



Department
of Health

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Leeds

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Andy Williams
Chief Executive,
NHS Digital
1 Trevelyan Square, Boar Lane
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Dear Andy

RE: Breast and Cosmetic Implant Registry

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 establish and operate the Breast and Cosmetic Implant Registry (BCIR). This service will support 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 would also include 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.

The Health and Social Care Act 2012 makes provisions for Secretary of State to direct NHS Digital to exercise functions on the basis that Secretary of State considers it to be in the interests of the health service in England.

Under section 254 of the 2012 Act, NHS Digital is directed to:

- host a Breast and Cosmetic Implant Registry to support the collection and storage of appropriately consented participant information;
- 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.

NHS Digital will 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.

Please accept this letter as a direction given under subsection (1) of section 254 of the 2012 Act to NHS Digital to establish and operate the Breast and Cosmetic Implant Registry, details of which are set out in the attached schedule.

The Department of Health acknowledges that the Last Resort Purpose has been planned on the basis of, and is scoped for, those patients that have given their active consent as set out below, however nothing in this direction restricts the NHS Digital's power to process and disseminate information as set out in sections 261(1)(a)(b),(2)(c) and section 270 of the Act.

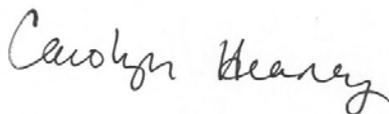
NHS Digital is directed to publish and disseminate data in line with its responsibilities under relevant legislation and guidance following consultation with DH.

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 where patient consent is received and will follow a schema agreed between NHS Digital and the Department of Health. The initial dataset schema is attached in the schedule below.

Yours sincerely



Carolyn Heaney
Deputy Director, Portfolio Management
Public & International Health Directorate
..Ends

Schedule to Direction Breast and Cosmetic Implant Registry

System Scope

1. The Service will enable NHS Digital to collect patient identifiable data with the appropriate patient consent 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. 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.
 - 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 following consultation with DH
 - Disseminate data in line with its responsibilities under relevant legislation and guidance following consultation with DH.
 - 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

The detailed schema detailing how the breast and cosmetic implant registry will work has been developed and agreed separately.