Surgical Devices and Implants Direction Requirement Specification

Glossary of Terms

Term / Abbreviation	What it stands for
APC	Admitted Patient Care
DARS	Data Access Request Service
DHSC	Department for Health and Social Care
HCO	Health Care Organisation
HES	Hospital Episode Statistics
IGARD	Independent Group Advising on the Release of Data
IHCSOs	Independent Health Care Sector Organisations
MHRA	Medicines and Healthcare products Regulatory Agency
MPS	Master Patient Service
PHIN	Private Healthcare Information Network
POP	pelvic organ prolapse
SUI	stress urinary incontinence

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Purpose of document

This document sets out the requirements for the Surgical Devices and Implants Directions 2020 and should be read alongside the:

- Direction issued by the Secretary of State for Health and Social Care
- Surgical Devices and Implants Directions Technical Output Specification.

This document has been published with a focus on the priority collection systems identified in the Governments response to the First Do No Harm Report, July 2020. It will be updated to reflect the policy requirements to underpin the Medicines and Medical Devices Act 2021, and the subsequent regulations, following public consultation planned in 2022..

Introduction

Procedures where medical devices are either implanted, or are the primary mode of therapy, cover hundreds of thousands of patients each year. In recent years there have been several high-profile device safety issues and product recalls including metal on metal hip resurfacing, Poly Implant Protheses implants and vaginal mesh, Aortic Stent Grafts, bioresorbable stents. In addition, there has also been a steadily increasing number of product recalls and safety concerns generally across medical devices. Currently, tracking of medical device usage is primarily paper-based and as a result it is not understood how many patients undergo a procedure with high-risk devices or how many are affected by device recalls or safety alerts.

The Surgical Devices and Implants Information System addresses the Governments response to the Independent Medicines and Medical Devices Safety Review: First Do No Harm (Cumberlege Report) recommendation seven which advocates a UK-wide solution, including NHS (England, Scotland, and Wales), healthcare organisations in Northern Ireland, and independent health care sector organisations across all four home nations.

The First Do No Harm report provided a focused review on the use of abdominal and vaginal pelvic mesh procedures and called for a new registry.

Recommendation 7 from the Independent Medicines and Medical Devices Safety Review First Do No Harm Report requests:

'A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.'

NHS Digital received a Direction from the Secretary of State for Health under s254 of the Health and Social Care Act 2012 (Act) to establish and operate an information system to support the development of a single Surgical Device and Implant Information System which would 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. This will include reference data about manufacturers of devices and implants, e.g. batch number, serial number;

- collect and analyse information regarding alternative[1] procedures for the same medical conditions which do not result in a surgical device or implant, in order to enable comparison of patient outcomes associated with 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 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 such as review or recall of specific devices.

The Information System will initially support the recommendation of the Independent Medicines and Medical Devices Safety Review by collecting data about surgical mesh used within pelvic floor surgery and NICE Guidance.

http://www.immdsreview.org.uk/index.html

https://www.nice.org.uk/guidance/ng123/chapter/Recommendations#collecting-data-on-surgery-and-surgical-complications

The Information System will also support the reporting of other Surgical Devices and Implants on a voluntary basis, for both prospective and retrospective historic data.

Data Collection

Scope

The scope of these Directions is the Surgical Devices and Implants Information System and data collection to support the implementation of a system-wide surveillance mechanism.

This comprises:

Surgical Devices and Implants Core Data Module

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

Data Captured includes unique identifier (UDI) to the patient identifier (NHS Number), the named clinicians undertaking the procedure(s) (GMC number, or equivalent) and the location of the activity (Health Care Organisation ODS code),

[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, for example use of a Coronary Artery Bypass Graft (CABG) instead of a coronary angioplasty involving an insertion of a stent

Data will be captured for any surgery involving the implanting, revision 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;*
>
> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

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.

Surgical Devices and Implants Registry (Clinical Data Module)

Clinical information associated with the Surgical Device and Implant for any surgical device or implant which has been implanted, revised, or removed from a patient. Initially, separate registries may be required to capture more specific clinical information. 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 Registry (Registry Data Module)

This will support the collection of a clinically agreed set of data items relating to pelvic floor surgery for an individual patient, including patient outcomes and data about pelvic floor surgery which does not involve surgical mesh for comparison purposes.

Data captured includes: any relevant clinical activity relating to patients who have received Pelvic Floor Surgery for the treatment stress urinary incontinence (SUI) and pelvic organ prolapse (POP) and alternative treatments.

Pelvic Floor Patient Questionnaire (Patient Data Module)

Patient submitted information, captured via a Patient Questionnaire mechanism, and relevant Patient Reported Outcome Measure (PROM) systems, collated to capture a core set of patient reported outcomes, for Pelvic Floor and alternative procedures, as defined by patient groups and clinicians.

Data captured includes patient reported co-morbidities, quality of life, complications, experience, complaints, and outcomes

Data captured by existing local or national systems will be used where available to avoid duplication and burden.

The use of the Questionnaire may support the audit and the capture of historical data from patient groups.

NHS Digital will also collect and analyse existing information relating to alternative procedures 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 alternative procedures.

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.

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, and Northern Ireland in agreement with each.

Data Collection

The reporting of surgical devices and implants data is mandated in relation to Health Care Organisations (HCOs) of NHS funded care including NHS Health Care Organisations and Independent Health Care Sector Organisations (IHCSOs), and requested as a voluntary submission from Independent Health Care Sector Organisations, in relation to the following:

Surgical Devices and Implants Core Data Module

Capture of generic 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 or removal of a Class III and Class IIb implantable medical devices, defined 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 Registry:

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).

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

- Use of surgical mesh or alternative procedures for:
    - pelvic floor surgery (stress urinary incontinence (SUI) and pelvic organ prolapse (POP))
    - prolapsed bladder
    - prolapsed uterus and
    - prolapsed rectum

Retrospective submission of historic data for surgical mesh implants, and alternative procedures, described above undertaken from July 2017 to April 2021 (or date of first submission) should be provided as a one-off data submission (although multiple submissions will be supported)From April 2021, any implant, revision or removal of surgical mesh for the types of surgery listed above, and alternative procedures, should be reported to NHS Digital within 10 working days of the procedure occurring using an agreed submission methodology (e.g. MESH).

Other Surgical Devices and Implants

The Information System also supports 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. Mandatory submission of data for all implantable devices will be introduced, phased by speciality areas.

- Voluntary retrospective submission of historic data for all surgical devices and implants provided as a one-off data submission (although multiple submissions will be supported)
- Voluntary submissions for all implants to Information System for the core and clinical data modules, including implant, revision or removal
- Transition to mandatory submissions of the core and clinical data modules for all speciality areas with order of priority to be confirmed and formally communicated to Health Care Organisations

Reference, Alerting and Messaging Data

The information System will collect reference data about manufacturers, distributors and suppliers, from MHRA or other organisations that have collated and catalogued this data, to provide look-up tables for UDIs, and associated classifications. Initially, this data will be collected from a representative sample of NHS Health Care Organisations that hold these catalogues and validated by MHRA.

The information system will support collection of device alerts, messaging, or workflow instructions from other healthcare systems partners e.g., MHRA.

Patient Data

The information system will support collection of data directly from patients or via intermediary systems that have captured patient reported outcomes or complications related to their care.

Source

The information system will collect data from any health and care organisation who undertakes surgery involving surgical devices and implants. This will include:

- Health Care Organisations of NHS funded care including NHS Health Care Organisations and Independent Health Care Sector Organisations (IHCSOs) in England
- Independent Health Care Sector Organisations in England

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

The information System will collect reference data, alerts, messaging, and workflow instructions including:

- product classification data from MHRA that has been collected from, manufacturers, distributors, and suppliers, to provide look-up tables to translate UDI numbers into specific catalogue items attributed to a unique manufacturer or supplier.
- catalogue and product data collected 'Trust information systems.
- product information from existing registries and other NHS bodies that are involved in classification and attribution.
- alerts, messages, or workflow instructions from healthcare systems

The information System will collect data from patients:

- Information will be collected directly from patients using the patient questionnaire.

Category

The data collection comprises confidential patient information – this includes both personal data e.g., NHS Number, Date of Birth, Postcode, and special category data relating to the patient's health e.g., procedure, patient reported outcome measures, surgical device or implant details (Unique Device Identifier).

It also includes the personal details of the surgeon who performed the surgery to implant the surgical device or implant which would constitute personal data.

The full technical output specification is published on our website:

https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/directions-and-data-provision-notices/data-provision-notices/surgicaldevicesandimplantsdatasettechnicalspecification_v1.01.xlsx

Frequency

NHS Digital will collect the data to a frequency appropriate to meet the requirements outlined within this Direction and following engagement with NHS and Independent Health Care Organisations.

Analysis and Linkage

Internal processing

NHS Digital will analyse the data collected under the Directions, including by such reference or linkage to other data held by NHS Digital as NHS Digital determines is necessary to achieve the Purpose set out in the Directions.

Data will be validated upon submission, with submitting organisations or persons e.g., patients notified where errors are present within their data submissions.

NHS Digital will derive a variety of new data items based upon the submitted data including calculations and reference data lookups e.g., the manufacturer of the device or the age of the patient.

NHS Digital will undertake analysis to monitor the outcomes for patients achieved by manufacturer of device or implant, hospital and surgeon, using performance measure agreed with key stakeholders and clinical input, and highlight where these fall below an expected performance in order to allow prompt investigation from the Medicines and Healthcare products Regulatory Agency (MHRA), Care Quality Commission (CQC), British Medical Association (BMA) or Health Care Organisations and to support any follow-up action such as recall of patients.

Data will be processed through the NHS Digital Master Patient Service (MPS) and Personal Demographics Service (PDS) to confirm the patient's identity and to trace the patient's NHS Number where this has not been supplied (but can be traced) to support unique patient identification and data linkage.

Data will also be processed through the PDS/MPS to verify the patient's last known address so that that the Health Care Organisation can be notified to contact the patient in the event of a product recall, or letters not sent where they are deceased. Where a Health Care Organisation has gone out of business or ceased to operate, NHS Digital's medical director will contact patients directly.

NHS Digital will work with stakeholders including NHSx, MHRA, NHS England and Improvement, and clinicians to develop a surveillance system and operating model to:

- use NHS Digital's MPS/DBS to verify addresses and contact details of England residents in the case of malfunctioning medical device recall event or requirement for urgent clinical follow-up
- draw on NHS Digital existing experience, and system capabilities, for tracing and contacting patients for follow-up (e.g., screening invitations).
- ensure alignment of system and infrastructure design to MHRA and Health Care Organisations for patient safety alerts

Data linkage

NHS Digital will create a longitudinal database to support improved patient safety, to enable surveillance of surgical devices and implants through linkage of the data, as set out below, to support patient focussed activities such as review or recall of specific devices.

The longitudinal database will link the Surgical Devices and Implants Data Modules, at an identifiable record level to relevant key data sets, including patient outcomes data, to be agreed by Department of Health and Social Care and NHS Digital are but are likely to include:

- Commissioning Data Set (CDS) /Hospital Episode Statistics (HES)
- National Perioperative Data
- Mortality data
- Patient Reported Outcomes Measures (PROMS)
- Patient Reported Experience Measures (PREMS)
- Secondary Uses Service
- National Clinical Audits
- MHRA Yellow Card incident data

. The resultant longitudinal database will be stored in the NHS Digital Data Processing Service (DPS) and access restricted using NHS Digital's Clear Data Access control procedures. The longitudinal database will be used, in conjunction with NHS Digital analytical tools and messaging systems, to create a surveillance system.

The surveillance system and operating model will be defined in conjunction with other government agencies including NHSX, MHRA, NHS England and Improvement, and clinicians to finalise the scope and clinical use of the longitudinal database by the relevant government agencies and Health Care Organisations. NHS Digital's delivery of the surveillance system, starting with mesh and related procedures, will be defined in separately funded work package.

Analysis for Life Sciences Purposes

The information obtained may be analysed by NHS Digital as NHS Digital considers appropriate and, in a manner, that NHS Digital considers appropriate, so as to enable and facilitate the achievement of the Purpose and Key Objectives of the Life Sciences Directions 2019 issued to NHS Digital by the Secretary of State on 21 October 2019 (as the same may be amended from time to time).

Consultation

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 for Health and Social Care (on behalf of the Secretary of State for Health and Social Care).

- Representatives of those who are likely to use the information collected: NHS England and 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, Royal College of Anaesthetists

Regular workshops have been held with NHS Secondary Health Care Organisations to explore the drivers, data requirements and use cases for the data collection.

- Webinars were conducted with NHS and Independent Health Care Organisations in July/August 2020 to set out the data for collection and submission methods used in the collection.
- From August 2020 several Health Care Organisations took part in a series of pilots to help with the development of the Surgical Devices and Implant Information System.

In addition, monthly consultation via the Pelvic Floor Oversight Group (and the Pelvic Floor Sub Registry Group) established by NHS England and Improvement (with membership from NHS Digital) including the following stakeholders:
British Society of Urogynaecology (BSUG); British Association of Urological Surgeons (BAUS); the Royal College of Obstetricians and Gynaecologists (RCOG), and the Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE), the Department of Health (DH) and patient members.

Prior to commencement of the data collection, and periodically where changes to the data specification are required, wider stakeholder consultation will be undertaken with key organisations including:

- Patients and the public
- NHS Secondary Care Organisations
- Independent Health Care Sector Organisations (IHSCOs)
- Royal College of Surgeons
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Private Healthcare Information Network (PHIN)
- Devolved Administrations

The data for collection has been reviewed and approved by the Data Standards Assurance Service and the Data Alliance Partnership Board (DAPB).

A full consultation on the proposals is published on the NHS Digital Consultation Hub (Citizen space) and is open to the public and key stakeholders including secondary care Health Care Organisations, healthcare professionals, arms-length bodies, research organisations and system suppliers.

Dissemination/Sharing

Regular Dissemination/Sharing

NHS Digital will disseminate information which it collects under these directions, back to the organisations which provided it under s261(4) for the purposes of:

a. correcting data validation errors to ensure the completeness and quality of the submitted data

b. enabling local monitoring of surgical devices and implants for their patients such as measuring outcomes and to support benchmarking

NHS Digital may disseminate information it collects and analyses under these directions where there is an overriding public interest such as to the Medicines and Healthcare products Regulatory Agency (MHRA) in the event of product recall, where it would otherwise be lawful for NHS Digital to do so under section 261 or any other legislation.

Data Access Request Service (DARS)

NHS Digital may disseminate information to the Department of Health and Social Care, NHS England and Improvement, the Care Quality Commission, the National Institute for Health and Care Excellence, the Office for Life Sciences 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 where it would be lawful for NHS Digital to do so. The information disseminated will be subject to appropriate data sharing agreements via DARS.

Any other information disseminated will be via DARS and will be subject to scrutiny by the Independent Group Advising on the Release of Data (IGARD) where appropriate.

In line with the National Data Opt-Out operational policy guidance national data opt-outs will NOT apply to the collection of surgical devices and implants data by NHS Digital which are required or requested under s259 of the Health and social Care Act 2012.

National data opt-outs will be applied to any dissemination of surgical devices and implants data by NHS Digital that are in scope of the national data opt-out operational policy guidance, including to information which relates to private patients.

Publication

Data to be published

A twice-yearly publication to demonstrate Health Care Organisation level compliance to the Pelvic Floor Registry has been commissioned by NHS England and Improvement.

Data prohibited from being published

NHS Digital must NOT publish any information it obtains through these Directions unless such a publication is requested by or agreed with Department of Health and Social Care and would otherwise be lawful.

System Delivery Function

In accordance with Regulation 32 of the Regulations, the Secretary of State directs NHS Digital to exercise such systems delivery functions of the Secretary of State as are necessary for it to deliver the **Surgical Devices and Implants Information System**.

It is expected that NHS Digital will utilise its existing strategic toolset to meet this requirement wherever possible.

Change control process

This requirements specification will be subject to formal change control.

Any changes to this specification will be formally agreed by NHS Digital and Department for Health and Social Care following consultation in line with s258(1) Health Social Care Act 2012.

Further information and support

For further information about this specification please contact

Telephone: 0300 303 5678

Email: enquiries@nhsdigital.nhs.uk (please reference Surgical Devices and Implants Data Collection within the subject line)