issue. Should a product recall arise, an agreed process will be followed.

In agreement with the Department of Health Northern Ireland and the Scottish Government, NHS England may 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, Northern Ireland or Scotland. 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 provided by NHS England to the relevant organisations in Northern Ireland and Scotland attempt to trace the patients' current address using Health and Care Number (for Northern Ireland) and the CHI number (for Scotland).

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

Collection and analysis

NHS England has been requested by both the Department of Health, Northern Ireland and from the Scottish Government under section 255 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 requests, which sets out the legal basis under which the Department of Health, Northern Ireland and from the Scottish Government have made these requests, is published on the NHS England website:

The Non-Mandatory Request from the Department of Health Northern Ireland is published at: <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/northern-ireland-non-mandatory-requests/collection-and-analysis-of-breast-and-cosmetic-implant-information-from-northern-ireland-healthcare-providers-request-2020>

The Non-Mandatory Request from the Scottish Government is published at: <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/nhs-scotland-non-mandatory-requests/breast-and-cosmetic-implant-registry-non-mandatory-request-nhs-scotland>

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

Publication

BCIR data will be published in the form of an Annual Report and supporting data dashboard, providing aggregate and anonymised data.

Dissemination

Under section 261 of the Act, NHS England may normally disseminate the information it obtains by complying with the section 255 request to an organisation that has a legal basis for receiving the information. Dissemination of data by NHS England is managed by the Data Access Request Service (DARS).

However, in the case of the BCIR, data for patients treated in Scotland or Northern Ireland cannot be disseminated. This is as a result of decisions made by the Public Benefit and Privacy Panel in Scotland and the Privacy Advisory Committee in Northern Ireland. The only exception is for specific cancer related cases to be shared with the Medicines and Healthcare products Regulatory Authority (MHRA) for patient safety.

Persons consulted

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

Department of Health Northern Ireland, as one of the requesting organisations

NHS National Services Scotland, as one of the requesting organisations

Members of the Breast and Cosmetic Implant Registry Stakeholder Group which includes members of the Association of Breast Surgery; British Association of Aesthetic Plastic Surgeons; British Association of Plastic Reconstructive and Aesthetic Plastic Surgeons; Medicines and Healthcare Regulatory Agency, Patient Representatives; Private Healthcare Information Network.

Scope of the collection

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:

Cosmetic surgery providers within both Health and Social Care Trusts in Northern Ireland and the Independent Sector in Northern Ireland are requested to provide information to the Registry including NHS funded and non-NHS funded patients.

Cosmetic surgery providers within both Regional Health Boards in Scotland and the Independent Sector in Scotland are requested to provide information to the Registry including NHS funded and non-NHS funded patients.

The organisation types specified above are requested to 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:
<http://digital.nhs.uk/bcir>

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 / CHI Number / Health & Care Number (mandatory where available)
- First name (optional, mandatory if NHS/ CHI/ H&C Number not provided)
- Surname (optional, mandatory if NHS/ CHI/ H&C Number not provided)
- Gender (optional, mandatory if NHS/ CHI/ H&C Number not provided)
- Date of birth (mandatory)
- Post code (optional, mandatory if NHS/ CHI/ H&C 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 for data from England was published in November 2018 and a report has been published in each following year, incorporating data from Scotland and Northern Ireland following the commencement of their respective requests. 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.