Professional Record Standards Body

Better records for better care

Core Information Standard Clinical Safety Case Report October 2019

Document Management

Revision History

Version	Date	Summary of Changes
0.1	03.07.2019	First draft created by Dr Annette Gilmore (AG)
0.2	08.07.2019	Updated by Dr John Robinson (JR), CSO
0.3	12.07.2019	Updated by Dr Annette Gilmore following meeting with JR
0.4	24.07.2019	Updated following comments from CSC meeting and Hazard log workshop attendees
0.4	09.08.2019	Reviewed and agreed by PRSB Assurance Committee
05	06.08.2019	Final edits by Dr John Robinson
0.6	16.08.2019	Edits to include late feedback.
1.0	16.08.2019	Version to distribute to NHS Digital Clinical Safety Team
1.1	30.09.2019	'Sex and Gender Risk mitigated by implementation' - NHSD Clinical Safety Group comments addressed by JR and AG Following advice from NHSD CSG additional information was added to CIS Implementation Guidance (version 1.2) regarding all CIS risks and 'sex' field

Reviewed by

This document must be reviewed by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr John Robinson	16.08.2019
PRSB Executive	Martin Orton	15.08.2019
PRSB Assurance Committee		09.08.2019
NHSD Clinical Safety Group		30.08.2019 and 21.11.2019

Approved by

This document must be approved by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr John Robinson	16.08.2019

PRSB Executive	Lorraine Foley	15.08.2019
PRSB Assurance Committee		24.09.2019
NHS Clinical Safety Group		21.11.2019

Glossary of Terms

Term / Abbreviation	What it stands for
API	Application Program Interface
CCIO	Chief Clinical Information Officer
CNIO	Chief Nursing Information Officer
CIS	Core Information Standard
CSCR	Clinical Safety Case Report
CSG	Clinical Safety Group
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
DCB	Data Coordination Board
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GUI	Graphical User Interface
IG	Information Governance
ISB	Information Standards Board
ISN	Information Standard Notice
LCR	Local Care Record
NHS	National Health Service
NHSD	NHS Digital
NHSE	NHS England
PAS	Patient Administration System
PDS	Patient Demographic Service
PRSB	Professional Record Standards Body
RBAC	Role Based Access Control
SNOMED CT®	Systematized Nomenclature of Medicine – Clinical Terms

Related Documents

Ref no	Title
[1]	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;
[3]	Core Information Standard Final Report v1, July 2019, Professional Record Standards Body;
[4]	Core Information Standard: Survey Results and Analysis, July 2019, Professional Record Standards Body;
[5]	Persons Core Information Standard v1, July 2019, Professional Record Standards Body;
[6]	

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1. Executive Summary and Safety Statement

This PRSB Core Information Standard (CIS) standard has been developed following extensive consultation with patients, carers and other citizens, health and care professionals and system vendors as set out in the Core Information Standard Final Report and Core Information Standard Survey Results and Analysis Report. It is intended to be used as the standard set of headings, under which data can be viewed in any shared care record, with a clear aim that different shared care records should be interoperable. Local care records (LCR) will consist of data from multiple sources in both health and social care settings. It will not include all data from all sources and is intended to be information which is felt to be important to share.

PRSB has been asked to define a CIS which is "A set of "Concept" headings under which users need to be able to view the data. This will sit in a local care record; the development and design of which will be done locally."

However, the data viewable under these headings is entirely dependent on the source data being shared and processed appropriately so that the correct information is available under the right heading at the right time and is readily accessible. The user experience is dependent on the design of the systems and the graphical user interface (GUI). All these things on which the headings are dependent are out of scope of this clinical safety review.

The CIS is only a single component of a shared care record and a separate end to end safety case will need to be made for each record system. Such a safety case may reference this clinical safety case for the Core Information Standard element of it.

The CIS model does not contain all the contextual information available for data items and therefore it is not expected that the Core Information Standard will be the only view available in any shared record system.

The CIS view of information is over and above and in no way a replacement for existing health record systems. It is also a "Core" record and will not, by definition, contain all data.

The safety case is for a read only record for direct care and if it should become a read/write record and source of original data, the safety case would need to be reviewed. Any use for secondary uses of the data should also consider any clinical safety impacts.

The Hazard workshop identified 30 hazards. All but five of these are regarded as acceptable with a residual risk of 2. The others have a residual risk of 3.

Many of the hazards are concerning the data, which could be missing, misplaced, inaccurate or conflicting and potentially present but inaccessible. Mitigations for all of these include system design and training.

There are hazards related to some specific section headings. These are Allergies, Medications, Problems and Diagnoses, Alerts and Care plans. In these areas the concerns are about the different data models in contributing systems and the need for training in both using local care records and recording data in source systems, which needs to be shared. Also, the significance of getting the information wrong.

One hazard was initially identified as being at risk level 4 is:
Sex data item may cause accidental disclosure of gender reassignment without consent
This is because there are two fields in the demographic model. Sex and Gender. Having both may show a difference and therefore disclose gender reassignment without consent. This risk can be mitigated to a level three risk by appropriate implementation in a shared care record. Two options are proposed, either “Sex” can be left out or the system must be designed so that the risk of unlawful disclosure is reduced to an acceptable level. This will be clearly stated in the implementation guidance document which forms part of this standard and therefore the risk is transferred.

The other hazards with a residual undesirable risk level of 3 are:

a. **The Problems and Diagnoses section heading**: It is recognized that further work needs to be done to develop a clear idea of precisely what data should be contained in it. Methods for updating and curating the data will also need to be established.

b. **Context being lost**: The CIS is a set of headings under which information is displayed, but that this view does not allow all the useful context and provenance of the information. Other views of the data should be made available using the relationships between data items defined in the Logical Data Model for LCRs.

c. **Failure to adopt the CIS**: The development of the CIS standard needs to be supported in its adoption by promotion by NHS Digital, NHS England, PRSB and pharmacy bodies and stakeholder organisations who have provided endorsement for the standard. Failure to adopt it risks multiple different models being adopted, resulting in lack of interoperability and lack of user familiarity. Leading to loss of benefit and potential patient harm.

d. **CIS used out of scope:** The safety case is based on the CIS being used in scope. The implementation guidance should be followed.

All risks identified in the Hazard log are transferred, to those who incorporate the Core Information Standard into their EHR (Electronic Health Record). Particular note should be taken of the Sex and Gender risk, as that will only be reduced to level 3 if action is taken, but there are also mitigations and training recommended for the other risks which should be undertaken where possible to reduce them to the lowest possible risk.

Any safety incidents occurring, which might be due to the CIS must be reported promptly to the PRSB for review.

2. Introduction

2.1 Purpose of Local Care Records and the PRSB Core Information Standard

The aim of the local health and care records programme is to help local organisations move from today's position, where each health and care organisation holds separate records for the individuals they care for, to one where an individual's records are connected up from across the health and care system.

This will help health and care professionals to share information safely and securely as the people they care for move between different parts of the NHS and social care. It also enables individuals to be able to access their own records irrespective of which part of the health and care system that has provided them with their care. The design of such Patient portals is out of scope of this safety review.

The PRSB Local Care Records' Core Information Standard has been developed following extensive consultation with patients, carers and other citizens, health and care professionals and system vendors. It is intended to be used as a standard set of headings, under which data can be viewed in all local care records, with a clear aim that different LCRs should be interoperable.

The Core Information Standard gives one view of the data. A data item should only appear under one section heading, although this is not a hard and fast rule. It does not show all the relationships of data items. Electronic health records generally allow the user to view the data in several different ways and these are used to validate and further understand the history of the record subject – the patient/ service user. For instance, a journal or historic view may be compared with a problem orientated view or an encounter or episode orientated view. The logical data model developed by NHS Digital is designed to hold links between the data items and provide the context and provenance of the data. It may be used by the system designers to develop a variety of other views of the data. It is therefore expected that the Core Information Standard will not be the only view available in any shared record system.

The Core Information Standard view of the data is supplementary to the primary clinical systems. It is a way of sharing more data about a record subject and should therefore contribute to improving the quality and safety of care. The addition of this view is over and above and in no way a replacement for existing record systems.

The LCR is for a read only interface initially. This safety case is for a read only record for direct care and if it should become a read/write record and source of original data, the safety case would need to be reviewed.

2.2 Purpose of the Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for the Local Care Record Core Information Standard (CIS) addresses the requirements of DCB/ ISB 0129 V4.2 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. Compliance to requirements from DCB0129 are summarised in section 14.

3. System Definition/ Overview/ Scope

Local care records will consist of data from multiple sources in both health and social care settings. It will not include all data from all sources and is intended to be information which is felt to be important to share.

The data will be shared with the LCR using FHIR resources and APIs. It will then be normalised and de-duplicated before being stored in, in most cases, a database. The design of the database is expected to be informed by the logical data model, for the LCRs, developed by NHS Digital. This will define the provenance, context and relationships of data items.

Some LCRs may dispense with the database and pull data when it needs to be viewed.

The LCR Core Information Standard is a set of “Concept” headings under which users need to be able to view the data. This is not necessarily a physical entity and data may be rendered in that view at time of access.

There are currently in excess of sixty local shared care records in operation across the country. NHS England has established a programme, the Local Health and Care Records (LHCR) programme, to expand the coverage of local shared care records to cover larger populations. This will make important information available to health and care professionals and people using services across wider geographic areas, covering populations of three to five million, to improve the quality of care and care co-ordination. In order to realise these benefits, the core information standard was developed which defines and standardises the type of information that should be shared by systems that will talk to one another across health and social care, with the right safeguards in place.

The standard was developed in two phases: the first phase reviewed evidence from existing standards and shared care records in order to produce a draft core information standard. ~~The draft core information standard was developed~~ This was achieved by mapping NHS England’s definition of the core information set, the Greater Manchester core dataset and the PRSB Standards for the Structure and Content of Health and Care Records (PRSB 2018) against the national and international standards and records. These are all referenced in the CIS final report. The second phase developed the standard in key areas where it was seen that further work was needed (e.g. mental health and social care). The PRSB carried out broad and in depth consultation and engagement across health and social care using online workshops, a national deliberative face to face workshop, social media (to obtain more diverse input from the public), expert reviews, an online workshop for vendors and an online survey. This allowed the content of the information standard to be refined and started to build awareness and support among all the key groups with an interest in information sharing in health and care.

The standard does not define how the data is viewed in individual systems, which will be down to the individual GUI of each system. The data items under each heading will retain information about the date the item was recorded and the author of it. However other pieces of contextual data such as which encounter, problem or document it was a part of, are not be part of the standard. The logical data model is expected to manage these links. Other views of the data, based on that are expected to be created to show more provenance and context but are not a part of this standard.

3.1 Illustration of shared care record creation

This is a graphical representation of the process involved in creating the local shared care patient record. It illustrates the interdependencies in the LCR creation and deployment. The PRSB CIS is one component in the process. The scope of this clinical safety case includes the PRSB CIS component only.

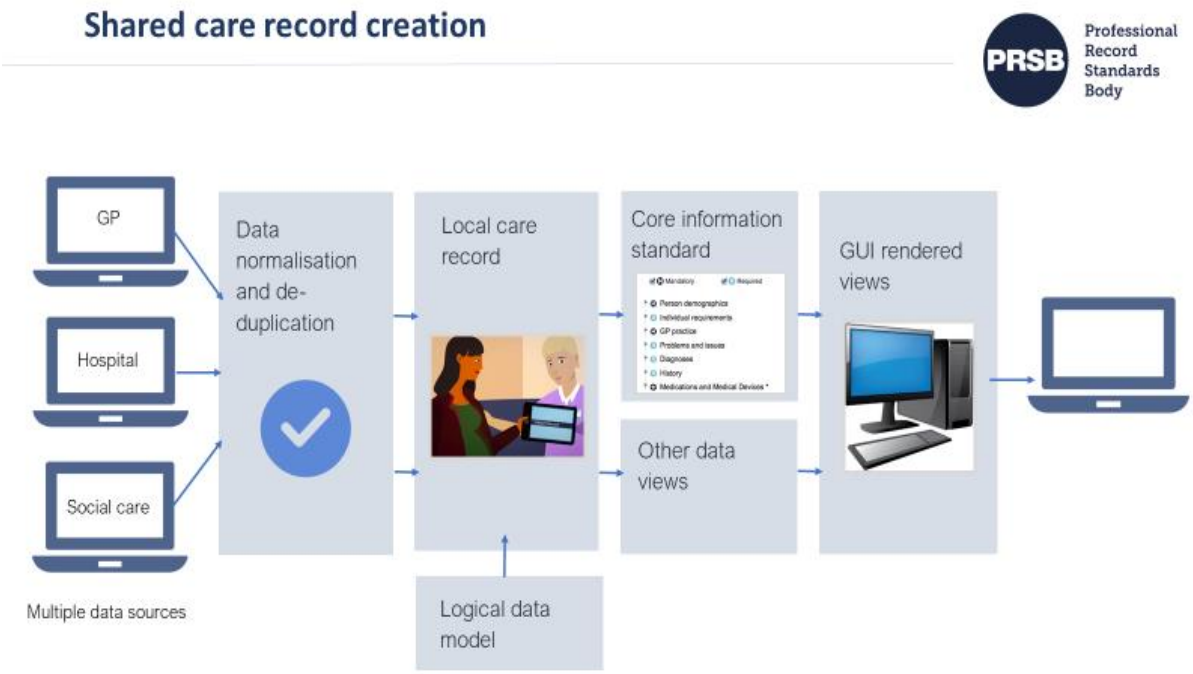

Diagram A: Local shared care record creation

3.2. Inclusions to Scope

The following are included in the clinical safety case:

- The LCR CIS set of “Concept” headings (under which users can view the shared information);
- The definitions of the headings and descriptions of the data to be stored and viewed under the heading;
- The data attributes of the headings.

3.3. Exclusions to Scope

The following are out of scope of this clinical safety case:

- The source of the data and structure of data being shared;
- The normalisation and de-duplication process;
- The logical data model and database design;

- The graphical user interface (GUI) and the way in which the data is rendered in that view.

3.4. Use

Initially the LCR is intended to be a read only interface. Writing to the record has not been included in this clinical safety case.

4. Clinical risk management system

The NHS Digital 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 Information Standards Board (ISB) 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 CIS. Governance structures, project methodology and stakeholder engagement are described in the PRSB CIS final report and CIS survey results and analysis report. [Ref.3 and Ref.4]. 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. [Ref.2].

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 handed over to NHS Digital Clinical Safety Group. The clinical safety case report is published on the PRSB website. Updates to the clinical safety case is the responsibility of PRSB.

5. Hazard identification & Clinical Risk Analysis

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

- Safety issues identified by clinical informaticians and advisors and patient advisors participating in hazard workshop on 31st May 2019.

- Safety issues identified by clinical informaticians and clinical and patient advisors participating in clinical safety meeting on 22nd May 2019.
- Safety issues identified by clinical informaticians and clinical and professional advisors participating in project clinical experts' meetings held on 1st May and 16th May 2019.
- Potential clinical safety issues identified by stakeholder participants during consultation survey (n=1000) and other consultations undertaken during the development of the CIS.
- Production of a hazard log for the project.
- 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 Digital clinical safety case review.

6. Clinical risk evaluation and clinical risk control

6.1 Patient safety risk assessment approach

The patient safety risk assessment approach was as follows:

- What could go wrong, and how often? (Hazard and likelihood) [See Appendix A for risk matrix]
- Possible main causes
- Most likely consequences / potential clinical impact (i.e. for patient safety)
- Mitigations (and recommendations to improve patient safety) leading to a reduced residual risk
- Clarification regarding actions required and risk transferred to implementers.

6.2. Hazard log composition

The Hazard log is contained in an Excel Spreadsheet and contains the following sections:

- Hazard name
- Hazard description
- Potential patient safety impact
- Potential causes
- Existing controls
- Initial hazard rating including likelihood and consequence
- Dependencies and assumptions

- Proposed mitigations
- Revised hazard ratings
- Summary of actions and approvals

6.3 Risk assessment methodology

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

When assessing the risk severity and likelihood, the highest combined value was used. However, where that can be arrived at by different values for severity and likelihood, such as major but very low versus considerable and low, generally the lower severity has been used. It is recognized that very occasionally the absence of information in the record might lead to death of a patient, but that the likelihood is very low indeed, especially given that this record is additional to existing systems.

6.4 Hazard workshop and clinical safety cases meetings

Potential clinical safety risks were identified throughout the development of the CIS and specifically explored at several expert group meetings. A hazard workshop was convened to explore all the risks to patient safety and develop the CIS Hazard log. Details of these specific meetings are described here:

Hazard Workshop			
Date	31.05.2019	**Time**	10:00 – 15:00
Location	Face to face workshop at PRSB offices		
Attendees:			
	Name	**Role**	
Chair	John Robinson	Clinical Safety Officer / GP/ Clinical informatician	
	Maggie Lay	Integrated Care Lead/CSO/ CNIO/ Community nurse	
	Matt Butler	Clinical informatician/ Mental health nurse	
	Ron Newall	PRSB patient advisor and subject matter expert	
	Annette Gilmore	Clinical informatician/ Acute care nurse	

Clinical safety case Meeting			
Date	22.05.2019	**Time**	9:30 – 10:30
Location	Meeting by teleconference		
Attendees:			
	Name	**Role**	
Chair	John Robinson	Clinical Safety Officer (CSO) / GP Clinical informatician	

	Laura Fulcher	PRSB Patient Advisor and Assurance Committee member
	Maggie Lay	Integrated Care Lead/CSO/ CNIO/ Community nurse
	Matt Butler	Clinical informatician/Mental health nurse
	Prof Iain Carpenter	Clinical informatician/CSO/Consultant Geriatrician
	Annette Gilmore	Clinical informatician/ Acute nurse

Potential clinical safety risks and hazards were explored at the LCR project Expert review group meetings on the following dates: 1st May 2019; 9am to 1.30pm and 16 May 2019; 9am to 12.30pm

Expert review group (attendees)

Expert Group Role	Name
Consultant Psychiatrist & CCIO & clinical informatician	James Reed
Emergency care physician	Tony Shannon
Geriatrician & clinical informatician	Iain Carpenter
GP & clinical informatician	Ian McNicoll
GP & clinical informatician	Nick Booth
General Practitioner & clinical informatician	John Robinson
General Practitioner & clinical informatician	Phil Koczan
Mental Health Nurse & clinical informatician	Matt Butler
North Yorkshire county council, LCR (social care)	Neil Bartram
Physiotherapist (AHP)	Euan McComiskie
Renal physician, CCIO & clinical informatician	Afzal Chaudhry
Surgeon & CCIO	Dermott O' Riordan

7 Hazard log

The full hazard log is attached as a separate Excel document. The Hazard table below lists the hazards identified together with summary information about each hazard, the mitigations identified and the residual risk score. We have flagged some risks relating to implementation in this report but expect that further mitigations will be identified as clinical risk assessments and safety cases are developed by vendors and sites during the implementation.

8 Hazards

This section sets out identified hazards. The risk matrix is shown in Appendix A. Risk Acceptability is described in the table below.

	Risk Acceptability

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

There are 30 hazards identified. The hazards are classified as follows: issues relating to data and specific headings, issues relating to the model, issues relating to users of the shared care record, and issues relating to the IT systems.

Hazards:

Hazard Id:	1
Hazard Name	**Significant data not shared in record**
Hazard Description:	As a "Core Record Standard", by definition, it will not contain all data. Data important for the care of the patient may not be available.
Hazard Causes:	1) Not all data is included by design. 2) Core information model is incomplete- therefore missing an important heading. 3) Healthcare provider did not feel data was important or suitable to share. 4) Clinician assumes the shared record would contain safety significant data. 5) Complexity of the core information standard inhibits clinician sharing significant data.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care based on missing clinical information causing the patient harm.
Mitigation:	Design of shared care record system and logical data model (out of scope); End to end clinical testing; Training in data entry and sharing in local system.
Residual risk:	2
Hazard Id:	2
Hazard Name	**Data missing/ incomplete data**
Hazard Description:	Data important for the care of the patient may be missing or incomplete.
Hazard Causes:	1) There is no section/ heading in the Core Information Standard to hold the data. 2) End user systems too structured/inflexible to include all

	headings. 3) Data is not updated in the source system and therefore becomes out of date. 4) Data structure in source system does not match that of CIS. 5) Data missing in the source system. 6) Data processing and de-duplication loses important data item.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care based on missing clinical information causing the patient harm.
Mitigation:	Design of shared care record system and logical data model (out of scope); End user engagement in design (out of scope); End to end clinical testing; Training in data entry and sharing in local system; Ensure there are clear robust methods for updating and correcting the shared care record; Ensure stakeholders, including patients/ service users know how to get the record corrected and/ or updated as required; Ensure stakeholders know who holds responsibility for the integrity and maintenance of the record and the process of accountability.
Residual risk:	2
Hazard Id:	3
Hazard Name	**Incorrect data or data is misinterpreted, or data is represented incorrectly**
Hazard Description:	Data in the CIS is incorrect, misinterpreted or represented incorrectly such as being under the wrong heading.
Hazard Causes:	1) Incorrect data entered in source system and not corrected. 2) Information model in source system is misinterpreted/ not understood. e.g. Family History recorded using Disorder Concept, misinterpreted as Disorder present or differential diagnosis thought to be a confirmed one. 3) Logical data model is wrong leading to incorrect or missing data attributes. 4) Incorrect data cannot be corrected on LCR which is read only. Mechanisms for achieving that are poorly developed. 5) Data processing and de-duplication loses important data item. 6) Headings have similar meanings so users are unsure where to find the information they need e.g. About Me, Individual Requirements and Social Context. 7) Consequence of different professional groups with different roles and emphasis in creating' electronic health and care records. 8) Semantics and language difference between the different professions. 9) CIS model is inconsistent. 10) CIS is defined by users wishes not clinical modelling of data that is already in source systems e.g. need to manipulate existing data models.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care based on incorrect clinical information.

Mitigation:	Design of shared care record system and logical data model (out of scope); End to end clinical testing; Good professional practice and understanding of shared care record use; Ensure there are clear robust methods for updating and correcting the shared care record; Ensure stakeholders, including patients/ service users know how to get the record corrected and/ or updated as required; Ensure stakeholders know who holds responsibility for the integrity and maintenance of the record and the process of accountability.
Residual risk:	2
Hazard Id:	4
Hazard Name	**Conflicting information**
Hazard Description:	Two pieces of information directly conflict in shared record. Such as a history of venous thrombosis and an entry for 'No past history for venous thrombosis'. Or Allergy and no Allergy.
Hazard Causes:	1) Data in one source may be more up to date or accurate than another. 2) Lack of context and provenance of data items may make them appear conflicting. 3) Conflict between different patient care plans e.g. Advanced treatment decisions and end of life care plans (hospice).
Potential Clinical Impact:	Healthcare provider delivers inappropriate care based on mis information or appropriate care and treatment is delayed.
Mitigation:	Design of shared care record system and logical data model (out of scope); End to end clinical testing; Good professional practice and understanding of shared care record use; Ensure there are clear robust methods for updating and correcting the shared care record; Ensure stakeholders, including patients/ service users know how to get the record corrected and/ or updated as required; Ensure stakeholders know who holds responsibility for the integrity and maintenance of the record and the process of accountability.
Residual risk:	2
Hazard Id:	5
Hazard Name	**Poor quality data**
Hazard Description:	Data in source system is of poor quality. Good quality data should be Complete, Accurate, Relevant, Accessible, Timely and Consistent.
Hazard Causes:	1) Data is rejected by the database in the data cleaning process.

	2) Data may be wrong - clinical or patient demographics. 3) Data may be inconsistent. e.g. different entries for severity of disease on same day. 4) Provenance of data is not available to verify. 5) Inaccurate recording of date of event. 6) Data relates to different patient. 7) Important data recorded in unstructured manner.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care based on mis information about the patient.
Mitigation:	Design of shared care record system and logical data model (out of scope); End to end clinical testing; Good professional practice and understanding of shared care record use; Ensure there are clear robust methods for updating and correcting the shared care record; Ensure stakeholders, including patients/ service users know how to get the record corrected and/ or updated as required; Ensure stakeholders know who holds responsibility for the integrity and maintenance of the record and the process of accountability.
Residual risk:	2
Hazard Id:	6
Hazard Name	**User cannot find data they need**
Hazard Description:	The information is in the shared record but is not found by the user
Hazard Causes:	1) Core information model poorly laid out. 2) Data badly presented (GUI). 3) End user not able to use the system effectively potentially through lack of training. 4) System not available. 5) Wrong patient. 6) Information not found because of volume of data. 7) Lack of metadata, restricting searching and views.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care based on incomplete clinical information.
Mitigation:	Design of shared care record system and logical data model (out of scope); End user engagement in design (out of scope); End to end clinical testing; Good professional practice and understanding of and training/ education in shared care record use.
Residual risk:	2
Hazard Id:	7
Hazard Name	**Unstructured data may not be reviewed in a timely manner**
Hazard Description:	Data can exist in both structured and unstructured form. The latter can be in documents making data more difficult to find.

Hazard Causes:	1) Sections with unstructured data such as ' About Me' may not be reviewed in a timely manner. 2) Some sections allow both structured and unstructured data such as 'Problem List' , the unstructured data may not be found as easily. 3) Unstructured data will not be found in searches.
Potential Clinical Impact:	Important information about the patient may be missing from the decision-making process; inappropriate or sub-optimal care planning and treatment/ interventions given; distressed patient.
Mitigation:	Design of shared care record system and logical data model (out of scope); End to end clinical testing; Professional interaction; Education in understanding of the different professions' roles and language semantics; Understanding of and training/ education in shared care record use.
Residual risk:	2
Hazard Id:	8
Hazard Name	**The context of the information is lost**
Hazard Description:	Clinicians interpret information without understanding the context
Hazard Causes:	1)This Core Information Standard model shows data from all sources under defined headings. The elements of the items under each heading do not consider the full amount of contextual data available. This may lead to hazards 4 and 5. Contextual data may be used to view a data item as part of a problem or part of an encounter, for example, and can therefore help to understand the provenance and context in which it was entered. 2) Losing the link to a source document. For example, elements from the PRSB e-Discharge Summary separated under different headings in the CIS and links to the whole document lost.
Potential Clinical Impact:	Misinterpretation of patient's diagnoses and problems; Wrong investigations, treatment and advice given; Appropriate investigations, treatment and advice not given or delayed.
Mitigation:	Design of shared care record system and logical data model (out of scope); End user engagement in design (out of scope); End to end clinical testing.
Residual risk:	3
Hazard Id:	9
Hazard Name	**Medication section: Differences in system representation of medication and workflows around medication**

Hazard Description:	Medication history and/ or current medication is inaccurately represented in the CIS.
Hazard Causes:	1) Misinterpretation of ' acute' verses repeat prescription medications in system- acute has no end date so the system interprets it as ongoing medication. 2) Misinterpretation of repeat dispensing by system. 3) Some medication is dispensed by hospital and some by community. 4) Record curation differences; local and professional semantics. 5) Source data not included e.g. as per referral. 6) Clinical data also used for contractual and admin purposes - for example entering ' medication contraindicated' verses ' medication not indicated' had a different impact on reimbursement. 7) Mandatory fields may adversely affect data quality especially if they are linked to KPIs.
Potential Clinical Impact:	Patient does not get a medication they should or gets one they should not, or interactions are overlooked with another drug.
Mitigation:	Design of shared care record system and logical data model (out of scope); Using approved standards for medication management and medicines reconciliation; End to end clinical testing and overall clinical safety assurance; Education and training in standards medication management and medications reconciliation; Education about how information is going to be shared and used.
Residual risk:	2
Hazard Id:	10
Hazard Name	**Allergies not present or correct in the CIS**
Hazard Description:	Allergy information in the source system is not faithfully reproduced in the CIS
Hazard Causes:	1) The allergy information model in the source system is not understood by the shared record. 2) Allergy information not correctly recorded in the source system. 3) Important allergy information lost in the data processing e.g. where two conflicting pieces of information exist. 4) Information not easily accessible in GUI.
Potential Clinical Impact:	An allergy is not taken account of in clinical decision making and patient is harmed.
Mitigation:	Design of shared care record system and logical data model (out of scope); End to end clinical testing and overall clinical safety assurance; Professional responsibility; Understanding of and training/ education in shared care record use.

Residual risk:	2
Hazard Id:	11
Hazard Name	**Significant problems, diagnoses, conditions or procedures are not visible to healthcare user**
Hazard Description:	Important clinical data is not found in the Problem list section either because it is not present, or it is lost in the mass of data.
Hazard Causes:	1) Difficulty in defining the list of important conditions and symptoms that should be shared. 2) Classification of problems differ between professions and different types of professionals who have responsibility for different types of problems. 3) Primary care uses a problem orientated model whereas secondary care uses an episode orientated model. 4) Primary care records do not distinguish between problems and diagnoses. 5) Problems may be transient, acute, long term and depend on context. 6) Patient/ service user may have different view of what a problem is. 7) Misinterpretation of where to look for a procedure. 8) System suppliers already have established methods of recording problems and diagnoses e.g. EMIS defaults to making some data entries into problems.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care causing the patient harm.
Mitigation:	Design needs to take account of the user role and views of data that they wish to see; Further work is needed on what should be shared in this view; There is ongoing work in this area. End to end clinical testing and overall clinical safety assurance; Educate professionals about the differences in professionals use of language; Educate and train professionals in shared care record use.
Residual risk:	3
Hazard Id:	12
Hazard Name	**Care plans are not up to date**
Hazard Description:	The care plan has been superseded or updated elsewhere and not replicated in CIS.
Hazard Causes:	1) A new care plan is created and is not shared e.g. advanced treatment decisions; end of life plans etc. 2) A care plan becomes obsolete and is not removed from the system. 3) Patient under the care of multiple organisations.
Potential Clinical Impact:	Patient doesn't receive the care they planned.

Mitigation:	Design of shared care record system and logical data model (out of scope); End to end clinical testing; Professional responsibility; Understanding of and training/ education in shared care record use.
Residual risk:	2
Hazard Id:	13
Hazard Name	**Pregnancy status data item misinterpreted**
Hazard Description:	Misunderstanding about the information contained under 'Pregnancy status'.
Hazard Causes:	1) Due to the transient nature of the condition, whether a patient is currently pregnant or not must be calculated using algorithms. There could be issues updating the information on which these run to ensure it is current or the information may be missing. 2) Section heading may be misunderstood. 3) Incorrect information because it is not seen as a priority to keep updated.
Potential Clinical Impact:	Incorrect information may be missing from the decision-making process; inappropriate or sub-optimal care planning and treatment/ interventions given; distressed patient.
Mitigation:	The design needs to make clear whether the pregnancy status flag is imported from existing data or calculated. If calculated this needs to happen in real time from existing data. If calculated this will need to be tested as a medical device. End to end clinical testing. User education and training to keep the source information updated. Professional accountability - check status with patient.
Residual risk:	2
Hazard Id:	14
Hazard Name	**Alerts missed by users**
Hazard Description:	Semantic difference in what 'Alerts' mean in different systems. Users may expect this section to contain all the alerts they would expect in their system, whereas this is limited to a small subsection of alerts which can occur.
Hazard Causes:	1) Alerts are not viewed because professionals are unaware where to look for them or are used to ‘pop-ups’. 2) User relies on LCR for all alerts and misses alert in source system. 3) Alert model in source system is not understood by the LCR. 4) Decision support alerts are not supported by the CIS model.
Potential Clinical Impact:	Alerts are not viewed because professionals are unaware where to look for them - which may be detrimental to the care and wellbeing of the patient/ service user.

Mitigation:	System design; Clarity about which alerts are shared. Decision support alerts based on data in source system should not be shared; Ensure clear instruction in the implementation guidance; End to end testing with clinicians; Understanding of and training/ education in shared care record use; Understanding of and training in alerts and their usage.
Residual risk:	2
Hazard Id:	15
Hazard Name	**Consent for information sharing heading may cause confusion**
Hazard Description:	Although recognised as a 'Placeholder' until guidance is available nationally, if used currently it may be misinterpreted to suggest any data can be shared or conversely none can be shared.
Hazard Causes:	1) Confusion with current rules around consent for information sharing for direct care which precludes the need to gain consent from the patient (but must consider objections to information sharing by the patient/service user).
Potential Clinical Impact:	Risk that professionals do not share information required for direct care at all, or in a timely manner, because the heading has introduced another layer of confusion about what information must and can be shared - leading to delayed or incorrect care and patient harm.
Mitigation:	Implement the NHS England IG framework for shared care records, when available; System design – follow National IG good practice guidance in use of shared care records, when available; Professional responsibility; Understanding of and training/ education in shared care record use.
Residual risk:	2
Hazard Id:	16
Hazard Name	**Sex data item may cause accidental disclosure of gender reassignment without consent**
Hazard Description:	Accidental disclosure of gender reassignment, without consent, due to inclusion of both patient's 'sex/ phenotypic sex' and 'gender' in demographics section.
Hazard Causes:	1) Display of patient 'sex' and 'gender' information, in demographics, which do not match e.g. one states 'male' and the other states 'female'.
Potential Clinical Impact:	It is unlawful to disclose, without consent, a person's gender reassignment with or without a gender reassignment certificate. Potential severe psychological harm to patient and possibly significant others by sensitive information being accidently disclosed without consent. Disclosure adversely effects patient's social wellbeing and support networks.

Mitigation:	The inclusion of both 'sex/ phenotypic sex and gender in the patient's demographic's section may inadvertently result in disclosure. CIS is a set of headings for information that people want to share. This risk must be mitigated in the implementation of this standard in any shared care record. This can be done by only including "Gender" or by ensuring the design of the Shared Care Record including its Information Governance model reduce this risk to an acceptable level. PRSB to include this requirement in the Implementation guidance document which accompanies the CIS standard. Additional necessary mitigations to ensure the risk is reduced to an acceptable level include: Adequate training so staff are competent users of the system. Staff IG training. Staff vigilance and audits. Public engagement with development of local shared care records. Implement the NHS England IG framework for shared care records, when available. Clarity in national policy regarding the recording of 'sex' and 'gender' in EHRs with due regard for the practical risks posed in clinical practice to patients, practitioners and healthcare providers.
Residual risk:	3
Hazard Id:	17
Hazard Name	**Using locally developed codes**
Hazard Description:	Using local proxy codes which may not be properly interpreted.
Hazard Causes:	1) There is not an appropriate code/ term available for the information that needs to be expressed so local codes are developed. 2) Process for creating nationally agreed codes is difficult. 3) System suppliers and care providers have their own code space e.g. EMIS, hospitals.
Potential Clinical Impact:	The code is not found on a search or does not trigger a decision support protocol.
Mitigation:	Design of shared care record system and logical data model (out of scope); Implementation of national levers and incentives to adapt national coding system; Ensure code development and maintenance is effective and responsive to care provider and IT system supplier needs; End to end clinical testing; Education and training in coding best practice; Provide opportunities for clinicians and others (e.g. clinical coders) to train as SNOMED- CT terminologists in their specialities.
Residual risk:	2
Hazard Id:	18
Hazard Name	**Different versions of SNOMED CT in use**

Hazard Description:	Different sources may be using different versions of SNOMED or implementing it in different ways.
Hazard Causes:	1) SNOMED is dynamic with frequent updates. 2) Some providers are not updating to the latest versions of SNOMED CT. 3) Codes can become inactive and moved or not retained creating difficulty in retrieving historic information. 4) Source systems make extensive use of their own namespace.
Potential Clinical Impact:	Inhibits or complicates interoperability and sharing of important patient information between organisations leading to suboptimal, delayed or inappropriate patient care.
Mitigation:	Design of shared care record system and logical data model (out of scope); Clarity in national policy re; coding practice; End to end clinical testing; Education and training in coding best practice.
Residual risk:	2
Hazard Id:	19
Hazard Name	**Risk of sharing confidential information inappropriately;**
Hazard Description:	Risk of sharing confidential information inappropriately; Too little or too much.
Hazard Causes:	1) Healthcare provider worried about sharing data, GDPR etc. 2) Lack of granularity in RBAC in system, meaning inappropriate people have access. 3)Lack of granularity in sharing of individual data items. 4)Lack of patient confidence in system leading to refusal of consent to share.
Potential Clinical Impact:	Psychological harm to patient by confidential data being shared with inappropriate people. Not sharing data appropriately could lead to healthcare provider delivering inappropriate care based on missing clinical information leading to patient(s) harm.
Mitigation:	Design of shared care record system and logical data model (out of scope); National IG strategy built into LCR programme; End to end clinical testing; Adequate training so staff are competent users of the system; IG training; Staff vigilance and audits; Public engagement with development of local shared care records.
Residual risk:	2
Hazard Id:	20
Hazard Name	**Patient sees information that they were not aware existed and might be sensitive**

Hazard Description:	Patient sees information which they were not aware of such as: a) This could be new results or diagnoses such as Cancer. b) It could also be descriptions of the patient or their habits, with which they would not agree or be aware of. Examples include "Binge Drinker" or "Vulnerable Adult" or "Adopted". c) Third party data about, for instance, a parent.
Hazard Causes:	1) Results being added to shared record before having been reviewed by the healthcare user. 2) Shared data not being screened for third party or sensitive data.
Potential Clinical Impact:	Psychological harm to patient and possibly significant others by sensitive information being shared that patient/ service user was not aware existed or was being shared. Adversely effects patient's psychological and/ or social wellbeing and support network.
Mitigation:	Design of shared care record system and logical data model (out of scope); Only posting data when it is reviewed; Mechanisms for patients to know who and how to make contact for support; End to end clinical testing; Understanding of and training/ education in shared care record use. For example, importance of making sure the patient knows what is on the system - e.g. diagnosis of cancer; Education and training to use appropriate language in record keeping.
Residual risk:	2
Hazard Id:	21
Hazard Name	**Competent patient or their carer unable to understand information recorded in headings**
Hazard Description:	Where a copy of the record is shared with the patient - headings may be difficult to understand/interpret by patient.
Hazard Causes:	1) Unfamiliar context/terminology used in headings. 2) Clinician fails to populate headings appropriately.
Potential Clinical Impact:	Competent patient/carer fails to engage with healthcare system/ professionals. Patient is not empowered to self-care and participate in their care. Adds to unnecessary patient and carer anxiety.
Mitigation:	Design of shared care record system and logical data model (out of scope); Provide links to reliable resources for patients to consult; End to end clinical testing; Provide training and guidance for clinicians in good recording practise and use of shared care records; Training and education in using 'plain English'.
Residual risk:	2
Hazard Id:	22

Hazard Name	**Users don't value the product**
Hazard Description:	Poor reputation or poor accessibility of system lead to users not looking at data or not valuing it if they do.
Hazard Causes:	1) Poor accessibility - difficulty in seamlessly accessing data. 2) Poor GUI - difficult to find data. 3) Frequency of identified hazards occurring leading to lack of confidence in system. 4) Does not meet patients' reasonable expectations.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care or care is delayed because they do not utilise the information in the system.
Mitigation:	Design of shared care record system and logical data model (out of scope); End user engagement in design of system (out of scope); End to end clinical testing; Understanding of and training/ education in shared care record use.
Residual risk:	2
Hazard Id:	23
Hazard Name	**Confusion re: shared care record; LCR, summary care record, etc**
Hazard Description:	More than one shared record available and lack of clarity over how each works and should be used.
Hazard Causes:	1) Several shared care records available. 2) Patient or healthcare provider straddle geographical boundaries between shared care records. 3) Lack of understanding about which record to consult.
Potential Clinical Impact:	Healthcare provider delivers inappropriate care or care is delayed because there is confusion about which source of information to use.
Mitigation:	Design of shared care record system and logical data model (out of scope); Management of edge cases; End to end clinical testing; Understanding of and training/ education in shared care record use.
Residual risk:	2

Hazard Id:	24
Hazard Name	**Failure to adopt record standard**
Hazard Description:	Service providers may refuse to adopt and use the record standard.

Hazard Causes:	1) Confusion in the System about the relative status of the standard and if it is mandated to implement. 2) Providers and suppliers prioritising secondary uses services DCB standards over PRSB standards because they have ISN status. 3) Misalignment of PRSB standards and related DCB standards leading to difficulties with implementation. 4) Lack of understanding about the role and importance of the standard. 5) Lack of co-ordination and common approach between the different elements in the system.
Potential Clinical Impact:	Failure to deliver optimum care based on inconsistent guidance.
Mitigation:	Design of shared care record system and logical data model (out of scope); End user engagement in design (out of scope); Clarity, from the Centre, about the role and importance of implementing the standard; National levers and incentives to adopt the standard; see notes in column Q; End to end clinical testing; Understanding of and training/ education in shared care record use; IT commissioners and system developers educated and trained in the importance of clinical standards.
Residual risk:	3
Hazard Id:	25
Hazard Name	**CIS used out of scope.**
Hazard Description:	Information in the core information standard is used for supporting decisions make beyond which it has been designed and assured for.
Hazard Causes:	1) Lack of understanding and controls about the purpose and limitations of the information. 2) Being used as the sole source of truth. 3) Data being used for purposes other than the purpose for which is was recorded. 4) Implementation guidance is not followed.
Potential Clinical Impact:	a) The information influences the criteria for service provision. b) Denial of services to patient.
Mitigation:	Design of shared care record system and logical data model (out of scope); Follow implementation guidance; End to end clinical testing; Understanding of and training/ education in shared care record use.
Residual risk:	3
Hazard Id:	26

Hazard Name	**Assumption that data will replace human interaction**
Hazard Description:	Users will rely on the data in the shared care record and not verify it with the patient and/ or other colleagues caring for the patient.
Hazard Causes:	1) Reliance on shared care record as the source of truth. 2) Assumption that it is not necessary to take the history and verify the information in the record with the patient. 3) Using the shared care record for decision support without appropriate input from the patient.
Potential Clinical Impact:	Failure to discuss issues with the patient and build a therapeutic and shared understanding of the patients' needs because of over reliance on the shared record. May lead to sub-optimal care.
Mitigation:	Design of shared care record system and logical data model (out of scope); Patients/ service users have access to their record and empowered to review and discuss it with their care professionals; End to end clinical testing; Professional accountability; Understanding of and training/ education in shared care record use.
Residual risk:	2
Hazard Id:	27
Hazard Name	**System not available**
Hazard Description:	The shared record system is not available.
Hazard Causes:	1) Power outage. 2) Cyber-attack.
Potential Clinical Impact:	Shared significant clinical information is not available for decision making.
Mitigation:	System design and maintenance.
Residual risk:	2

Hazard Id:	28
Hazard Name	**System performance inadequate**
Hazard Description:	Poor response times from the system itself or its external dependencies.
Hazard Causes:	1) Lack of capacity or, anticipated volumes of data throughput exceed design estimations. 2) Excessive demand e.g. recovery after a period of downtime. 3) Local network or associated networks experiencing poor performance.

Potential Clinical Impact:	Poor performance of a system could result in the system not being suitable for use in the clinical environment in which it was intended. This may require the health care provider to revert to alternative means of communication with the potential for a delay in clinical care.
Mitigation:	System design and maintenance:
Residual risk:	2
Hazard Id:	29
Hazard Name	**Modification to system and interconnecting system**
Hazard Description:	Changes made to systems may introduce unexpected defects in existing System.
Hazard Causes:	1) System configuration changes, upgrades, bug fixes or maintenance releases. 2) Interconnecting system configuration changes, upgrades, bug fixes or maintenance releases.
Potential Clinical Impact:	Failure to correctly/fully communicate messages to a health care provider could contribute to a delay in care whilst a health care provider attempts to obtain information via alternative methods. This could contribute to inappropriate delay in clinical care.
Mitigation:	System design and maintenance.
Residual risk:	2
Hazard Id:	30
Hazard Name	**Patient data error in interconnecting systems (Out of scope for Middleware Manufacturer noted here for Health Organisation only)**
Hazard Description:	Local or National (e.g. Patient Administration System [PAS] or national Patient Demographic Service [PDS]) data may be missing, incorrect, incomplete, out of date or corrupt.
Hazard Causes:	1) Failure to identify duplicates of patients in local master patient Index. 2) Missing, incorrect, incomplete, out of date or corrupt local data resulting in inability to identify patient or misidentification. 3) Inconsistency of patient record identifiers between interconnecting systems. 4) Data incorrectly entered into national records e.g. PDS multiple active (non-end-dated) address records exist.
Potential Clinical Impact:	A care provider organisation may act on inaccurate information. If not detected, this may lead to a patient experiencing a delay in clinical care, delay in contacting a patient requiring clinical care or clinical decisions being made on incorrect information.

	Duplicate patient records may be created if the national equivalent of a local record cannot be found.
Mitigation:	System design and maintenance.
Residual risk:	2

9. Residual Hazard Risk Assessment

There are five hazards with a residual risk of 3, which is undesirable.
Hazard 16 is of particular note as it was rated at level 4 and can only be mitigated to level 3 at the implementation stage. All the above risks will be transferred to those incorporating the CIS into an EHR. Action is essential to mitigate Hazard 16 and should be seriously considered in all level 3 risks. The residual hazards are as follows:

Risk level 3
Hazard no 16: **Sex data item may cause accidental disclosure of gender reassignment without consent**
This relates to both Sex (Phenotypic Sex) and Gender (Self-declared Gender) being fields in the demographic information model. The risk is that this will identify a patient who has transitioned and could do psychological harm to the patient. The risk acceptability of a level 4 risk is defined as “Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level”. This can be reduced to a level 3 risk by implementation. Removing the “Sex” field is one option, the other is to ensure the design and information model of the Shared Care Record reduce this risk to an acceptable level. This advice will form part of the implementation guidance accompanying the CIS.

Specific actions to mitigate this risk by design of the LCR are:
Option 1: to only include the Gender field and this will greatly reduce the risk.
Option 2: ensure through the design of the system and the information governance model that the risk of unlawful disclosure is reduced to an acceptable level.

Additional necessary mitigations to ensure the risk is reduced to an acceptable level include:
Adequate training so staff are competent users of the system.
Staff IG training.
Staff vigilance and audits.
Public engagement with development of local shared care records.
Implement the NHS England IG framework for shared care records, when available.
Clarity in national policy regarding the recording of 'sex' and 'gender' in EHRs with due regard for the practical risks posed in clinical practice to patients, practitioners and healthcare providers.

Hazard no 8: The context of the information is lost.

It is recognised that the CIS is a set of headings under which information is displayed, but that this view does not allow all the useful context and provenance of the information to be seen. The mitigation for this is the development of other views of the information being made available using the relationships defined by the logical data model for LCRs.

Hazard no 11: Significant problems, diagnoses, conditions or procedures are not visible to healthcare user.

The section headed Problems, Diagnoses, Conditions and Procedures is recognised to be an issue because of the semantics of language between different professional groups and the structure of the data held in different clinical systems. In addition, as a “Core” information standard a subset of the available data will be required and at this stage there is no clarity as to how that will occur. Not creating a subset risks an overload of data obscuring the information required. The section will also need to be updated and curated. A problem which is not yet well handled in individual clinical systems.

Hazard no 23: Failure to adopt record standard.

The development of the CIS standard needs to be supported in its adoption by promotion by NHS Digital, NHS England, PRSB and pharmacy bodies and stakeholder organisations who have provided endorsement for the standard. Failure to adopt it risks multiple different models being adopted, resulting in lack of interoperability and lack of user familiarity. Leading to loss of benefit and potential patient harm.

Hazard no 24: CIS used out of scope.

The clinical safety case is based on the CIS being used in scope. Failure to stick to the scope defined and use it for purposes beyond its intended purpose would pose a risk to patient safety. It should be implemented following the implementation guidelines.

It should be noted that it has been assessed as a “Read only” record system. A read only shared record system can only reflect information supplied by other systems and should not be regarded as the single source of truth.

10 Training

Training of the end users of the local care record is offered as a mitigation for many of the hazards identified. This should be considered, when developing these systems and be provided by the system suppliers or the deployers of such 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. Implementation guidance is provided as a part of the CIS and PRSB provide a support service where implementors can get advice about implementing the CIS

11 Test Issues

As the Core Information Model 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 local care records doing full end to end clinical safety testing.

12 Summary safety statement

Thirty potential hazards were identified. All hazards were identified through the consultation processes carried out to assure the PRSB core information standard developed to underpin and support the implementation and use of LCRs. The consultation process is described in detail in the project final report and section 6. It included patient and carer representatives as well as professionals from Royal Colleges, specialist societies, allied health professions, health informatics professionals, pharmacists and vendors.

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

(B) or the residual risk has been transferred (with guidance) to the implementers.

It is worth drawing attention to two groups of hazards. Issues with the data generally and issues with specific sections of the data. In terms of the first of these, data may be absent, incorrect, conflicting or present but not found. These hazards are all dependent on the design of the shared record system.

Allergies, Medications, Problems and Diagnoses, Care plans and Alerts are all sections where it was felt to be worth highlighting the hazards specifically. In some cases, further work needs to be done to define the content or ensure the different way in which the data is represented in different systems is fully understood and correctly mapped to the CIS. For instance, Primary Care systems do not specifically define a diagnosis in their information models and Diagnoses tend to be used rather differently in primary and secondary care. The alerts section has been designed to hold a limited range of specific alerts and exactly how it is designed to work in particular systems will need to be conveyed in training.

The heading Pregnancy status is designed to alert users to whether a patient is currently pregnant. It seems unlikely that this information can be reliably imported from a single system and so, is likely, to be a calculated field. This is unique in this model and may be defined as a medical device, for which separate safety assessment and registration will be required. System manufacturers will need to consider this.

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.

Most hazards are rated as a risk acceptability level of 2. This level is tolerable where cost of further reduction outweighs benefits gained. But should nevertheless be considered by those deploying the standard. The five rated at level 3 have been described in section 9. The mitigations for the level 3 risks are outside the control of PRSB and these risks are therefore transferred to the system developers and deployers of this standard. Level 3 risks are defined

as “An 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”.

13. Document control and post standard approval maintenance

Future governance of the development and maintenance of the CIS is the responsibility of the PRSB.

14. DCB 0129 compliance matrix

The table below summarises the compliance status of this safety case for the PRSB CIS.

Requirement	Compliant (Y/N)?	Comments
2. General Requirements and Conformance Criteria for Clinical Risk Management	Y	See section 4
2.1 Clinical risk management process	Y	See section 4
2.2 Top Management responsibilities	Y	See section 4
2.3 Clinical Safety Officer	Y	See section 4
2.4 Competencies of personnel	Y	See section 4 & 6
3.1 Clinical risk management file	Y	This document in its entirety, including supporting evidence, the CIS and implementation guidance.
3.2 Clinical risk management plan	Y	See section 5 & 6
3.3 Hazard log	Y	See section 7
3.4 Clinical safety case	Y	This document in its entirety, including supporting evidence, the CIS and implementation guidance
4 Clinical risk analysis	Y	See section 5
4.1 Clinical risk analysis process	Y	See Section 6
4.2 Health IT System scope definition	Y	See section 2
4.3 Identification of hazards to patients	Y	See section 5

4.4 Estimation of the clinical risk(s)	Y	See section 6
5 Clinical risk evaluation	Y	See section 6/7/
6 Clinical risk control	Y	See section 6/7
6.1 Clinical risk control option analysis	Y	See section 6/ 7
6.2 Clinical risk/benefit analysis	Y	See section 6/7
6.3 Implementation of clinical risk control measures	Y	See section 6/ 7
7.1 Delivery	Y	This document in its entirety, including supporting evidence, the CIS and implementation guidance.
7.2 Post-deployment monitoring	N	Not required for a professional standard.
7.3 Modification	Y	See section 13

15 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
		Consequence				

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

Consequence Category	**Interpretation**	
	Consequence	**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. Mandatory elimination or control to reduce risk to an acceptable level.
4	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk. Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	Tolerable where cost of further reduction outweighs benefits gained.
1	Acceptable, no further action required