Professional Record Standards Body

Better records for better care

Diabetes Record Information Standard and Self-Management Information Standard

Clinical Safety Case Report

April 2022

Document Management

Revision History

Version	Date	Summary of Changes
0.1	24.03.2022	First draft created by Andy Rooks, CSO and Sarah Jackson based on the Core Information Standard safety case
1.0	21.07.2022	Uplifted version number to 1.0 for approved version, added hyperlinks to published documentation and removed comments.
1.1	30.12.2022	Updated version following endorsement to include standard name changes revised for ISN. Removed reference to generic hazard list.

Reviewed by

This document must be reviewed by the following people:

Name	Signature	Date
Clinical Safety Officer	Andy Rooks	30/06/2022
PRSB Assurance Committee	PRSB Assurance Committee	26/04/2022

Approved by

This document must be approved by the following people:

Name	Signature	Date
Clinical Safety Officer	Andy Rooks	30/06/2022
PRSB Assurance Committee	PRSB Assurance Committee	26/04/2022
Project Board	Project Board	01/06/2022
NHS Digital Clinical Safety Group	NHS Digital Clinical Safety Group	11/07/2022

Glossary of Terms

Term / Abbreviation	What it stands for
CGM	Continuous Glucose Monitor
CIS	Core Information Standard

CSCR	Clinical Safety Case Report
CSG	Clinical Safety Group
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
DCB	Data Coordination Board
EMIS	Egton Medical Information Systems
GP	General Practitioner
GUI	Graphical User Interface
NICE	National Institute for Health and Care Excellence
PRSB	Professional Record Standards Body
SNOMED CT®	Systematized Nomenclature of Medicine – Clinical Terms
TPP	The Phoenix Partnership

Related Documents

Ref no	Title
[1]	Core Information Standard v2.0, 2021, 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]	Core Information Standard Clinical Safety Case Report v1.7, April 2021, Professional Record Standards Body
[6]	DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems
[7]	Diabetes Self-Management Information Standard v1.0, Professional Record Standards Body
[8]	Diabetes Record Information Standard v1.0, Professional Record Standards Body

[9]	Diabetes Information Standards Final Report v1.1, Professional Record Standards Body
[10]	Diabetes Information Standards: Survey Results and Analysis v1.1, Professional Record Standards Body
[11]	Diabetes hazard log v1.0

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1 Executive Summary and Safety Statement

This is a Clinical Safety Case Report (CSCR) for both the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard. The clinical co-dependency of both standards on the information flow and ultimately clinical management of diabetic patients was obvious. This led to the decision to combine both standards into one CSCR. This allows hazards from both standards to be explored in a practical manner following the information flow.

The PRSB Core Information Standard (CIS) [Ref.1] is an information model for a shared care record designed to support bringing together information from multiple sources across health and social care that it was felt to be important to share.

The two diabetes standards - the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard are based on the Core Information Standard and therefore the hazard log and CSCR for the CIS (which have been updated as the standard has developed over time) were used as a starting point in the development of this CSCR.

The PRSB standards are developed with extensive consultation. The consultation for the Core Information Standard (CIS) on which the diabetes standards were based is set out in the final report [Ref.4] and the Survey Results and Analysis [Ref.2].

The development of the two diabetes standards also involved extensive consultation with people with diabetes, their carers, health and care professionals and medtech (device suppliers) and clinical systems suppliers as set out in the Final Report [Ref.9] and Diabetes Information Standard Survey Results and Analysis [Ref.10].

PRSB was asked to define two standards:

- a Diabetes Record Information Standard (an information model for the information that should be shared across the system between healthcare professionals to enable them to provide care and support for the person with diabetes).
- a Diabetes Self-Management Information Standard (an information model for information that people use at home to manage their diabetes that they want to share with their healthcare teams).

The standards are information models which are structured into sections e.g. demographics, investigation results and assessments, with mandatory, required or optional data items under each section. They set out the content and structure of the information that should be shared or available.

The actual data visible in the clinical systems, however, is entirely dependent that data having been recorded, shared and processed appropriately. The user experience is dependent on the design of the systems and the graphical user interface (GUI). We have given very limited generic ideas of how the design of the system and GUI may help with mitigation but essentially this is out of scope of the CSCR.

Implementation of clinical systems using these two standards would require local clinical safety cases.

The two information models are not exhaustive and do not represent all information that would be recorded about a person with diabetes in clinical systems. For example, if a person with diabetes becomes pregnant, information about that and previous pregnancies would also be required and recorded. The scope of the standards is limited to the information required by health and care professionals in the management of a person's diabetes. Therefore, it is expected that other information would be recorded and available to the health and care professionals in the clinical systems. As a result, the information shared using the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard is in no way a replacement for existing health record systems.

This safety case is for sharing key information about a person's diabetes across the system for the purpose of direct care. This will require the ability to read from and write to existing records across the system, including GP, community and hospital records. Any use for secondary uses of the data should also consider any clinical safety impacts.

The hazard workshops over the course of the iterative development of the Core Information Standard identified 44 hazards details can be found in the CIS CSCR [Ref.5]. This remains an overarching reference report for all clinical safety work on new standards.

In developing this CSCR the 44 hazards were reviewed and combined and a generic list of 10 hazards has been developed for consideration in the development of CSCRs for future standards (see this report and hazard log).

The generic hazards were considered against the clinical scope of the two diabetes standards. All 10 generic hazards were found to be appropriate to the safety argument for both information standards.

The two hazard workshops for diabetes standards identified 4 unique hazards.

The generic hazards and unique hazards were combined to form a hazard log for this CSCR. A summary of the hazard log can be found in the table below.

Risk Classification	No of Risks	Status		Stage		AFAP	
Class 5 – Very High	0	N/A		N/A		N/A	
Class 4 – High	0	N/A		N/A		N/A	
Class 3 – Medium	2	Partially Mitigated by Design and Control	2	Open Transferred	2	Undesirable	2
Class 2 - Low	12	Mitigated by Design and Control Partially Mitigated	12 0	Open Transferred	12	Tolerable	12
Class 1 – Very Low	0	Mitigated by Design Mitigated by Control Mitigated by Design and Control Partially Mitigated Live	0 0 0 0 0	Satisfied Open Transferred	0 0 0	Acceptable	0
Class 0 – Nil	0	Mitigated	0	Mitigated	0	No Clinical Risk	0
Total	**14**						

There were 2 Medium risks identified that remained undesirable and 12 low risks that were acceptable. All risks identified in the hazard log are transferred, to those who implement clinical systems that incorporate the two diabetes standards. Further details in the hazard log.

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

This clinical safety case should be reviewed on an annual basis.

2 Introduction

2.1 PRSB diabetes standards – the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard

The aim of diabetes standards project is to address two key challenges:

1. With increased self-management of diabetes (and other long-term conditions) and increasing use of devices and apps (such as Flash Glucose Monitors and Continuous Glucose Monitors (CGMs) to monitor glucose levels and pumps or connected pens to administer insulin) to support self-management, the data generated can be shared with clinicians and used in clinic or during remote consultations. However, there is currently no information standard for self-reported data related to diabetes, which means that different devices and apps cannot always share data with clinical systems. Healthcare professionals often have to access the data via third-party (proprietary) software meaning they may have to access multiple platforms to view the data they need to help a person manage their diabetes. Clinicians are not always

able to access the proprietary software (because of local restrictions) and information cannot be brought together for comparison if, for example a person is using a pump by one manufacturer and a CGM device from another manufacturer. The information cannot be easily imported in a structured way into the person's electronic health record.

2. It is also difficult to digitally share diabetes information about a person (e.g., care plans) between professionals across different settings and within multidisciplinary teams, leading to a risk of harm. This may also lead to patients having to tell their story more than once and duplication of clinical effort or investigations, for example patients under consultant-led care may have blood tests performed in the hospital setting but because the information is not shared with the GP the blood tests are repeated, if a person is admitted to hospital, information about the latest foot check is not always available in the hospital setting. There is no nationally agreed information standard for the information structure and content for a diabetes record in England.

These standards 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.

The PRSB diabetes standards have been developed following extensive consultation with people with diabetes, their carers, health and care professionals and medtech (device suppliers) and specialist diabetes and non-specialist clinical systems suppliers.

They are intended to be information models that define the structure and content of information about a person with diabetes that:

- the person with diabetes collects and uses at home to manage their diabetes and wants to share with their healthcare team; and
- healthcare professionals working in multi-disciplinary teams across all settings (primary, community, secondary and social care) have said it is important to share about a person's diabetes across the system to support the person in the management of their diabetes.

The standards do not set out how the information should be displayed in the clinical systems for healthcare professionals viewing the information.

Also, it does not set out all the information that is required in the clinical system, just a subset – specifically the key information for helping someone to manage their diabetes. For example, if the person is pregnant, it describes the information related to the pregnancy that is important for managing the diabetes but does not describe the information needed to manage the person's pregnancy.

Implementation and use of the two information standards will require retrieval of information from and writing of information to a person's electronic records (including GP, community and hospital records) to make the information available for the purposes of direct care. This Clinical Safety Case Report is based on the use of the

information standards to support direct care. Any use for secondary uses of the data should also consider any clinical safety impacts.

2.2 Purpose of the Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for both the Diabetes Self-Management Information Standard and the Diabetes Record Information Standard addresses the requirements of DCB 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 standards themselves are not manufactured health IT systems. 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 Scope

The Diabetes Record Information Standard and the Diabetes Self-Management Information Standard are based on the information model for the CIS.

The diabetes standards were developed using the same methodology as the main CIS, with a review of the evidence then wide stakeholder consultation and iterative development of the standard.

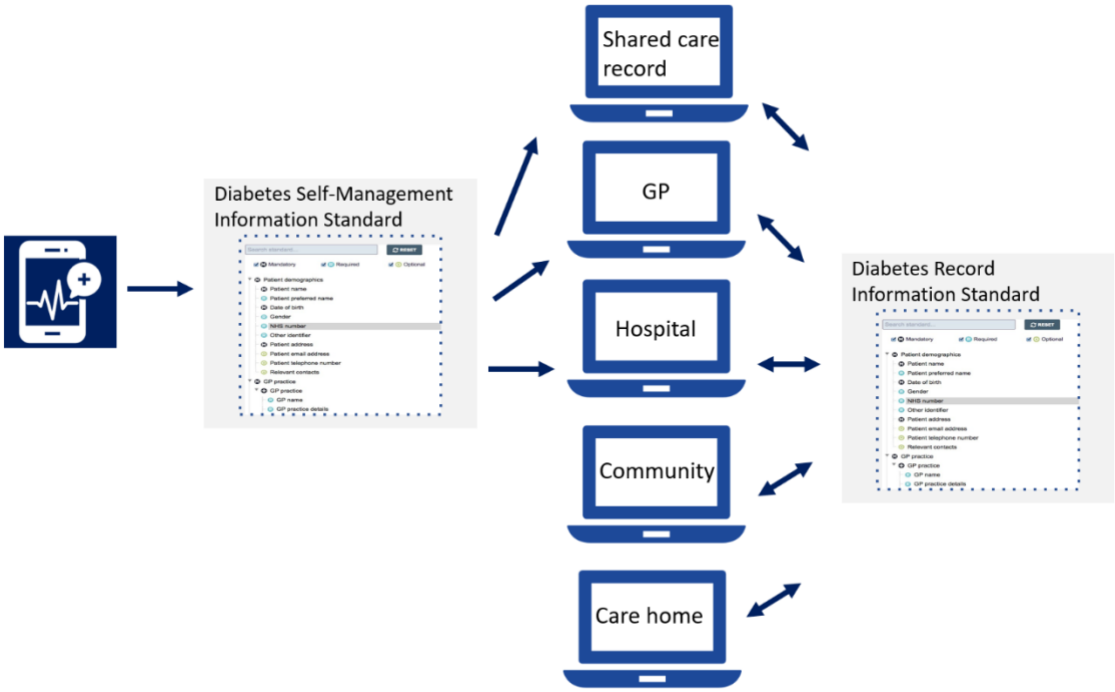
The scope of the diabetes standards is:

- all types of diabetes including type 1, type 2, gestational and monogenic diabetes.
- the 9 care processes defined by NICE for diabetes management (and the SIGN guidelines). The 9 care processes are:
    - Glycated haemoglobin (HbA1c) measurement.
    - Blood pressure (BP) measurement.
    - Cholesterol level measurement.
    - Retinal screening.
    - Foot checks.
    - Urinary albumin testing.
    - Serum creatinine testing.
    - Weight check.
    - Smoking status check.
- regular glucose monitoring and insulin dosing (outside the 9 care processes).
- children and adults (note: the Core Information Standard and Personalised Care and Support Plan standard have been tested for adults only).
- primary, community, mental health and secondary care services and in council provided and independent residential care homes and support workers providing to support to people in shared lives / supported accommodation, domiciliary care and informal carers.

The Diabetes Self-Management Information Standard is a subset of the Diabetes Record Information Standard and is to support the information that people with diabetes want to share with their healthcare team collected and recorded by medical devices (e.g. Continuous Glucose Monitors and insulin pumps) or in lifestyle apps and is needed to support the 9 care processes, glucose monitoring and insulin dosing.

The Clinical Safety Officer was keen to interrogate the two diabetes information standards together as the information flows that the standards support are linked. The hazard workshops were well attended by key qualified staff.

3.1 Illustration of the application of the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard



3.2 Out of Scope

The following are out of scope of this CSCR:

- Medical devices do not form part of this CSCR as they are MHRA regulated, however the ultimate information from the device does fall in scope
- The graphical user interface (GUI) in clinical systems for viewing the information and the way in which the data is rendered in that view. However very broad guidelines that would help to mitigate risk do form part of the hazard log.

3.3 Use

The standards would support all people with diabetes and health and care professionals who are involved in the management of the person's diabetes e.g. GP,

podiatrist, community / district nurses, Diabetes Specialist Nurses, hospital team including paediatrician, endocrinologist, vascular surgeon, ophthalmologist etc.

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 Data Alliance Partnership Board (DAPB) and the process in which professional standards are developed in the CSMS framework. The essential structures of a CSMS have been implemented in this project through the consultation with healthcare professionals, people with diabetes, informaticians and medtech and clinical system suppliers, during the development of the diabetes standards. Governance structures, project methodology and stakeholder engagement are described in the Diabetes Information Standards Final Report [Ref.9]. 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 CSCR 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 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 people with diabetes include:

- Safety issues identified by clinical and citizen advisors and patient advisors participating in two hazard workshops (on 8th and 10th February 2022).
- Safety issues identified by clinical and citizen advisors participating in weekly project meetings over the course of the project.
- Potential clinical safety issues identified by stakeholder participants during consultation survey (n=280) and other consultations (4 online workshops, engagement with medtech and clinical systems suppliers) undertaken during the development of the diabetes standards.
- 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 clinical safety case report (approaches to mitigating the risks identified).
- Final draft of hazard log and clinical safety case 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 for these standards 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 project to develop the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard. These risks were specifically explored at two hazard workshops and project team meetings.

Details of these meetings are described below:

Hazard Workshop 1			
Date	08.02.2022	**Time**	13:00 – 14:00
Location	Conducted via MS Teams		
Attendees:			
	Name	**Role**	
Chair	Andy Rooks	Clinical Safety Officer Clinical Safety Officer– Data and Digital, North of England Commissioning Support	
	Dr Iain Cranston	Consultant Physician, Diabetes and Endocrinology Portsmouth Hospitals NHS Trust	
	Ojaih Willow	Citizen Lead	
	James Luke	Senior Project Manager - Data and Digital, North of England Commissioning Support	
	Charlie McCay	PRSB Non-Executive Director, Technical	
	James Critchlow	PRSB Researcher and Analyst	
	Sarah Jackson	PRSB Project Manager	

Hazard Workshop 2			
Date	10.02.2022	**Time**	10:00 – 11:00
Location	Conducted via MS Teams		
Attendees:			
	Name	**Role**	
Chair	Andy Rooks	Clinical Safety Officer Clinical Safety Officer– Data and Digital, North of England Commissioning Support	
	Dr Neel Basudev	GP, Lambeth CCG	
	Dr Steve Bentley	GP, PRSB Clinical Advisor	
	Ojaih Willow	Citizen Lead	
	James Luke	Senior Project Manager - Data and Digital, North of England Commissioning Support	
	Charlie McCay	PRSB Non-Executive Director, Technical	
	James Critchlow	PRSB Researcher and Analyst	
	Sarah Jackson	PRSB Project Manager	

7 Hazard log

The Hazard log was constructed in two sections.

The original CIS hazards were combined and the wording standardised as necessary to create 10 generic hazards for consideration in relation to all future PRSB standards. This generic list of potential hazards was utilised in the two diabetes standards being assessed. The risk scores were reviewed and modified where necessary for the standards under review in the CSCR. Please be assured this did not change the original CIS CSCR original risk scores.

The generic hazards that were felt to be applicable to these standards were then added to the unique hazards identified for these standards.

The full hazard log is attached as a separate Excel document [Ref.11] The hazard table lists the hazards identified together with summary information about each hazard, the mitigations identified and the residual risk score. Some risks have been flagged relating to implementation in this report but expect that further mitigations will be identified as clinical risk assessments and safety cases are developed by systems suppliers and sites during the implementation.

8 Hazards

There were 14 hazards identified in total that are listed in the hazard log. Ten were identified from the generic hazard list (all were in scope for these standards) (see table below).

Hazard Number	Title	Definition	In Scope?
PRSB_1	Important data not available	The information standards are designed for supporting data sharing for specific scenarios. They will not include all the information that exists in health and care systems about the patient/service user.	Y
PRSB_2	Poor data quality	Data in source system is of poor quality. It is incomplete, incorrect, out of date or inconsistent. For example, data which has a time limit is retained past that limit. Such as information on the Child Protection Register.	Y
PRSB_3	Important data not found or incorrectly interpreted	Critical data in the system is hard to locate, missed, misinterpreted or represented incorrectly. Where the record is shared with the patient, information may be difficult to understand/interpret by patient.	Y
PRSB_4	Accidental disclosure of gender reassignment	Accidental disclosure of gender reassignment, without consent, due to inclusion of both patient's 'sex/ phenotypic sex' and 'gender' in demographics section.	Y
PRSB_5	Use of different versions of the standards	Using different versions of standards (including terminology standards, e.g. SNOMED CT) or use of local proxy codes which may not be recognised or properly interpreted by receiving systems.	Y
PRSB_6	Inappropriate data sharing	Risk of sharing confidential information inappropriately - too little or too much. Patient sees information that they were not aware existed and might be sensitive for example new test results or diagnoses, information about a third party e.g. a parent or information they disagree with or are not aware of. Examples include "Binge Drinker" or "Vulnerable Adult" or "Adopted".	Y
PRSB_7	Failure to adopt standards	Service providers may refuse to adopt and use the standards or systems suppliers may not implement the standards.	Y
PRSB_8	Information is available in formats that are not accessible	The information may be entered into the source system and shared in a format that in inaccessible in the receiving system such as multimedia attachments.	Y
PRSB_9	Burden on healthcare professionals	Unrealistic data entry burden for healthcare professionals meaning that most important information is not recorded. Or overpopulation of information means that healthcare professional is unable to view all the information.	Y
PRSB_10	Utilising standards for out of scope and out	The standard is used to provide information for purposes for which it was not designed e.g. in prisons and it does not fully support the information needs for that cohort of patients.	Y

	of context reasons.		

A further 4 hazards were identified as unique to these standards. Diab_2 was like PRSB_9. However, it was felt it had unique aspects that added strength and depth to the safety argument. (See table below).

Hazard Number	Title	Definition
DIAB_1	Inappropriate treatment or delay to patient care from information sent from a medical device	Patients requires a device eg mobile phone / laptop / tablet to access information from their medical device in order for them to manage their health effectively. Clinician also have a reliance on this information to give appropriate care. .Health IT Systems that allows a constant flow of patient-generated information to healthcare professionals can blur the boundary of accountability for acting on the information
DIAB_2	The volume of clinical information presented to health care professionals hinders the consultation given to the patent, (similar to PRSB_9).	It is recognised that data from medical devices can give overwhelming levels of detail and frequency of data. This can impact on the patient and clinicians consultation.
DIAB_3	Health care professional provides inappropriate advice based on unvalidated data.	Utilising patient information that is not validated and cannot be verified this information can be harmful and could lead to healthcare professionals providing advice based on unvalidated data.
DIAB_4	Health care professional unaware of critical piece of information that requires clinical intervention.	Information from the medical device or other Health IT systems is not compliant with the standard and therefore misinterpreted, incorrect, or missing in the record.

9 Hazards with a risk score higher than 3 following mitigation

The updated hazard log consists of 14 hazards. Four unique hazards were identified in the development of the diabetes standards.

There are 6 hazards with an initial risk of 3 or more. After controls and mitigations there remain two hazards with a residual risk of 3, which is undesirable.

All the residual risks in the Hazard log will be transferred to those incorporating the diabetes standards into clinical systems.

Action is essential to mitigate Hazard PRSB_4 and PRSB_7 as they are undesirable. 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:

Hazard PRSB_4: Accidental disclosure of gender reassignment

As both ‘sex’ and ‘gender’ are included in the demographics section of the standard. Display of this information in clinical systems needs to be carefully considered as gender reassignment maybe disclosed if these do not match. Disclosure without consent could cause severe psychological harm to patient and possibly significant others. Some systems e.g. EMIS and TPP only display ‘gender’ which would mitigate this risk.

Hazard PRSB_7: Failure to adopt standard

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 organisations 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.

10 Dependencies

Mitigations include:

- Effective system design including – deduplication and processing of data, user interface design and display of data using graphs and summary metrics, appropriate archiving of information.
- Conformance with latest versions of national standards such as SNOMED CT.
- Ensuring the provenance of all information is shared with the information and is clearly displayed.
- Full end to end clinical safety testing by those implementing the standards, they should provide evidence of successful testing as part of their own clinical risk management activities.
- Training of the end users in understanding 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.

11 Summary Safety Statement

The original CIS hazards were formalised with consultation from 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. This resulting in the CIS

CSCR. The hazards identified were then combined into generic hazards to allow the golden thread of this fundamental work to be used in clinical safety reviews of other standards developed by the PRSB.

The diabetes standards (based on the core information standard) were developed through consultation with people with diabetes, multi-disciplinary teams and system and technology suppliers [Ref. 9].

Two hazard workshops took place for the diabetes standards attended by the CSO, a Consultant Physician, two GPs, citizen lead, PRSB non-executive director, PRSB analyst and PRSB project manager (see section 6.4). The generic hazard checklist was scrutinised, and applicable hazards were identified together with unique hazard for the two standards.

There were 14 hazards identified that are listed in the hazard log. Ten were identified from the generic checklist and 4 were unique to this standard

The hazard overview box below gives an overview of all hazards identified in this CSCR. Please see hazard log for more information.

Risk Classification	No of Risks	Status		Stage		AFAP	
Class 5 – Very High	0	N/A		N/A		N/A	
Class 4 – High	0	N/A		N/A		N/A	
Class 3 – Medium	2	Partially Mitigated by Design and Control	2	Open Transferred	2	Undesirable	2
Class 2 - Low	12	Mitigated by Design and Control Partially Mitigated	12 0	Open Transferred	12	Tolerable	12
Class 1 – Very Low	0	Mitigated by Design Mitigated by Control Mitigated by Design and Control Partially Mitigated Live	0 0 0 0 0	Satisfied Open Transferred	0 0 0	Acceptable	0
Class 0 – Nil	0	Mitigated	0	Mitigated	0	No Clinical Risk	0
Total	**14**						

12 risks are rated as a risk acceptability level of 2. This level is acceptable but should nevertheless be considered by those deploying the standard therefore they have been left open and transferred.

2 risks 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”. Both of these are transferred risks.

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.

Accredited CSO Safety Statement: Clinical safety risk of the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard has been assessed by an accredited Clinical Safety Officer (CSO) as being acceptably safe for general release; according to the safety argument and evidence summarised in this Diabetes Record Information Standard and Diabetes Self-Management Information Standard Clinical Safety Case Report.

12 Document Control and Post Standards Approval Maintenance

Future governance of the development and maintenance of the Diabetes Record Information Standard and the Diabetes Self-Management Information Standard is the responsibility of the PRSB.

13 DCB 0129 Compliance Matrix

The table below summarises the compliance status of this safety case for the PRSB Diabetes Record Information Standard and Diabetes Self-Management 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 Diabetes Record Information Standard and the Diabetes Self-Management Information

		Standard 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 Diabetes Record Information Standard and the Diabetes Self-Management Information Standard 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 Diabetes Record Information Standard and the Diabetes Self-Management Information Standard Information products and implementation guidance.
7.2 Post-deployment monitoring	N	Not required for a professional standard.

7.3 Modification	Y	See section 13

14 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