



Department
of Health &
Social Care

Room 2N15
Quarry House,
LS2 7UB
Leeds
20 November 2018

Mrs Sarah Wilkinson
Chief Executive,
NHS Digital
1 Trevelyan Square, Boar Lane
Leeds LS1 6AE

Dear Sarah

Breast and Cosmetic Implant Registry Direction (No 2) 2018

I am writing to direct the Health and Social Care Information Centre, now known as [NHS Digital](#) and thereafter referred to by this name, to continue to operate the Breast and Cosmetic Implant Registry (BCIR).

This Direction is given in exercise of the powers conferred on the Secretary of State for Health and Social Care by sections 254(1) and (6), and 304(9), (10) and (12) of the Health and Social Care Act 2012 (**the Act**).

This service supports the implementation of Recommendation 21 of the Keogh Review of the Regulation of Cosmetic Interventions:

“A National Breast and Cosmetic Implant Registry should be established and operational within 12 months. All cosmetic surgery providers need to keep a minimum data set that should be defined by the RCS Inter-specialty Group. This should include details of the implant, the surgeon, the hospital and appropriate outcomes, and these data need to be held in electronic format until the registry is operational. These data should be easily accessible in the case of a product recall”.

The provision of the BCIR also includes the function of informing people who have an implant of any safety risks if the provider of their implant is no longer in business (known as “the Last Resort Purpose”).

The priority is to develop and maintain a breast implant registry. However, the long-term vision is to expand the registry to other types of implant, for example, buttock and calf implants.

In accordance with section 254(2)(b) of the Act, the Secretary of State considers that this information is necessary or expedient to have in relation to his functions in connection with the provision of health services in England.

The Direction is to be known as the **Breast and Cosmetic Implant Registry Direction (No 2) 2018** and comes into effect on 20 November 2018.

Under section 254 of the Act, NHS Digital is directed to:

- host a Breast and Cosmetic Implant Registry to support the collection and storage of patient information relating to implants provided for cosmetic or reconstructive surgery;
- trace NHS numbers, where not available, and where possible to trace for those patients whose NHS number was not initially supplied to allow unique identification within the registry;
- track latest known patient address in the event of a product failure;
- monitor the outcomes achieved by 'brand' of prosthesis, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action;
- undertake the Last Resort Purpose to write to patients to inform them of a product failure in the event of their cosmetic surgery provider no longer being in business, to support the provision of health care, and promotion of health.

The Breast and Cosmetic Implant Registry shall be established for England. NHS Digital should work with the devolved administrations to enable those administrations to request that NHS Digital collect data on their behalf.

Implementation

Data can be submitted to the Breast and Cosmetic Implant Registry for implants, including implants received prior to its launch date and will follow a schema agreed between NHS Digital and the Department of Health and Social Care. The initial dataset schema is at Appendix A.

In accordance with section 254(5) of the Act, NHS Digital has been consulted before this Direction has been given.

Please accept this letter as a Direction given under section 254(1) of the Act to NHS Digital to continue to operate the Breast and Cosmetic Implant Registry, details of which are set out in the schedule at Appendix A.

This Direction replaces the Breast and Cosmetic Implant Registry Direction issued on 6th October 2016.

Yours sincerely

A handwritten signature in black ink, appearing to read 'S. Reeve', is positioned below the text 'Yours sincerely'.

Simon Reeve
Deputy Director - Public Health Systems and Strategy

Schedule to Direction Breast and Cosmetic Implant Registry

System Scope

1. The Service will enable NHS Digital to collect patient identifiable data on implant devices e.g. breast implants which have been inserted into the body for cosmetic or reconstructive surgery.
2. The data shall be securely stored and managed by NHS Digital acting as an agent for the Department of Health and Social Care. No one outside NHS Digital will have access to the registry. The Breast and Cosmetic Implant Registry will track and trace patients where the Medicines and Healthcare Products Regulatory Agency considers the risk to be high and referral back to a surgeon advisable.
3. The priority is to develop and maintain a breast implant registry. However, the long-term vision is to expand the registry to other types of implant, for example, buttock and calf implants.
4. NHS Digital will become the Data Controller for data that is submitted to the registry. The key NHS Digital deliverables are as follows:
 - Develop an appropriate dataset for the Breast and Cosmetic Implant Registry. This will include mapping to existing clinical terminologies and classifications as appropriate.
 - Data will be collected from:
 - Private cosmetic surgery clinics, providing breast augmentation services.
 - NHS Providers of reconstructive and plastic surgery.
 - Issue providers with Data Provision Notices (DPNs) under section 259 of the Act. Providers acting in compliance with a DPN do not breach the common law duty of confidentiality when they provide the information to NHS Digital.
 - Trace NHS numbers, where not available, and where possible to trace for those patients whose NHS number was not initially supplied to allow unique identification within the registry.
 - Track latest known patient address in the event of a product failure.
 - Monitor the outcomes achieved by 'brand' of prosthesis, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action.
 - Publish data in line with its responsibilities under the Statistics and Registration Services Act 2007 (SRSA) and relevant professional guidance including the UK Statistics Authority Code of Practice for Official Statistics. NHS Digital may also publish in other forms, manner and times that it considers appropriate.

- Disseminate data in line with its responsibilities under relevant legislation and guidance.
- Write to patients to inform them of a product failure in the event of their cosmetic surgery provider no longer being in business. It is recognised that the provision of a steering group will be essential to the approval of content of the letter(s) and thus a joint responsibility of the parties.