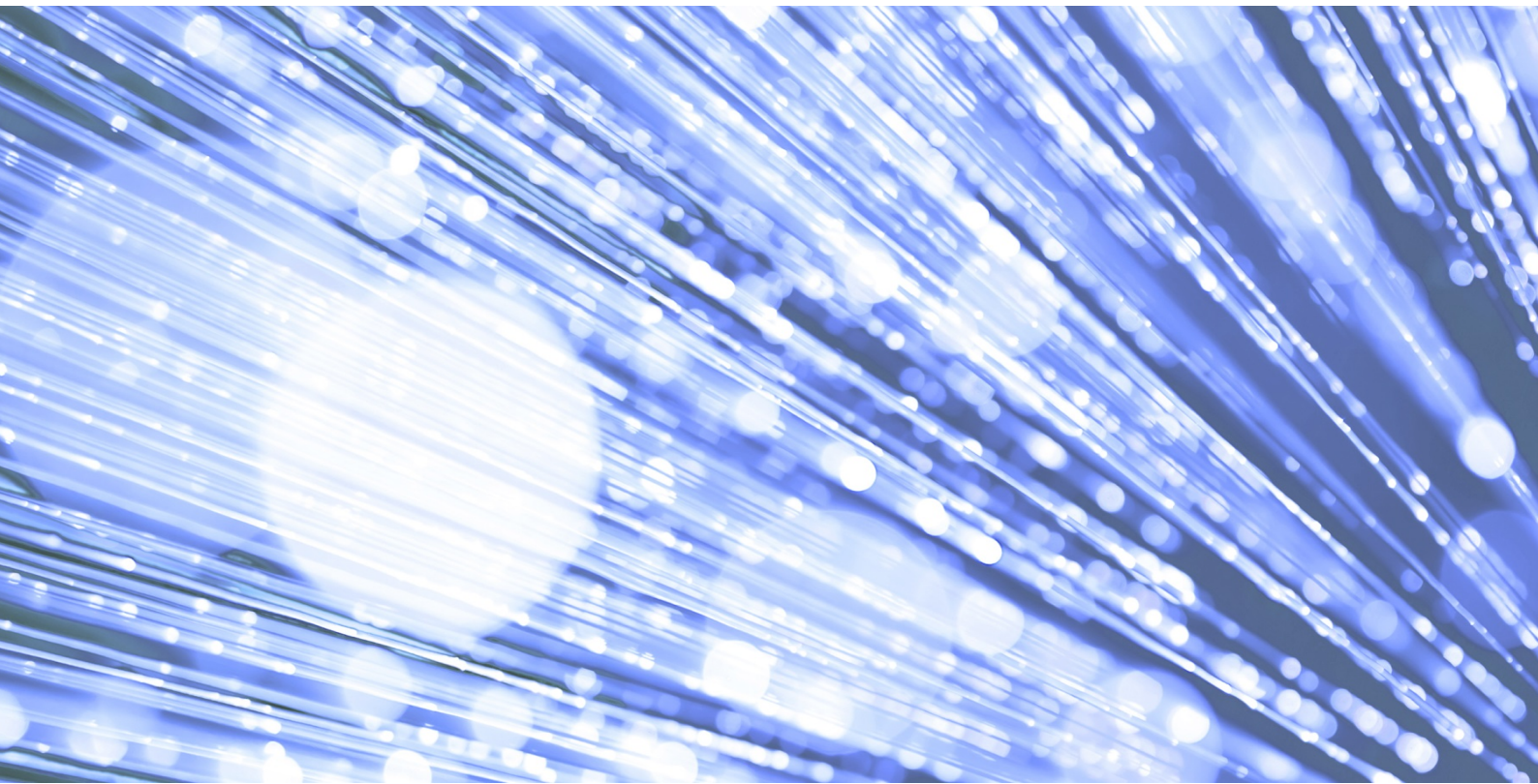


DCB1513 Amd 10/2018

Maternity Services Data Set Version 2.0 Requirements Specification

Published September 2018



Information and technology
for better health and care

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Data Coordination Board

This information standard (DCB1513) has been approved for publication by the Department of Health and Social Care 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 Coordination Board (DCB), a sub-group of the Digital Delivery Board.

This information standard comprises the following documents:

- Change Specification
- Data Set Specification
- Implementation Guidance
- Requirements Specification.

An Information Standards Notice (DCB1513 Amd 10/2018) 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.

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Glossary of terms

| Term/Abbreviation | Definition |
|------------------------|---|
| Acute Trust | An NHS organisation responsible for providing a group of healthcare services. An Acute Trust provides hospital services, including Maternity Services. |
| AHP | Allied Health Professionals work across a wide range of locations and sectors within acute, primary and community care. They are made up of the following staff groups: <ul style="list-style-type: none"> • Art, Drama, Music Therapists • Chiropodists/Podiatrists • Occupational Therapists • Orthoptists • Physiotherapists • Prosthetists and Orthotists • Radiographers Diagnostic and Therapeutic • Speech and Language Therapists • Dietitians |
| Anonymisation | A method applied to patient identifiable data items to protect the identity of individuals. Under anonymisation, the relevant data items are either randomly encrypted or completely removed. Anonymised data cannot be linked with other data sets, nor can it be reversed to expose the identity of an individual. Anonymisation is different from Pseudonymisation. |
| BSP | Bureau Service Portal is the secure online submission platform used for submissions to MSDS v1.5 that allows providers of relevant NHS services to upload their data at regular intervals. At the end of a given period the portal produces extracts for providers, commissioners and NHS Digital which can be downloaded. This is to be replaced by the DSP for MSDS v2.0. |
| Care Pathway | Care pathways describe the route that a patient will take from their first contact with a healthcare provider to the completion of their treatment. |
| CCG | Clinical Commissioning Group |
| CDS | Commissioning Data Sets. CDS form the basis of data on activity carried out by NHS Trusts reported centrally for monitoring and payment purposes. They support the current Healthcare Resource Group (HRG) version 4 for calculation of payment to trusts and monitoring of other initiatives including the 18 weeks Referral to Treatment standard. |
| Central Data Warehouse | A repository of data relating specifically to the MSDS. Could also be known as a Central Data Repository. |
| Clinical Governance | Clinical governance is defined by the Department of Health and Social Care ¹ as describing “the structures, processes and culture needed to ensure that healthcare organisations - and all individuals within them - can assure the quality of the care they provide and are continuously seeking to improve it” |

¹ <https://www.gov.uk/government/news/clinical-governance-guidance>

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| Collection Start Date | The date when services within the scope of this standard should start data collection in their electronic systems. |
| Commissioned Currencies | The payment system in England under which commissioners pay healthcare providers for each patient seen or treated, taking into account the complexity of the patient's healthcare needs. The two fundamental features being nationally determined currencies and tariffs. Currencies are the unit of healthcare for which a payment is made and can take a number of forms covering different time periods from an outpatient attendance or a stay in hospital, to a year of care for a long-term condition. Tariffs are the set prices paid for each currency. |
| Conformance Date | The date when services and IT systems must conform to standards and meet the specification as set out in the mandate and guidance. This can usually be read as when the first submission window closes for this new version. |
| CMHT | Community and Mental Health Team |
| CQC | Care Quality Commission monitor, inspect and regulate health and social care services. |
| CTV3 | Clinical Terms Version 3 – a Clinical coding Language used for diagnosis and treatment. |
| DARS | <p>The Data Access Request Service can offer clinicians, researchers and commissioners the data required to help improve NHS services.</p> <p>Organisations and individuals wanting to use certain kinds of data need to show they meet strict data governance standards by completing the DARS application process.</p> <p>The DARS team makes sure NHS Digital only supply sensitive patient level data to organisations that look after it according to Information Governance (IG) requirements and use it to improve health and care services.</p> |
| DCB | The Data Coordination Board (DCB) is a sub-group of the Digital Delivery Board. Empowered by the Health and Social Care Act 2012, the DCB has delegated responsibility for approving information standards for the health and social care system in England. The DCB membership is drawn from a range of organisations operating within health and social care. |
| Data Controller | <p>A person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data is, or is to be, processed.</p> <p>A data controller must be a "person" recognised in law, that is to say:</p> <ul style="list-style-type: none"> • individuals; • organisations; and • other corporate and unincorporated bodies of persons. <p>Data controllers will usually be organisations, but can be individuals, for example self-employed consultants. Even if an individual is given responsibility for data protection in an organisation, they will be acting on behalf of the organisation, which will be the data controller.</p> |
| Data Group | A collection of data items that describe a distinct event or episode. This can also be referred to as a table of data. |
| Data Item | A single component of a data set that holds one type of information and relates to a specific record. |

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| Data Set | The full collection of data groups arranged in a logical manner with relationships between one another. See 'Technical Output Specification' |
| Data Submission File | A single file related to the MSDS that data providers submit to the central data warehouse. A data submission consists of an XML file containing the data for a single reporting period in the format specified by NHS Digital. |
| Derived | A data item populated at the central data warehouse as part of post-deadline processing. The derived data item is based on the manipulation of the 'source' data items using mathematical, logical or other types of transformation process, or by using source data to derive further data from national look-up tables. |
| DMS | Data Management Service |
| DSAS | Data Standards Assurance Service, an NHS Digital team operating on behalf of the DCB, ensures that the Information Standard meets the requirement of the Health and Social Care Act 2012 and is appropriate for the use specified in the Requirements Specification. DSAS also carries out a burden assessment to ensure that information demands on the NHS are minimised, fit with current national health policies and are carried out in the most efficient way without duplication. It covers the Department of Health and Social Care and its Arm's Length Bodies. |
| DSDS | Data Set Development Service – the team within NHS Digital responsible for developing a number of national data sets, including MSDS v2.0. |
| DSP | Data Services Platform – the new secure online landing platform being developed by NHS Digital to receive patient level data, including MSDS v2.0 data. The DSP will improve the security, processing and transparency of data for NHS planning and research. |
| ERG | The NHS Digital MSDS Expert Reference Group comprises care provider, system supplier and NHS Digital representatives. It is currently chaired by NHS Digital. Its main focus is on contributing to the understanding of requirements and the development of viable solutions. |
| FPN | Fair Processing Notice |
| GDPR | General Data Protection Regulation |
| HSCN | The Health and Social Care Network is a new data network for health and care organisations which replaced N3. It provides the underlying network arrangements to help integrate and transform health and social care services by enabling them to access and share information more reliably, flexibly and efficiently. See https://digital.nhs.uk/health-social-care-network . |
| HSCIC | Health and Social Care Information Centre - A non-departmental body created by statute, also known as NHS Digital. |
| ICD 10 | International Classification of Diseases (Revision 10) |
| Information Standard | An information standard is a formal document approved and issued by the Data Coordination Board (DCB). It defines technical criteria, content, methods, processes and practices for implementation across health and social care in England. |
| Maternity Service | A service specialising in the treatment and care of women and babies during the maternity care pathway (antenatal, intrapartum and postnatal care). |
| MSDS | The Maternity Services Data Set is an Information Standard, approved by the governing standards body, which defines a patient-level data set. The |

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| | MSDS is an 'output data set'; therefore, it sets out to describe "what should be extracted" from local IT systems and periodically be submitted to the Central Data Warehouse by NHS-funded Maternity Services. |
| MDT | Multi-Disciplinary Team |
| N3 | The NHS national broadband network formerly used to link hospitals, medical centres and General Medical Practices in England and Scotland. Now replaced by the Health and Social Care Network (HSCN). |
| NHS Digital | A data, information and technology resource for the health and care system which plays a fundamental role in driving better care, better services and better outcomes for patients in England. Previously (and still legally) known as the HSCIC. |
| NICE | National Institute for Health and Care Excellence |
| OAT | Operational Acceptance Testing The assurance of functionality relating to the flow of data through the landing portal. This could include the use of test XML files containing perfect and imperfect test data. Testing will include a cross section of providers nationally using different systems and submitting different volumes of data on the spectrum of small to large users. |
| OPCS-4 | The OPCS Classification of Interventions and Procedures (OPCS-4) is a Fundamental Information Standard which is revised periodically. The classification is used by Health Care Providers and national and regional organisations to support operational and strategic planning, resource utilisation, performance management, reimbursement, research and epidemiology. It is used by NHS suppliers to build/update software to support NHS business functions and interoperability. |
| Output Data Set | A set of standardised data items defining "what should be extracted" from local clinical IT systems. NHS trusts have the flexibility of adopting any local data collection process and system they see fit, so long as the system can extract data as per the Technical Output Specification (TOS). An output data set is not for direct patient care and is only for secondary uses purposes e.g. national reporting. |
| PAS | Patient Administration System used by trusts to record patient data. |
| Patient Level | Relating to a single data subject, as opposed to an aggregate data set. |
| PHQ-9 | Patient Health Questionnaire - 9 |
| Post-deadline Processing | The processing undertaken at the close of a submission window by the central data warehouse. |
| Pre-deadline Processing | The processing carried out immediately on a submitted file to validate the file as a whole, extract the records that are (or may be) for the particular reporting period, and validate those records. |
| Pseudonymisation | A method applied to identifiable data items to protect the identity of individuals. Under pseudonymisation, a standard encryption key is used to encode patient identifiable data items so that data linkages within and outside the data set, for the same individual, are feasible. Because the encryption key is retained by a single "Data Controller", there is also the potential to reverse the process (de-code) and expose the identity of the individual. The encryption key is only decoded for specific purposes (e.g.: migration of data into another platform). Pseudonymisation is different from Anonymisation. |
| Read V2 | Clinical coding language used for diagnosis and treatment |

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| Reporting Period | The period (usually a calendar month) for which a particular data submission file or extract refers. |
| Secondary Uses | Re-using clinical and operational information for purposes other than direct patient care; for example, national reporting. |
| SNOMED CT | SNOMED CT is an international clinical terminology that provides machine readable codes for clinical concepts; the clinical concepts being also represented in a consistent and human readable form through descriptions. SNOMED CT has been selected and approved as the terminology to be adopted by the NHS in England. |
| SRO | Senior Responsible Owner |
| SCCI | The Standardisation Committee for Care Information (SCCI) was a committee with membership drawn from a range of health and social care organisations with responsibility for overseeing the development, assurance and approval of information standards, data collections and data extractions used within the health and social care system. On 1 April 2017, the Data Coordination Board (DCB) took over responsibility for the approval of standards from SCCI. |
| Submission Period or Submission Window | The period (usually initially approximately 2 calendar months), during which a data provider may submit data uploads for a given reporting period. |
| TOS | The Technical Output Specification fully defines each data item within the data set. This document splits the data set into a number of groups (tables), each containing data items and values. The 'Change Control' tab within this document defines the individual changes made to tables and data items as part of the <i>Change Request</i> . To be referred to alongside the data model. |
| TRUD | Technology Reference data Update Distribution. A website that hosts technology reference data files from NHS Digital. https://isd.digital.nhs.uk/trud3/user/guest/group/0/home |
| UAT | User Acceptance Testing |

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1. Overview

This product precisely defines the patient-level Maternity Services Data Set (MSDS) standard. The Summary section below describes the standard; the following Requirements and Conformance Criteria sections explain what is required of care providers and systems to conform to the standard, and the way this will be tested respectively.

This document is the formal definition of the standard.

1.1. Summary

| Standard | |
|-----------------|--|
| Standard Number | DCB1513 |
| Standard Title | Maternity Services Data Set (MSDS) |
| Description | <p>The MSDS is a patient-level data set that captures key information at each stage of the maternity care pathway including mother's demographics, booking appointments, admissions and re-admissions, screening tests, labour and delivery along with baby's demographics, admissions, diagnoses and screening tests.</p> <p>As a secondary uses data set it re-uses clinical and operational data for purposes other than direct patient care. It defines the data items, definitions and associated value sets extracted or derived from local information systems.</p> <p>MSDS v2.0 is an update to the existing data set that introduces a new structure and content, including clinical terminology, in order to meet current clinical practice and incorporate new requirements. MSDS v2.0 also mandates the submission of all maternity records in scope of the data set, including records that are held on paper which must be submitted in the required electronic format.</p> <p>MSDS v2.0 is designed to meet requirements that resulted from the National Maternity Review, which led to the publication of the Better Births report in February 2016. Better Births highlighted the need for maternity services in England to become safer, more personalised and provide better access to information for pregnant women. The publication of Better Births resulted in the establishment of the Maternity Transformation Programme, and the updated version of the data set forms part of the 'Sharing Data and Information' workstream of the programme.</p> <p><u>In Scope</u></p> <p>This standard mandates the central submission of administrative and clinical information for secondary uses purposes. The standard defines a 'data set specification' based on extracts from clinical records. The scope includes all activity undertaken by Maternity Services funded, and/or provided, by the NHS. This could include NHS Foundation and non-Foundation Trusts, as well as independent organisations providing NHS-funded Maternity Services.</p> <p>The scope of the data set includes all activity carried out by Maternity Services relating to the mother and baby or babies, from the point of the first booking appointment until mother and baby or babies are discharged from Maternity Services.</p> |

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| | <p>In summary, this includes the following:</p> <ul style="list-style-type: none"> • Mother's Details • Mother's Booking, Pregnancy and Diagnosis Details • Care Contacts and Activities • Mother's Labour and Activity Details • Anonymous Assessments and Findings • Baby's Details • Hospital Provider Spells (inpatient stays in hospital during the pregnancy) • Header and Reference Data <p>Further guidance on definitions and technical aspects for monthly data submissions to a central data warehouse are provided to support the implementation of the standard and can be found here:</p> <p>www.digital.nhs.uk/isce/publication/dcb1513</p> <p>https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/maternity-services-data-set</p> <p><u>Out of Scope</u></p> <p>The following areas are exceptions to the MSDS scope:</p> <ul style="list-style-type: none"> • Local system functionality or design: whilst the standard provides details of 'what' and 'how' data should be submitted, it does not stipulate any standard for the functionality or design of local clinical and operational systems, although if data is easy to collect and synchronise with care pathways it will improve the quality of the data provided. Separate work is ongoing on a primary data standard for maternity records². • Activities undertaken after mother and baby are discharged from Maternity Services, e.g. activity carried out by health visiting services. • Non-NHS funded services provided by independent organisations, e.g. private clinics and independent midwives, who are not required to make submissions unless commissioned by the NHS. • Activity carried out by other care services, e.g. by GPs. • Services rendered outside England. |
| Applies to | <p><u>Organisation Types</u></p> <p>The MSDS will be used in all organisations providing Maternity Services, and the standard applies to all NHS-funded Maternity Services in England, including Acute Trusts and Foundation Trusts actively involved in the maternity care pathway (antenatal, intrapartum and postnatal/postpartum episodes). This also includes private services commissioned by the NHS and provided by independent organisations.</p> <p><u>Services</u></p> <p>The standard primarily, but not exclusively, must be read and used by all NHS-funded Maternity Service providers, and related services that have an active involvement in the maternity care pathway, including:</p> <ul style="list-style-type: none"> • Obstetric Services. • Midwifery Services. |

² <https://theprsb.org/projects/standard-maternity-record/>

| | |
|----------------|--|
| | <ul style="list-style-type: none"> • Fetal Medicine Services. • Radiology Services. • Pathology Services. • Gynaecology Services. • Neonatal Services. • Community Providers. <p><u>Professionals</u></p> <p>The standard primarily, but not exclusively, applies to the following professionals:</p> <ul style="list-style-type: none"> • Maternity Services administrative personnel. • Obstetricians. • Midwives. • Neonatologists. • Paediatricians. • Information and IT Professionals. <p><u>IT Systems</u></p> <p>The standard predominantly, but not exclusively, relates to the following electronic information systems:</p> <ul style="list-style-type: none"> • Patient Administration Systems (PAS). • Electronic Patient Records (EPR). • Commercial and National Maternity Systems. • Radiology Systems. • Pathology Systems. • Neonatal Systems. <p><u>Data Subjects</u></p> <p>The standard primarily, but not exclusively, aims to capture information on two data subjects:</p> <ul style="list-style-type: none"> • Pregnant women. • Babies. <p>Data will be captured for women and babies presenting for any part of the maternity care pathway. It is not necessary for the woman or baby to have a 'full data record', i.e. all antenatal, intrapartum and postnatal care delivered at the same organisation.</p> <p>In addition, limited information about women's partners (or the father of the baby) is captured.</p> |
| Release | |
| Release Number | Amd 10/2018 |
| Release Title | Version 2.0 |
| Description | <p>An ongoing requirement exists to update the Maternity Services Data Set (MSDS) in order to ensure the data set remains 'fit for purpose'.</p> <p>This release of the MSDS (v2.0) represents a significant change to the existing structure of the MSDS (v1.5) and brings the MSDS into line with the core structures of other data sets maintained by NHS Digital, specifically the</p> |

| | |
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| | <p>Community Services Data Set (CSDS) and the Mental Health Services Data Set (MHSDS).</p> <p>The changes included in this release relate to new government policy initiatives, resolution of issues within the current data set, and inclusion of other key stakeholder requirements as set out in more detail in the MSDS v2.0 Change Specification.</p> |
| Implementation Date | <p><u>System Conformance</u></p> <p>From 1 April 2019 maternity systems MUST be fully conformant with this standard.</p> <p><u>Health and Care Organisations</u></p> <p>From 1 April 2019 providers of NHS-funded maternity services, as defined in this Information Standard, MUST be able to collect the information as defined in the Technical Output Specification for local use.</p> <p>From 1 May 2019, providers of NHS-funded maternity services MUST begin submitting MSDS submissions in accordance with this standard.</p> <p>Providers of NHS-funded maternity services may also volunteer to participate in pilot trials ahead of the Implementation Completion Date to test the process ahead of full data collection, upon discussion and agreement with NHS Digital. Pilot data MAY be provided ahead of the full conformance date.</p> |
| Full Conformance Date | 30 June 2019 - This is the date the April MSDS v2.0 submission window closes. Providers must have made a valid submission prior to this date, which will include data collected from 1 April 2019 until 30 April 2019. |

1.2. Supporting documents

This document should be read in conjunction with the following:

| Ref # | Title |
|-------|---|
| 1 | MSDS v2.0 Change Specification |
| 2 | MSDS v2.0 Data Model |
| 3 | MSDS v2.0 Technical Output Specification |
| 4 | MSDS v2.0 System Conformance Checklist |
| 5 | MSDS v2.0 Implementation Guidance |
| 6 | MSDS v2.0 User Guidance |
| 7 | MSDS v2.0 Technical Guidance |
| 8 | NHS Data Model and Dictionary MSDS Change Request |
| 9 | MSDS XML Schema (hosted on TRUD – login required) |

Please see section 2.4 of the *Implementation Guidance* for a full list and descriptions of each related document.

1.3. Related standards

| Reference | Title |
|------------|---|
| SCCI1069 | Community Services Data Set (CSDS) |
| DCB0011 | Mental Health Services Data Set (MHSDS) |
| ISB0149-02 | NHS Number for Secondary Care |
| ISB0149 | NHS Number |
| SCCI0034 | SNOMED CT |
| SCCI0021 | International Classification of Diseases |
| ISB0092 | Commissioning Data Sets (CDS) |
| DCB0090 | Health and Social Care Organisation Reference Data |
| ISB1553 | Read Clinical Terms Version 2 (Deprecated) |
| ISB1552 | Read Clinical Terms Version 3 (Deprecated) |
| SCCI0075 | Neonatal Critical Care Minimum Dataset |
| ISB 1555 | Birth Notifications |
| DCB3017 | Overseas Visitor Charging Category |
| SCCI2112 | FGM Risk Indication System (FGM RIS) - Local System Integration |

1.4. Information governance and linkage

The data held in the MSDS may also be linked to data held by NHS Digital from various other data sets and collections. The MSDS data may also be linked to external data sources. More information about the data sets and collections that NHS Digital hold and that may be used for linkage can be found on the [NHS Digital website](#).

2. Health and care organisations

2.1. Requirements

2.1.1. Timeframe

- 1) From 1 April 2019, providers of maternity services as defined in this Information Standard **MUST** be able to collect the information locally that they use to produce the monthly MSDS v2.0 extract, as defined in the Technical Output Specification (TOS).
- 2) From 1 May 2019, providers of maternity services as defined in this Information Standard **MUST** begin ongoing monthly MSDS submissions as per the instructions in the MSDS Technical Guidance and Implementation Guidance. The providers **MUST** allow time to review and implement corrections to their submission files within the designated window.

2.1.2. Scoping

- 3) Providers new to submitting MSDS **MUST** review the 'In scope' and 'Out of scope' sections of this Requirements Specification to establish what elements of their service the standard applies to.
- 4) All providers **SHOULD** review all related documents to ensure they fully understand the background, objectives and scope of this information standard.

2.1.3. Feasibility assessment

- 5) Providers of maternity services **MUST** review the MSDS TOS, MSDS User Guidance, MSDS Implementation Guidance and suggested clinical terminology mappings to understand the scope and definition of each data item.
- 6) As an Output Data Set, the MSDS is intended to only define "what should be extracted" from local IT systems, not "what should be captured". A clinical data set will need data items beyond what the MSDS specifies; consequently, providers of maternity services **SHOULD NOT** use this data set to support their clinical and operational data capture. The ethos around the MSDS is to only re-use clinical data and not specify standards for capturing clinical data.
- 7) Providers of maternity services **SHOULD** familiarise themselves with the MSDS XML schema and conversion tool³ to understand how data items are grouped for the Data Submission File.
- 8) Providers of maternity services **MUST** carry out a 'data mapping exercise' to understand how well their existing electronic systems align to the MSDS TOS and take appropriate action to ensure that the standard is fully met. The self-assessment 'System Conformance Checklist' tool is available on the NHS Digital website to support this mapping exercise. The mapping exercise is likely to need the involvement of experienced

³ An XML conversion tool for the MSDS has been developed by NHS Digital. This enables providers to load or copy their data into the provided table structure. Once complete, a routine can be run that will export the submission into the required XML format ready for submission to the central data warehouse. Use of the conversion tool is optional. Further information can be found in the MSDS Technical Guidance.

MSDS leads, the organisation's Information Management Service and the appropriate IT system suppliers.

2.1.4. Information governance

- 9) Data Controllers responsible for maternity services **MUST** ensure they are fully conversant with pertinent information governance legislation and guidance, including patient objections and [GDPR](#)⁴.
- 10) Providers of maternity services (including the Caldicott Guardian) **SHOULD** review the [NHS Digital web pages](#)⁵, in relation to keeping patient data safe, to ensure they are fully conversant with pertinent information governance legislation and guidance, including:
- Consent and opt-out
 - Compliance against statutory requirements
 - Potential safety/confidentiality/risk considerations
- Further information can be found in the MSDS v2.0 Implementation Guidance.
- 11) Providers of maternity services **MUST** make available information and guidance to patients stating that their clinical care data may be re-used for data analysis and reporting.
- 12) Providers of maternity services **MUST** ensure that local data systems and warehouses comply with appropriate data security controls by ensuring they achieve Data Security and Protection Toolkit standards.
- 13) Any staff responsible for controlling the dissemination of data **MUST** read the Implementation Guidance to understand the information governance approach. This will help inform the handling of sensitive data and ensuring identifiable data is not included in fields marked for inclusion in external extracts as identified in the enhanced Technical Output Specification, and inform responses accordingly. Understanding, behaviours and accountability **SHOULD** be appropriate to the level and nature of responsibility of the staff member.
- 14) Providers of maternity services (including the Caldicott Guardian) **SHOULD** ensure they are aware of requirements in respect of the [General Data Protection Regulation \(GDPR\)](#).⁶ Additional guidance will be updated on the [NHS Digital website](#)⁷ when it becomes available.
- 15) Any immediate concerns regarding information governance issues relating to MSDS **SHOULD** be addressed to the standard's developers at NHS Digital, or the [Independent Group Advising on the Release of Data \(IGARD\)](#)⁸ if the concerns relate to data dissemination.

⁴ <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga/general-data-protection-regulation-gdpr-guidance>

⁵ <https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe>

⁶ <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/>

⁷ <https://www.digital.nhs.uk/article/1414/General-Data-Protection-Regulation-guidance>

⁸ <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data/igard-member-profiles#further-information>

2.1.5. Clinical governance

16)The data set **MAY** be used for clinical governance purposes such as:

- Monitoring of year on year service improvement by governing and audit bodies.
- Benchmarking performance to drive service improvements.

2.1.6. Clinical risks

17)When procuring new systems or modifying agreements with existing system suppliers, providers of maternity services **SHOULD** ensure that supplier organisations are compliant with the clinical safety standards [DCB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems](#) and [DCB0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems](#).

2.1.7. Central Data Submission

18)Clinical staff **MUST** capture the information locally that their organisation intends to use to produce the monthly MSDS v2.0 extract in an accurate and timely manner.

19)Providers of maternity services **MUST** create a monthly data submission as set out in the MSDS Technical Guidance. Therefore, providers of maternity services **MUST** be able to:

- Collate and extract data from local IT systems as per the MSDS TOS.
- Structure the data and create a data submission file as per the MSDS Technical Guidance.
- Apply the basic validation rules and ensure that the submission file conforms to these.
- Ensure the data submission file only contains data for a single month and relates to one provider organisation.
- Submit the data submission file as per the data submission protocol set out in the Technical Guidance.

20)Providers of maternity services **MUST** submit data on a monthly basis to the central data warehouse, based on the schedule that is published on the [NHS Digital website](#) in advance of the conformance date.

21)The schedule outlines the timeframe (Submission Window) within which data relating to a monthly period (Reporting Period) **MUST** be submitted.

22)Providers of maternity services **SHOULD** check pre-deadline validation and data quality reports provided by NHS Digital after each submission, correct errors and make re-submissions at the earliest opportunity. Further details on error correction and re-submissions are explained within the Technical Guidance.

23)Providers of maternity services **MUST NOT** attempt to submit data items not defined in the TOS.

2.1.8. Constructing a Data Submission File

The MSDS Technical Guidance and User Guidance documents provide information on how to create a monthly submission file.

- 24) Providers of maternity services, and in particular informatics staff who are likely to be involved in making data submissions, **MUST** review and follow the guidance in these documents. However, noted below are key requirements of the technical submission architecture.
- 25) A submission **MUST**:
- Only contain data for a single provider organisation.
 - Only contain data relating to activities occurring in a single month.
 - Meet the conditions and validation rules explained in the MSDS TOS.
- 26) Each Data Submission File **MUST** consist of a:
- Header group.
 - Three or more data groups, including MSD001, MSD002 and MSD101 entries for each record.
- 27) Each group consists of one or more data items. The groupings of data items for each table **MUST** be as per the layout specified in the MSDS TOS.
- 28) Providers of maternity services **MUST** include in their submission all data groups they can generate from local records.
- 29) The first data submission **MUST** include data relating to pregnancies/bookings that were open on 1 April 2019 and all subsequent new pregnancies/bookings.
- 30) Subsequent submissions **MUST** include data for all pregnancies/bookings that were open during that month, including new pregnancies/bookings where the booking appointment with the maternity service took place during that month.
- 31) The Information Standard does not stipulate how data should be collected locally, so the groups **MAY** generate data from one or more data sources. It **MAY** be that providers of maternity services adopt a local data warehouse to aggregate data from all relevant sources and use this to generate the Data Submission File. A conversion tool has also been provided which **MAY** be used to collate data from multiple systems and produce a submission file in the correct XML format.

2.1.9. Validation Rules

- 32) Providers of maternity services **MUST** review the MSDS TOS to understand the data validation rules that will be applied to each data group on arrival at the central data warehouse to all incoming Data Submission Files. Any validation rules not adhered to will result in appropriate groups or the entire submission being rejected.
- 33) Where error reports are generated due to non-conformance against validation rules, providers of maternity services **MUST** take immediate action and resubmit the corrected file within the submission window. Details of the rejection and error messages contained within the reports are provided within the MSDS TOS.

2.1.10. Data Quality Feedback

- 34) Providers of maternity services **SHOULD** review reports generated by NHS Digital highlighting issues with data quality to allow them to take further action before the submission window closes.
- 35) Providers of maternity services **SHOULD** make every effort to resolve inherent systemic errors and address recurring data quality issues, as once the submission window closes for a reporting period there will not be a further opportunity to resubmit the data.
- 36) Providers of maternity services **SHOULD** always seek to understand the context of published national reports and be aware that the information presented depends greatly upon the quality of information submitted. Ongoing efforts **SHOULD** be made to ensure that data quality is of the highest standard before forming judgements about reports and introducing changes to improve data quality.

2.1.11. Issues and Maintenance

- 37) To support the implementation of this information standard, providers of maternity services **SHOULD** highlight any persistent issues and feed these back to the standard's developers. Feedback will be used by the developers to improve the implementation and data collection processes for future consideration towards a data set change or, indeed, further implementation phases. Feedback can be sent via enquiries@nhsdigital.nhs.uk.

2.1.12. Resources

- 38) Heads of Maternity Services **MUST** ensure their service is appropriately resourced to conform to the requirements stated in this Requirements Specification.

2.1.13. Communication

- 39) Chief executives **MUST** be held accountable to comply with the dates instructed by the mandate. Chief executives **SHOULD** therefore ensure awareness by all clinicians and operational staff involved in care delivery by cascading the mandated MSDS v2.0 standard and an appropriate project brief to all maternity leads and other relevant staff.
- 40) Instructions **MUST** also be communicated to the organisation's information leads to initiate collaborative work with informatics services and maternity services as soon as possible.

2.1.14. System upgrades

- 41) This Standard looks to re-use clinical and operational data for national analysis and reporting. Providers of maternity services **SHOULD** conduct a mapping exercise to determine how well local systems map to the MSDS TOS (using the MSDS System Conformance Checklist).
- 42) Where the mapping exercise identifies gaps, providers of maternity services **SHOULD** plan to undertake development efforts with their IT system suppliers to upgrade existing IT systems.

How MSDS providers should look to capture data

- 43) This standard defines the data items that should be extracted from local electronic systems. Providers of maternity services **SHOULD** continue to develop their electronic systems to support the clinical data capture which best supports their working practices and business plans, and to ensure conformance with best practice guidelines set out by the Professional Records Standards Body (PRSB) in the maternity primary data standard.
- 44) Providers of maternity services **SHOULD** work towards ensuring the required information for submission is available electronically. In the interim, providers **MAY** need to consider the provision of adequate resources to make plans for any transcription requirements of paper records to electronic forms in order to conform with the entire mandated data standard for central returns.
- 45) When planning to improve systems and services, consideration **MUST** be made to the extraction of data for this Information Standard during the development and implementation stages. The TOS and User Guidance provide further information on the data items which need to be captured.

How to achieve timely data capture and file submission

- 46) The data set has been deliberately split into a number of data groups. The data groups are intended to support the business processes of maternity service providers. Providers of maternity services **MUST** make every effort to record clinical information in real time or as a minimum, transcribe information to an electronic form at the earliest opportunity to support clinical interventions and decisions. This procedure will also support seamless data extraction from electronic systems for the required monthly central return.

How to manage data submissions if data is captured across several systems

- 47) The Information Standard makes it clear that a single submission file should be submitted for each organisation on a monthly basis, though repeated attempts can be made. The submission file can only include data pertaining to one organisation and for reporting periods that are open. Therefore, providers of maternity services **MAY** wish to consider developing a local data warehouse to generate the monthly submission files.

2.1.15. Demonstrating readiness

- 48) During February 2019 a state of readiness questionnaire will be circulated to assess conformance with this standard. This **MUST** be completed by providers of maternity services and returned to NHS Digital within the specified deadline.

2.2. Conformance Criteria

This section describes the tests that can be measured to indicate that the information standard is being used correctly by a provider organisation (conformance criteria). Conformance of provider organisations is also assessed through analysis of the submitted data, once it is received by NHS Digital. In each case, the requirement(s) being measured by each criterion is shown in brackets.

- 1) All relevant data from the MSDS TOS, i.e. mandatory items and required items that should be reported where they apply, are collected locally from 1 April 2019. This will be measured by assessing the data received by providers from the submissions commencing. (1)
- 2) Submissions to the MSDS, constructed in accordance with the MSDS Technical Guidance and TOS, are made from 1 May 2019 and on a monthly basis thereafter. This will be measured by assessing the data received by providers from the submissions commencing. (2), (18), (20), (24), (25), (26), (27), (35)
- 3) The MSDS Information Standards Notice, Requirements Specification (this document), and other supporting documents have been reviewed within one month of the publication date of this Information Standard, in order to establish which services are covered by the scope, how the data items within the data set are defined, and what data items should be included in submissions. This will be measured using the state of readiness questionnaire. (3), (5), (22), (48)
- 4) Prior to the start of local data collection on 1 April 2019, the Information Governance and clinical governance considerations around the MSDS have been reviewed by Caldicott Guardians and the Heads of Maternity Services, and relevant information communicated to patients about the collection and submission of their data. This will be measured using the state of readiness questionnaire. (9), (10), (11), (12), (13), (14), (15), (16), (17), (48)
- 5) By 1 April 2019 the MSDS TOS has been reviewed and the relevant data validation and data quality rules are understood. Any such issues are identified and acted upon after each submission. This will be measured by assessing the data received by providers from the when submissions commencing and assessing any improvements in data quality. (32), (33)
- 6) From 1 May 2019, all error reports generated due to non-conformance with validation rules are reviewed in a timely manner, allowing for re-submission of a corrected file within the submission window. This will be measured by assessing the data received by providers from the submissions commencing when submissions commence and assessing any improvements in data quality between primary and refresh submissions. (34), (35), (36)
- 7) Key personnel involved in the delivery of the MSDS understand their obligations in relation to local data capture, the submission of MSDS data, and the required information governance approach, prior to local data collection commencing on 1 April 2019. This will be measured using the state of readiness questionnaire, as well as through routine data quality reporting and absence of incidents impacting on NHS Digital. (34), (35), (36), (38), (48)
- 8) From 1 April 2019, submissions of MSDS data include all relevant data from local records, including electronic systems and paper records where applicable. This will be measured through assessing data completeness and quality, comparing this to other sources (e.g. National Maternity and Perinatal Audit, Commissioning Data Sets), specific data quality exercises (e.g. assessing the data against NHS Resolution Clinical

Negligence Scheme for Trusts incentive scheme criteria) and the state of readiness questionnaire. (34), (35), (36), (41), (42), (48)

- 9) The MSDS state of readiness questionnaire is completed and returned to NHS Digital by the communicated deadline (likely to be 1 March 2019). This will be measured by the submission of the completed state of readiness questionnaire and will be used to assess conformance with the other stated requirements. (48)

3. Systems

3.1. Requirements

3.1.1. Timeframe

- 49) From 1 April 2019 systems used by maternity services **MUST** be able to capture the information locally that is intended for use to produce the monthly MSDS v2.0 extract, as defined in the MSDS TOS. This includes information required to derive data items as defined within the standard. Suppliers **MAY** assess this against the System Conformance Checklist which can be found on the [NHS Digital website](#).
- 50) From 1 May 2019 systems used by maternity services **MUST** be able to derive the data items defined within this standard, where they are not collected directly. This includes mapping of local codes to national codes, and the ability to extract this information as envisaged within this standard, e.g. without interim workarounds and in the specified format.
- 51) Changes made to systems **SHOULD** result in minimal increased burden for care providers in capturing and extracting the information defined in the MSDS TOS, and any additional burden **SHOULD** be proportionate.

3.1.2. Scoping

- 52) IT systems suppliers **SHOULD** review all related documents to fully understand the background, objectives and scope of this information standard.

3.1.3. Feasibility assessment

- 53) IT systems suppliers **SHOULD** review the MSDS TOS and MSDS User Guidance to understand the scope and definition of each data item.
- 54) As an Output Data Set, the MSDS is intended to only define “what should be extracted” from local IT systems, not “what should be captured”. A clinical system or data set will need data items beyond what the MSDS specifies. While IT systems suppliers **SHOULD** use this data set to support their system development, they **SHOULD NOT** use the data set exclusively and **SHOULD** also consider the full requirements of the care setting where it is used. The approach to the MSDS is to only re-use clinical data, not specify standards for capturing clinical data.
- 55) IT systems suppliers **SHOULD** familiarise themselves with the MSDS XML schema and conversion tool to understand how data items are grouped for the Data Submission File.
- 56) IT systems suppliers **SHOULD** provide tools to enable a ‘data mapping exercise’ to be carried out and where possible complete the mappings to the national codes on behalf of the MSDS providers. A self-assessment System Conformance Checklist tool is available on the [NHS Digital website](#) to support this mapping exercise.

3.1.4. Information governance

The MSDS Implementation Guidance explains the information governance issues surrounding the data set.

57) IT systems **MUST** 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.

3.1.5. Clinical risks

58) IT system suppliers **SHOULD** always ensure that any changes resulting from the implementation of the MSDS are compliant with the safety standards DCB0129 and DCB0160.

3.1.6. Constructing a data submission file

59) The MSDS Technical Guidance document provides information on how to create a monthly submission file. IT systems suppliers **SHOULD** review this document and the requirements for health and care organisations above.

3.1.7. Validation rules

60) IT systems suppliers **SHOULD** review the Technical Guidance and TOS on the NHS Digital website to understand the data validation rules that will be applied at the central data warehouse to all incoming data submission files. Validation rules not adhered to may result in appropriate groups or the entire data submission file being rejected, depending on the particular validation rule.

3.1.8. Data quality feedback

61) IT systems suppliers **SHOULD** review the MSDS TOS to understand the data quality rules that will be applied to each data group on arrival at the central data warehouse.

62) From 1 April 2019, all systems used by maternity services **MUST** have the ability to produce data quality reports to support providers in producing their submission files in line with the MSDS TOS.

3.1.9. Demonstrating readiness

63) During February 2019 a state of readiness questionnaire will be circulated to assess conformance with this standard. This **SHOULD** be completed by all suppliers of systems used by maternity services and returned to NHS Digital within the specified deadline.

3.2. Conformance Criteria

- 1) All relevant data from the MSDS TOS, i.e. mandatory items and required items that should be recorded where they apply, can be captured by systems used by maternity services from 1 April 2019. Functionality to map local codes/values to national codes/values is included, and the system is able to extract this information as envisaged within this standard. This will be measured using the state of readiness questionnaire and, later, through provider submissions. (49), (52), (53), (54), (55), (56), (59), (63)
- 2) Systems used by maternity services are able to extract data for the MSDS, with minimal additional burden for providers, from 1 April 2019. The format is compatible with the XML schema without a reliance on interim workarounds. This will be measured using the state of readiness questionnaire. (49), (63)
- 3) Systems used by maternity services are able to produce data quality reports to support providers in producing their submission files in line with the MSDS TOS, from 1 April 2019. This will be measured using the state of readiness questionnaire and later, through assessing the data quality of provider submissions. (60), (62)
- 4) Systems used by maternity services have the required functionality, from 1 April 2019, to allow providers to identify records where there is a legal requirement to restrict the flow of identifiable information for a patient. Other information governance and clinical risks have been considered, particularly in extract design. This will be measured using the state of readiness questionnaire, as well as through submitter feedback following go live (57), (58), (63)
- 5) The MSDS state of readiness questionnaire is completed and returned to NHS Digital by the communicated deadline (likely to be 1 March 2019). This will be measured by the submission of the completed state of readiness questionnaire. (63)