Professional Record Standards Body

Better records for better care

COMMUNITY PHARMACY STANDARD

CLINICAL SAFETY CASE REPORT

May 2023

Document Management

Revision History

Version	Date	Summary of Changes
0.1	18.12.2018	First draft created by Darren Wooldridge, Senior Project Manager, RCP Health Informatics Unit
0.2	24.01.2019	Updated in line with comments received at team meeting of 21.01.19.
0.3	12.02.2019	Updated in line with comments received from project clinical safety officers.
1.0		Approved version
1.1	24.11.2020	Updated following the revision of standard.
1.2	19.02.2021	Updated following enhancement of standard.
1.3	04.05.2021	Updated following feedback from NHS England Clinical Safety Group team
1.4	05.04.2023	Updated following uplift to standard
3.0	06.04.2023	Updated to V3.0 to reflect the revised V3 standard which incorporates changes for revised services being provided under the England Community Pharmacy Framework Contract.
3.0.1	26.05.2023	Update after comments from NHSE Clinical Safety Team

Reviewed by

This document must be reviewed by the following people:

Name	Date	Version
Clinical Safety Officer (Dr Steve Bentley)	26.05.2023	3.0.1
PRSB Assurance Committee	14.04.2023	3.0
Project Board	14.04.2023	3.0

Approved by

This document must be approved by the following people:

Name	Date	Version
Clinical Safety Officer (Dr Steve Bentley)	26.05.2023	3.0.1
NHS England Clinical Safety Group	08.06.2023	3.0.1

Glossary of Terms

Term / Abbreviation	What it stands for
CIS	Core Information Standard
CPCF	Community Pharmacy Contractual Framework
CSCR	Clinical Safety Case Report
CSG	Clinical Safety Group
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GP	General Practice
GPSoC	General Practice System of Choice
GUI	Graphical User Interface
IG	Information Governance
NHS	National Health Service
NHSD	NHS Digital – Now merged into NHS England
NHSE	NHS England
NPSA	National Patient Safety Agency
PDS	Patient Demographic Service
PRSB	Professional Record Standards Body
RBAC	Role Based Access Control
SNOMED CT®	Systematized Nomenclature of Medicine – Clinical Terms

Related Documents

Ref no	Title
[1]	DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems. https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems
[2]	DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems. https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collection_s-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems

Table of Contents

1 Introduction

The community pharmacy information standard was developed to enable information about person-centered services provided by community pharmacies to be recorded in the community pharmacy and transferred in a safe and efficient manner into the patients record, held by their GP practice, providing a more complete record of care to support better, safer, and more connected care. This also ensures that the professional contribution by community pharmacy staff can be shared with the wider NHS.

The standard was originally developed in 2018/19 for 6 use cases, with the use cases for flu vaccinations and emergency supply of medications piloted and tested, and then rolled out nationally through the 2 main community pharmacy suppliers and 2 main GP systems suppliers. It was updated in 2020/21 to allow new services under the new Community Pharmacy Framework Contract (CPCF).

The standard was further updated and enhanced in 2022/23 to incorporate changes in the services provided under the CPCF and to ensure consistency by bringing in updates for changes to other standards. Details of the process, engagement and consultation for the updates are provided in the final reports for those development projects.

As part of the 2022/23 update to V3 of the standard, the hazard log and safety case were reviewed and updated to reflect changes in the updated standard for the revised services being performed, including a new hazard and some additional controls to hazards previously identified.

1.1 Purpose of Community Pharmacy Standard

The purpose of this standard is to define the information that should be recorded in community pharmacies for the services they undertake under the community pharmacy contractual framework (CPCF), and the information that should be sent to the person's GP practice following provision of these services. The standard will facilitate interoperability between pharmacy and GP systems, thereby enabling pleasant patient experience between care settings. This will enable patient information from all pharmacies to be seamlessly transmitted to GP systems and update patient record with minimum disruption to both GP and pharmacies workflow.

1.2 Purpose of the Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for the Community Pharmacy Standard addresses the requirements of DCB0129 its Application in the Manufacture of Health IT Systems.

The full application of DCB0129 cannot be applied, as the professional standard itself is not a manufactured health IT system. However, 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.

2 System Scope

It should be noted that the scope of this CSCR is restricted to consideration of hazards that are directly associated with the implementation of the standards. Hazards associated with the deployment of any supporting technical solution, software or other system are out of scope and safety cases for their development and deployment must be provided separately. Furthermore, any such 'technical' safety justifications must satisfy the requirements of DCB0129[2] and DCB0160[3] respectively.

3 Clinical risk management system

The NHS England Clinical Safety Group (CSG) operates a full Clinical Safety Management System (CSMS) that encompasses integration with health organisations and professional bodies. The CSMS considers integration with the Data Alliance Partnership Board 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 this standard. Governance structures, project methodology and stakeholder engagement are described in the Community Pharmacy Standard final report. The PRSB remit, organisational structure, roles and responsibilities of key personnel are fully described on the PRSB website: www.theprsb.org.

It should be noted that this clinical safety report is necessarily limited in 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.

The role of the 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 reviewed and approved by the NHS England 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.

4 Hazard identification & Clinical Risk Analysis

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

- Safety issues identified by clinical informaticians and advisors and patient advisors participating in hazard workshops for previous versions of the standard.
- Potential clinical safety issues identified by stakeholder participants during consultation survey and other consultations undertaken during the previous developments of the standard, and the revision involving a stakeholder webinar (7 Feb-23), supplier webinar (2 Feb-23) and GP focus group (9 Mar-23).
- Production of a hazard log for the project.
- Review of the hazard log and any associated safety risks.
- Review of mitigation of risks.

- Clinical safety mitigation and confirmation of risks to be passed to implementation / maintenance stages identified.
- Drafting of safety case (approaches to mitigating the risks identified).
- Final draft of hazard log and clinical safety report.
- NHS England clinical safety case review.

A further review of the hazard log by the project team developing the revised V3 standard was performed to ensure the safety case addressed changes in the revised standard. The reviews were carried out in workshops on 30th March and 6th April. The team comprises:

Clinical lead – Pharmacist
Clinical lead – GP
Person lead
NHSE Commissioning lead
Project analyst
Junior project analyst
Project manager

5 Clinical risk evaluation and clinical risk control

5.1 Patient safety risk assessment approach

The patient safety risk assessment approach was as follows:

- What could go wrong, and how often [See Appendix A for risk matrix]
- Possible main causes.
- 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.

5.2 Hazard log composition

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

- Hazard name
- Hazard description
- Potential patient safety impact
- Potential causes
- Existing controls
- Initial hazard rating including likelihood and consequence
- Dependencies and assumptions
- Proposed mitigations
- Revised hazard ratings
- Summary of actions and approval

5.3 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, generally the higher severity has been used. It is recognized that very occasionally the absence of information on the record might lead to the death of a patient, but that the likelihood is very low indeed, especially given that this record is additional to existing systems.

6 Hazard log

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

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

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

There are 21 hazards identified. The hazards are classified as follows: issues relating to data and specific headings, issues relating to the model, issues relating to users of the shared care record, and issues relating to the IT systems.

Hazards

Hazard Id	1
Hazard Name	Clinical safety significant data missing or inaccurate

Hazard Description:	Clinical safety significant data is not recorded or recorded inaccurately.
Hazard Causes	1) Clinician unaware of the requirement to record clinically significant data 2) Clinician forgets to record clinically significant data 3) Clinician enters clinically significant data inaccurately 4) End user systems too structured/inflexible to include headings 5) Clinically significant data is not updated and therefore becomes out of date. 6) Complexity of the standard inhibits clinician recording of clinical safety significant data
Potential Clinical Impact	Healthcare provider delivers inappropriate care based on missing clinical information leading to patient(s) harm/death.
Mitigation:	1) The standard includes headings and fields to capture safety significant data 2) The standard Includes mandatory fields to prevent sending of messages without key information 3) End users have been involved in the design of the standards to ensure the content is appropriate. 4) PRSB provides a maintenance function to update standards when issues are found - e.g. if it is found that a significant piece of data has been omitted from the standard. 5) Recommend training/training materials in good recording practice 6) Implementation of the new pharmacy services which this standard supports will need to be supported by effective user training. 7) Implementation of the new pharmacy services which this standard supports will need to be supported by effective business process change When implementing the standard suppliers and implementer should ensure that the design supports; 1) prompts to remind clinicians to enter safety significant data, 2) functionality to autofill data fields when the information is already know by the system 3) good user interface design to follow/support the user through good clinical practice
Residual risk	2

Hazard Id	4

Hazard Name	Record sent to GP not presented properly.
Hazard Description:	The record shared with the GP systems may not be presented properly.
Hazard Causes	1) Poor engagement with pharmacy system & GP system vendors 2) Lack of understanding of data. 3) Poor engagement with GP clinicians on viewing pharmacy data on their systems
Potential Clinical Impact	Failure to deliver optimum care based on inconsistent guidance leading to patient' harm/death.
Mitigation:	1) Information display standards are not specifically defined by the standard. 2) This standard will be implemented using FHIR messages defined by NHSE. These messages should be populated by the pharmacy system suppliers in a conformant manner. This will enable the GP system to display the information in a clinically safe manner. 3) End to end testing of the information flows from Pharmacy system to GP systems should occur. This testing should be clinically assured.
Residual risk	2

Hazard Id	5
Hazard Name	Failure to adopt the record standard
Hazard Description:	System suppliers (vendors) may refuse to adopt and use the record standard.
Hazard Causes	End-users are unable to deliver service in line with the standard due to system design.
Potential Clinical Impact	Failure to deliver optimum care based on inconsistent guidance leading to patient harm/death.
Mitigation:	1) An ISN is produced as part of the standards process which mandates the implementation of the standard. 2) Pharmacies providing the services covered by the standard are mandated to implement the standard 3) This standard will be implemented using FHIR messages defined by NHSE. 4) Communication of the standards by NHS Digital, NHS England, PRSB and pharmacy bodies. 5) Championing by stakeholder organisations who have provided endorsement for the standards.

Residual risk	2

Hazard Id	6
Hazard Name	Hospital discharge summary, when sent to pharmacy services does not contain all the information required by the pharmacist.
Hazard Description:	The PRSB eDischarge Summary is a complete document and there are risks of breaking it up when sending the document to different recipients (e.g. GPs and pharmacists).
Hazard Causes	A reduced data set is sent to the pharmacist i.e., not all of the discharge summary, which is sent to the GP, is sent to the pharmacist. Or the full discharge summary is missing key information.
Potential Clinical Impact	Failure to deliver optimum care based on insufficient clinical information leading to patient harm/death.
Mitigation:	1) Through consultation the PRSB has recommended that the full hospital discharge summary should be sent to pharmacy services 2) Guidance to be provided for users 3) Standards to be championed and endorsed by key stakeholders 4) System designers and implementers should ensure that the full discharge summary is sent to pharmacies. They should ensure that the systems providing hospital discharge summaries are compliant with the PRSB e-Discharge standard. 5) There is a requirement that pharmacies implementing this standard and the service which this standard supports should have adequate information from the hospitals. 6) That this occurs should be tested.
Residual risk	2

Hazard Id	8
Hazard Name	Nested algorithms not correctly implemented e.g., NEWS 2, Q- Risk.
Hazard Description:	System suppliers (vendors) may not follow guidance correctly in the implementation of algorithms.
Hazard Causes	Incorrect implementation of algorithm
Potential Clinical Impact	Failure to deliver optimum care based on inconsistent guidance leading to patient harm/death.

Mitigation:	1) Need to follow NHSE technical specifications. 2) Implementation guidance provided to support suppliers with implementing the standards in their systems. 3) Adequate system testing must be performed to ensure that the algorithms are correctly implemented
Residual risk	2

Hazard Id	9
Hazard Name	Unstructured data may not be reviewed in a timely manner
Hazard Description	Data can exist in both structured and unstructured forms. The latter can be in documents making data more difficult to find.
Hazard Causes	1) Sections with unstructured data may not be reviewed in a timely manner. 2) Some sections allow both structured and unstructured data, the unstructured data may not be found as easily. 3) Unstructured data will not be found in searches.
Potential Clinical Impact	Failure to deliver optimum care based on insufficient clinical information leading to patient(s) harm/death.
Mitigation:	1) The standard defines sections. These sections allow information, including textual information, to be grouped under headings to enable clinicians to find information. 2) System designers and implementors should ensure that excessive test is not used. Then information can be broken down into sections. Functionality to search text using key words should also be considered. 3) The use of scanned documents should be minimised. 4) End to end clinical testing 5) Users should be adequately trained. This should include functionality to quicky search through textual documents.
Residual risk	3

Hazard Id	10
Hazard Name	Service users may not share important information with pharmacists e.g., past medical history or allergies.
Hazard Description:	Pharmacy intervention may be dependent on patient information on prescribing or missed diagnosis.
Hazard Causes	1) Clinicians or patients may not recognise the importance of the missing information.

	2) Patient lack of understanding of pharmacist knowledge and experience 3) Patients are not knowledgeable or trust data sharing of their personal records.
Potential Clinical Impact	Failure to deliver optimum care based on inconsistent guidance leading to patient harm/death.
Mitigation:	1) Implementation of 111 and e-discharge standards in the health community. Use of Summary care records and Shared Care Records. 2) "Provide training and guidance to clinicians in good recording practise. 3) Public engagement to build up trust relationship between the public and community pharmacists."
Residual risk	3

Hazard Id	12
Hazard Name	Safeguarding concerns may not be acted on
Hazard Description:	Safeguarding concerns may not be acted on as data sent to GP is assumed as sufficient action.
Hazard Causes	1) Clinician has inadequate safeguarding training 2) Interface does not facilitate the recording of safeguarding data sufficiently 3) Clinician forgets to record safety significant data 4) Clinician assumes data shared will be acted on
Potential Clinical Impact	"Risk of safeguarding alerts not being raised. Responsibility cannot be passed onwards. Failure to pass on concerns could result in patient harm/death"
Mitigation:	1) The standard contains section for "Actions for clinician" these should be used. 2) The standard contains section to describe safeguarding concerns 3) Need to work with users to implement interface tools that aid safeguarding referral 4) Provide training and guidance to clinicians in handling safeguarding concerns
Residual risk	2

Hazard Id	13
Hazard Name	Clients obtaining duplicate or multiple prescriptions.

Hazard Description	Clients using repeated services to obtain medication illegally.
Hazard Causes	1) Patient misuse of services 2) Pharmacy systems not receiving data from shared records 3) Carer/patient communication error
Potential Clinical Impact	Risk of overdose, incorrect prescribing or illegal activity.
Mitigation:	1) The service that the standard supports helps to decrease the chance of this happening. 2) Prescription interception information is included in the standard. 3) Working towards joined up services with bidirectional interfaces.
Residual risk	2

Hazard Id	14
Hazard Name	Blood pressure results not recorded correctly.
Hazard Description:	Where BP has been taken the systolic and diastolic readings should remain together. BP should indicate how the result was taken e.g. sitting/standing, or left arm
Hazard Causes	1) Separation of results can occur when multiple readings have been taken - e.g. sitting then standing BP 2) BP should record position of patient and which arm is used.
Potential Clinical Impact	Risk of missed diagnosis. Failure to deliver optimum care based on inconsistent guidance leading to patient harm/death.
Mitigation:	1) The standard defines a standard model for the representation of blood pressure. 2) Need to work with users to implement interface to a good standard 3) Clinician training on capturing blood pressure
Residual risk	2

Hazard Id	15
Hazard Name	SNOMED codes mismatch
Hazard Description:	Different suppliers using different SNOMED or implementing in different ways.
Hazard Causes	1) SNOMED is dynamic with frequent updates; extensive 2) Some providers are not updating to the latest versions of SNOMED CT 3) Codes can become inactive and moved or not retained creating difficulty in retrieving historic information

Potential Clinical Impact	Inhibits or complicates interoperability and sharing of important patient information between organisations leading to suboptimal, delayed or inappropriate patient care leading to patient harm/death.
Mitigation:	1) The standard provides vocabularies of SNOMED CT concepts to be used. 2) Need to follow NHSE technical specification. 3) End to end clinical testing 4) Education and training in using SNOMED CT.
Residual risk	2

Hazard Id	19
Hazard Name	User cannot find data they need.
Hazard Description:	The information is not found by the user.
Hazard Causes	1) Data model poorly laid out. 2) Data badly presented (GUI). 3) End user not able to use the system effectively potentially through lack of training. 4) Information not found because of volume of data. 5) Lack of metadata, restricting searching and views.
Potential Clinical Impact	Failure to deliver optimum care based on incomplete clinical information leading to patient harm/death.
Mitigation:	1)The standard defines sections for the logical grouping of information. 2) The standard defines the minimum data for safe practice 3) The system designers and implementor, must ensure that a clinical safety user interface is delivered. That allow the data to be displayed, searched and sorted in appropriate ways. 4) End to end clinical testing 5) Good professional practice and understanding of and training/ education in system use.
Residual risk	2

Hazard Id	20
Hazard Name	Sex data item may cause accidental disclosure of gender reassignment without consent
Hazard Description:	Accidental disclosure of gender reassignment, without consent, due to inclusion of both patient's 'sex/ phenotypic sex' and 'gender' in demographics section.
Hazard Causes	1) Display of patient 'sex' and 'gender' information, in demographics, which do not match e.g. one states 'male' and the other states 'female'.
Potential Clinical Impact	Potential severe psychological harm to patient and possibly significant others by sensitive information being

	accidently disclosed without consent. Disclosure adversely effects patient's social wellbeing and support networks.
Mitigation:	1) Some Systems use 'gender' only, in person demographics 2) This risk must be mitigated by design. One option is to only include Gender and this will greatly reduce the risk. The second option is ensure through the design of the system and the information governance model that the risk of unlawful disclosure is reduced to an acceptable level. 3) Adequate training so staff are competent users of the system 4) IG training 5) Staff vigilance and audits 6) Public engagement with development of local shared care records 7) Implement the NHS England IG framework for shared care records, when available. Clarity in national policy regarding the recording of 'sex' and 'gender' in EHRs with due regard for the practical risks posed in clinical practice for patients, practitioners and healthcare providers.
Residual risk	3

Hazard Id	21
Hazard Name	New services
Hazard Description:	New services are currently being trialled, which may be implemented at a future date e.g. Cancer referral, menopause, Weight management.
Hazard Causes	Data items required for a new service may not be available, may not have the required vocabulary
Potential Clinical Impact	Failure to deliver optimum care based on incomplete clinical information leading to patient harm/death.
Mitigation:	1) The standard has a defined scope. The standard should only be used within this scope 2) When new services are implemented, the standard will need to be updated to ensure it meets the requirements of the new scope. 3) System Designers and implementors should only use the standard for the defined scope
Residual risk	2

7 Residual Hazard Risk Assessment

There are 3 hazards with a residual risk of 3, which is undesirable and no hazard with a residual risk of 4 which is an unacceptable level of risk. The above risks will be transferred to those implementing the community pharmacy standard. It is as follows:

Risk level 3

Hazard 9: Unstructured data may not be reviewed in a timely manner.
The risk is that as data can exist in structured and unstructured forms, the latter may be more difficult to find in a timely manner. This can lead to suboptimal care if key information is missed, which may lead to harm or death.

The design of the standard begins to mitigate the risk as the standard defines sections. These sections allow information, including textual information, to be grouped under headings to enable clinicians to find information more easily.

Further mitigations can be used to ensure that the risk level does not increase to a level 4 risk, including:

- System designers and implementors should ensure that excessive text is not used. Then information can be broken down into sections. Functionality to search text using key words should also be considered.
- The use of scanned documents should be minimised.
- End to end clinical testing.
- Users should be adequately trained. This should include functionality to quicky search through textual documents.

Hazard 10: Service users may not share important information with pharmacists e.g., past medical history or allergies.
The risk is that service users may not share important information with pharmacists, leading to suboptimal care based on inconsistent guidance, which may lead to harm or death. 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 through implementation. Implementation of the PRSB 111 standard and the E-Discharge standard defines the key clinical information required.

Mitigations that can ensure the risk is reduced to an acceptable level are:

- Implementation of 111 and e-discharge standards in the health community.
- Use of Summary care records and Shared Care Records.
- Provide training and guidance to clinicians in good recording practice.
- Public engagement to build up trust relationship between the public and community pharmacists.

Hazard 20: 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 inflict psychological harm upon the patient. Implementation can ensure that the risk level does not increase to level 4. Removing the “Sex” field is one option, the other is to ensure the design and information model of the Shared Care Record reduce this risk to an acceptable level. This advice will form part of the implementation guidance accompanying the community pharmacy standard.

Specific actions to mitigate this risk by design are:

Option 1: to only include the Gender field. This will 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 mitigations to ensure the risk is reduced to an acceptable level include:

- Adequate training so staff are competent users of the system.
- IG training.
- Staff vigilance and audits.
- Public engagement with the development of local shared care records.
- Implement the NHS England IG framework for shared care records.
- 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.

8 Training

Training of the end users of the community pharmacy standard is offered as a mitigation for many of the hazards identified. This should be considered when developing these 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.

9 Test Issues

As the Community Pharmacy Model is a conceptual model and, as yet, has not been implemented in any systems, it has not been possible to test the model. It is therefore dependent on those developing the systems to do full End-to-end clinical safety testing.

10 Summary Safety Statement

Twenty one potential hazards were identified. All hazards were identified through the consultation processes carried out to ensure the PRSB Community Pharmacy Standard V2 is developed to underpin and support its implementation and use. The consultation process is described in detail in the V2 standard final report section 6, and the revised V3 standard is described in the V3 final report. It included patient and carer representatives as well as professionals from Royal Colleges, specialist societies, allied health professions, health informatics professionals, pharmacists and vendors.

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

(A) mitigated by the development of the standard

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

The hazard log (a separate document) provides guidance for system developers and implementers. It is important that this guidance in relation to those hazards, regarded as system issues, become requirements for implementation.

Most hazards are rated as a risk acceptability level of 2. That is acceptable. The 1 rated at level 3 has been described in section 9. The mitigations for the level 3 risks are outside the control of PRSB and these risks are therefore handed on to the deployers of this standard.

11 Document control and post standard approval maintenance

Future governance of the development and maintenance of the Community Pharmacy standard is the responsibility of the PRSB.

12 DCB 0129 compliance matrix

The table below summarises the compliance status of this safety case for the PRSB Community Pharmacy 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 Community Pharmacy Standard 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 Community Pharmacy Standard 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 Community Pharmacy Standard and implementation guidance.
7.2 Post-deployment monitoring	N	Not required for a professional standard.
7.3 Modification	Y	See section 13

13 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.