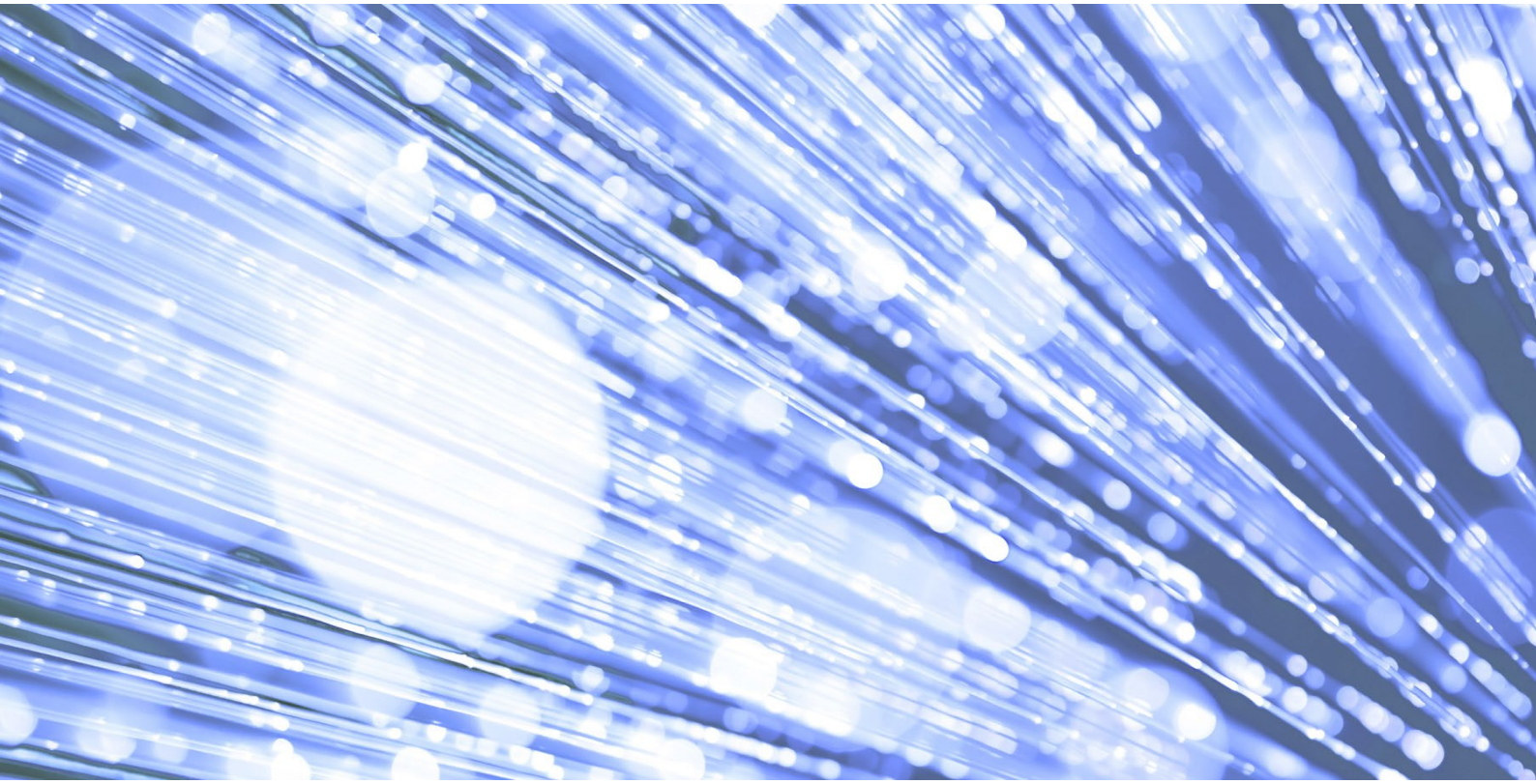
Surgical Devices and Implants Core Data Set V1.0

Implementation Guidance

Published 3 February 2022



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Data Alliance Partnership Board

The Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, has approved a new information standard for publication under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and endorsed by the Data Alliance Partnership Sub Board (DAPSB). This information standard comprises the following documents:

- Requirements Specification
- Implementation Guidance
- Technical Output Specification.

An Information Standards Notice (DAPB3103 Amd 100/2021) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the NHS Digital website. Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 3 February 2022

Glossary of terms

A full Glossary of Terms for the SDICDS Information Standard can be found within the SDICDS Requirements Specification.

Term/ Abbreviation	Definition
CQC	Care Quality Commission
DAPB	Data Alliance Partnership Board
DHSC	Department of Health and Social Care
DSA	Data Sharing Agreement
DSDS	Data Set Development Service
GMC	General Medical Council
HES	Hospital Episode Statistics
HSCA	Health and Social Care Act 2012
ICO	Information Commissioners Office
IGARD	Independent Group Advising on the Release of Data
ISHPs	Independent Sector Healthcare Providers
MESH	Message Exchange for Health and Social Care
MHRA	Medicines and Healthcare products Regulatory Agency
MMD	Medicines and Medical Devices
MPS	Master Patient Service
ODS	Organisation Data Service
OLS	Office for Life Sciences
PAS	Patient Administrative Systems
PDS	Personal Demographics Service
POP	Pelvic Organs Prolapse
SDIS	Surgical Devices and Implants System
SDICDS	Surgical Devices and Implants Code Data Set
SUI	Stress Urinary Incontinence
TOS	Technical Output Specification
UDI	Unique Device Identifier
UK GDPR	UK General Data Protection Regulation

Implementation issues - contact details

In the event of issues or questions concerning the implementation of this Standard contact enquiries@nhsdigital.nhs.uk.

Contents

1 Introduction

1.1. Purpose of Document

The following guidance is intended to support preparations for the implementation of the Surgical Devices and Implants Core Data Set Standard (SDICDS) v1.0 which is mandated for local collection from 1 July 2022. This document is not exhaustive but aims to make users aware of guidance available, drawing attention to essential steps and helping services assess their state of readiness. This document also includes information on a variety of topics that impact implementation of the data set such as information governance, training and ongoing maintenance. All aspects of this Implementation Guidance should be considered during initial set up. Users should make use of this document when preparing a high-level picture of how their organisation intends to tackle this implementation to meet the required timescales.

1.2. Scope of the Document

This document provides guidance on how to implement the SDICDS data set as a new user. This document should be read in conjunction with the following documents:

- SDICDS v1.0 Requirements Specification
- SDICDS Technical Output Specification

1.3. SDIS User Guidance Out of Scope of the Implementation Guidance

The following areas are out of scope of this document:

- Detailed background and justification for the development of the Information Standard.
- Detailed commentary on the data submission framework (i.e., how data is submitted by data providers to the NHS Digital by either the web form or MESH tool). Further information about both options are available on the Surgical Devices and Implants webpage or by contacting your Data Liaison Representative.
- Restating information already accessible from the Technical Output Specification.

2. Background

The SDICDS is a patient level, secondary uses data set which is intended to capture generic data to link patients to specific implants or device inserted by specific clinicians at a specific location in a robust, comprehensive, nationally consistent and comparable patient-based manner.

This data set is intended to support collection of Surgical Devices and Implants data as required by the Surgical Devices and Implants Direction 2020.

The collection of this data set supports the Secretary of State's strategic requirements to ensure patient safety in the use of surgical devices and implants, and the equivalent requirements raised by the Independent Medicines and Medical Devices Safety Review: First Do No Harm (Cumberlege Report) recommendation seven.

Recommendation 7: 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 then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures

The data set covers NHS funded services located in England or located outside England but treating patients commissioned by an English provider

As a secondary uses data set it re-uses clinical and operational data for purposes other than direct patient care, for example: healthcare planning, commissioning services, national Tariff reimbursement and developing national policy. It defines the data items, definitions and associated value sets extracted or derived from local information systems.

Data collected as part of the SDICDS is intended to be both historic and current surgical device, implant and alternative data[1] directly from NHS and private healthcare providers. Data pertaining to NHS funded care will be mandated, and privately funded care will be voluntary.

Data collected will support establishment of clinical registries across surgical disciplines and the generation of new insights that benefit direct patient care. The initial specialty focus is urogynaecology, starting with data collection for a Pelvic Floor registry. Transition to mandatory submissions for other clinical specialties will be confirmed and formally communicated to provider organisations once agreed with NHS England and NHS Improvement and the Department of Health and Social Care.

2.1. Legal Basis

The legal requirement for data collection and processing is a Direction from the Secretary of State for Health and Social Care under section 254 of the Health and Social Care Act (HSCA) 2012 to establish and operate a system for the collection and analysis of Surgical Devices and Implants data.

The Surgical Devices and Implants Directions 2020 can be found on the NHS Digital webpages.

The HSCA 2012 assigns NHS Digital 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. To comply with the direction received, NHS Digital has published a Data

[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 a coronary angioplasty involving an insertion of a stent

Provision Notice (DPN) using its powers under 259(1)(a) of the HSCA 2012 which is published on the NHS Digital Data Provision Notices web page.

2.2. Information Standards Notice Process

All approved new data standards, and changes to existing standards, are communicated to the providers and system suppliers through the publication of an ISN. These notices are published and available to view on the ISN web pages.

This Information Standard has been put through rigorous assurance prior to approval by the Data Alliance Partnership Board (DAPB). The resulting Standard has been assigned release number Amd 100/2021) and standard number DAPB3103. The ISN formally requires care providers to submit data as per the HSCA (section 250).

The ISN does not directly place any requirement on system suppliers to accommodate the SDICDS within their systems. It is the service providers who must ensure that they have a system or systems to deliver the requirements specified in the standard. The IT Suppliers need to be aware of these requirements so that they can respond to the service providers they support. The contractual agreement between data providers and system suppliers will dictate whether system suppliers have to abide by the ISN and at what cost.

More information on the stages of information standard development is available on the NHS Digital information standards and data collections (including extractions) web page.

2.3. Related Standards

Reference	Title
ISB 0149-02	NHS Number for Secondary Care
SCCI0034	SNOMED CT
DCB0090	Health and Social Care Organisation Reference Data
DCB2094	Sexual Orientation Monitoring
DCB3103-01	Surgical Devices and Implants, Phase 1: Pelvic Floor Registry

Further details regarding the above standards can be found on the DAPB Standards and Collections webpage. This webpage also contains a list of all current information standards and collections.

2.4. Future plans

The Medicines and Medical Devices Act (MMD) 2021 was introduced in February 2020 with agreement from the Department of Health and Social Care (DHSC). Section 19 of the MMD Act 2021 empowers the Secretary of State to make regulations about the establishment and operation by NHS Digital of information system(S) relating to safety etc. of medical devices, which may be referred to as the Medical Devices Information System (MDIS) Regulations.

The regulations made under section 19 of the MMD Act 2021 could provide NHS Digital with powers enabling it to mandate data submission from all UK private healthcare providers and NHS providers in the Devolved Administrations. These changes were requested to support the delivery of the Pelvic Floor Data Module Project, commissioned by the DHSC, to address the anticipated recommendation of the Independent Medicines and Medical Devices (IMMDS) Safety Review, led by Baroness Cumberlege (known as the Cumberlege Review). It is anticipated that MDIS will build on the design and base infrastructure of the Surgical Devices and Implants Information System and will help trace high-risk implantable medical devices over the next 3-5 years.

The Medicines and Medical Devices Act 2021 obtained royal assent on 11 February 2021.

Learning from the pilots and implementation of the surgical devices and implants system will support the future development of a UK-wide Medical Devices Information System (MDIS), which will also be dependent on the regulations being introduced under the Medicine and Medical Devices Act.

The Medical Device Information System (MDIS), will operate in accordance with regulations that will set out how medical device information from NHS and private healthcare providers across the UK is collected, analysed, and used.

MDIS will be a UK wide system underpinned by a central patient-identifiable database for all implanted medical devices and will include outcomes and comparator data.

In time, the system will enable interoperable message exchange and alerting across the health and care system. This will ensure a consistent UK wide approach to the monitoring of medical device safety. It will allow recalls and alerts where issues are identified and will provide an improved flow of appropriate data to clinical registries and regulators.

The current standard may be superseded by an MDIS standard or updated to incorporate MDIS changes within it. This will be decided at a future date and communicated to stakeholders once known.

3. Organisational Guidance

The SDICDS Information Standard must be used across the range of health and care providers who undertake surgery involving surgical devices and implants and alternative procedures. Health and care organisations and System Suppliers should be aware of the requirements and conformance criteria specified for the standard. These are outlined in the Requirements Specification document.

This section provides guidance on the implementation considerations for organisations seeking to implement the SDICDS within their services.

3.1. Resources/Costs

Health and Care Providers have a routine requirement to collect data for both clinical and patient administration primary purposes. The SDICDS is designed to build on this requirement by gathering this information and using it for a number of secondary purposes including: healthcare planning, commissioning services, national tariff reimbursement and developing national policy. Funding is not available for sites to:

- procure or install data collection systems
- train staff in order to facilitate data collection
- undertake additional activities required to facilitate data extract submission.

It is not within the scope of this document to provide advice on the procurement of systems, however further advice is available by contacting NHS Digital at enquiries@nhsdigital.nhs.uk

Providers should however expect some resource to be required in order to uplift data collection to enable extraction of the required data items and any system changes required. This is likely to be the case whether the provider is new to the data set or making amendments following publication of the ISN, and these resources should be provided for as part of the contract between commissioner and provider.

3.2. Information Governance

All data providers should be aware of their legal and professional obligations with regard to information governance as it applies to the mandated SDICDS standard. The NHS and government publish a significant amount of guidance that can assist data providers to comply with their obligations. Some of this information is signposted below. Please also see the NHS Digital Looking after information web page for an overview of information published by NHS Digital.

- The NHS Confidentiality Code of Practice (2003)

"This document is a guide to required practice for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent to the use of their health records."

- Report of the Review of Patient Identifiable Information (1997) (Caldicott Report)

"A review commissioned in 1997 by the Chief Medical Officer of England which highlighted six key principles and made 16 specific recommendations regarding the transfer of patient identifiable information from NHS organisations to other NHS and non-NHS organisations."

- The Information Governance Review (2013) (Caldicott 2):

"The guidance in this report is intended to help health and social care professionals and staff in sharing information appropriately in their day-to-day activities. There will however, always be exceptional and difficult circumstances where solutions are not obvious. In these situations, professionals and staff should seek advice from Caldicott Guardians or their professional bodies, and use their judgement to act in the best interests of their patients and clients."

- Guide to the General Data Protection Regulation (GDPR)

"The guide to the General Data Protection Regulation contains:

  - *information about consent*
  - *an explanation of rights under GDPR*
  - *descriptions of special category and criminal offence data*
  - *guidance on protecting children's data"*

- NHS Digital has also published A Guide to Confidentiality in Health and Social Care (2013) which provides good practice advice and guidance for healthcare staff.

All data providers must ensure compliance with the transparency/fair processing requirements of the Data Protection Act 2018 and the UK GDPR. To meet these requirements, data providers must make available information and guidance to patients and/or their legal guardians regarding the processing of their data (or their child's data where applicable) for secondary uses purposes (such as service development analysis and national statistical research). Information must be provided in a concise, transparent, intelligible and easily accessible form and should include details such as an understanding of the data in question, what it will be used for and the patient's rights. This should be in the form of transparency/fair processing wording.

As a result of this new information standard, users should create their transparency wording as part of a wider Data Protection Impact Assessment (DPIA).

NHS Digital is also required to provide a Transparency notice.

Data providers should note that the transparency requirements under GDPR replace the prior requirement to provide 'fair processing' or 'privacy' information.

3.2.1. National opt out as applied to SDICDS

NHS Digital is not reliant on "section 251 support" when mandated to collect data via Directions from NHS England and NHS Improvement or the Department of Health and Social Care and when acting as data controller. This is set out in sections 254 and 255 of the Health and Social Care Act 2012. As a result, explicit consent to flow data from providers to NHS Digital is not required; however, providers are required to inform patients that their information will be used to support secondary uses and should highlight the national data opt-out process as part of their transparency information.

The national data opt-out is a process which allows patients to opt-out of sharing their information for research or planning purposes once it is held by NHS Digital. This process replaces the previous 'type 2' opt-out which required NHS Digital to refrain from sharing a patient's confidential patient information for purposes beyond their direct care. Further information about patient opt-outs is available on the National data opt-out web pages which include resources for health and care staff to use when informing patients.

Other potentially identifiable information

The SDICDS also flows data about the healthcare professional, usually a surgeon who undertook surgery on the patient. This will be in the form of their GMC number

or equivalent. Healthcare Professionals would reasonably expect that their details will be included within the records of patients whom they treat. Similar information is already collected across the majority of data sets that NHS Digital collect.
GDPR allows naming of health and social care professionals (and other persons) if the inclusion has been assessed that it is reasonable to disclose without that individual's consent taking into account the relevant circumstances, including:

- the type of information that you would disclose
- any duty of confidentiality you owe to the other individual
- any steps you have taken to seek consent from the other individual
- whether the other individual is capable of giving consent
- any express refusal of consent by the other individual.

Staff members should be notified by the provider where their data will flow as part of SDICDS.

3.2.2. Compliance Against Statutory Requirements

The specification and guidance for implementing this data set have been designed to support organisations in adhering to their statutory responsibilities relating to Information Governance, Data Protection Act 2018, the Freedom of Information Act 2000 and UK GDPR. It is the responsibility of the providing organisation to ensure that these statutory responsibilities are adhered to.

3.2.3. Potential Safety/Confidentiality/Risk Considerations

The SDICDS utilises information already collected in potentially a variety of different provider systems. The primary purpose of the SDICDS standard is for secondary uses only and will therefore have no direct impact on Clinical Safety. However, there are use cases for the data to be used for direct care in the future, and a clinical safety report is in development and the standard will be updated to reflect this. At present though this standard is not in scope of DCB0129 - Clinical Risk Management: its Application in the Manufacture of Health IT Systems and consequently, a Clinical Safety Case Report is not currently required to support this standard.

However, implementation of this standard may require the modification to the health IT system from which the collection/extraction is made. The safety implications of any such flows and modifications must be considered by the manufacturer and all other parties involved under DCB0129 and the health organisation under DCB0160 - Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems. It is expected that manufacturers and organisations will take ownership of this risk and make the necessary additions to their respective Clinical Safety Case Reports.

1) Providers of SDIS services must ensure that their IT system suppliers include a mechanism to allow providers to identify records where there is a legal requirement to restrict the flow of identifiable information for a patient. Guidance on legally restricted codes is found within the Secondary Uses Services Guidance Webpage

Stakeholders including the NHS (NHS England and NHS Improvement, care providers, commissioners) and the Department of Health and Social Care (DHSC) are actively encouraged to raise any potential safety risks or adverse incidents

during definitional testing and consultation exercises throughout the development of release of this standard.

Any concerns, potential safety risks identified or adverse incidents resulting from the implementation of these changes to SDICDS should be reported immediately to the user's local service desk. This will then be escalated through the correct process.

3.3. Data Quality

NHS Digital is committed to supporting providers in improving their local data quality at various stages of the data set life cycle, including:

- before submissions are made, the technical output specification and guidance documents should be read which will help providers to construct their file and understand DQ rules. Additional questions can be made via enquiries: enquiries@nhsdigital.nhs.uk or by contacting your Data Liaison Team Representative
- at the point of submission, via data item validation checks
- following submission, via additional data reports that are provided to you from the Data Liaison Team. Data quality is a consideration as part of the mandated requirements for providers and as such should review the Data Quality Feedback section within the Requirements Specification.

As an output data set, the SDICDS does not pose any requirement for the modelling and design of local systems and, subsequently, local data quality measures. However, highlighted below, are areas the data set developers recommend should be considered by data providers within their local governance arrangements

3.3.1. Corporate Data Quality Framework

Each organisation will have its own corporate framework for managing data quality in respect to data collection, submission and publication. Such a framework is likely to involve a number of components such as leadership and direction from a senior officer, organisational and departmental data quality objectives, data quality audits and a performance management framework. It is recommended that appropriate components of the corporate data quality framework include the SDICDS, so that data quality relating to the data set is at the heart of the organisation's data quality framework.

3.3.2. Data Quality Risks

At organisational, departmental and individual levels, risks related to data quality should be identified and mitigated. Examples of risks, which could be considered, are:

- Organisational - does the organisation have corporate policy and objectives for managing data? Is there a senior officer with overall responsibility for data quality?
- Team - are all relevant staff aware of the purpose and importance of collecting data for this national data set? Are there sufficient resources available to continue data collection during staff absences?
- Individuals - do staff have sufficient time within their work routine to collect the data? Is there a need for additional training so staff can possess appropriate skills to collect the data, especially where systems are upgraded?

3.3.3. Organisational and Departmental Objectives

In any organisation, resources should be deployed towards organisational and departmental objectives. The organisation's performance management framework will identify the extent to which objectives are met, and where necessary, revised.

Where the data set is used to monitor progress towards objectives, there should be greater emphasis on collecting good quality data. It may be necessary to embed the data set subject area into the organisation's performance management framework and therefore set local objectives, to ensure data is collected in a reliable and timely manner.

Some organisations will have well developed processes and systems that, with minimum effort, will accommodate the data set. Other organisations, for which processes and systems are underdeveloped or in their infancy, or which are new to submission of the SDICDS may require significant changes. In such instances, organisations may choose to plan the implementation of this Information Standard as a priority to ensure sufficient resources are deployed for conformance. The implementation of a new or re-engineered process may be more successful where organisations use peer organisations to identify and replicate areas of good practice.

3.3.4. Timelines

The data should be entered in local systems and submitted in a timely manner no later than 10 days from the date of the procedure. This will ensure that the data set can deliver meaningful, relevant and timely reports for stakeholders. This should be followed by a review of data quality feedback provided back by the Data Liaison Team.

Please note that any delay in data submission may have adverse impact on data quality if insufficient time is allowed to make improvements following the production of the data quality report provided after each submission and prior to associated reporting.

3.3.5. Utilisation of Data Quality Feedback

The validations applied on data submission, are designed to report errors and inconsistencies within a single submission. The Requirements Specification includes a requirement to utilise these reports as early as possible following the initial submission. Such data quality feedback is not designed to replace local data validation but is intended to facilitate and assist with this activity.

3.3.6. Local Data Validation

The validations which are applied on submission only relate to the structure and validity of the submitted data. On submission it will be impossible to identify whether data is accurate, complete and representative of local activity, which should be assessed via local data quality measures.

3.4. Skill Mix Changes and Training

Health and Care providers and system supplier organisations will benefit from developing a local implementation strategy. The strategy should include the identification of skills gaps which might impact on the implementation and maintenance of the SDICDS extract within the organisation. Staff that are impacted

by this will typically include; clinicians, administration personnel, informatics personnel and IT services.

The data set is an output-based specification for data submission, consequently, 'in scope' services will normally collect information locally using an electronic system, whether this is a commercial or a bespoke system. To ensure systems are used in the correct manner, system suppliers and/or care providers will need to provide guidance for staff on how to use the local system. Training that might need to be considered includes:

Technical skills:

- Data input training
- Using new technologies such as hand-held devices
- Using new applications
- Understanding of the SDICDS Information Standard
- Uploading data from remote devices to provider network / system
- Collation of data from clinical system(s)
- Validation of extract
- Rectification of poor data quality
- Usage of the MESH tool including and the web form
- Analysis of data quality reports.

Soft skills:

- Collaboration skills between clinical and informatics staff to identify and resolve errors in data entry and address systemic data quality issues
- Information governance expertise.

Clinicians:

- A local implementation strategy may require additional skills and training for clinicians in using new functions and modules within an existing or new IT system.

Administration Personnel:

- A local implementation strategy may require additional skills and training for administration personnel in using new functions and modules within an existing or new IT system. Additionally, administration personnel may be responsible for transcribing data to a new or existing IT system.

Informatics and IT Support Services:

From an IT or Information Management Service perspective, skills may be required in:

- configuring local systems to capture information using SNOMED CT as required
- developing and maintaining a local data warehouse
- creating a submission extract from a spectrum of local IT systems
- creating uni- or bi-directional interfaces between electronic systems.

Information Governance:

The SDICDS facilitates the flow of patient confidential data. All organisations involved in the collection and dissemination of data that will ultimately form part of

the SDICDS must ensure that staff involved in data handling in any respect are fully conversant with the organisational information governance responsibilities.

For further information regarding the information governance responsibilities of care provider organisations with respect to patient confidential data, please see section 3.2 Information Governance.

NHS Digital does not offer explicit training in any of these areas; however we are able to help users through:

- regular sessions with the Data Liaison Team to help familiarise users with the data set
- response to queries sent to the NHS Digital queries mailbox enquiries@nhsdigital.nhs.uk
- written guidance referenced elsewhere in this document and other documents on the SDIS webpages

3.5. Step-by-step Implementation Guide

3.5.1. First time submitters – Implementing the SDICDS

The table below provides a high-level summary of essential steps for implementing the SDICDS within your organisation

Activity	Step	Description
Background, Objectives and Scope	Understand the background and the scope of the Information Standard	Establish whether the SDICDS implementation applies to your organisation. Review this Implementation Guidance along with the Requirements Specification to fully understand the background, objectives and scope to this Information Standard.
Communication	Identify and engage with key stakeholders	Identify the key stakeholders for your SDICDS implementation and ensure they are aware of the requirement. In particular: Read section '3.4 Skills Mix Changes and Training' to fully understand what local support may be required for different stakeholder groups. Inform local commissioners of progress with implementation and discuss plans for utilising the commissioner extracts made available post-submission. Ensure relevant systems suppliers and involved stakeholders are aware of the requirements for SDIS systems as per the Requirements Specification. Maintain ongoing stakeholder engagement.
	Keep up to date with news and updates	Attend any of the regular stakeholders' events which may have relevance to your organisation and keep in contact with your Data Liaison Team Representative
Information Requirements	Understand how the data is grouped within the data set	Review the Technical Output Specification to understand at a higher level how the data items are grouped, and how those groups relate to each other.
	Decide whether and how data items will be collected and what data is in scope – Data Mapping.	Look more closely at each individual data item in the Technical Output Specification and the specialties as defined by the DPN and check whether local systems record the data in a way that means it can be submitted within the SDICDS, either directly or with local transformation. Contact

		your Data Liaison Team Representative who can facilitate a mapping a data mapping session.
	Prioritise approach to meeting information requirements.	Prioritise your approach to implementing the SDICDS and achieving full coverage of the information requirements. This should involve agreeing how implementation might be phased, for example by identifying those services that are well placed to collect SDICDS as 'early adopters' – the current focus and mandate is to collect data in relation to Pelvic Floor. You may choose to prioritise: • by data items (e.g. all mandatory data across all systems in all services first) • by service (e.g. starting with largest services) • by system (e.g. all data from a particular clinical support system first).
Information Governance	Ensure the organisation complies with Information Governance requirements.	The Implementation Guidance signposts additional information relating to Information Governance (IG) issues surrounding the use of health service data. Caldicott Guardians lead(s) MUST: • Review the Information Governance Guidelines signposted within the Implementation Guidance to understand the issues around data submission, storage and reporting processes when handling identifiable and sensitive data items. • Review management of the consent issues and put in place local processes. • Review the Information Governance guidelines outlined on the NHS Digital webpages here.
Submission Process	Understand the end-to-end submission process.	Review the SDIS Web page to fully understand the data submission process.
	Ensure compliance with technical requirements to enable data submission.	Look more closely at the technical requirements needed to get ready for data submission. In particular, ensure sufficient time is allowed to take action where required. These requirements are found in the User guidance and on the MESH webpage and SDIS webpage. Your Data Liaison Team representative will also have knowledge of the technical requirements for submission.
	Obtain credentials for submission using the web form or through MESH	Undertake the authorisation process to enable members of staff to be authorised to submit data through the web form or MESH. These requirements are found in the User guidance and on the MESH webpage and SDIS webpage. Your Data Liaison Team representative will also have knowledge of the process for receiving credentials for submission
	Construct extract data submission file or submit directly in to the webform	Use local processes and technologies to generate an extract for submission through MESH. The Information Standard does not stipulate any particular local processes that should be used to generate the required output file. It may be that some data providers will construct a temporary local data warehouse to enable them to aggregate data

		from a number of different sources. Please contact your Data Liaison Team representative for help developing your extract or see the SDIS webpage. Please see the user guidance on how data is submitted through the web form, it is advised that the data gathering exercise has been completed and is available to the submitter if a web form submission is used. Data must be submitted within 10 days of a surgical procedure taking place.
	Fully understand the validation feedback presented back through the webform or MESH.	The Technical Output Specification defines structure of the data items upon which base validations are applied. The reports that will be returned to data providers and lists all the error and warning messages that are produced.
	Understand the data quality reports that will be received post submission.	Post submission you will receive data quality reports from your Data Liaison Team Representative. Please engage with your representative to understand issues in data quality. These should be rectified as soon as possible with data resubmitted again correcting any issues raised.
Share your implementation experience.	Get in touch with the team	The SDIS team welcome any feedback you may have on the submission process and data set design. You can contact us via enquiries@nhsdigital.nhs.uk or provide feedback through your Data Liaison Team Representative

3.5.2. Further Guidance

Detailed submission guidance to support the SDICDS standard can be found in the User Guidance, Technical Output Specification and the SDIS web page. Further assistance and guidance can be received by contacting your Data Liaison Team representative or the Data Liaison Team mailbox (data.liaisonteam@nhs.net).

3.6. Implementation Timescales

The proposed timetable for implementing the Standard is set out in the table below. This outlines dates when applicable organisations MAY and MUST implement the Surgical Devices and Implants Core Data Set.

Task	Date
Organisations are preparing for implementation of the Standard, including a thorough assessment of their current systems and processes, and developing and commencing roll-out of a local implementation plan to achieve implementation of and compliance with the Standard in line with published deadlines. This may require the commissioning of information system changes with relevant software suppliers.	Immediate.

Task	Date
Implementation date: organisations MAY begin to implement the Standard and submit test files to the relevant team at NHS Digital	Immediate
Organisations MUST have made the necessary changes such that they can routinely identify, and record data items used in the production of the Standard.	1 June 2022
Organisations MUST be fully compliant with all aspects of the Standard.	1 July 2022

4. Human Behavioural Guidance

The following section describes how the data set should be used by clinical and operational staff and providers. Providers should meet the compliance requirements for their IT system or systems to implement the SDICDS standard. This section also explains where data, in relation to the data set, can be found in the care pathway.

- Clinical and Administrative Staff: will be responsible for capturing information as part of the on-going care of the patient i.e. for primary use purposes and will be responsible for capturing information such as demographics, procedure details, type of device or implant used. May also be responsible for the submission of the patient record through the web form. This will include ensuring completeness and data quality of the information within the data set.
- Informatics Staff: will be responsible for the collation of information, which may come from a range of disparate systems, into a single data extract which can be submitted to NHS Digital using the MESH transfer tool or web form. This will include ensuring completeness and data quality of the information within the data set.
- Systems: should be implemented by providers ensuring that data items can be captured electronically and output produced or derived to nationally agreed standards to allow extraction and/or derivation to produce the SDICDS.

4.1. Data Users

4.1.1. Primary Users

The SDICDS is not intended for primary data use. The SDICDS is not a specification for the standardisation of a patient care record at this stage, but it is based on clinical and operational information. Service Providers have the flexibility to adopt any local data collection process or system as long as the local data collection frameworks can output a suitable data extract as per the data set specification, for submission through MESH or through direct entry of the record in to the webform. Providers should therefore look to re-use their clinical and operational systems to extract SDICDS data.

4.1.2. Secondary Users

As a secondary uses data set the SDICDS will be made up of existing data extracted from one or more Patient Administrative Systems (PAS) and clinical systems. Information generated by this NHS Information Standard through individual record-level data extracts or published aggregate reports is likely to be used by the following organisations:

At a local level:

- Health and Care Providers that provide surgery involving surgical devices and implants and alternative procedures[2].
- Commissioners including CCGs

At a national level:

- NHS England and NHS Improvement
- Department of Health and Social Care (DHSC)
- Care Quality Commission (CQC)
- NHS Digital
- Commercial companies (where approved through the Data Access Request Service)
- Research organisations including Universities
- MHRA
- NICE
- OLS.

The following practitioners are likely to analyse information captured through SDICDS:

- Service managers
- Performance analysts
- Commissioners
- Clinicians
- Researchers.

Analysis carried out by NHS Digital and any future publications will be found on the NHS Digital website.

5. Technical Guidance

Technical guidance in support of the SDICDS can be found in a number of supporting documents described at the beginning of this document, section 1.2.

Key documents include:

- SDICDS v1.0 Requirements Specification
- SDICDS Technical Output Specification
- SDIS User Guidance

Users should also review:

[2] 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 a coronary angioplasty involving an insertion of a stent”

- NHS Data Model and Dictionary
- SNOMED CT web pages
- SDIS Web page

6. Maintenance

6.1. Implementation Strategy

NHS Digital will review the ISN publication annually. Where transition to mandatory submissions for other clinical specialties in relation to this information standard is due to occur, this may necessitate a more frequent review and publication cycle.

Relevant policy, practice and classifications, including NHS Data Model and Dictionary and ISNs, are continually monitored by the Data Set Development Service (DSDS). Where changes are identified, the risk and benefits in relation to timescales will be assessed to prioritise the requirement into a planned annual release.

This annual update strategy will aid local planning and development by providing a consistent six-month window in order to make a limited set of changes, making implementation deadlines more achievable.

Any national measures using amended data will be experimental for an initial period, with remaining official measures being unaffected.

6.2. Data Set Maintenance

The SDICDS Information Standard will be formally maintained by NHS Digital in accordance with the Data Set Development Service maintenance procedures.

The data set is subject to ongoing maintenance to ensure it remains ‘fit for purpose’. The data set maintenance process ensures the information standard continues to reflect changes to priorities, policy, practice and/or underlying classifications.

SDIS users are integral to the maintenance strategy for the SDICDS. As such, the content of the data set is determined from consultation with various stakeholder groups. Stakeholders include various sections of Department of Health and Social Care policy, NHS England and NHS Improvement, MHRA, service providers and commissioners. Other changes arise from service providers identifying issues in the current requirements which do not align with current practice, such as the need for permissible value amendments. Commissioners raise issues around the availability of data which will allow them to undertake their duties.

Changes identified are likely to require the inclusion of new data items, amendment of existing items or removal of no longer required items which in turn will require a change to provider extracts.

The scope of the maintenance process covers:

- Management of change requests from users and stakeholders. Changes have been raised and implemented are logged and can be found in the TOS under the change log tab (see section 6.4)
- Elaboration of data requirements through engagement with senior stakeholders, including provision of support and guidance to external stakeholders in developing the data set changes to meet information/policy requirements

- Development of options papers when required to enable senior stakeholders and the Programme/Project Board to make informed design decisions
- Liaison with health and care provider and system supplier organisations to develop appropriate technical solutions
- Establishment and maintenance of data set specific expert reference groups, which consist of care provider and system supplier representatives
- Specification of changes to the data set in response to changes in policy, practice, coding and classifications
- The process for authorisation and approval of changes to data set items, including obtaining DPAB standard change acceptance
- Undertaking periodic reviews of the data set including data items, definitions and data values
- Updates to the Implementation Guidance
- Ongoing updates to associated guidance documents outside the new version development cycle responding to changes in policy and practice; to clarify or improve pre-existing guidance; and amend identified errors. Documents affected include: User Guidance and the Technical Output Specification (provided this does not change the published standard).

6.3. Data Set Requirements

Requirements for future versions of the Data Set can be submitted to NHS Digital by the sponsor and users.

Requests can be submitted, describing any proposed changes to the SDICDS, to NHS Digital via enquiries@nhsdigital.nhs.uk. Your Data Liaison Team representative may also be able to feedback changes on your behalf.

Each request should be supported by a valid business requirement i.e., what change is needed, justification (i.e. why is it needed) and also any associated timescales. Any requirement requests will be considered and agreed by the Sponsor prior to submission to the DPAB for formal assurance and the publication of an ISN. The ISN will inform the NHS and systems suppliers of the changes and timescales.

6.4. Data Alliance Partnership Board (DAPB)

DAPB oversees the development, assurance and approval of information standards, data collections, and data extractions.

Further acceptance of an NHS Information Standard Change submission by DAPB will be required prior to publication and implementation of any data set change.

6.5. Information Standards Notice (ISN)

Any changes to this Information Standard will be communicated to the relevant providers of services affected, and their associated system suppliers, via the publication of an ISN. This will outline any new or changed requirements and associated timescales for implementation.

7. Risk and Issues

In the event that a service provider or system supplier needs to raise a technical risk or issue, please contact NHS Digital by writing to us at: enquiries@nhsdigital.nhs.uk.

8. Implementation Support

8.1. Support

For specific enquiries relating to the SDICDS Information Standard please contact NHS Digital via the central customer service centre:

Telephone: 0300 303 5678

Email:enquiries@nhsdigital.nhs.uk

8.2. Surgical Devices and Implants News and Service Updates

The SDIS webpage will provides regular timely information to users relating to various aspects of the SDICDS. You will also receive regular communications and updates through your Data Liaison Team Representative.

8.3. Additional Sources of Information

NHS Data Model and Dictionary

Full details of changes to data items, including definitions and associated value lists are available on the NHS Data Model and Dictionary website: http://www.datadictionary.nhs.uk

Terminology and Classifications

SNOMED International: https://www.snomed.org/

UK National Release Centre (part of NHS Digital): https://hscic.kahootz.com/t_c_home/grouphome

Data Alliance Partnership Board (DAPB)

DAPB oversees the development, assurance and approval of information standards, data collections, and data extractions: https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions

Data Security and Information Governance

NHS Digital offers guidance on protecting data and handling information securely. Our guidance is designed to help health and care organisations meet the standards required to handle care information: https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance

8.4. Disclaimer

This document is intended to provide guidance for users in relation to the capture and submission of information for the Surgical Devices and Implants Core Data Set (SDICDS). It is not intended to represent official policy or legislative guidance.

If you are concerned that any aspect of this guidance does not accurately reflect the intended purpose and/or official policy, legislative or practice guidance; please send details to NHS Digital at enquiries@nhsdigital.nhs.uk