Breast Implant Registry: Data Collection Form

Data fields marked with an (M) are mandatory and must be completed

Patient Demographics				
NHS Number (Mandatory if known)				
CHI Number (Mandatory if known)				
Date of Birth **(M)** (Date format dd/mm/yyyy)	--/--/----			
First Name (Mandatory if no NHS/CHI number)				
Family name/Surname (Mandatory if no NHS/CHI number)				
Gender (Mandatory if no NHS/CHI number)	Female □	Male □	Not Known □	Not Specified □
Postcode (Make sure format correct) (Mandatory if no NHS/CHI number)				
Is this patient a medical tourist? (If Yes answer next question)	Yes □		No □	
If Yes record country of residence (Mandatory if Yes to Medical Tourist)				

Laterality/Which breast was operated on **(M**) (Then complete relevant section/s e.g., Left, Right or Both)	Same procedure on each breast □ Left only □ Right only □ Different procedure on each breast □
Operation Type/Category of Operation (**M**)	Primary Cosmetic Augmentation □ Reconstruction □ Replacement □ Reposition □ Explant □

Data fields marked with an (M) are mandatory and must be completed

Device	Left	Right
Implant Manufacturer **(M)**		
Device Identifier **(M)** (14 digits see information button)		
Device Catalogue ref number (Mandatory if Device identifier not provided)		
Device Serial number **(M)**		
Device Lot number (Mandatory if Device identifier not provided)		

You can insert copies of the product stickers here if it helps with data collection remember to label left and Right

Operation	
Site code/name of hospital where surgery was performed **(M)**	
Responsible Consultant of Care **(M)** (GMC Number should be 7 digits)	
Operating Surgeon **(M)** (GMC Number should be 7 digits)	
Operation Date (Date format dd/mm/yyyy) **(M)**	--/--/----

ASA Grade	1: A normal healthy patient	□
	2: A patient with mild systemic disease	□
	3: A patient with severe systemic disease that limits function, but is not incapacitating	□
	4: A patient with severe systemic disease that is a constant threat to life	□
	5: A moribund patient who is not expected to survive without the operation	□

Data fields marked with an (M) are mandatory and must be completed

Surgery Details (Please tick relevant boxes)		Left	Right
Previous radiotherapy	Yes		
	No		
	Not Known		
Type of Operation	Tissue expander insertion		
	Implant Insertion		
	Tissue expander removal & implant insertion		
	Tissue expander revision, removal & replacement		
Incision site	Axillary		
	Areolar		
	Infra-mammary		
	Previous mastectomy scar		
	Mastopexy reduction wound		
Plane	Sub-glandular/fascial		
	Sub-pectoral		
	Sub-flap		
Mastectomy	Yes		
	No		
	Unknown		
Nipple sparing	Yes		
	No		
	Unknown		
Mastopexy concurrent/previous	Yes		
	No		
	Unknown		
Flap Cover	Yes		
	No		
	Unknown		
Fat Grafting	Yes		
	No		
	Unknown		
Fat Volume (mls)			
Tissue Expander Volume (mls)			
Nipple absent	Yes		
	No		
	Not Known		

Peri-operative antibiotics? (this includes any given pre-op, intra-op or post-op)	Yes	
	No	
	Not Known	
Did the patient return to theatre within 48 hrs of initial surgery	Yes	No

Revision Procedure (please tick relevant boxes)		Left	Right
Reason for Revision **(M)**	Complication		
	Patient Preference		
If Implant was removed, was the implant inserted overseas?	Yes		
	No		
	Unknown		
Volume of implant removed (mls)			
Manufacturer of explanted device			
Serial number of explanted device	Number		
	Not Known		
Capsulectomy	Full		
	Partial		
	None		
Complications (Please tick relevant boxes)		**Left**	**Right**
Silicone extravasation found	Intracapsular		
	Extracapsular		
	Distant		
Device rupture / deflation	Yes reason for revision		
	Yes found incidentally		
	No		
Capsular contracture	Yes reason for revision		
	Yes found incidentally		
	No		
Skin Scarring problems	Yes reason for revision		
	Yes found incidentally		
	No		
Device Malposition	Yes reason for revision		
	Yes found incidentally		
	No		
Deep wound infection	Yes reason for revision		
	Yes found incidentally		
	No		
Seroma / Haematoma	Yes reason for revision		
	Yes found incidentally		
	No		
Histology sent	Yes		
	No		
Breast Cancer	Yes reason for revision		
	Yes found incidentally		
	No		
Anaplastic Large Cell Lymphoma (ALCL)	Yes reason for revision		
	Yes found incidentally		
	No		

Data fields marked with an (M) are mandatory and must be completed

Infection Control (Please tick relevant boxes)		Left	Right
Antibiotic dipping solution?	Yes		
	No		
	Not Known		
Was an Antiseptic Rinse used?	Yes		
	No		
	Not Known		
Were surgical gloves changed for implant insertion?	Yes		
	No		
	Not Known		
Was a Sleeve/funnel (Keller funnel) used?	Yes		
	No		
	Not Known		
Were Nipple guards used?	Yes		
	No		
	Not Known		
Were Drains used?	Yes		
	No		
	Not Known		

Mesh		Left	Right
Was a Mesh/Dermal sheet used?	Yes		
	No		
Mesh/Dermal sheet manufacturer **(M)**			
Device Identifier **(M)-** (14 digits see information button)			
Catalogue ref number for Mesh/Dermal sheet (Mandatory if Device identifier not provided)			
Mesh/Dermal sheet Serial number **(M)**			
Mesh/Dermal sheet Lot number (Mandatory if Device identifier not provided)			

You can insert copies of the product stickers here if it helps with data collection remember to label left and Right

Breast and Cosmetic Implant Registry

July 2018 to June 2019 Data Summary (England, management information)

Published 17 October 2019

The registry is designed to record the details of any individual, who has a breast implant operation 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. The registry will also allow the identification of possible trends and complications relating to specific implants.

This report is to provide information on the status of operations recorded in the registry. It does not provide a comprehensive view of the number of breast implant operations undertaken.

Key findings

- 340 submitting organisations from England are currently registered to enter data in the registry. Since the registry opened in October 2016, data has been entered by 300 English submitting organisations.
- 15,235 patients have been recorded as having at least one operation in the last year, between July 2018 and June 2019.
- Data has been submitted to the registry about 15,570 operations undertaken between July 2018 and June 2019 at 130 NHS and 163 independent sector provider sites.

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Data Quality and Product Recalls

The efficacy of product recalls based on the Breast and Cosmetic Implant Registry are reliant on the quality of the data that it holds.

Product recalls within the registry are only possible based on the manufacturer.

Due to problems with coverage, quality and lack of reference data for the device identifiers, serial numbers, catalogue reference numbers and lot numbers, it is not possible to carry out a product recall based on these fields.

Introduction

The Breast and Cosmetic Implant Registry (BCIR) is designed to record the details of any individual, who has a breast implant operation 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. In time the registry will also allow the identification of possible trends and complications relating to specific implants.

NHS Digital has worked closely with the Department of Health and Social Care, Medicines and Healthcare Products Regulatory Agency (MHRA), patient representatives, relevant professional bodies and other agencies to develop the BCIR. Representatives of these groups have provided clinical input and advised on content, governance and outputs via the BCIR Steering Group.

This report provides an overview of the data collected in the registry for July 2018 to June 2019. The registry started collecting data on 10 October 2016.

Further information on how the registry collects data, and what it does with it, can be found here: https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/our-clinical-audits-and-registries/breast-and-cosmetic-implant-registry

The aspiration of the BCIR is that it should facilitate international comparison by analysis of measures reported by other registries such as the Australian Breast Device Registry. This will only be possible when the BCIR holds enough data of the required quality to ensure statistical robustness. We are working with organisations to improve data quality and this report is part of that ongoing work.

Organisations represented on the BCIR Steering Group

Association of Breast Surgery

British Association of Aesthetic Plastic Surgeons

British Association of Plastic Reconstructive and Aesthetic Surgeons

Care Quality Commission

Medicines and Healthcare Products Regulatory Agency

NHS Digital

NHS National Services Scotland

NHS Partners Network

Patient Representatives

Private Healthcare Information Network

Activity

National Level Data

Data has been collected since the registry was opened on 10 October 2016. Some activity that took place prior to this date has also been submitted. Patterns of submission over the duration of the registry can be seen in Table 1.

Table 1: Overview of activity – provider organisations, patients and operations: by quarter, up to June 2019

Number

Quarter	Provider Orgs	Patients	Operations
Pre-Collection	85	475	500
Quarter 3 2016/17	168	1,560	1,570
Quarter 4 2016/17	204	2,655	2,675
Quarter 1 2017/18	219	3,690	3,720
Quarter 2 2017/18	219	3,385	3,410
Quarter 3 2017/18	214	3,120	3,135
Quarter 4 2017/18	212	3,250	3,275
Quarter 1 2018/19	229	3,840	3,865
Quarter 2 2018/19	234	3,450	3,480
Quarter 3 2018/19	233	3,645	3,680
Quarter 4 2018/19	256	4,065	4,100
Quarter 1 2019/20	249	4,275	4,310
Total	*318*	*36,195*	*37,725*

Source: NHS Digital

Patient and operation values between 1 and 7 are rounded to 5 - all other values are rounded to the nearest 5. The number of provider organisations has not been rounded.

Organisations in BCIR

Provider organisation / site = The place / hospital at which the patient's operation took place.

Submitting organisation / site = The institution which signed up to submit data to the registry.

Submitting organisations may input data about operations taking place at other provider sites.
(e.g. Baddow Hospital may submit information about operations taking place at Baddow Hospital and operations taking place at Aspen – The Holly.)

The number of operations is greater than the number of patients as a person may have had more than one operation during a quarter.

Some people may have had operations in more than one quarter. They will be counted once in the number of patients in each quarter, but only once in the total. The total number of patients entered in the registry is therefore lower than the sum of the number of patients recorded for each period.

The registry is expected to capture the details of all breast implant procedures completed in England by both the NHS and private providers.

Following a formal request from NHS Scotland, data from Scottish NHS and private providers has recently begun to be collected in the registry. Information on patients and operations from providers in Scotland is not included in this report.

Case ascertainment in 2017-18

Entry into the registry was originally based on patient consent. The basis for collection has been changed, and consent is no longer required for operations that took place from 14 January 2019 onwards to be entered in the registry. Patients can request that earlier activity related to them may be added to the registry. It is likely that the registry will never fully capture all activity that took place during the time period when consent was required.

To ascertain the proportion of procedures recorded in the BCIR, figures from Hospital Episodes Statistics (HES) and the Private Healthcare Information Network (PHIN) were required. The data received from PHIN was for the period July 2017 to June 2018 so that is the time period used for comparisons.

Preliminary figures indicate that between July 2017 and June 2018:

1. 13,860 people had operations recorded in BCIR (England only)
2. 18,860 people had operations as NHS patients recorded in HES (England only)
3. 20,900 people had operations as private patients recorded in PHIN (England, Scotland and Wales).

There are a number of extant issues with the data, which would require further work to resolve, that the registry is unable to undertake under present resource constraints. Therefore, ascertainment figures are not available at provider organisation level.

Currently, data suggests that the BCIR had an approximate case ascertainment of just over one-third. This suggests that two-thirds of all people that had breast implant surgery in July 2017 to June 2018 are not recorded in the registry.

One source of difference between these two sets of figures is consent, as it was still required for inclusion in the registry during the comparison period (consent was necessary until January 2019). Differences may be because consent was not given or asked for, because an institution did not participate in the registry, or because their participation was incomplete.

Operations

Table 2 shows that the majority of breast implant operations recorded in the BCIR occur in the independent sector, but a substantial minority of activity takes place in NHS providers.

Table 2: Overview of BCIR activity – provider organisations, patients and operations: by provider organisation type, July 2018 to June 2019

	Provider Organisation Type	
	NHS	**Independent**
Provider organisations	130	163
Patients	3,065	12,175
Operations	3,265	12,310

Source: NHS Digital

Patient and operation values between 1 and 7 are rounded to 5 - all other values are rounded to the nearest 5.
The number of provider organisations has not been rounded.

This overall pattern varies between the category of operation undertaken. This can be seen in Table 3. The independent sector accounts for most primary cosmetic augmentations and replacements, while most reconstructions are carried out by the NHS.

Table 3: Number of operations: by category of operation, by provider organisation type, July 2018 to June 2019

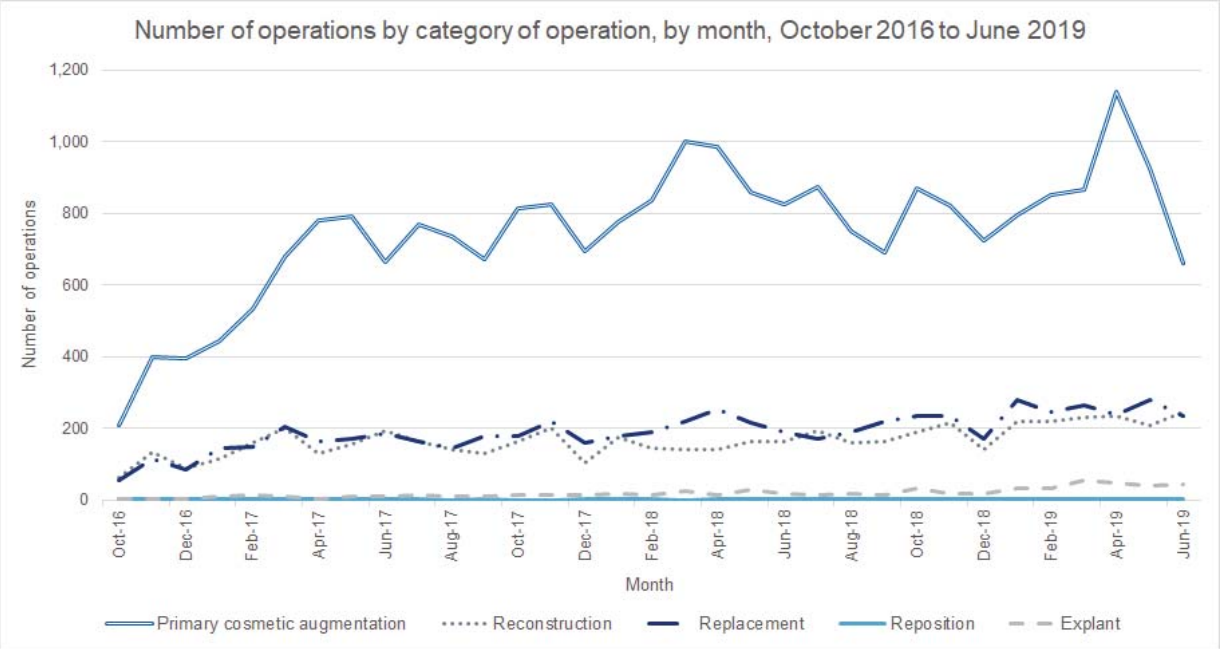
		Provider Organisation Type	
Category of operation	**NHS**	**Independent**	**Total**
Primary cosmetic augmentation	210	9,755	9,965
Reconstruction	2,080	345	2,425
Replacement	745	2,015	2,760
Reposition	5	25	35
Explant	220	165	385

Source: NHS Digital

Values between 1 and 7 are rounded to 5 - all other values are rounded to the nearest 5.

Below, Figure 1 shows the number of each category of operation recorded in the registry by month of the operation.

Figure 1: Number of operations by category of operation, by month, October 2016 to June 2019



Following the initial increase - likely due to submitting organisations gradually beginning to add data to the registry – submissions have been fairly steady. The removal of consent in January 2019 coincided with a slight increase in the level of reconstructions and replacements entered into the registry, but little change to the number of operations was seen amongst other categories.

Manufacturers

The registry collects information related to the device and/or mesh that has been implanted during the operation.

Table 4 shows the number of devices that have been implanted, by manufacturer and provider organisation type. Table 5 shows the number of meshes that have been implanted, by manufacturer and provider organisation type.

Table 4: Number of devices implanted: by device manufacturer, by provider organisation type, July 2018 to June 2019

	Provider Organisation Type		
Device manufacturer	**NHS**	**Independent**	**Total**
Allergan	565	1,645	2,210
GC Aesthetic	5	10	15
Mentor Medical Systems	2,380	13,765	16,150
Motiva	5	2,635	2,635
Polytech	295	1,165	1,460
Silimed	0	5	5
Groupe Sebbin	195	1,410	1,605
Orbix Medical	0	5	5
Eurosilicone	15	725	740
Nagor	455	2,065	2,525
Lifecell Corporation	5	5	5
G&G biotechnology Ltd	5	215	220

Source: NHS Digital

Values between 1 and 7 are rounded to 5 - all other values are rounded to the nearest 5.

Not all operations recorded in BCIR involve implanting a device. A device is only recorded in the registry where the operation involves reconstruction, replacement or primary cosmetic augmentation.

Bilateral operations involve two devices / meshes, which may be from the same or different manufacturers. Left or right side only operations involve a single device / mesh.

Table 5: Number of meshes implanted: by mesh manufacturer, by provider organisation type, July 2018 to June 2019

	Provider Organisation Type		
Mesh manufacturer	**NHS**	**Independent**	**Total**
Allergan	5	0	5
GC Aesthetic	5	5	5
Mentor Medical Systems	10	5	10
Motiva	0	0	0
Polytech	5	0	5
Silimed	0	0	0
Meso Biomatrix – Groupe Sebbin	35	5	40
Orbix Medical	0	0	0
Eurosilicone	0	0	0
Nagor	5	0	5
Strattice - Lifecell Corporation	105	20	120
Surgimend - Integra	520	90	610
Native or Braxon - MBP GmbH	425	40	465
Veritas - Baxter	20	0	20
TiLOOP - pfm medical	190	15	205
Permacol - Covidien/Medtronic	0	0	0
Lifecell	15	5	20
Tigr - Novus Scientific	45	5	50
G&G biotechnology Ltd	0	0	0
GalaFLEX - Tepha Inc.	5	10	10
Artia - Lifecell	35	20	60
Cellis Breast - Meccellis Biotech	0	0	0
Exaflex – Maggi SRL	10	5	10

Source: NHS Digital

Values between 1 and 7 are rounded to 5 - all other values are rounded to the nearest 5.

Not all breast implant operations involve meshes. A mesh is only recorded in the registry where the operation involves reconstruction or replacement

Complications

The registry collects information on complications related to the patient's breast implant operation. The complication may or may not be the reason that the operation took place, and in a bilateral operation, complications may be found on one or both sides.

Between July 2018 and July 2019, 15 people had breast implant operations during which anaplastic large cell lymphoma (ALCL) was found. The registry cannot identify whether these cases of ALCL are instances of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

Provider Level Data

There is an Excel file accompanying this report which provides information on the individual provider organisations recorded within the registry. This is in Table 6. The number of patients and operations are provided, alongside whether the site is part of an NHS or an independent provider.

Data Quality

In the Excel file accompanying this report, Table 7 provides information on the quality of the data within the registry.

Numbers and measures, for each data field in the registry, are given for whether information has been completed, and whether that information is valid. Information is also given as to whether each field is mandatory or optional, and what validation rules exist.

Information on device identifiers, serial numbers, catalogue reference numbers and lot numbers are collected within BCIR. It is not possible to carry out a recall on based on these fields due to problems with coverage, quality and lack of reference data to interpret these codes. Product recalls within the registry are only possible based on the manufacturer.

Data quality information by provider organisation can be found in Table 8 in the Excel file accompanying this report.

Data Quality and Product Recalls

The efficacy of product recalls based on the Breast and Cosmetic Implant Registry are reliant on the quality of the data that it holds.

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