Professional Record Standards Body

Better records for better care

Core Information Standard

Clinical Safety Case Report

April 2021

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
0.5	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
1.2	29/09/2020	First draft created by James Critchlow. This is an updated version of the Core Information Standard (CIS) Safety Case, which now includes Digital Social Care Information products made up of an updated standard for "About Me", a standard for the sharing of data from Local Authorities and guidance on which sections of the CIS should be in the Care Homes view.
1.3	07/10/2020	Updated by Dr John Robinson
1.4	29/10/2020	Updated following assurance committee feedback on hazard log
1.5	29/10/2020	Appendix B removed
1.6	09/03/2021	Edits made following feedback from NHS Digital Clinical Safety Team
1.7	06/04/2021	Edits made following feedback from NHS Digital Clinical Safety Team

Reviewed by

This document must be reviewed by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr John Robinson	30/10/2020
PRSB Assurance Committee	PRSB Assurance Committee	07/10/2020

Approved by

This document must be approved by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr John Robinson	30/10/2020
PRSB Assurance Committee	PRSB Assurance Committee	07/10/2020
Project Board	Project Board	30/09/2020
NHS Digital Clinical Safety Group	NHS Digital Clinical Safety Group	01/04/2021

Glossary of Terms

Term / Abbreviation	What it stands for
CCG	Clinical Commissioning Group
CIS	Core Information Standard
COVID-19	Coronavirus disease 2019
CPR	Cardio - Pulmonary Resuscitation
CQC	Care Quality Commission
CSCR	Clinical Safety Case Report
CSG	Clinical Safety Group
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
DCB	Data Coordination Board
dm+d	Dictionary of Medicine and Devices
EHR	Electronic Health Record

EMIS	Egton Medical Information Systems
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GP	General Practitioner
GUI	Graphical User Interface
IG	Information Governance
IHD	Ischaemic Heart Disease
ISN	Information Standard Notice
IT	Information Technology
KPI	Key Performance Indicator
LCR	Local Care Record
NHS	National Health Service
NHSD	NHS Digital
NHSE	NHS England
NPSA	National Patient Safety Agency
OPCS	Office of Population Censuses and Surveys Classification
OTC	Over the Counter
PAS	Patient Administration System
Patient	Subject of the record
PDS	Patient Demographic Service
PRSB	Professional Record Standards Body
RBAC	Role Based Access Control
READ	READ - coded thesaurus of clinical terms
SNOMED CT®	Systematized Nomenclature of Medicine – Clinical Terms

Related Documents

Ref no	Title
[1]	Persons Core Information Standard v1, July 2019, Professional Record Standards Body;
[2]	Core Information Standard: Survey Results and Analysis, July 2019, Professional Record Standards Body;
[3]	DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems;
[4]	Core Information Standard Final Report v1, July 2019, Professional Record Standards Body;
[5]	Digital Social Care Information Final Report v1, September 2020, Professional Record Standards Body;
[6]	DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems;

Table of contents

1 Executive Summary and Safety Statement

This is an updated version of the Core Information Standard (CIS) Safety Case, which now includes Digital Social Care Information products made up of an updated standard for “About Me”, a standard for the sharing of data from Local Authorities and guidance on which sections of the CIS should be in the Care Homes view. This clinical safety case should be reviewed on an annual basis.

This PRSB Core Information Standard (CIS) standard [Ref.1] 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 [Ref.2]. 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 that is felt to be important to share.

PRSB has been asked to define a CIS, which is “A set of “Concept” headings, referred to as “Sections” 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 sections is entirely dependent on the source data being shared and processed appropriately so that the correct information is available under the right section 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 sections 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 for the CIS identified 30 hazards. The addition of the digital social care information products identified an additional six hazards. Twenty nine of these have an acceptable residual risk of 2. The remaining seven have a residual risk of 3, which includes two of the new hazards.

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 sections. 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:

Hazard 16: 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:

- **Hazard 8: The context or provenance of the information is lost, unknown or misunderstood.** The CIS is a set of sections 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. The addition of data from Local Authorities (which may include child protection or vulnerable adult data) and the About Me section, (which is created by the subject of the record or their proxy) have increased the importance of users of the system understanding the source of the data and its context when making judgements on the validity of an entry.

- **Hazard 11: Significant problems, diagnoses, conditions or procedures are not visible to healthcare user.** The Problems and Diagnoses section 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.

- **Hazard 24: 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, social care bodies including care home and local authority representatives and pharmacy bodies and stakeholder organisations who have provided endorsement for the standard. The heterogeneity in the data items recorded by different local authorities and care homes will increase this risk as certain centres may consider the scope of the standards as limited or difficult to implement. 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 25: CIS used out of scope.** The safety case is based on the CIS being used in scope. The heterogeneity in the data items recorded by different local authorities and care homes will increase this risk as certain centres may consider the scope of the standards as limited or difficult to implement. The implementation guidance should be followed.

- **Hazard 30: Patient data error in interconnecting systems (Out of scope for Middleware Manufacturer noted here for Health Organisation only).** The addition of data from Local Authorities has increased this risk to a level 3 and it remains at this level of residual risk. Identifying demographics information should be obtained from established sources such as the Patient Administration System [PAS] or national Patient Demographic Service [PDS]) – however, it is recognised that data may be missing, incorrect, incomplete, out of date or corrupt; creating a clinical safety risk. Local Authorities have identified significant issues in NHS number tracing, which is legal requirement.

- **Hazard 31 – Data in the legal section misunderstood or missing:** The importance of being able to locate original documents was strongly emphasised. It is critical during transfers of care that there are processes in place to ensure original documents (e.g. DNACPR forms) can be viewed and mechanisms are there to ensure that these documents are up to date. It is recognised that national solutions are currently being sought to this problem.

All risks identified in the Hazard log are transferred, to those who incorporate the Core Information Standard and the Digital Social Care information 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 sections, 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 (CIS) gives one view of the data. A data item should only appear under one section, although this is not a hard and fast rule. It does not show all the relationships of data items. In addition, users may see filtered views of the CIS depending on the setting and situational requirements e.g. views based on the PRSB Care Homes View, About Me, Local Authority Information, Digital Care and Support Plan etc. 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 being developed by NHS Digital and PRSB 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.3].

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, being 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" sections 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 original 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. 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 [Ref.4]. 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.

This update to the standard includes Digital Social Care Information, which consists of a standard for data being shared from local authority records into the CIS, a revised standard for the “About Me” section, which is now much more structured than previously and guidance on a “Care Homes” view of the data. These additions were developed in the same manner as the main CIS, with a review of the evidence then wide stakeholder consultation.

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 section 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.

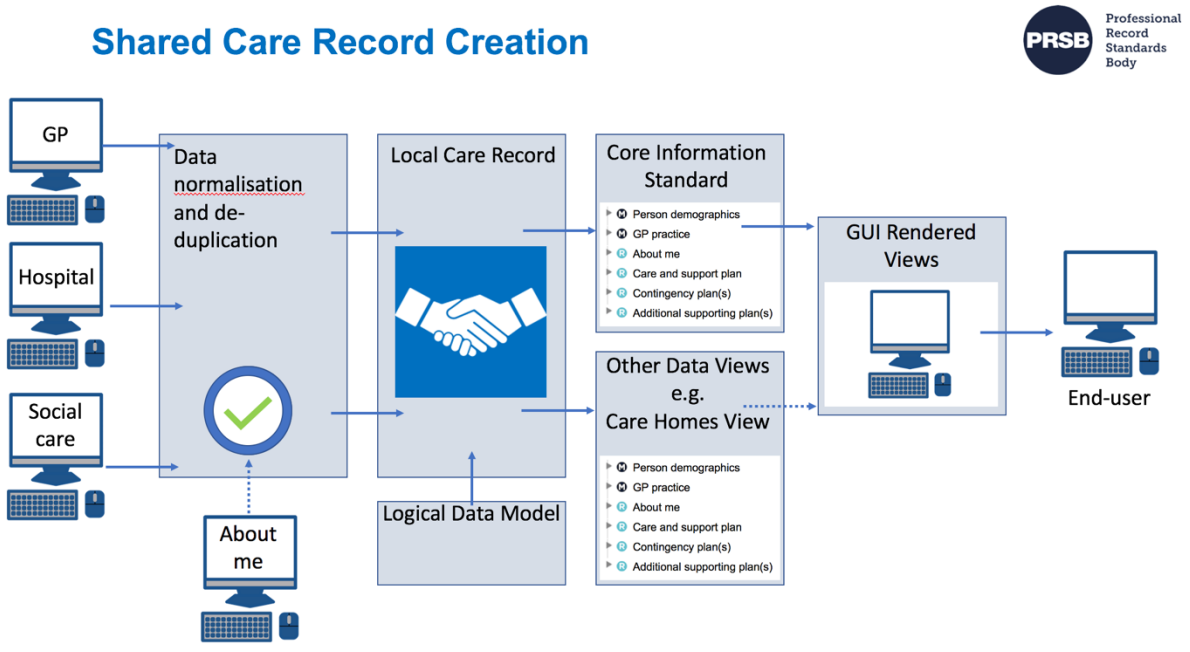

Diagram A: Local shared care record creation

3.2 Inclusions to Scope

The following are included in the clinical safety case:

- The LCR CIS set of “Concept” sections (under which users can view the shared information);
- The definitions of the sections and descriptions of the data to be stored and viewed under the section;
- The data attributes of the sections.
- Guidance on the sections to be included in the Care Homes view

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 Digital Social Care Information products. Governance structures, project methodology and stakeholder engagement are described in the Digital Social Care Information final report [Ref.5]. 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.6].

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 and Clinical Risk Analysis

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

5.1 Original CIS Consultation

- 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 (CIS original) and clinical safety report.
- NHS Digital clinical safety case review.

5.2 Digital Social Care Information consultation (Updated CIS):

- Safety issues identified by clinical informaticians, clinical and professional advisors and patient advisors participating in hazard workshops on 8th July and 15th July 2020

- Safety issues identified by clinical informaticians, clinical and professional advisors and patient advisors participating in clinical safety meeting on 19th August 2020.
- Potential clinical safety issues identified by stakeholder participants during consultation surveys (n=763) and other consultations undertaken during the development of the Digital Social Care Information products.
- Updates to original CIS hazard log for the project.
- Review of the updated CIS hazard log and any associated safety risks.
- Review of mitigation of risks.
- Clinical safety mitigation and confirmation of residual 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 of updated CIS.

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 number
- Hazard name
- Hazard description
- Potential clinical impact
- Possible causes
- Existing controls
- Unmodified risk rating including likelihood and consequence
- Proposed mitigations (In design, testing, training or business process controls)
- Modified risk ratings (taking into account proposed mitigations)

- Summary of actions / notes
- Owner of the residual risk
- Hazard status

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 workshops and clinical safety case meetings

Potential clinical safety risks were identified throughout the development of the CIS and the updates conducted as part of the Digital Social Care Information project. These risks were specifically explored at several advisory group meetings.

6.4.1 Original consultation:

A hazard workshop was convened to explore all the risks to patient safety and develop the original CIS hazard log. Details of these meetings are described below:

Hazard Workshop 1			
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

6.4.2 Digital Social Care Information consultation:

A hazard workshop (two sessions) was convened to explore all the risks to patient safety and develop updated CIS hazard log. Details of these meetings are described below:

Hazard Workshop 2			
Date	08.07.2020	**Time**	12:00 – 13:30
Location	Conducted via teleconference call following COVID-19 pandemic		
Attendees:			
	Name	**Role**	
Chair	Dr John Robinson	PRSB Clinical Advisor for Digital Social Care Information Project, PRSB Clinical Safety Officer, Retired General Practitioner and Clinical Informatician	
	Annette Gilmore	Clinical informatician (PRSB) / Acute care nurse	
	Beverley Latania	PRSB Social Care Advisor for Digital Social Care Information Project, Head of Mental Health Social Work – Islington Council	
	Helene Feger	PRSB, Director of Strategy, Communications and Engagement	
	James Critchlow	Associate Medical Researcher (PRSB)	
	Katie Thorn	PRSB Social Care Advisor for Digital Social Care Information Project, Digital Engagement Manager – Registered Nursing Home Association, Project Lead – Digital	

		Social Care
	Martin Orton	PRSB, Director of Delivery & Development
	Samantha Goncalves	PRSB Citizen Lead for Digital Social Care Information Project
	Sarah Jackson	PRSB Project Manager

Hazard Workshop 3			
Date	15.07.2020	**Time**	12:00 – 13:00
Location	Conducted via teleconference call following COVID-19 pandemic		
Attendees:			
	Name	**Role**	
Chair	Dr John Robinson	PRSB Clinical Advisor for Digital Social Care Information Project, PRSB Clinical Safety Officer, Retired General Practitioner and Clinical Informatician	
	Professor Adam Gordon	PRSB Clinical Advisor, Clinical Associate Professor of Medicine of Older People – University of Nottingham, Consultant Geriatrician – Derby Teaching Hospitals NHS Trust, Vice President for Academic Affairs – British Geriatric Society	
	Annette Gilmore	Clinical informatician (PRSB) / Acute care nurse	
	Beverley Latania	PRSB Social Care Advisor for Digital Social Care Information Project, Head of Mental Health Social Work – Islington Council	
	Helene Feger	PRSB, Director of Strategy, Communications and Engagement	
	James Critchlow	Associate Medical Researcher (PRSB)	
	Katie Thorn	PRSB Social Care Advisor for Digital Social Care Information Project, Digital Engagement Manager – Registered Nursing Home Association, Project Lead – Digital Social Care	
	Martin Orton	PRSB, Director of Delivery & Development	
	Samantha Goncalves	PRSB Citizen Lead for Digital Social Care	

		Information Project
	Sarah Jackson	PRSB Project Manager

Clinical Safety Meeting			
Date	19.08.2020	**Time**	12:00 – 13:00
Location	Conducted via teleconference call following COVID-19 pandemic		
Attendees:			
	Name	**Role**	
Chair	Dr John Robinson	PRSB Clinical Advisor for Digital Social Care Information Project, PRSB Clinical Safety Officer, Retired General Practitioner and Clinical Informatician	
	Professor Adam Gordon	PRSB Clinical Advisor, Clinical Associate Professor of Medicine of Older People – University of Nottingham, Consultant Geriatrician – Derby Teaching Hospitals NHS Trust, Vice President for Academic Affairs – British Geriatric Society	
	Beverley Latania	PRSB Social Care Advisor for Digital Social Care Information Project, Head of Mental Health Social Work – Islington Council	
	Helene Feger	PRSB, Director of Strategy, Communications and Engagement	
	James Critchlow	Associate Medical Researcher (PRSB)	
	Katie Thorn	PRSB Social Care Advisor for Digital Social Care Information Project, Digital Engagement Manager – Registered Nursing Home Association, Project Lead – Digital Social Care	
	Martin Orton	PRSB, Director of Delivery & Development	
	Samantha Goncalves	PRSB Citizen Lead for Digital Social Care Information Project	
	Sarah Jackson	PRSB Project Manager	

7 Hazard log

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

Include URL to Hazard log (in final version)

8 Hazards

There were 36 hazards identified that are listed in the hazard log.

9 Residual Hazard Risk Assessment

The updated hazard log consists of 36 hazards. Six new hazards were identified in the Digital Social Care information consultation. Additional elements were added to existing hazards, during this consultation as well. The majority of which did not alter the risk of the hazard. Where the initial risk was raised following the Digital Social Care Information consultation, the hazard is discussed below.

There are 14 hazards with an initial risk of 3 or more. After controls and mitigations there remain seven 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. Also hazard 30 (level 3), which has been raised by the inclusion of social care data and can only be mitigated further at implementation.

All the residual risks in the Hazard log will be transferred to those incorporating the CIS and associated products into an EHR. Action is essential to mitigate Hazard 16 and should be seriously considered in all level 3 risks. Consideration should also be given to further reducing those at level 2 where it is possible to do so. The residual risks at level 3 are as follows:

Risk Level 3

Hazard 8: The context or provenance of the information is lost, unknown or misunderstood

It is recognised that the Core Information Standard is a set of sections under which information is displayed, but that this view does not allow all the useful context and provenance of the information to be seen. Examples may include:

- This Core Information Standard model shows data from all sources under defined sections. The elements of the items under each section do not take into account the full amount of contextual data available. 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.
- Losing the link to a source document. For example; Elements from the PRSB eDischarge or local authority assessment.
- Summary separated under different sections in the CIS and links to whole document lost.
- Inability to distinguish clinical information shared by care home or local authority with that entered by clinicians
- Healthcare provider is unsure of the provenance of the CPR decision information and is thus unable to be sure of actions to take regarding CPR.
- It is unclear whether clinical information was derived from a professional source e.g. consultant physician or from a patient history
- Clinician unclear about the purpose of About Me (*NB*: The About Me section has been updated in the latest version of the CIS as part of the PRSB Digital Social Care Information project)

The mitigation for this is the development of other views of the information being made available to the end user, ensuring that the context and provenance of the data is retained. As well as ensuring users of systems understand the source of the data and the importance of context to support judging the validity of an entry - especially understanding the structure and purpose of the About Me section.

Hazard 11: Significant problems, diagnoses, conditions or procedures are not visible to healthcare user

The sections containing Problems, Diagnoses, Conditions and Procedures is recognised to be an issue because of the semantics of language between different professional groups (i.e What is regarded as a problem) and the structure of the data held in different clinical systems. In addition, there is a risk of an overload of data obscuring the information required. It is well known that GP problem lists are often extensive and are not curated.

Hazard 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 records reduce this risk to an acceptable level. This advice will form part of the implementation guidance accompanying the standards.

Specific actions to mitigate this risk by design of the shared record 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 audit.
- Public engagement with development of local transfers of care records.
- Implement the NHS England IG framework for digital 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.

It is essential that necessary checks are made to ensure that implementation is compliant with UK law.

Hazard 24: Failure to adopt CIS

The development of the standard needs to be supported in adoption by promotion by NHS Digital, NHS England, PRSB and stakeholder organisations who have provided endorsement for the standard, including bodies representing local authorities and care homes. The heterogeneity in the data items recorded by different local authorities and care homes will increase this risk as certain centres may consider the scope of the standards as limited or difficult to implement. 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 25: 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.

Hazard 30: Patient data error in interconnecting systems (Out of scope for Middleware Manufacturer noted here for Health Organisation only)

The addition of data from Local Authorities has increased this risk to a level 3 and it remains at this level of residual risk.

Identifying demographics information should be obtained from established sources such as the Patient Administration System [PAS] or national Patient Demographic Service [PDS]) – however, it is recognised that data may be missing, incorrect, incomplete, out of date or corrupt; creating a clinical safety risk. Examples of possible causes may include:

- Failure to identify duplicates of patients in local master patient Index.
- Missing, incorrect, incomplete, out of date or corrupt local data resulting in inability to identify patient or misidentification.
- Inconsistency of patient record identifiers between interconnecting systems.
- Data incorrectly entered into national records e.g. PDS multiple active (non end-dated) address records exist.
- Data does not match demographics. NB Systems completed manually.

In addition, Local Authorities have identified significant issues in NHS number tracing and this may cause any of the above. *NB*: The use of NHS number or equivalent is a legal requirement for local authorities unless they are unable to reasonably comply – The Health and Social Care (Safety and Quality Act) 2015. Mitigations are required at the implementation stage.

Hazard 31: Data in legal section misunderstood or missing.

This hazard was introduced because of the introduction of legal data from local authorities, although it applies to all data in the legal section. The data may refer to the presence of a legal document such as an advance directive, but the actual document may not be accessible. The record might be out of date or misinterpreted. As this is a UK wide standard there was concern that there are differences in the legal requirements across the different UK countries.

This can be mitigated by ensuring that the original documents are accessible, and this is made clear in the implementation guidance. We are aware that work is going on nationally to create a single repository for documents. Training users to understand what is in this section and how it should be interpreted is also important.

Risk Level 2

The Hazards 2 and 3 described below are where initial risk has increased to level three following the Digital Social Care Information Consultation, but controls and mitigations have reduced the residual risk to level 2.

Hazard 2: Data missing/ incomplete data

This risk increased because of the addition of Local Authority data. It is important to ensure the design of shared care record system can handle the local authority data model (out of scope) - (LA information).

Hazard 3: Incorrect data or data is misinterpreted, or data is represented incorrectly.

The inclusion of data from Local authorities and in the About Me section has increased this risk. It is mitigated by ensuring that users understand the issues around different semantic use of terms in different environments and are clear about the provenance and context of data being displayed.

Hazards 33 and 34 are new and were identified following the Digital Social Care Information consultation and a review of the existing safety case for the CIS. They have an initial risk of three but are mitigated to two.

Hazard 33: Inappropriate role-based access control (RBAC) implementation

Either an appropriate end-user does not see information that they need to see, or an end-user has access to information that they should not see due to inappropriately allocated RBAC.

The initial design of the Care Homes View of the CIS included two different RBAC view proposals one for clinical care staff and one for others. These were both filtered views of the data. Following consultation these have been removed from the standard. PRSB recommends that all data must be viewable for appropriate users and should not be filtered unnecessarily, as this may lead to data not being visible. It was noted that Care homes very often do not have clinically qualified staff.

More generally this hazard increases with the rise in the number of organisations having access to the CIS data. This can be mitigated by ensuring that those administering RBAC privileges have adequate training and local policy is well communicated. As well as ensuring that there is adequate granularity in the RBAC roles. It is recognised that with the rising complexity of the data from multiple sources, the functionality of RBAC is increasingly challenged in managing confidentiality.

Hazard 34: The care home view of the CIS record does not include some important information

The initial design of the Care Homes View of the CIS included two different RBAC view proposals, which were both filtered views of the data. Following consultation these have been removed from the standard. Therefore, this hazard has been controlled.

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. Training should facilitate good communication practices. Implementation guidance is provided as part of the CIS and PRSB provide a support service where implementors can get advice about implementing the CIS. *NB*: Additional implementation guidance is available on the PRSB website relating to the following Digital Social Care Information products that form part of the CIS:

- About Me
- Care Homes View (of Shared Health and Care Records)
- Local Authority Information (For Shared Health and Care Records)

11 Test Issues

As the Core Information Model has as yet not been implemented in any systems, it has not been possible to test the model in vivo. It is therefore dependent on those implementing the standards doing full end to end clinical safety testing and for them to provide evidence of successful testing as part of their own clinical risk management activities.

12 Summary Safety Statement

Thirty-six potential hazards were identified. All hazards were identified through the consultation processes carried out to assure the PRSB Core Information Standard or the Digital Social Care Information products that form part of the updated CIS; developed to underpin and support the implementation and use of LCRs. The original and subsequent consultation processes are described in detail in the Core Information Standard and Digital Social Care Information final project reports

respectively and section 6 of this document. The consultations included patient and carer representatives as well as professionals from Royal Colleges, specialist societies, allied health professions, health informatics professionals, pharmacists, local authority and care home representatives 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 section 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 seven with a residual risk 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 Standards Approval Maintenance

Future governance of the development and maintenance of the Core Information Standard 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 Core Information Standard

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 Digital Social Care Information products 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 Digital Social Care Information products 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 Digital Social Care Information products 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