Data Provision Notice

Surgical Devices and Implants Pilot Data Collection

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Version: 1.0
Published: 3 August 2020
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Background

The Health and Social Care Act 2012 (the Act) gives the Health and Social Care Information Centre, now known as NHS Digital and hereafter referred to by this name, statutory powers, under section 259(1)(a), to require data from health or social care bodies, or organisations that provide publicly funded health or adult social care in England, where it has been Directed to establish an information system by the Secretary of State for Health and Social Care or NHS England, or as part of a Mandatory Request from a Principal Body defined in section 255(9) of the Act. NHS Digital also has statutory powers, under section 259(1)(b), to request data from any other person.

The data, as specified by NHS Digital in this published Data Provision Notice, is required to support a Direction from the Secretary of State for Health and Social Care to NHS Digital. Therefore, organisations that are in scope of the notice falling under section 259(1)(a), are legally required, under section 259(5) of the Act, to provide the data in the form and manner specified below. Organisations falling under section 259(1)(b) are requested to provide the data in a form and manner specified below.

Purpose of the collection

The purpose of the data collection is to support the initial discovery and piloting of the national reporting of surgical devices and implants in health care settings.

High-profile incidents such as Poly Implant Protheses (PIP) silicone breast implants and metal-on-metal hip replacements have highlighted the lack of data available nationally to support surveillance and monitoring of surgical devices and implants and to assist in subsequent patient recall for review or removal.

This has resulted in the establishment of multiple specific purpose clinical registries and registers to capture information about patients who have received certain types of surgical devices or implants, revised, replaced or removed, including the specific details of the device or implant.

The Independent Medicines and Medical Devices Safety Review under Baroness Cumberlege has recently published its report “First Do No Harm” covering the use of abdominal and vaginal pelvic mesh procedures. This data collection will support Recommendation 7 to create a central patient level database of all implantable devices.

https://www.immdsreview.org.uk/Report.html

This also supports the NICE Guidelines on Urinary incontinence and pelvic organ prolapse in women:

There is also a completely separate requirement to capture information about the use of the UroLift® System – a rapid uptake product within the NHS Accelerated Access Collaborative.


NHS Digital has received a Direction from the Secretary of State for Health and Social Care under section 254 of the Health and Social Care Act 2012 to establish and operate an information system to support the development of a single Surgical Device and Implant Registry which will support the national reporting of any surgical device or implant.

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

- collect and analyse patient information relating to surgical devices and implants;
- 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 and linkage;
- track latest known patient address in the event of a product failure;
- monitor the outcomes achieved by ‘brand’ of device or implant, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action.

The Surgical Device and Implant Information System will support improved patient safety by enabling analysis to facilitate surveillance of surgical devices and implants through linkage of component data modules, including associated patient outcomes, to support patient focussed activities.

This data will be processed for the following purposes:

- to enable surveillance of specific medical devices through linkage to other data assets including patient outcomes, to enable the earlier identification of potential issues with a specific surgical device or implant which may warrant further investigation e.g. by the Medicines and Healthcare products Regulatory Agency (MHRA) which could result in a product recall
- to support identification of a cohort of patients and verify their latest address and deceased status as part of a patient recall for review or removal of a particular implanted device in the event of a product recall being issued

Benefits of the collection

The following benefits are associated with this collection:

- Helps support improved patient safety across the health and care system
- Supports the surveillance of a wider range of surgical devices and implants through linkage to other data sets (administrative and clinical) and patient outcomes, thus enabling the early identification of potential issues with a particular surgical device or implant which may warrant further investigation including improved post-market surveillance of Class III and Class IIb implantable medical devices
• Supports quicker identification and investigation of poorer patient outcomes which could be related to a specific surgical device or implant and which may warrant investigation by appropriate bodies
• Supports the identification of a cohort of patients and the recall of patients for review or removal in a more timely and effective manner in the event of a product recall
• Supports the voluntary collection of a wider range of surgical devices and implants data without the need for the creation of separate specific registries, with associated cost and burden savings
• Provides the ability to compare patient outcomes and longer-term effect of surgical devices and implants against comparable alternative procedures which do not involve a surgical device and implant
• Will support the assessment of rapid uptake products within the NHS Accelerated Access Collaborative.

Legal basis for collection, analysis, publication and dissemination

Under section 254 of the Act, NHS Digital has received a Direction from the Secretary of State for Health and Care to establish and operate a system for the collection and analysis of surgical devices and implants data as follows:

• Data collection - ability for secondary care providers to submit surgical device and implants data, including identifiable data, securely to NHS Digital;
• Data quality and validation
• Data linkage – linkage of surgical devices and implants data to Hospital Episode Statistics (HES) Admitted Patient Care (APC), National Perioperative Data Set (once available) and mortality data. It will also be linked to the Master Patient Service (MPS) and/or Personal Demographics Service (PDS) to ensure that the patients’ details are accurate to support possible patient recall activities.
• Data dissemination – dissemination of surgical devices and implants data to customers under a Data Sharing Agreement (DSA) and via the Data Access Request Service (DARS) with scrutiny from the Independent Group Advising on the Release of Data (IGARD).

The signed Surgical Devices and Implants Directions are available here:


This information is required by NHS Digital under section 259(1)(a) of the Health and Social Care Act 2012.

This information is also requested by NHS Digital under section 259(1)(b) of the Health and Social Care Act 2012 from private healthcare providers in relation to non-NHS funded patients.

In line with section 259(5) of the Act, all organisations in scope, in England, must comply with the requirement under section 259(1)(a) and provide information to NHS Digital in the form, manner and period specified in this Data Provision Notice.
Organisations from whom information is requested under section 259(1)(b) are requested to provide the information to NHS Digital in the form, manner and period specified in this Data Provision Notice.


This Notice is issued in accordance with the procedure published as part of NHS Digital duty under section 259(8).

**Dissemination**

NHS Digital may disseminate information to the Department of Health and Social Care, NHS England and NHS Improvement, the Care Quality Commission and the Medicines and Healthcare products Regulatory Agency, to support them in carrying out their functions regarding the health sector and to support assurance of the quality and safety of care, or other organisations with a legitimate purpose and legal basis to process the data.

Any information disseminated will be via application to the NHS Digital Data Access Request Service (DARS) and require a data sharing agreement. Applications will be subject to scrutiny through the application process and, where appropriate, by the Independent Group Advising on the Release of Data (IGARD).

Data will also be returned to the submitting organisations (their own data only). Under section 261(4), NHS Digital is permitted to disseminate the information it collects to any person to whom the information could have been lawfully disclosed by the person from whom NHS Digital collected the information. This will include returning the collected data to the submitting organisation for the purpose of:

a. correcting data validation errors to ensure the completeness and quality of the submitted data
b. supporting local monitoring of surgical devices and implants for their patients such as measuring outcomes and to support benchmarking.

**Persons consulted**

Initial consultation, as required by section 258 of the Health and Social Care Act 2012, has been completed by NHS Digital including:

- The issuing organisation: Department of Health and Social Care (on behalf of the Secretary of State for Health and Social Care);
- Representatives of those who are likely to be required to provide the information: NHS Providers including Scan4Safety Sites and Independent Healthcare Providers Network (IHPN), private healthcare providers
- Representatives of those who are likely to use the information collected: NHS England and NHS Improvement (NHSE/I), Public Health England (PHE), Medicines and Healthcare products Regulatory Agency (MHRA), NHSX;
• Representatives of those from whom the information will be collected: Royal College of Surgeons of England
• Any other person it is appropriate to consult: Professional Record Standards Board (PRSB), Private Healthcare Information Network (PHIN), GS1
• Members of the Mesh Oversight Group which also includes the following stakeholders: British Society of Urogynaecology (BSUG); British Association of Urological Surgeons (BAUS); the Royal College of Obstetricians and Gynaecologists (RCOG), National Institute for Health and Care Excellence (NICE), and patient members.

Representatives from the Devolved Nations have also been consulted.
Further stakeholder engagement will be completed during piloting and prior to the national roll-out of the finalised data collection.
This will include extensive engagement with providers including secondary care providers and Independent Sector Healthcare Providers, as well as relevant Royal Colleges. In addition, approval will be sought from the Data Coordination Board (DCB).
A full consultation on the proposals will be published on the NHS Digital Consultation Hub (Citizensspace) and will be open to the public and key stakeholders including secondary care providers, healthcare professionals, arms-length bodies, research organisations and system suppliers.

Scope of the collection

Under sections 259(1)(a) and 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 Digital duty under section 259(8).

The scope of the data collection is any Class III or Class IIb implantable medical device which is implanted, revised, replaced or removed for any patient in England.

This data will be collected from any health and care organisation which undertakes surgery involving surgical devices and implants. This will include:

• providers of NHS funded care including NHS Providers and Independent Sector Healthcare Providers (ISHPs) in England
• private healthcare providers in England

This data may be captured within local systems or be available within patient clinical notes.

The data collection comprises the following:

Surgical Devices and Implants (Core Data Module)

Capture of data to link patients to specific implant or device inserted by specific clinicians at a specific location.

Data will be captured for any surgery involving the implanting, revision, replacement or removal of a Class III and Class IIb implantable medical devices as defined by the
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as:

*Any device, including those that are partially or wholly absorbed, which is intended:*
  
  – to be totally introduced into the human body, or  
  – to replace an epithelial surface or the surface of the eye,  
*by clinical intervention and which is intended to remain in place after the procedure.*

*Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;*


**Surgical Devices and Implants Registry (Clinical Data Module)**

Clinical information associated with the Surgical Device and Implant. This data module will capture clinical information, in relation to the scope as described above, to support outcome analysis and post-market surveillance.

**Pelvic Floor Surgery Data Module**

Any relevant clinical activity relating to patients who have received Pelvic Floor Surgery for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

**UroLift© System Data Module**

Any relevant clinical activity relating to patients who have received UroLift© System for Benign Prostatic Hyperplasia (BPH) or an enlarged prostate.

The Surgical Devices and Implants Information System should support the reporting of surgical devices and implant information, including retrospective reporting of historic data where this is available or can be easily ascertained and collected, and associated clinical items.

Information relating to the removal of surgical devices or implants from deceased patients i.e. prior to cremation is **out of scope** and should not be submitted within the data collection.

The scope of the data collection is England. The Surgical Devices and Implants Information System may also be used to support data collection from outside of England including in home countries of the UK, that is Wales, Scotland, Northern Ireland, or the Isle of Man or Channel Islands in agreement with each.

Please note that this may be subject to change prior to national roll-out based upon feedback during piloting and further stakeholder engagement.

**Sensitive and legally restricted data**

Legal restrictions must be applied to the processing of the Surgical Devices and Implants Data Set including the exclusion of patient information relating to In vitro fertilisation (IVF) and gender recognition where this information can identify the data subject.
• NHS Digital MUST NOT collect personal information about legally restricted terms relating to In Vitro Fertilisation (IVF) or Gender Recognition in line with the restrictions imposed by the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008 or the Gender Recognition Act 2004.

• In order to comply with the above Acts, any theatre data set records containing procedure codes relating to IVF or Gender reassignment MUST be anonymised at source, with all patient identifiers removed, prior to submission to NHS Digital for piloting purposes. Where it is not possible to anonymise records, records should be fully containing such legally restricted codes should be removed prior to submission to NHS Digital.

• To align with Secondary Uses Service (SUS) submission rules the latest anonymous and legally restricted codes should be applied (or their equivalent where local procedure codes or SNOMED CT codes are used):

https://digital.nhs.uk/binaries/content/assets/website-assets/services/sus/sus-guidance/legally_restricted_codes.xlsx

• NHS Digital will anonymise any records containing procedure codes relating to IVF or Gender reassignment upon receipt which it inadvertently receives.

Under section 259(5) of the Health and Social Care Act 2012 the organisation types to who the requirement to provide information to NHS Digital under section 259(1)(a) applies, as specified in the above Scope, must comply with the Form, Manner and Period requirements below. Organisations from who information is requested under section 259(1)(b) are requested to comply with the Form, Manner and Period requirements below:

Form of the collection
Activity to be submitted

The collection will include a single row per surgical device or implant event (implant, revision, replacement, removal/explant) for a specific patient.

Data items will include details of:

Core surgical devices and implants module:

• Patient details (NHS Number, patient name, date of birth, postcode, gender, local patient identifier etc)

• Surgery details (date of surgery, operating surgeon (GMC Number), procedure codes, laterality)

• Medical device details (manufacturer, medical device identifier (Unique Device Identifier), serial number, type of surgery)

Specialty/treatment/type of device specific modules:

• Clinical data items relating to a specific clinical specialty, treatment or type of device which is not captured within the core module or other routine national data flows e.g. specific details relating to the surgery, risk factors and comorbidities, complications, patient outcomes (pre and post-operative assessments) etc.
N.B. Where appropriate to do so NHS Digital will also collect and analyse information relating to alternative procedures\(^1\) for the same medical conditions which do not result in a surgical device or implant where this information is not already collected via national data submission to NHS Digital. This is to enable comparison of patient outcomes associated with surgical devices and implants with those of alternative procedures.

The data will comprise both personal data and special category/confidential information.


The data file will be securely submitted to NHS Digital either via a web-based data collection form or as a batch file submission in a format to be agreed with providers.

**Manner of the collection**

Trusts may securely transfer data to NHS Digital using either:

1. NHS Digital Surgical Devices and Implants Web-based form functionality to support data entry where the required information is currently only available in the patient’s clinical notes
2. secure batch file submission functionality to support the submission of data by providers where this is already captured in electronic form in local systems

The exact mechanism will be agreed with pilot sites.

The collection will also be supported by a range of technical and business controls at NHS Digital, including validation of data submitted.

**Period of the collection**

This pilot data collection will commence from 1\(^{st}\) August 2020. This will be an ongoing data collection and will continue until this Data Provision Notice is reviewed or withdrawn.

All in scope organisations are required or requested (as appropriate) to submit data to the following frequency:

Providers of NHS funded care are **required** to submit surgical devices and implants information relating to NHS funded patients as follows:

Private healthcare providers are **requested** to submit information relating to private patients as follows:

**Surgical Mesh and Urolift System**

The reporting of information relating to surgical devices and implants as specified will be mandated in relation to the following:

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\(^1\) An alternative procedure is any procedure undertaken that did not involve a surgical device or implant which was carried out as an alternative to a procedure involving a surgical device or implant, e.g. use of a coronary artery bypass graft (CABG) instead of an coronary angioplasty involving a insertion of a stent
• use of surgical mesh for:
  o pelvic floor surgery (stress urinary incontinence (SUI) and pelvic organ prolapse (POP)) including:
    ▪ prolapsed bladder
    ▪ prolapsed uterus and
    ▪ prolapsed rectum
• use of the UroLift® System for treatment of Benign Prostatic Hyperplasia (BPH) or an enlarged prostate

The information for these should be reported as follows:

• Any future implant, revision, replacement or removal for the devices listed above should be reported to NHS Digital within 10 working days of the procedure occurring.
• Where possible, particularly for surgical mesh, a retrospective submission of historic data the procedure listed above undertaken since 1st July 2017 until present should be provided as a one-off data submission (although multiple submissions will be supported).

Other surgical devices and implants

The Information System will also support the reporting of other implantable medical devices on a voluntary basis. Such reporting should be encouraged, particularly where such data is already captured electronically within local systems.

This may include the retrospective submission of historic data where this is available or could reasonably be provided.

Further communications will be issued in relation to changes to the collection, including mandation of reporting for other categories of surgical devices and implants, and may require publication of a new Data Provision Notice.

Data quality

Providers are expected to undertake data quality assurance activities prior to submitting the data to ensure that the data is of sufficient quality.

The data may be used for recall of patients in the event of issues being identified with a particular device. As a result, it is important that patient identifiers are accurate to enable tracing of the patient. Where NHS Number is not available this will be traced using the details held on Personal Demographics Service (PDS).

Data validation will be applied by NHS Digital at file level and individual record level in line with standard NHS Digital processes. Where data does not pass validation rules the data will be rejected and submitter notified to enable them to correct and resubmit the data.

The webform will validate data upon entry to help ensure the quality of the data.

NHS Digital will analyse the collected data to identify data quality issues and will work with providers to help them improve their data quality.
Burden of the collection

Steps taken by NHS Digital to minimise the burden of collection

In discharging its statutory duty to seek to minimise the burden it imposes on others NHS Digital has:

- Sought to only collect the necessary items required to meet the national requirement and minimise the collection of duplicate data items already reported in other national data collections
- Reuse of surgical device and implant data where this is already reported through other national data collections such as Breast and Cosmetic Implant Registry (BCIR) or National Joint Registry (NJR)
- Worked closely with a number of NHS and private healthcare providers to ensure that the data specification is implementable
- Only mandated the collection for a subset of surgical devices and implants relating to surgical mesh initially, with voluntary reporting of other surgical devices and implants
- Limited the timescales for the retrospective data capture of historical surgical device and implants data.

In seeking to minimise the burden it imposes on others, in line with sections 253 (2a) and 265(3) of the Health and Social Care Act 2012, NHS Digital has an assessment process to validate and challenge the level of burden incurred through introducing new information standards, collections and extractions.

This assurance is carried out by the Data Standards and Assurance Service (DSAS) which assures burden assessment evidence provided as part of the overarching Data Coordination Board (DCB) process. The DCB, acting under authority of the Secretary of State, oversees the development, assurance and acceptance of information standards, data collections and data extractions for the health and social care system in England.

As this data collection is still in its pilot/discovery phase, the burden assessment is not yet required but will be undertaken as part of the DCB approval process.
For further information

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