Professional Record Standards Body

Better records for better care

Shared Decision Making Standard
Clinical Safety Case Report

October 2022

Document Management

Revision History

Version	Date	Summary of Changes
0.1	13.06.2022	First draft created by Steve Bentley, CSO and James Critchlow
0.2	07.07.2022	Minor formatting updates
0.3	10.10.2022	Updates following feedback from NHSD clinical safety group
1.0	12.10.2022	1st Version after NHS Digital Clinical Safety Group approval

Reviewed by

This document must be reviewed by the following people:

Name	Signature	Date
Clinical Safety Officer	Steve Bentley	10.10.2022
PRSB Assurance Committee		
Project Board		

Approved by

This document must be approved by the following people:

Name	Signature	Date
Clinical Safety Officer	Steve Bentley	08.10.2022
NHS Digital Clinical Safety Group	NHS Digital Clinical Safety Group	12.10.2022

Glossary of Terms

Term / Abbreviation	What it stands for
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
NHSEI	NHS England and Improvement
NICE	National Institute for Health and Care Excellence
PCSP	Personalised care and support plan
PRSB	Professional Record Standards Body
SDM	Shared decision making
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]	Shared Decision Making Standard v1.0, Professional Record Standards Body
[8]	Shared Decision Making Standard Business Rules v1.0, Professional Record Standards Body
[9]	Shared Decision Making Standard Final Report v1.0, Professional Record Standards Body
[10]	Shared Decision Making Standard: Survey Results and Analysis v1.0, Professional Record Standards Body
[11]	Shared Decision Making Standard Hazard Log v1.0
[12]	Diabetes Information Record Standard and Self-management Data Standard Clinical Safety Case Report v1.0, Professional Record Standards Body
[13]	NICE guideline [NG197]: Shared Decision Making, June 2021, National Institute for Health and Care Excellence
[14]	GMC guidance: Decision Making and Consent, November 2020, General Medical Council

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1 Executive Summary and Safety Statement

This is a Clinical Safety Case Report (CSCR) for the Shared Decision Making (SDM) Standard.

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

PRSB has developed a list of generic hazards based on the Core Information Standard that may apply to many of our standards moving forwards and this was used as a starting point in the development of this CSCR with additional SDM specific hazards generated during the clinical safety review process. The use of generic hazards was originally piloted in the diabetes clinical safety case [Ref.12]

The development of the Shared Decision Making Standard also involved extensive consultation with patients, their carers, health and social care professionals and clinical systems suppliers as set out in the Final Report [Ref.9] and Shared Decision Making Standard Survey Results and Analysis [Ref.10].

PRSB was asked to define the following standard:

- a Shared Decision Making standard that provides a framework for clinicians to record the SDM process where a preference sensitive decision has been discussed. Development was informed by professional guidance, General Medical Council guidance on decision making and consent and the NICE guideline on shared decision making, evidence review, and extensive consultation with healthcare professionals, people and carers.

The standard is an information model that is structured into sections i.e. contacts with professionals, problem list, shared decision point and consent form details 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 on 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 this standard into clinical systems would require local clinical safety cases.

The information model is not exhaustive and does not represent all information that would be recorded about a person participating in a shared decision that would need to be available in clinical systems. For example, information in a person's about me record, personalised care and support plan (PCSP), or other sections defined in the

CIS (e.g. investigation results) may be relevant and would need to be available in the system to inform the SDM process. The scope of the standard is limited to the information required by health and care to record the pertinent components of the SDM process including the details of the discussion(s) had with the person(s) involved. Therefore, it is expected that other information would be recorded and available to the health and care professionals in the clinical systems where the SDM standard is used. As a result, the information shared using the SDM standard is in no way a replacement for existing health record systems.

This safety case is for sharing key information about the shared decision making process undertaken by a healthcare professional, a patient and involved others where a preference sensitive decision was discussed. It is expected that this information will be available across the system on a need to know basis 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 (e.g. anonymised collection of data around use of clinical decision support tools) 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 development of a previous CSCR [Ref.12] the 44 hazards were reviewed and combined into a generic list of 10 hazards for use in CSCRs of future standards. The generic list has been considered in the development of this SDM standard CSCR.

The generic hazards were considered against the clinical scope of the shared decision making standard. All 10 generic hazards were found to be appropriate to the safety argument for both information standards. The two hazard workshops (see tables 2 and 3 below) conducted on 12/05/22 and 19/05/22 for the shared decision making standard identified 8 unique hazards.

The generic hazards and unique hazards were combined to form a hazard log [Ref.11] for this CSCR. A summary of the hazard log can be found in table 1 below.

Table 1

Risk Classification	**Risk No.**	**Status**		**Stage**		**AFAP**	
Class 5 – Very High	N/A	N/A		N/A		N/A	
Class 4 – High	N/A	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	15	Mitigated by design and control	15	Open transferred	15	Acceptable	15
Class 1 – Very Low	1	Mitigated by design	0	Open transferred	1	Acceptable	1

		Mitigated by control	0	Open	0		
		Mitigated by design and control	0	Transferred	0		
		Partially mitigated	0	Closed	0		
		Live	1				
Class 0 - Nil	0	Mitigated	0	Mitigated	0	No clinical risk	
Total	**18**						

There were 2 Medium risks identified that remained undesirable and 15 low risks and 1 very low risk that were acceptable. All risks identified in the hazard log are transferred, to those who implement clinical systems that incorporate the shared decision making standard. Further details in the hazard log.

Any safety incidents occurring, which might be due to the shared decision making standard 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 Shared Decision Making Standard

The overall aim of the shared decision making standard project is to support the widespread adoption and use of shared decision making with an information standard that:

- Defines what should be recorded in a person's record about a shared decision.
- Supports ongoing discussions and provides an audit trail.
- Supports good professional practice as outlined in the GMC and NICE guidance on SDM.
- Supports evidence of compliance with the Montgomery judgement.
- Support sharing of SDM information with other professionals.
- Developed by wide consultation with of professionals, people, suppliers and informaticians; engaging beyond those who are supporters of SDM.

This standard will help health and care professionals to share information about a person's shared decisions safely and securely between relevant parts of the NHS.

The PRSB shared decision making standard has been developed following extensive consultation with patients, their carers, health and care professionals and clinical systems suppliers. It is intended to be an information model that defines the structure and content of information about a person's preference sensitive decision and the related SDM process.

The standard does 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 to inform the SDM process, just a subset – i.e. contacts with professionals, problem list, shared decision point and consent form details. For example, information from person demographics and in a person's About record, personalised care and support plan (PCSP), or other sections defined in the CIS (e.g. investigation results) may be relevant and would need to be available in the system to inform the SDM process.

Implementation and use of this information standard 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 (e.g. anonymised collection of data around use of clinical decision support tools) should also consider any clinical safety impacts.

2.2 Purpose of the Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for the Shared Decision Making 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 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 Scope

Certain components of the Shared Decision Making Standard are based on the information model for the CIS.

The SDM standard was 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.

3.1 In scope

The scope of the SDM standard includes:

- Applicable to all UK nations
- For all ages including children
- Alignment with NICE & GMC guidance
- The standard should be developed as far as is reasonably possible to be generic for wide use across all areas of care, and supported by high level use cases for these 8 areas:
    - Elective surgery including orthopaedics
    - Multiple long-term conditions

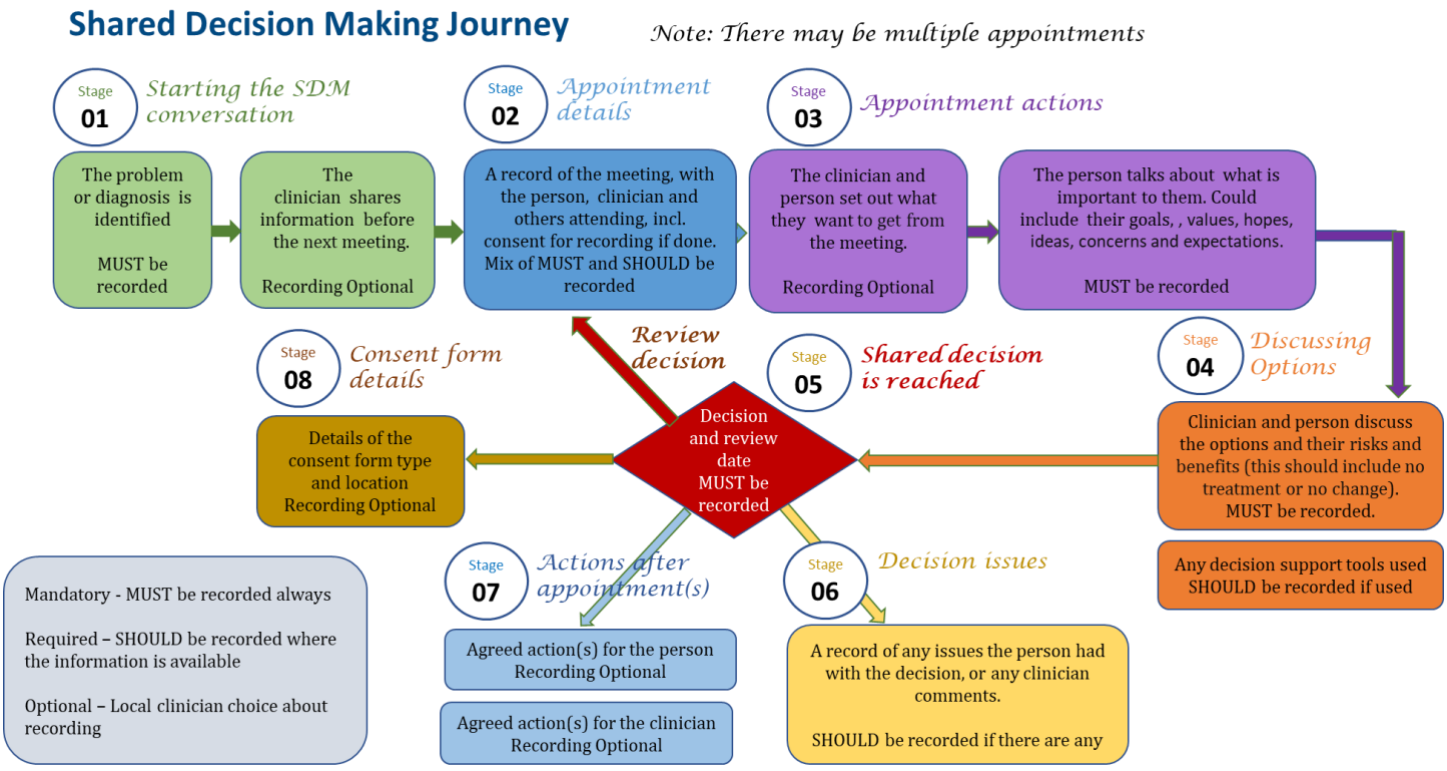
- Mental Health
- Cancer
- Children
- Genetic conditions
- Polypharmacy
- Gynaecology

- Endorsement by relevant professional bodies
- Approval of an Information Standards Notice (ISN) by the DAPB

The Clinical Safety Officer oversaw 2 hazard workshops (see tables 2 and 3) that were well attended by key qualified staff.

3.2 Illustration of the shared decision making process

The standard is evidence based and in particular draws on the NICE guideline [Ref.13] and GMC guidance [Ref.14]. The generic SDM journey below shows key stages of the SDM process and a high level view of the information recorded as specified in the standard. This journey will often be over multiple appointments and could be with different clinicians. The standard is designed for this and to allow for pauses in the process for consideration and reflection and for changes of the decision.



3.3 Out of Scope

The scope of the SDM standard does not include:

- Maternity. The standard may work for maternity, but it is believed that this complex area justifies specific additional work and potentially an extended standard.
- Social Care. SDM is defined for clinical uses and the consultation was targeted at healthcare professionals **not** social care professionals. However, the SDM principles may work in social care and in the future the standard could potentially be adapted for use in social care.
- Pilot testing – potentially part of a further phase of work
- Implementation support – potentially part of a further phase of work
- The major change programme around adoption of an SDM approach – this work will remain closely connected to related programmes which are dealing with the cultural and behavioural change involved but the work will be undertaken under those programmes and initiatives

3.4 Use

The standard would support all patients and health and care professionals who are involved in making a preference sensitive decision about their care using the SDM process.

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, patients, informaticians and clinical system suppliers, during the development of the shared decision making standard. Governance structures, project methodology and stakeholder engagement are described in the Shared Decision Making 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 12th and 19th May 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=498) and other consultations (1 online workshop (n=110)) undertaken during phase 2 and phase 1 respectively of the development of the SDM standard.
- 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.
- Review and approval of safety case deliverables by programme CSO
- 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 [Ref.11] 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 Information Record Standard and the Self-Management Data Standard. These risks were specifically explored at two hazard workshops and project team meetings.

Details of these meetings are described in tables 2 and 3 below:

Table 2

Hazard Workshop 1			
Date	12.05.2022	**Time**	09:00 – 10:00
Location	Conducted via MS Teams		
Attendees:			

	Name	Role
Chair	Dr Steve Bentley	GP and PRSB Clinical Safety Officer Clinical Safety Officer.
	Mr James Brown	Consultant vascular surgeon – Clinical Lead
	Lawrence Mudford	Citizen Lead
	Dr Nilesh Bharakhada	GP – Clinical Lead
	Martin Orton	PRSB Senior Project Manager
	Johnathan Berry	NHSE/I National Lead for Shared Decision Making
	Jeremy Wilkinson	NHSE/I Senior Manager, Digital Architecture – Personalised Care Group
	Surfraz Ahmed	NHSE/I Personalised Care Manager (Choice, SDM, PCSP)
	Helene Feger	PRSB Director of Strategy, communications and engagement
	James Critchlow	PRSB Researcher and Analyst
	Maria Griffin	PRSB Data Analyst
	Rebecca Hughes	PRSB Head of Partner Solutions

Table 3

Hazard Workshop 12			
Date	19.05.2022	**Time**	09:00 – 10:00
Location	Conducted via MS Teams		
Attendees:			
	Name	**Role**	
Chair	Dr Steve Bentley	GP and PRSB Clinical Safety Officer Clinical Safety Officer.	
	Mr James Brown	Consultant vascular surgeon – Clinical Lead	
	Lawrence Mudford	Citizen Lead	

	Dr Nilesh Bharakhada	GP – Clinical Lead
	Martin Orton	PRSB Senior Project Manager
	Johnathan Berry	NHSE/I National Lead for Shared Decision Making
	Jeremy Wilkinson	NHSE/I Senior Manager, Digital Architecture – Personalised Care Group
	Surfraz Ahmed	NHSE/I Personalised Care Manager (Choice, SDM, PCSP)
	Helene Feger	PRSB Director of Strategy, communications and engagement
	James Critchlow	PRSB Researcher and Analyst
	Maria Griffin	PRSB Data Analyst

7 Hazard log

The Hazard log [Ref.11] was constructed in two sections.

In previous work [Ref.12] 10 generic hazards from the original CIS hazards were combined and the wording standardised as necessary to create for consideration in relation to all future PRSB standards. This generic list of potential hazards was utilised in the assessment of the SDM standard. The risk scores were reviewed and modified where necessary for the standard under review in the CSCR, which did not change the original CIS CSCR risk scores.

The generic hazards that were felt to be applicable to this SDM standard were then added to the unique hazards identified for the standard.

The full hazard log [Ref.11] 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. 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. *NB*: This hazard log uses a legacy format and work to update this for future clinical safety cases is currently underway. It has been agreed with the NHSD clinical safety team that retrospectively updating these CSC documents is not required for approval.

8 Hazards

There were 18 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).

Table 4

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 8 hazards were identified as unique to these standards. SDM_3 was like PRSB_10 and SDM_5 was like PRSB_3. However, it was felt both had unique aspects related to shared decision making that added strength and depth to the safety argument. (See table below).

Hazard Number	Title	Definition
SDM_1	Ability to share the Shared Decision Making consultation data and decision	Sharing SDM data is key to supporting patient care enabling clinicians to see the shared decision and the steps to how the decision was reached. The risk is that professionals do not share a care decision leading to delayed or incorrect care that does not align with the agreed clinician and patient decision. A shared decision should be shared both with the patient and with other clinical professionals.
SDM_2	Key data not recorded or available in the system resulting in incorrect treatment.	The most important information must be available in a manner that supports shared decisions making. This includes recording the person's viewpoint towards a shared decision with equal importance to that of the clinician and ensuring care or treatment options, benefits, risks and the agreed decision are fully and accurately recorded. Incorrect or conflicting information that does not provide the full picture may result in incorrect decision making or lack of support for patients. If not recorded accurately, then it could adversely impact the decision (this applies to either person aspects or clinical options).
SDM_3	Standard used out of scope resulting in incorrect treatment.	The SDM standard is a generic standard designed to follow the shared decision making pathway and incorporate both GMC and NICE guidelines on shared decision making. The standard may need further testing and adoption for very specific areas of care. At present Maternity and Social Care are not in scope. To use the standard out of scope or without further testing for specific areas of care may lead to inappropriate shared decisions on a persons' care and treatment.
SDM_4	No diagnosis or diagnosis incorrect	Whilst the clinician is going through the process of SDM with a patient the clinician either, selects an incorrect diagnosis (reason for treatment), or no diagnosis is available on the system. The potential clinical impact is that incorrect decisions and treatments are made due to the incorrect diagnosis being selected.
SDM_5	Data misrepresented/not clearly displayed	This is particularly important for the final decision regarding the agreed options. This needs to be clearly displayed in systems, to ensure that options considered but not to go forward are clearly marked as such. The potential risk is that patient could have a wrong procedure scheduled or even performed.
SDM_6	Clinician uses SDM standard as a 'tickbox exercise'.	System users will be more focused on filling in the form than communicating with the patient and this may result in poor shared decision making.
SDM_7	Not all options are adequately	The system used to record the decision making process does not have enough fields to record all the

	recorded in the patient record.	options discussed. The unmitigated risk is that not all options discussed are recorded.
SDM_8	Shared decision status of “in progress” not noticed risking incorrect treatment	When a shared decision process is in progress it could be possible for the final decision to be filled in. Thus the record would look as if a final decision had been made when in fact it had not. The potential clinical impact is that it could be assumed that the patient had made a decision or declined a decision for a specific treatment. So, the patient may or may not receive the treatment in error.

9 Hazards with a risk score higher than 3 following mitigation

The updated hazard log consists of 18 hazards. Eight unique hazards were identified in the development of the SDM standard.

There are 11 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 shared decision making standard 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. The standard will be most effectively used where the end user has been trained in the shared decision making process

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 resulted in the CIS CSCR. In a subsequent project 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. In this project these generic hazards have been considered alongside SDM specific hazards.

The shared decision making standard contains some components based on the core information standard and requires the end user to have access to other CIS components for effective use including but not limited to the information in a person's about me record, personalised care and support plan (PCSP), or other sections defined in the CIS (e.g. investigation results). It was developed through consultation with patients, multi-disciplinary teams and systems suppliers.

Two hazard workshops took place for the SDM standard attended by the CSO, a Consultant surgeon, two GPs, citizen lead, three NHSEI representatives, PRSB director, two PRSB analysts 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 standard.

There were 18 hazards identified that are listed in the hazard log. Ten were identified from the generic checklist and 8 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	**Risk No.**	**Status**		**Stage**		**AFAP**	
Class 5 – Very High	N/A	N/A		N/A		N/A	
Class 4 – High	N/A	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	15	Mitigated by design and control	15	Open transferred	15	Acceptable	15
Class 1 – Very Low	1	Mitigated by design	0	Open transferred	1	Acceptable	1
		Mitigated by control	0	Open	0		
		Mitigated by design and control	0	Transferred	0		
		Partially mitigated	0	Closed	0		
		Live	1				
Class 0 - Nil	0	Mitigated	0	Mitigated	0	No clinical risk	
Total	**18**						

15 risks are rated as a risk acceptability level of 2 and 1 risk rated at level 1. 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 (version 0.5, 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. *NB*: This hazard log uses a legacy format and work to update this for future clinical safety cases is currently underway.

Accredited CSO Safety Statement: Clinical safety risk of the Shared Decision Making 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 Shared Decision Making Standard Clinical Safety Case Report.

12 Document Control and Post Standards Approval Maintenance

Future governance of the development and maintenance of the Shared Decision Making 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 Shared Decision Making 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 shared decision making standard information product 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 shared decision making standard information product 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 shared decision making standard information product 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

15 Appendix B – SDM Specific Hazards

Hazard Id:	SDM_1
Hazard Name	Ability to share the Shared Decision Making consultation data and decision
Hazard Description:	Sharing SDM data is key to supporting patient care enabling clinicians to see the shared decision and the steps to how the decision was reached.
Hazard Causes:	1) Lack of interoperable systems 2) Shared Decision Making data is not part of the shared care record. 3) Incomplete data or limited data items are shared
Potential Clinical Impact:	Risk that professionals do not share a care decision leading to delayed or incorrect care that does not align with the agreed clinician and patient decision. A shared decision should be

	shared both with the patient and with other clinical professionals.
Mitigation:	**Design:** Suppliers must not build closed systems, but include the ability to share the shared decision standard as part of the system. Design interoperable systems End user engagement in design (out of scope). Clarity, from the Centre, about the role and importance of implementing an interoperable standard. Engage with NHSE and NHSX on technical (FHIR) specifications to enable sharing of the SDM content between systems and within shared care records.
	Test: End to end clinical testing
	Training: Understanding of and training/ education in shared care record use. IT commissioners and system developers educated and trained in the importance of clinical standards
	Business process control: None
Residual risk:	2

Hazard Id:	SDM_2
Hazard Name	Key data not recorded or available in the system resulting in incorrect treatment.
Hazard Description:	The most important information must be available in a manner that supports shared decisions making. This includes recording the person viewpoint towards a shared decision with equal importance to that of the clinician and ensuring care or treatment options, benefits, risks and the agreed decision are fully and accurately recorded.
Hazard Causes:	1) There could be issues where the full shared decision making pathway is not captured 2) Partial or incomplete information on the key decision points is not recorded 3) Incomplete data or limited data items are recorded
Potential Clinical Impact:	Incorrect or conflicting information that does not provide the full picture may result in incorrect decision making or lack of support for patients. If not recorded accurately, then it could adversely impact the decision (this applies to either person aspects or clinical options)
Mitigation:	**Design:** Ensure system design and logical data model follow the SDM pathway; Ensure appropriate use of value sets and constraints; System to support the process (e.g. prompts, hover over giving example responses etc) Include system prompts & maybe ability to adapt e.g. to a decision support tool being used.

	Test: End to end clinical testing. Provide an NHS app for patients to review and comment on their information and decisions taken on their behalf
	Training: Understanding of and training/ education in shared care record use, For example, importance of making sure the patient knows what is on the system - e.g. diagnosis of cancer. IT commissioners and system developers educated and trained in the importance of clinical standards
	Business process control: Ensure discussion take place that capture the patients and carers priorities and wishes about shared decision making. Provide patient advocacy.
Residual risk:	2

Hazard Id:	SDM_3
Hazard Name	Standard used out of scope resulting in incorrect treatment
Hazard Description:	The SDM standard is a generic standard designed to follow the shared decision making pathway and incorporate both GMC and NICE guidelines on shared decision making. The standard may need further testing and adoption for very specific areas of care. At present Maternity and Social Care are not in scope.
Hazard Causes:	The SDM standard is generic standard but lack of training on its scope and use or lack of testing across specific areas of care may lead to adoption of the standard without full clinical oversight
Potential Clinical Impact:	To use the standard out of scope or without further testing for specific areas of care may lead to inappropriate shared decisions on a person's care and treatment.
Mitigation:	**Design:** SDM systems needs to incorporate Shared Decision Making tools in their design. The standard cannot be changed or adopted for non-generic use without consultation with the PRSB and clinical leaders
	Test: Test new applications of the SDM standard in consultation with the PRSB and leading stakeholders
	Training: Understanding of and training/ education in shared care record use. IT commissioners and system developers educated and trained in the importance of clinical standards
	Business process control: None
Residual risk:	2

Hazard Id:	SDM_4
Hazard Name	No diagnosis or diagnosis incorrect

Hazard Description:	Whilst the clinician is going through the process of SDM with a patient the clinician either, selects an incorrect diagnosis (reason for treatment), or no diagnosis is available on the system.
Hazard Causes:	1) Implementation of the SDM process into the clinician system does not provide linkage to diagnoses recorded in the system 2) Clinician chooses the wrong diagnosis to discuss 3) No diagnosis is recorded in the clinical system
Potential Clinical Impact:	Incorrect decisions and treatments are made due to the incorrect diagnosis being selected.
Mitigation:	**Design:** The standard itself specifies mandatory field, this is one. Design of the user interface needs to allow the clinician to choose the correct diagnosis
	Test: System testing required to ensure that diagnoses are offered to the clinician.
	Training: System training. Training on the process.
	Business process control: Talking to the patient. Good communication. Verifying information with the patient.
Residual risk:	2

Hazard Id:	SDM_5
Hazard Name	Data misrepresented/not clearly displayed
Hazard Description:	This is particularly important for the final decision regarding the agreed options. This needs to be clearly displayed in systems, to ensure that options considered but not to go forward are clearly marked as such.
Hazard Causes:	The way that the system displays options of treatments needs to be clear. Clear differentiation between options which are considered and those which are chosen must be in place.
Potential Clinical Impact:	The patient could have a wrong procedure scheduled or even performed.
Mitigation:	**Design:** Good user interface design with clear labelling of sections and labels.
	Test: System user testing.
	Training: System training. Training on the process.
	Business process control: Talking to the patient. Good communication. Verifying information with the patient.
Residual risk:	2

Hazard Id:	SDM_6

Hazard Name	Clinician uses SDM standard as a 'tickbox exercise'
Hazard Description:	System users will be more focused on filling in the form than communicating with the patient.
Hazard Causes:	Too much information to be collected.
Potential Clinical Impact:	Poor shared decision making.
Mitigation:	**Design:** Design of the standards - includes fields which are mandated and those which are optional or required. So only the essential information needs to be collected.
	Test: System user testing.
	Training: System training. Training on the process.
	Business process control: Adequate time allocated for a SDM consultation.
Residual risk:	2

Hazard Id:	SDM_7
Hazard Name	Not all options are adequately recorded in the patient record.
Hazard Description:	The system used to record the decision making process does not have enough fields to record all the options discussed.
Hazard Causes:	Poor system design.
Potential Clinical Impact:	Not all options discussed are recorded.
Mitigation:	**Design:** Expandable options to be allowed - number of options has not be defined - needs to give suppliers some idea of potential numbers to help system design.
	Test: None
	Training: None
	Business process control: None
Residual risk:	1

Hazard Id:	SDM_8
Hazard Name	Shared decision status of “in progress” not noticed risking incorrect treatment
Hazard Description:	When a shared decision process is in progress it could be possible for the final decision to be filled in. Thus the record

	would look as if a final decision had been made when in fact it had not.
Hazard Causes:	Data input error - inputting data into the final decision field before a decision was finalised.
Potential Clinical Impact:	It could be assumed that the patient had made a decision or declined a decision for a specific treatment. So the patient may or may not receive the treatment in error.
Mitigation:	**Design:** User interface design to take the user through the process. Not allow a final decision to be recorded before the status of the process is set to complete. Not allow an entry into the final decision field if the status is not set as complete.
	Test: Test the process described in design.
	Training: Users need to be aware of this possibility if not disabled in system design.
	Business process control: None
Residual risk:	2