Professional Record Standards Body

Better records for better care

Digital Maternity Record Standard

Release 2

CLINICAL SAFETY CASE REPORT

February 2025

Document Management

Revision History

Version	Date	Summary of Changes
0.1	19/03/24	First draft
0.2	26/03/24	Updated following feedback on hazard log by CSO
0.3	24/10/24	Updated following review of NHS England Clinical Safety Group
0.4	16/01/25	Updated following review of NHS England Clinical Safety Group
1.0	03/02/25	Finalised following NHS England Clinical Safety Group approval

Reviewed by

This document must be reviewed by the following people:

Reviewer	Version	Date
NHS England Clinical Safety Group	0.4	30/01/25
NHS England Clinical Safety Group	0.3	16/12/24
Clinical Safety Officer - Steve Bentley	0.3	21/11/24
PRSB Assurance Committee	0.2	26/03/24
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NHS England Clinical Safety Group	0.2	12/09/24

Approved by

This document must be approved by the following people:

Name	Version	Date
Clinical Safety Officer - Steve Bentley	0.3	21/11/2024
NHS England Clinical Safety Group	0.4	30/01/2025

Glossary of Terms

Term / Abbreviation	What it stands for
CSCR	Clinical Safety Case Report
CSG	Clinical Safety Group
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
IT	Information Technology
NHSE	National Health Service England
PRSB	Professional Record Standards Body

Related Documents

Ref no	Title
[1]	DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems; https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems
[2]	DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems; https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems

1. Introduction

1.1. Background and Context

1.1.1. Strategic Context

The Better Births Report (2016) was the output of a Maternity Review commissioned by NHS England. The report describes the vision for maternity services across England and makes recommendations as to how they become safer, more personalised, kinder, more family friendly and where everyone using maternity services has access to their own health and maternity information. It was intended these actions would enable people to make decisions about their care and know where to access support that is centred around their individual needs, preferences, and circumstances.

The Maternity Transformation Programme (MTP) led by NHS England followed. It was a major national programme whose aim was to drive the transformation of maternity services and deliver the vision set out in the Better Births Report. It brought together a wide range of organisations who led 10 work programmes which have been further developed by recommendations in subsequent reports such as the Long Term Plan (LTP, 2019), the East Kent Maternity Review *(2022)* and The Ockenden Review *(2022).* The MTP was also responsible for responding to the government's safety strategy which sets out a range of ambitions including to significantly reduce the rate of stillbirths, maternal and neonatal deaths and neonatal brain injuries.

The Digital Maternity Record Standard (DMRS) was initially published by the Professional Record Standards Body (PRSB) in October 2019 and the Data Coordination Board (DCB) issued an Information Standards Notice (ISN) in November 2019 i.e., the DCB 3066 Digital Maternity Record Standard, Release 1 (See Appendix B). This standard mandated that all maternity service providers MUST implement the entire record standard. However, a timescale for compliance was not defined and in January 2021 it was decided that, given the continued pressures on maternity services, the compliance date for this information standard should be put on hold.
The Three-Year Delivery Plan for Maternity and Neonatal Services was published in March 2023. It sets out objectives for NHS trusts to develop maternity strategy with a corresponding digital road map, for ICBs to procure EPR systems that comply with national specifications and standards including the maternity record standard and maternity services data set. The objective for NHSE is to 'set out the specification for compliant EPR' for maternity by March 2024' with the goal to publish a refreshed digital maternity record standard and maternity services data set standard by March 2024.

In response to the Three-Year Delivery Plan objectives, a refresh of the Maternity Record Standard was commissioned by NHSE in July 2023 to ensure that requirements were refreshed and incorporated the emerging new models of care in the new standard before compliance was mandated. This would provide an opportunity to undertake development work collaboratively and in consultation with clinicians and suppliers who would be charged with fulfilling the mandate.

1.1.2. Background

Maternity services in England are currently unable to capture easily all the national, regional, and local data requirements in one frictionless system. This has resulted in some resistance to fully embrace technology, wasted clinicians time, and resulted in poor quality data capture.
To enable the maternity safety ambitions, it is necessary to ensure that the correct digital infrastructure exists to support safe practice. The need for an up-to-date record standard that

reflects maternity care provision from start to finish of the pregnancy, birth, and post-delivery period, will provide confidence we have the right foundation for the digital future. The improved data capture will enable the 'Reading the Signals Data Co-ordination Group' referred to in the East Kent Maternity Review (who bring together a series of data projects which aim to make sure the right data is available and used in the right way) to identify and support trusts who may be vulnerable to poor outcomes.

The value of an improved maternity record should be better data which could enable quicker recognition of actual or potential harms or poorer outcomes, which should in turn assist with the development of safer clinical practice through quality improvement cycles.

1.2. Purpose of the Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for the Digital Maternity Record Standard (DMRS) addresses the requirements of DCB0129 V2.0 Clinical Risk Management: it's Application in the Manufacture of Health IT Systems [Ref.1].

The full application of DCB0129 cannot be applied, as the professional standard itself is not a manufactured health IT system. However, the guidance within DCB0129 concerning clinical risk management and appropriately governed hazard assessment has been considered. The hazards identified here, along with proposed mitigations, are for system suppliers and providers implementing the standards to pick up and consider when implementing the standard and doing their own assurance.

1.3. Scope

The Discovery phase recognised the following:

"Whilst models of care have evolved since the original DMRS was published in 2019, the development of the original standard was undertaken by robust evidence review of all Trusts' existing paper maternity records which were cross-referenced to identify the sections and elements of the original information model. This in turn went through an extensive process of consultation before being published.

The original DMRS has, therefore, been used as the starting point for this refresh as there is a high level of confidence that the model represented the basis for any standard going forward."

This phase focuses upon the requirements of the following new models of care:

- Personalised Care and Support Plan for maternity
- Informed consent tool (including decision support tools with patient information aids)
- Equality & Diversity maternity policy
- Midwifery continuity of carer
- Maternal medicine
- Fetal Medicine
- Perinatal pelvic floor health
- Smoking cessation
- MEWS / NEWTT-2
- Post natal GP
- Perinatal mental health

1.4. Exclusions from scope

The consultation will not revisit data elements which have been consulted upon and endorsed by previous projects unless a specific change is identified.

1.5. Critical success factors

It was agreed that the phase to March 31st, 2024, would be considered a success if it:

- Delivered the DMRS release 2 Information Model with supporting documentation and materials
- Delivered a high-quality final report which is signed off
- Makes the submission to the DAPB for an ISN
- Facilitates the request for endorsement from relevant members
- Delivers a refreshed DMRSv2 by 31st March 2024

The new models of care to be added to the refreshed standard will reflect the following requirements described in the Maternity Care Standard Consultation (PRSB, December 2023, unpublished) and include:

- Personalised Care and Support Planning for maternity services
- Informed decision making
- Midwifery continuity of carer
- Equality and Diversity data requirements
- Maternal medicine
- Fetal medicine
- Perinatal pelvic floor health
- Smoking Cessation
- MEWS/NEWTT-2
- Postnatal GP
- Perinatal Mental Health

Added since December 2023:
As part of the equality and diversity agenda:

- Care of women and birthing people under 18
- Care of women living in more diverse circumstances i.e. travellers and gypsies, those serving in the armed forces, women who are incarcerated or at risk of incarceration

As part of the equality and diversity agenda:

- Women having multiple births, suffering from bereavement or loss, or experiencing an unplanned pregnancy

The refresh will also include consideration of how other PRSB standards align to the DMRSv2, for example, the 'Personalised Care and Support' and 'About Me' standards

2. Clinical risk management system

The NHS England Clinical Safety Group (CSG) operates a full Clinical Safety Management System (CSMS) that encompasses integration with health organisations and professional bodies. The CSMS considers the integration with the Data Alliance Partnership Board (DAPB) and the process in which professional standards are developed in the CSMS framework. The essential structures of a CSMS have been implemented in this project through the consultation with healthcare professionals, patients, informaticians and clinical system suppliers, during the development of the standard. Governance structures, project methodology and stakeholder engagement are described in the Digital Maternity Record Standard final report. The PRSB remit, organisational structure, roles and responsibilities of key personnel are fully described on the PRSB website at: www.theprsb.org.

It should be noted that this clinical safety report is necessarily limited in its scope because it is neither directly related to software development nor to deployment. Suppliers developing software to implement these standards will therefore still be expected to fully apply DCB0129. Organisations involved in the deployment of such software will still be expected to fully apply DCB0160.

The role of a Clinical Safety Officer (CSO) was to review the clinical safety case using his/her clinical experience to judge the appropriateness and effectiveness of the risk management strategies and mitigating actions. The CSO monitored the execution of the clinical safety case and ensured that clinical safety obligations were discharged.

The clinical safety case documentation is reviewed and approved by the NHS England CSG. The clinical safety case report is published on the PRSB website. Updates to the clinical safety case is the responsibility of PRSB.

3. Hazard identification & Clinical Risk Analysis

Activities that have been carried out to clarify and address the potential risks to patients include:

- Potential clinical safety issues identified during consultation events and other activities during the development of the standard.
- Safety issues identified by a team of the clinical and patient leads, informaticians and clinicians participating in a series of 3 hazard workshops run using 1 hour team meetings over a period of about 3 weeks (See Table A).
- Production and review of a hazard log for the standard.
- Review of the hazard log and any associated safety risks.
- Review of mitigation of risks.
- Clinical safety mitigation and confirmation of risks to be passed to implementation / maintenance stages identified.
- Drafting of safety case (approaches to mitigating the risks identified).
- Final draft of hazard log and clinical safety report.

- NHS England clinical safety case review.

Workshop	Date	Attendees
Clinical safety workshop 1	19/03/2024	CSO, Clinical lead (Obstetrician), Business Analyst
Clinical safety workshop 2	21/03/2024	CSO, Clinical lead (Obstetrician), Clinical lead (Midwife), Standard Assessor, Business Analyst
Clinical safety workshop 3	26/03/2024	CSO, Project Manager, Business Analyst

Table A. Clinical safety workshop details.

4. Clinical risk evaluation and clinical risk control

4.1. Patient safety risk assessment approach

The patient safety risk assessment approach followed the new approach and template for hazard logs from the NHSE CSG and was as follows:

- Identify the hazard effect.
- Identify the actual hazard and the potential harm.
- Detail the possible causes.
- Assess the severity and likelihood and overall initial risk score for each possible cause. Derive an overall risk score for the hazard based on the worst case of the individual causes.
- Consider the mitigation controls which could be applied to reduce the risk for each possible cause.
- Consider the residual risk score based on revised severity and likelihood for each possible cause, and overall for the hazard based on the worst-case cause.

4.2. Hazard log composition

The Hazard log is contained in an Excel Spreadsheet which follows the NHSE CSG template.

4.3. Risk assessment methodology

Risk assessment was undertaken using the risk matrix and scoring tool shown in Appendix A. Note that severities were interpreted in terms of impact on outcomes including the person's experience of care.

The new way of working and template means that each effect, hazard and harm can have multiple possible causes. The approach used was to risk assess and consider controls for each possible cause.

4.4. Hazard log

The full hazard log is attached as a separate Excel document.

In total there are 5 hazards, but with each having several possible causes (36) which are risk assessed with additional controls at the cause level. In addition, each hazard has an overall risk score based on the worst-case cause.

5 hazards have an initial risk of 3, all staying at 3 after additional controls.
1 hazard with an initial risk score of 3 has 1 possible cause with an initial risk of 4 with the risk reduced to 3 with additional controls.

Below is a summary of each hazard. Full details of the hazards and causes are in the hazard log[1] which can be found on the PRSB website.

4.4.1. Hazard 1 – Important Information is Not Available

If important information is not available to a clinician, then inappropriate/delayed/wrong care may be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 6 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
If a system only implements the data items included in this information standard then it will not contain a complete record of a patient as this standard is only a part of the patient record.	In guidance documentation accompanying the standard it is made clear that the standard does not define the whole of a clinical record - but part of the record defined by the scope of the standard.	Major	Medium	**3**	• Suppliers/implementers should read the guidance before implementing a standard	Major	Low	**3**
In development of the information standard, critical information for a use case was not identified and therefore not included in the standard.	In development of a standard the PRSB goes through extensive consultation with stakeholders including open consultations.	Major	Very Low	2	• Suppliers/implementors are responsible for the safety of the systems being used. Any critical deficits should be identified and reported to PRSB.	Major	Very Low	2

When implementing the standard, local implementers do not implement support for all of the data elements in a standard. This may be due to a local decision on the importance of certain data items.	The standard uses compliance statements - specifying which data items are mandatory, required or optional. Compliance testing process. PRSB develops a minimum viable product specification for each standard and these form part of the standard documentation.	Major	Medium	**3**	• Suppliers could put their system through the PRSB standards conformance process. • Suppliers/implementors are responsible for the safety of the systems being used	Major	Low	**3**
The standards are complex and are misunderstood and therefore not fully implemented.	PRSB offers implementation guidance with examples and conducts compliance assessments for providers and suppliers. It also engages in targeted campaigns, presentations, and outreach to suppliers, clinical staff, and patients.	Major	Medium	**3**	• Suppliers/implementers should read the guidance before implementing a standard • Suppliers could put their system through the PRSB standards conformance process.	Major	Low	**3**
The information as defined in the standard is not able to be recorded in the source systems or is recorded in a different way or not structured. So, the information may not be available to the user.	The PRSB standard defines the information which should be collected and available to the user.	Major	Medium	**3**	• Suppliers/implementors should implement the standard as defined. Suppliers could put their system through the PRSB standards conformance process.	Major	Low	**3**

The user is unable to view information which is held in multimedia files e.g. About me.	The standard defines that particular information such as About Me is important to be understood by any care professional involved in a person's care.	Considerable	Medium	**3**	• The IT system should be designed to promote important information and provide ready access to it.	Considerable	Low	2

Table B. Hazard 1 details.

4.4.2. Hazard 2 – Poor Data Quality

Information captured in the information system is of poor quality, due to it being incomplete, incorrect, out of date, or inconsistent. Inappropriate/delayed/wrong care may then be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 7 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
Information in the system is not updated and therefore becomes outdated and potentially contradictory	All data items included in the standard have associated dates. Information of the same type can be identified using the data structures in the standard. Thus, allowing sorting of the data to allow users to interpret the information appropriately	Major	Medium	**3**	• IT systems should be designed to enable searching and sorting of data elements to enable the viewing of similar information types together. • Elements of the record - such as Medications, Allergies and The Problem list should be managed as a single list. • User training should include viewing the information in sortable/searchable lists. • Training should include the management of Medications, Allergies, and the Problem list.	Major	Low	**3**
Lack of context and provenance of data items may make them appear contradictory	The standards include definition of context and provenance information	Major	Low	**3**	• IT systems should maintain the context of data elements wherever possible	Major	Very Low	2

Inconsistency in recording of information by different care professionals in different systems.	The standard aims to minimise this by introduction of standard data items	Major	Medium	**3**	• Providing standardised templates with constrained vocabularies for data entry. • User training and understanding of the information being recorded. With regular reviews. This should be managed by system suppliers or service providers.	Major	Very Low	2
Too many mandatory data items may adversely affect data quality by increasing the burden on care professionals.	PRSB defines data items which are Mandatory/Required/optional for users to populate. Mandatory items are kept to a minimum to deliver safe care.	Major	Low	**3**	• IT Systems should be designed to auto-populate data fields whenever appropriate. Local implementers can define mandatory fields.	Major	Low	**3**
Change in information requirement of a standard. E.g. change in statutory requirements, change in policy or practice in response to COVID-19 pandemic	The PRSB will, wherever possible review its standards in response to a change in the requirements. Updating the standards where appropriate.	Major	Low	**3**		Major	Low	**3**

Failure to adopt PRSB information standards	The PRSB takes it's standards through the information standards process (DAPB). The outcome of which is an ISN which mandates the implementation of a standard. PRSB supports the implementation of the standards with implementation guidance. PRSB supports the implementation of standards via the Standards Partnership Scheme and conformance process PRSB engagement with system suppliers and provider organisation,	Major	Medium	**3**	• Suppliers should implement PRSB standards. Implementers of IT systems should ensure that the systems they deploy are compliant with PRSB standards.	Major	Low	**3**
PRSB standards are updated periodically which may result in changes to the structure or name of sections or elements	PRSB standards are updated in response to changes in requirements - these changes are clearly recorded and distributed to suppliers and implementors	Major	Low	**3**	• Suppliers and implementors should update to the latest version of the standard as soon as possible.	Major	Low	**3**

Table C. Hazard 2 details.

4.4.3. Hazard 3 – Important Data Not Found or Incorrectly Interpreted

If critical data in the system is hard to locate, missed, misinterpreted or represented incorrectly, then inappropriate/delayed/wrong care may be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 10 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
Unclear which sections should contain specific information.	PRSB standards contain descriptions and definitions of the information to be included in specific data elements. Examples and use cases further help to specify these. Specific vocabularies - SNOMED CT or NHS Data dictionary further guide.	Major	Medium	**3**	• Suppliers /implementors are responsible for the safety of the systems being used. • System suppliers should use good user inface design principles to help users to find the information they need.	Major	Medium	**3**
The data may have been entered into the wrong section of the record by mistake e.g. Reasonable adjustments or allergy information inappropriately included in the About Me, or not correctly populated.	PRSB standards contain descriptions and definitions of the information to be included in specific data elements. Examples and use cases further help to specify these. Specific vocabularies - SNOMED CT or NHS Data dictionary further guide.	Major	Medium	**3**	• The system should allow users to have the ability to edit data been entered into the patient record. • Users should be adequately trained in the safe use of the systems they use to provide care to patients.	Major	Low	**3**
Blank fields may be misinterpreted. There is a lack of clarity over what a blank field signifies (i.e. not recorded, not assessed, not present, etc).	PRSB guidance states that for mandatory data item, this data item must be included and a null entry included if there is no information. For required or optional data items, if there is no information then	Major	Medium	**3**	• Suppliers/ implementors should implement the standard as defined. • Users should be adequately trained in the safe use of the systems they use to provide care to	Major	Low	**3**

	these data items should not be recorded.				patients. Including the interpretation of missing information.			
Different systems and data structures, semantics and language and processes across different settings and users which may lead to incorrect interpretation / translation of clinical information	The standard aims to bring together a common representation of the data across the many systems involved. Engagement with clinical terminologist will ensure defined codes will be included in the implementation guidance. E,g, SNOMED CT parent concepts will be defined for each data item, when available.	Major	Medium	**3**	• Suppliers /implementors should implement the standard as defined.	Major	Low	**3**
Information not found because of volume of data / information overload - critical data such as significant problems or allergies could be missed.	PRSB carried extensive consultation in the development of the standard to define the essential information to be captured. PRSB defines data items which are Mandatory/Required/optional for users to populate. Mandatory items are kept to a minimum to deliver safe care.	Major	Low	**3**	• Good user interface design. • Local deployment template design. • Users should be adequately trained in the safe use of the systems they use to provide care to patients.	Major	Low	**3**

Inability to determine where, when and by whom clinical information was recorded means the context is lost	PRSB provenance data support the recording of the where when and who - which can support the linkage of documents/pictures to the record.	Major	Low	**3**	• Suppliers/ implementors should implement the standard as defined. • Systems to record information at point of care by the person giving care.	Major	Very Low	2
Clinician unclear about the purpose of some of the information	The standard has data definitions. Extensive consultation - high level of user recognition and understanding of approach.	Major	Medium	**3**	• Users should be adequately trained in the safe use of the systems they use to provide care to patients.	Major	Low	**3**
Sections with unstructured data such as 'About Me' can not be easily found in searches and therefore not reviewed in a timely manner	Text sections such as "About me" can be indexed using Record Artifact SNOMED CT codes. This will allow these section to be retrieved and displayed in IT systems. These are currently not available for all text sections.	Major	Medium	**3**	• Implement the usage of these Record Artifact SNOMED CT codes. • Where not available local codes could be used.	Major	Low	**3**
Unfamiliar context/terminology to patients/ service users used in populating the information.	The standard links to national policies. PRSB carried out extensive consultation with clinicians and the standard is designed to accommodate current practices.	Major	Low	**3**	• Users should be trained to understand the terminology used in their IT systems. • Users should be given support in understanding the use of terminology in their systems.	Major	Low	**3**

Different statutory and legal requirements across the four UK countries that may lead to confusion by clinicians about which sections are relevant to the country in which they work.	Standard is designed to be generic as much as possible to accommodate national and local implementation	Major	Medium	**3**	• Suppliers and implementers of the standards should ensure that the systems are compliant with the statutory and legal requirements of the country which the system is deployed.	Major	Low	**3**

Table D. Hazard 3 details.

4.4.4. Hazard 4 – Poor Data Quality Due to SNOMED CT and Other Vocabulary Content

If important information is not available to a clinician, then inappropriate/delayed/wrong care may be given to the patient. This could lead to varying levels of harm to the patient, including death. There are 7 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
There is not an appropriate code/ term available for the information that needs to be expressed so local codes are developed	The standard will include the provision of appropriate codes for data items completion with new codes requested by the NHS England's terminology team where not available. SNOMED CT content can be updated in response to requests for change.	Major	High	**4**	• PRSB has support and maintenance service to log issues. • Local systems running data quality searches. • Many systems use standard templates which help users find the appropriate SNOMED CT codes • Users should be adequately trained in the safe use of the	Major	Medium	**3**

					systems they use to provide care to patients.			
Process for creating nationally agreed codes is difficult.	PRSB works closely with the UK Terminology service to ensure that all the terminology content required to implement the standards are available.	Major	Medium	**3**	• Suppliers and implementers of standards should assure that the required SNOMED CT codes are available in their systems. • As new standards will always require new Terminology content to be created, suppliers and implementers must ensure that they have the latest releases of SNOMED CT available.	Major	Very Low	2
Some suppliers and care providers systems make extensive use of their own local codes.	PRSB attempts to include all the SNOMED CT concepts required for suppliers to implement the standards. Thus, minimising the use of local codes	Major	Medium	**3**	• Suppliers and implementers of standards should notify the PRSB if there are codes which they require to implement the standards. PRSB can then ensure that these codes are available in the national UK release	Major	Low	**3**

SNOMED CT is dynamic with frequent updates. PRSB may not be up to date with the latest changes to SNOMED CT.	PRSB will review the SNOMED CT content of standards regularly. Some SNOMED CT vocabularies will be identified as SNOMED CT reference sets - theses will be updated as part of the SNOMED CT release process.	Major	Medium	**3**	• Suppliers and implementers of standards should assure they are able to process concepts which are retired - (i.e. were part of the standard at some time in the past). • Suppliers and implementers of standards should assure that they update to the latest version of SNOMED CT as soon as possible.	Major	Low	**3**
Some providers are not updating to the latest versions of SNOMED CT	PRSB recommends that suppliers update to the latest version of SNOMED CT as soon as possible	Major	Medium	**3**	• Suppliers and implementers of standards should assure that they update their systems to the latest version of SNOMED CT as soon as possible.	Major	Low	**3**
Codes can become inactive and moved or not retained creating difficulty in retrieving historic information.	PRSB will review the SNOMED CT content of standards when they are upgraded. Some SNOMED CT vocabularies will be identified as SNOMED CT reference sets - theses will be updated as part of the SNOMED CT release process.	Major	Medium	**3**	• Suppliers and implementers of standards should assure that they are able to process SNOMED CT content which becomes inactive in an appropriate manner.	Major	Low	**3**
A Value set/reference set belongs to third	The SNOMED CT refset management process identifies	Major	Medium	**3**	• System suppliers and implementers should regularly carry out	Major	Low	**3**

party who no longer updates it. No identified owner for a value set or reference set.	owners for reference sets - when reference sets are no longer owned these are then retired. As part of the standards management process the SNOMED CT content is reviewed and updated with active content including reference sets.				checks to ensure the valuesets/ reference sets are valid.			

Table E. Hazard 4 details.

4.4.5. Hazard 5 – Documentation Burden

Excessive documentation requirements can divert nurses' attention away from patient care, this can lead to important information being missed and appropriate treatment is not provided. This could lead to varying levels of harm to the patient, including death. There are 5 possible causes.

Possible Causes	Existing controls	Severity	Likelihood	Risk	Additional controls	Severity	Likelihood	Risk
The standard requires numerous detail and data points resulting in valuable time been spent on data entry.	PRSB defines data items which are Mandatory/ Required/ optional for users to populate. Mandatory items are kept to a minimum to deliver safe care.	Major	Low	**3**	• IT Systems should be designed to auto-populate data fields whenever appropriate. • User should be adequately trained to use the systems they required to use to support the provision of care.	Major	Low	**3**

The end user having to enter the same data multiple times due to multiplicity of systems, forms etc	The standard is designed to avoid multiple entry of data by allowing re-use of information within and across systems. The standard does not address multiplicity of systems.	Major	Medium	**3**	• IT Systems should be designed to auto-populate data fields whenever appropriate. • User should be adequately trained to use the systems they required to use to support the provision of care.	Major	Medium	**3**
The end users are not adequately trained on the system and may struggle to understand what information needs to be recorded or how to efficiently input the data.	The standard does not address user training.	Major	Low	**3**	• User should be adequately trained to use the systems they required to use to support the provision of care.	Major	Low	**3**
The end user already has demanding workloads with limited time to spend on documentation, introducing a new system may increase the time required for documentation.	The standard does not address user workload.	Major	Low	**3**	• Communication on the benefit of standard should be undertaken as part of the implementation of the standard.	Major	Low	**3**
If end users are resistant to the system due to perceived added workload or lack of perceived benefit and this may lead to reduced	The standard does not address change management.	Major	Medium	**3**	• Ensure change management process is taken into consideration when implementing the standard.	Major	Low	**3**

motivation to complete documentation efficiently?								

Table F. Hazard 5 details.

4.5. Training

Training of the end users of the systems implementing the Digital Maternity Record Standard (DMRS) is recommended as a mitigation for a number of the possible causes of the hazards identified. This should be considered, when developing these systems. Users should understand the limitations of any system and how to use them to best understand the context and provenance of data. They should also understand that they are not designed to replace consulting the patient, which is an important mitigation in any clinical system. Recommendations for specific training packs are not within PRSB remit.

Implementation guidance is provided as a part of the Digital Maternity Record Standard (DMRS) and PRSB provide a support service (support@theprsb.org) where implementors can get advice about implementing the standard.

4.6. PRSB Standards Conformance Process

Some mitigations include suppliers putting their systems through the PRSB standards conformance process. Suppliers seeking conformance to receive the Quality Mark will be assessed for conformance against chosen PRSB standards. The conformance process provides crucially important information for supplier's customers, the wider system, and the supplier themselves. Once a standard is developed, the PRSB can assess the conformance of supplier's system to that standard. This conformance is evaluated on a three-tier scale: Level 1 (41-49% conformance), Level 2 (50-69% conformance), and Level 3 (70-100% conformance). Achieving level 1 requires 100% conformance to the standard's minimum viable information standard (MVIS), ensuring they meet the minimum necessary data requirements. To reach the higher levels of conformance means that suppliers must implement a broader range of data fields beyond the MVIS.

Further information on the Standards Conformance Process can be found on the PRSB website.

4.7. Test Issues

As the Digital Maternity Record Standard (DMRS) is a conceptual model and, as yet, has not been implemented in any systems, it has not been possible to test the model in vivo. It is therefore dependent on those developing systems doing full end to end clinical safety testing. Any issues with the standard identified during testing should be raised with the PRSB through the support service (or by email to support@theprsb.org). All enquiries will be responded to, and issues requiring changes to the standard will be put on the maintenance log and the standard updated at times in accordance with the urgency of the issues identified as detailed in PRSB's release policy.

4.8. Summary safety statement

Five potential hazards were identified with a total of 36 possible causes. All hazards were identified through the consultation processes carried out to develop and assure the standard. The consultation process is described in detail in the project final report. Part of the process

of updating the standard involved reviewing the previous safety case/hazard log and updating them to our new format. There are no outstanding issues regarding clinical safety.

During the consultations, hazards were identified, reviewed and mitigations/actions considered. Nevertheless, some risks are inherent in the standard, but most have been:

A. mitigated by the development of the standard (residual risk of 2 or less)
B. or the residual risk (level 3) has been transferred (with guidance) to the implementers.

The hazard log (a separate document) provides guidance for system developers and implementers. It is important that this guidance in relation to those hazards, regarded as system issues, become requirements for implementation.

The residual risk of the hazards and their possible causes after additional controls are all level 3 or 2. There are 29 possible causes across 5 hazards at residual risk level 3 and the mitigations for the level 3 risks are outside the control of PRSB and these risks are therefore handed on to the implementors and deployers of this standard. There are 6 possible causes (across 4 hazards) rated at level 2 and considered acceptable.

5. Quality Assurance and Document Approval

The hazard log and clinical safety case have followed the DCB0129 Risk Management standard and approach. The overall development of the Digital Maternity Record Standard (DMRS) has followed the PRSB methodology, proven and trusted by our members and stakeholders, overseen by a project board and the PRSB's independent assurance committee. Both the project board and the assurance committee have reviewed the hazard log and safety case with final approval residing with the NHSE Clinical Safety Group.

6. Configuration Control / Management

The hazard log and clinical safety case are both version-controlled documents held in the PRSB project files and managed under the PRSB information management policy.

Future governance of the development and maintenance of the Digital Maternity Record Standard (DMRS) is the responsibility of the PRSB.

7. Appendix A – Risk matrix

Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Severity				

Likelihood Category	**Interpretation**
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible possibility of occurring

Severity Classification	**Interpretation**	**Number of Patients Affected**
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term	Multiple

	Significant psychological trauma	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence	Single

	Risk Acceptability
5	Unacceptable level of risk.
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk. Attempts should be made to eliminate the hazard or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

8. Appendix B - DCB 3066 Digital Maternity Record Standard, Release 1

Find a link to the DCB 3066 Digital Maternity Record Standard, Release 1 here.