

**Healthcare Quality and Improvement
Directorate**

Dr Sara Davies
Consultant in Public Health Medicine
Room GE06
St Andrew's House
Regent Road, Edinburgh
EH1 3DG



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

20 November 2018

Dear Sarah Wilkinson

Request for collection of Breast and Cosmetic Implant Registry data

We are writing to the Health and Social Care Information Centre (now known and referred to in this letter as “NHS Digital”) to formally request under section 255(1) of the Health and Social Care Act 2012 (**the 2012 Act**) that NHS Digital establishes and operates a system for the collection and analysis of information relating to the Breast and Cosmetic Implant Registry for all relevant operative procedures carried out in Scotland by either NHS Scotland and the Independent Sector.

The Scottish Government considers that the information which could be obtained by NHS Digital complying with this request is information which is necessary or expedient for the Scottish Government to have in relation to the exercise of our functions, or carrying out of activities, in connection with the provision of health care in Scotland. In addition, and for the same reasons Scottish Government has encouraged the Independent Sector to gather such information for patients who undergo procedures privately.

In accordance with section 256(1) of the 2012 Act, this request is a confidential information collection request because we are asking NHS Digital to collect information which enables the identity of an individual to be ascertained. We are able to request the collection of this confidential information because in accordance with section 256(2)(c) the information may lawfully be disclosed to the Scottish Government or to NHS Digital by virtue of Articles 6 (c) and (e) of the EU General Data Protection Regulation, and of the National Health Service (Scotland) Act 1978 (c29) (**the 1978 Act**), which places a general duty on Scottish Ministers to promote the improvement of the physical and mental health of the people of Scotland and to

do anything which Scottish Ministers consider is likely to assist in discharging that duty.

The system to be established and operated is the Breast and Cosmetic Implant Registry.

The information to be collected is described in the Schedule to this Request and the dataset (v1.1) appended to this Request or subsequent version as published by NHS Digital on their website <http://digital.nhs.uk/bcir>

In accordance with section 257(4) of the Act, the Scottish Government has consulted with NHS Digital before making this request.

The Scottish Government hereby acknowledges that in submitting this Request under section 255 of the Act, NHS Digital is entitled to charge a reasonable fee pursuant to section 257(3) of the Act in respect of the cost of complying with this Request.

Yours sincerely




Professor AILEEN KEEL CBE



Professor JASON LEITCH

Appendix

Breast and Cosmetic Implant Registry Dataset v1.1

Breast Implant Registry	M	Mandatory data item					
	O	Optional data item					
		Response not applicable for Category of Operation					
		Response required for left and right					
	Primary cosmetic augmentation	Reconstruction	Replacement	Reposition	Explant	Left and Right	
Mandatory Data Items	11	14	14	9	9	39	
CHI number	Mandatory (if known)						
Date of Birth	M	M	M	M	M		
First name	Optional if NHS or CHI number is provided Mandatory if NHS or CHI number is not provided						
Surname							
Gender							
Postcode							
Is this patient a medical tourist	O	O	O	O	O		
Country of Residence	O	O	O	O	O		
Laterality	M	M	M	M	M		
Category of operation	M	M	M	M	M		
Device Manufacturer	M	M	M				Y
Device Identifier	M	M	M				Y
Device Catalogue Reference Number	O Mandatory if DI not available						Y
Device Serial Number	M	M	M				Y
Device Lot Number	O Mandatory if DI not available						Y
Site code and name	M	M	M	M	M		
Responsible Consultant GMC Number	M	M	M	M	M		
Operating Surgeon GMC Number	M	M	M	M	M		
Operation date	M	M	M	M	M		
ASA Classification Before Operation	O	O	O	O	O		
Previous Radiotherapy		O	O	O	O		Y
Type of Operation	O	O	O	O	O		Y
Incision Site	O	O	O	O	O		Y
Plane	O	O	O	O	O		Y
Mastectomy		O					Y
Nipple Sparing		O	O	O	O		Y
Mastopexy - Concurrent / Previous	O	O	O	O	O		Y
Flap cover		O	O	O	O		Y
Fat Grafting	O	O	O	O	O		Y
Fat Volume	O	O	O	O	O		Y
Tissue Expander Volume		O	O				Y
Nipple Absent		O					Y
Peri Operative Antibiotics	O	O	O	O	O		
Return to theatre within episode of care (48 hours)	O	O	O	O	O		

(continued on next page)

Reason for revision			M	M	M	Y
Removing implant inserted overseas			O		O	Y
Volume of implant removed			O		O	Y
Explanted device manufacturer			O		O	Y
Serial number of explanted device known			O		O	Y
Serial number of explanted device			O		O	Y
Capsulectomy			O	O	O	Y
Silicone extravasation found			O	O	O	Y
Device rupture / deflation			O	O	O	Y
Capsular contracture			O	O	O	Y
Skin Scarring problems			O	O	O	Y
Device Malposition			O	O	O	Y
Deep wound infection			O	O	O	Y
Seroma or Haematoma			O	O	O	Y
Histology Sent		O	O	O	O	Y
Breast Cancer		O	O	O	O	Y
Anaplastic Large Cell Lymphoma		O	O	O	O	Y
Antibiotic dipping solution	O	O	O	O		
Antiseptic Rinse	O	O	O	O		
Glove change for insertion	O	O	O	O		
Sleeve/funnel (Keller funnel)	O	O	O	O		
Nipple Guards	O	O	O	O		
Drain Used	O	O	O	O	O	
Mesh or Dermal Sheet		O	O			Y
Mesh Manufacturer		M	M			Y
Mesh Device Identifier		M	M			Y
Mesh Catalogue Reference Number		O Mandatory if DI not available				Y
Mesh Serial Number		M	M			Y
Mesh Lot Number		O Mandatory if DI not available				Y