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Digital Social Care Information: Transfers of Care Standards

Clinical Safety Case Report v 1.2

April 2021

Document Management

Revision History

Version	Date	Summary of Changes
0.1	22/07/2020	First draft created by James Critchlow
0.2	22/08/2020	Updated following clinical safety case sessions
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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
Red Bag	Urgent Referral from Care Home to Hospital Standard
SNOMED CT®	Systematized Nomenclature of Medicine – Clinical Terms

Related Documents

Ref no	Title
[1]	Hospital Referral for Assessment for Community Care and Support Information Model v 1.0
[2]	Urgent Referral from Care Home to Hospital Information Model v 1.0
[3]	Urgent Referral from Care Home to Hospital Implementation Guidance v 1.0
[4]	Digital Social Care Information Final Report v 1.0
[5]	Hospital Referral for Assessment for Community Care and Support Implementation Guidance v 1.0
[6]	DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems;
[7]	DCB0160: Clinical Risk Management: its Application in the Deployment and Use of

	Health IT Systems;

Table of contents

1 Executive Summary and Safety Statement 7

2 Introduction 9

3 System Definition / Overview / Scope 10

3.1 Purpose, definition and scope of Urgent Referral from Care Home to Hospital standard 10

3.1.1 What it is 10

3.1.2 What it is not 10

3.1.3 How it works 11

3.2 Purpose, definition and scope of Hospital Referral for Assessment for Community Care and Support 11

3.2.1 What it is 11

3.2.2 What it is not 12

3.2.3 How it works 12

3.3 Purpose, definition and scope of Clinical Safety Case Report 12

Inclusions to scope 13

3.3.1 13

The scope of the clinical safety case for transfers of care includes the following: 13

Exclusions to scope 13

3.3.2 13

The scope of the clinical safety case for transfers of care excludes the following: 13

3.3.3 Use 13

4 Clinical Risk Management System 14

5 Hazard Identification and Clinical Risk Analysis 14

6 Clinical Risk Evaluation and Clinical Risk Control 15

6.1 Patient safety risk assessment approach 15

6.2 Hazard log composition 15

6.3 Risk assessment methodology 16

6.4 Hazard workshops and clinical safety case meetings 16

7 Hazard Log 18

8 Hazards 19
9 Residual Hazard Risk Assessment 19
10 Training 21
11 Test Issues 22
12 Summary Safety Statement 22
13 Document Control and Post Standards Approval Maintenance 23
14 DCB 0129 Compliance Matrix 23
15 Appendix A – Risk Matrix 24

1 Executive Summary and Safety Statement

These two new transfers of care standards, “The Urgent Referral from Care Home to Hospital” and “The Hospital Referral for Assessment for Community Care and Support” have been developed following extensive consultation with patients, carers and other citizens, health and care professionals and system suppliers as set out in the Digital Social Care Information Final Report and Digital Social Care Information Survey Results and Analysis Report. They are intended to be used as the standard set of sections and elements in each section, under which data can be shared when these specific transfers of care are undertaken. Any other use is out of scope of this safety case. This clinical safety case should be reviewed on an annual basis.

The primary purpose of the Hospital Referral for Assessment for Community Care and Support standard is to enable the responsible health and social bodies to determine what care and support is required for a person post-discharge. It includes the sections to carry the information required for the Assessment, Discharge and Withdrawal and the Discharge to Assess processes, however it does not address the mechanisms by which this data is sent or received or metadata around the sending of the message such as responses.

The hazard workshop and subsequent meetings identified 48 hazards. All but five of these are regarded as acceptable with a residual risk of 2. One of these five, was assessed initially at level 4 the others initially at level 3. All were mitigated to level 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 digital transfers of care and recording data in source systems, which needs to be shared; a further concern is the significance of getting the information wrong.

The hazard identified as being at risk level 4 is:

- **Hazard 15 - 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 must

be mitigated in these standards. This can be done by only including "Gender" or by ensuring the design of the transfer of care process including its Information Governance model reduce this risk to an acceptable level. This requirement is in the Implementation guidance documents, which accompany the standards. The level of risk is reduced to 3, on the basis that these mitigations are undertaken.

The hazards with an undesirable risk level of 3 are:

- **Hazard 8 - The context or provenance of the information unknown or misunderstood:** The standards are a set of headings under which information is shared, but this view does not include all the context and provenance of the information. Particular concern was raised about the "About me" section and ensuring that users were trained to understand that this was data contributed by the patient or their sponsor on their behalf. Similarly, information from a care home will often be information collated by them from a variety of sources and may differ from the prime source of the information. For instance, past history might be from a resident's recollection.
- **Hazard 11 - Significant problems, diagnoses, conditions or procedures are not visible to healthcare user:** It is recognised that further work needs to be done to develop a clear idea of precisely what data should be contained in the problem list. Methods for updating and curating the data will also need to be established. The additional problem in the transfers of care covered in this document is that they take place between different disciplines and the use of language and semantics may lead to confusion.
- **Hazard 23 - Failure to adopt the transfers of care record standard(s):** The development of these standards needs to be supported in its adoption by promotion by NHS Digital, NHS England, PRSB and pharmacy bodies and bodies representing care home and local authority 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 30 – 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.

The safety risk identified by these hazards is beyond the control of PRSB and is handed over to the deploying organisation(s). This level of risk is regarded as undesirable and should be mitigated in implementation.

Although the remaining risks are deemed tolerable with a residual risk level of 2 the Hazard log outlines mitigations and controls to be implemented to minimize these risks.

Any safety incidents occurring, which might be due to the transfers of care standards must reported promptly to the PRSB for review.

2 Introduction

NHS Digital (NHSD) commissioned the Professional Record Standards Body (PRSB) to support the Social Care Pathfinder Programme; by development of (new and existing) national information standards and guidance product. It is intended that the above standards and guidance product will be used across the UK.

The programme has funded 16 local 'pathfinder' organisations to extend their successfully piloted digital solutions in health and social care to a national scale. From these, PRSB identified five use cases for consultation that were developed into the following national products:

Two new transfer of care standards:

- ***Urgent Referral from Care Home to Hospital [Ref.1]***
- ***Hospital Referral for Assessment for Community Care and Support [Ref.2]***

(*NB*: This document and the associated transfers of care hazard log relate only to the above two Digital Social Care Information products covering transfers of care)

A new standard for local authority data and update of relevant sections of the PRSB Core Information Standard (CIS):

- *Local Authority Information (For Shared Health and Care Records)*

A view of the PRSB Core Information Standard specifically for care home staff:

- *Care Homes View (Of Shared Health and Care Records)*

An update to the *About Me* section of the following standards:

- Core Information Standard, Urgent Referral from Care Home to Hospital, Care Homes View (of Shared Health and Care Records), Digital Care and Support Plan (DCSP)

(*NB*: The three Digital Social Care Information Products immediately above, which do not relate to transfers of care, are covered in the updates to the Core Information Clinical Safety case and Hazard Log).

3 System Definition / Overview / Scope

3.1 Purpose, definition and scope of Urgent Referral from Care Home to Hospital standard

A care home resident could be urgently referred to hospital after a GP has seen the resident (during normal working hours). Typically, in this case a GP referral letter would be transferred with the resident. However, in cases where the resident must be treated urgently and a GP cannot be contacted (out of hours), the care home staff would call an ambulance.

The standard defines what information should be shared by a care home to secondary care in an emergency and was based on the data requirements for the Hospital Transfer Pathway (Red Bag) initiative developed by NHS Sutton CCG. Further background information can be found in implementation guidance for the standard [Ref.3] and Digital Social Care Information final report [Ref.4].

3.1.1 What it is

The Urgent Referral from Care Home to Hospital standard **is**:

- a definition of the information required by the hospital team to holistically continue the care and treatment of an adult patient when admitted from a care home to hospital in an emergency
- applicable to urgent referrals from all care home types – nursing and residential (including those for people with severe learning or physical disabilities)
- IT system agnostic
- Designed to support the digital sharing of information

3.1.2 What it is not

The Urgent Referral from Care Home to Hospital standard **is not**:

- a definition of how information should be presented to professionals
- a definition of how the information should be captured / sourced

3.1.3 How it works

The standard includes a core set of information that is directly related to the referral and identifies other important information pertaining to the person, for example an end-of-life care plan, which should be available to health professionals responsible for the resident's hospital care. This additional information may be held by the care home, by the GP or in other records and may be in the form of structured data or documents.

Documents may be communicated as attachments or be made available from other records.

3.2 Purpose, definition and scope of Hospital Referral for Assessment for Community Care and Support

The Hospital Referral for Assessment for Community Care and Support standard defines the information requirements in respect of an adult person being referred from hospital to health and social care for the primary purpose of determining ongoing social and health care support following discharge from hospital.

The standard includes, but is not limited to, the minimum information which may be required for pathways 1 -3 of the Discharge to Assess process and also the information which currently must be sent to the person's local authority as part of the Assessment, Discharge and Withdrawal Standard notice(s) information, the purpose of which is set out in the Assessment, Discharge and Withdrawal Notices Information Standard (SCCI 2075, 2016). Further background information can be found in implementation guidance and Digital Social Care Information final report and implementation guidance [Ref.5].

3.2.1 What it is

The Hospital Referral for Assessment for Community Care and Support standard **is**:

- a definition of the information to be shared with the responsible body (local authority social care team or community health) for referring an adult for assessment for care and support by social services and/ or NHS services after discharge from an acute hospital

- the information set that should be available to the responsible body (local authority) to enable them to decide if the person needs to be assessed under the Care Act and what care and support is likely to be needed.
- applicable to individuals who require care and support, after discharge, in their own home or if placed in an accommodation setting such as a care home.
- supportive of and is an integral part of the discharge planning and process for these individuals.
- for adults only
- supportive of the information elements that are needed to extract ADW notices to the local authority.
- IT system and discharge pathway agnostic.
- compliant with Care Act 2014 discharge pathway information requirements.
- compatible with the Discharge to Assess process

3.2.2 What it is not

The Hospital Referral for Assessment for Community Care and Support standard **is not**:

- defining the discharge planning, process or pathway that takes place locally

- guaranteed to include all the referral information required for a person discharged from a mental health service because it is developed for a person who has received care in an acute hospital
- for adults who do not need care and support after discharge from hospital
- for people who wish to make private arrangements for care and support without the involvement of the local authority (it is recognised the local authority may still become involved for self-funded persons)

a definition of how information should be presented to professional

3.2.3 How it works

The standard includes a core set of information that is communicated in the referral and references other important documents pertaining to the person which should be accessible. These additional documents may be communicated as attachments or be available from shared care records. For example, if an end of life care plan exists it is important that this is communicated in the referral and the recipient is sent the document or knows where to access it.

3.3 Purpose, definition and scope of Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for the PRSB Digital Social Care Information products[1] relating to transfers of care addresses the requirements of DCB/ ISB 0129 V4.2Clinical Risk Management: it's Application in the Manufacture of Health IT Systems [Ref.6].

The full application of DCB0129 cannot be applied, as the professional products themselves are 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.

3.3.1 Inclusions to scope

The scope of the clinical safety case for transfers of care **includes** the following:

- The transfer of care standards 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

3.3.2 Exclusions to scope

The scope of the clinical safety case for transfers of care **excludes** the following:

- The source of the data and structure of data being shared;
- The logical data model and database design;
- The graphical user interface (GUI) seen by end users in hospitals, care homes, local authorities or elsewhere and the way in which the data is rendered in that view.

3.3.3 Use

This document and the associated transfers of care hazard log relate only to the following Digital Social Care Information products:

[1] In this document, the term 'Digital Social Care Information product(s)' refers to the following national products:

- **Urgent Referral from Care Home to Hospital**
- **Hospital Referral for Assessment for Community Care and Support**
- Local Authority Information (For Shared Health and Care Records)
- Care Homes View (Of Shared Health and Care Records)
- About Me

(*NB:* Items in bold relate to transfers of care)

- Urgent Referral from Care Home to Hospital standard
- Hospital Referral for Assessment for Community Care and Support Standard

Other Digital Social Care Information products (Local Authority Information (For Shared Health and Care Records), Care Homes View (Of Shared Health and Care Records), About Me) are covered in the forthcoming update of the PRSB Core Information Standard (CIS) Clinical Safety Case Report and Hazard Log.

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. 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.7].

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:

- 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.
- 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 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.

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 Digital Social Care Information products and specifically explored at several advisory group meetings. A hazard workshop (two sessions) was convened to explore all the risks to patient safety and develop the Transfers of Care Hazard log. Details of these specific meetings are described here:

Hazard Workshop 1			
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 2			
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

There are two hazard logs relevant to the Digital Social Care Information products:

- PRSB Transfers of Care Hazard Log. It covers hazards relating to the two transfers of care standards – the Urgent Referral from Care Home to Hospital and Hospital Referral to Local Authority, which this clinical safety case relates to.

- PRSB Core Information Standard (CIS) Hazard Log, which relates to the other standards in the Digital Social Care Information products. (Update in progress – Covers hazards relating to the Local Authority Information (For Shared Health and Care Records) and About Me standards and the Care Homes View (Of Shared Health and Care Records) Guidance product). When completed, consult the updated clinical safety case report and hazard log for the CIS.

The full Transfers of Care Hazard Log is attached as a separate Excel document. The Hazard table in Appendix B lists the hazards for the two transfers of care standards 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

There were 48 hazards identified that are listed in the Digital hazard log. The hazards are classified as either generic hazards or hazards specific to transfers of care.

9 Residual Hazard Risk Assessment

There are five hazards with a residual risk of 3, which is undesirable. Hazard 15 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 Digital Social Care Information products into an EHR. Action is essential to mitigate Hazard 15 and should be seriously considered in all level 3 risks. The residual hazards are as follows:

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

It is recognised that the standards are 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 related to transfers of care may include:

- 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 transfer of care standards)

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.

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 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. There is ongoing work in this area to establish what should be contained in these sections.

Hazard 15: 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.

Hazard 23: Failure to adopt record standard(s)
The development of the standards needs to be supported in their 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. 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 30: 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.

10 Training

Training of the end users of the Digital Social Care Information products 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.

11 Test Issues

As the Core Information Model and associated Digital Social Care Information products are conceptual models 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 implementing the standards doing full end to end clinical safety testing.

12 Summary Safety Statement

Forty-eight potential hazards were identified. All hazards were identified through the consultation processes carried out to assure the two Digital Social Care Information products relating to transfers of care, which includes the following:

- Urgent Referral from Care Home to Hospital
- Hospital Referral for Assessment for Community Care and Support

The consultation process is described in detail in the Digital Social Care Information final report and section 6 of this document. It included patient and carer representatives as well as professionals from Royal Colleges, specialist societies, allied health professions, health informatics professionals, and local authority and care home workers.

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

- mitigated by the development of the standards

or

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

Initially one Hazard was assessed at level 4 and fourteen at level 3. After mitigation, the residual hazards were assessed as being at level 3 in five cases and the remainder had been reduced to level 2. The five rated at level 3 have been described in section 9 of this document.

The hazard initially assessed at level 4 is where Sex and gender are both included in the model. This is regarded as unacceptable and the transfers of care are not deemed safe to deploy until that risk is controlled by one of the mechanisms described. These are outside the control of PRSB, but clearly stated in the implementation guidance. It is on this basis that the risk is reduce to level 3.

The mitigations for the level 3 risks are also outside the control of PRSB and these risks are therefore handed on to the deployers of this standard.

The majority of hazards are rated as a risk acceptability level of 2. That is regarded as an acceptable level of risk. However, developers and implementers should take note of the risks and where possible try to minimise them.

The transfers of care 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.

13 Document Control and Post Standards Approval Maintenance

Future governance of the development and maintenance of the Digital Social Care Information products 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 Digital Social Care Information products.

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