Professional Record Standards Body

Better records for better care

INTEROPERABLE DOSE AND TIMING INFORMATION: CLINICAL SAFETY REPORT

AUGUST 2019

Document Management

Revision History

Version	Date	Summary of Changes
0.1	06.03.2019	First draft
0.2	29.05.19	Update following comments from the NHS Digital Clinical Safety Group and CSO review
0.3	01.08.19	Update after further comments from the NHS Digital Clinical Safety Group
1.0	09.08.19	Changed to V1 following NHS Digital Clinical Safety Group approval

Reviewed by

This document must be reviewed by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr Ian M. Thompson	19.03.19
PRSB Assurance Committee		26.03.19
NHS Digital Clinical Safety Group representative		Apr-Aug 2019

Approved by

This document must be approved by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr Ian M. Thompson	01.08.19
NHS Digital Clinical Safety Group		07.08.19

Glossary of Terms

Term / Abbreviation	What it stands for
HIU	Health Informatics Unit (of the RCP)
PRSB	Professional Record Standards Body
RCGP	Royal College of General Practitioners
RCP	Royal College of Physicians

Related Documents

Ref no	Title
[1]	FHIR Dose Syntax Implementation Guidance https://developer.nhs.uk/apis/dose-syntax-implementation/
[2]	PRSB transfer of care medication information model, e.g. https://theprsb.org/standards/edischargesummary/
[3]	CareConnect API https://nhsconnect.github.io/CareConnectAPI/
[4]	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
[5]	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-collections-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. Executive summary and safety statement

12 potential hazards were identified with risk controls and mitigation also identified. Of the 12 potential hazards, 4 were generic, 7 were specific to dose timing information, 1 was deemed implementation issues. The mitigated hazards include information that should be addressed by implementers.

For generic hazards, the residual risk associated with all of the hazards was scored 2 or less.
Of the 7 hazards specific to dose timing, the residual risk associated with 10 the hazards was scored 2 or less and is hence considered broadly acceptable. The residual risk score of 3 for the remaining one hazard is judged only to be acceptable where further risk reduction is impractical.

All hazards were identified through the consultation steps carried out to assure dose timing solution. The consultations consisted of a clinician and clinical informatician review, online survey, consultation webinars and hazard workshops. These surveys and webinars included patient representatives as well as professionals from Royal Colleges, specialist societies, allied health professions, health informatics professionals, pharmacists and vendors.

During the consultation, 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 standards

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

Certain hazards were deemed system implementation matters. The hazard log (a separate document) however provides guidance for system developers and implementers. It is important that this guidance in relation to these hazards become requirements for implementation.

2. Introduction

NHS England and NHS Digital commissioned the Professional Record Standards Body (PRSB) to provide a validation and assurance exercise of an initial implementation guidance developed by The Digital Medicines and Interoperability teams, which is using a FHIR STU3 Dosage structure within CareConnect profiled resources. The project was managed by the Royal College of Physicians (RCP) Health Informatics Unit (HIU), under subcontract from the PRSB and following the PRSB process and methodology. Clinical leadership was provided by a clinical lead representing the Royal College of General Practitioners (RCGP) and an independent clinical informatician adviser.

The project has updated the previous PRSB medication information models with structured dose syntax.

The following approach was taken to develop the project deliverables:

- Project team review of technical guidance document.
- An online survey was used to gain professional input on a number of identified areas, including safety issues.
- Three consultation webinars were arranged for patients, healthcare professionals and clinical informaticians to discuss the project, safety issues and any other outstanding issues.
- Final draft deliverables were disseminated to the project board for their official sign off.

This document provides the report of the work done to manage identified clinical safety risks associated with the interoperable medications information project. The project has produced an update to a professional standard. 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 12.

3. Clinical safety governance

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 gives particular consideration to the integration with the Information Standards 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 by engagements with the following organisations:

- PRSB Advisory Board
- Project board
- Royal College of Physicians
- Royal College of Psychiatrists
- Royal College of Surgeons
- Royal College of Paediatrics and Child Health
- Royal College of General Practitioners
- Faculty of Clinical Informatics
- Other Royal Colleges and specialist societies
- Involvement of patient representatives
- NHS Digital terminology team
- NHS Digital messaging team
- NHS Digital clinical safety group

However, it should be noted that this clinical safety report is necessarily limited in its scope because it is neither directly related to software development nor to deployment. Suppliers developing software to implement these standards will therefore still be expected fully to apply DCB0129. Organisations involved in the deployment of such software will still be expected fully to apply DCB0160.

4. Safety organisation structure

The role of a Clinical Safety Officer (CSO) is 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 should monitor the execution of the Clinical Safety Case and ensure that clinical safety obligations are being discharged.

5. Hazard identification & assessment approach

The first step to preventing harm to patients through the use of these standards is to ensure a good development process that results in standards fit for purpose.

Activities that have been carried out to clarify and address this potential include:

- Initial patient safety issue list submitted by stakeholders participating in the consultation survey (n=504).
- Production of a hazard log for the project.
- Review of the hazard log and any safety risks associated with dose timing information.

- Additional safety issues identified by clinical informaticians participating in hazard workshop.
- Updating the hazard log.
- Second hazard workshop held.
- Review of mitigation of risks as part of the updating medication standard with structured dose timing information.
- 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 following end of consultation.
- Review and updating of safety case.
- NHS Digital clinical safety case review and approval.

The patient safety risk assessment approach that was used was:

- 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.

The full hazard log comprises:

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

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.

6. Consultation stakeholders

Hazard Workshop #1			
Date	07.02.2019	**Time**	10:00 – 11:30
Location	Meeting held by remotely via WebEx		
Attendees:			
	Name	**Role**	
	Ian M. Thompson	Clinical Safety Officer (CSO) / Project clinical lead	
	Neill Jones	Clinical informatician/CSO/GP	
	Phil Koczan	Clinical informatician/CSO/GP	
	Paul Miller	Clinical informatician/CSO/GP	
	Sameer Patel	Clinical informatician/CSO/Consultant Physician	

Hazard Workshop #2			
Date	28.02.2019	**Time**	13:00 – 14:30
Location	Meeting held by remotely via WebEx		
Attendees:			
	Name	**Role**	
	Ian M. Thompson	Clinical Safety Officer (CSO) / Project clinical lead	
	Sameer Patel	Clinical informatician/CSO/Consultant Physician	

7. Hazard log

The full hazard log is detailed in a separate document. A summary of hazards identified, including those deemed implementation issues is included in the following section.

Please note: The mitigations we have taken to address clinical safety risks are largely in relation to the design of the structure and description of the content of the information. Further mitigations will be required when the headings are implemented in electronic health record systems. 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. We would expect software developers and implementers to reduce the risk score to 2, or better than human transcription alone.

8. Hazards

This section sets out identified hazards. Risk Acceptability is included in the table below. See Appendix A for risk matrix.

	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

Relevant generic hazards are listed first, followed by specific additional headings related to dose and timing information.

Generic hazards:

Hazard Id:	1
Hazard Name	Critical data absent as not recorded
Hazard Description:	Critical data absent because it is not recorded e.g. allergies and adverse reactions, medication instructions
Hazard Causes:	Critical data not entered in the system, e.g. because clinician is not prompted for it or forgets to record it, or records in an incorrect field.
Potential Clinical Impact:	Patients receive incorrect treatment or advice
Mitigation:	Mitigated by system design e.g. Include headings and fields to capture critical data; also prompts and mandatory or required fields as per medication information model and PRSB implementation guidance; include coded text to indicate the absence of information Training in good recording practice e.g. indicating absence of information appropriately, adhering to mandatory and required fields
Residual risk:	2
Hazard Id:	2
Hazard Name	Blank fields

Hazard Description:	Lack of clarity over what a blank field signifies (i.e. not recorded, not assessed, not present etc)
Hazard Causes:	Due to the design
Potential Clinical Impact:	Recipients will have insufficient information to make appropriate clinical decisions. This could result in sub-optimal treatment.
Mitigation:	PRSB transfers of care implementation guidance System design should reduce this, i.e. as per PRSB implementation guidance, if an optional field is left blank the heading should not be communicated in the message. If a field is mandatory, the implementation guidance includes coded text for what should be recorded.
Residual risk:	2
Hazard Id:	3
Hazard Name	Inappropriate auto population of information
Hazard Description:	Inappropriate auto population could lead to excessive, superfluous information creating difficulty for the recipient to focus on the pertinent information. Auto population of medicines reconciliation could propagate error without human sense check
Hazard Causes:	Inappropriate auto population of information
Potential Clinical Impact:	Patients receive incorrect treatment
Mitigation:	Insist on using dm+d units of measure System design should reduce this. Headings specify that only relevant information should be recorded. Clinicians encouraged to review autopopulated information to make sure it is relevant.
Residual risk:	2
Hazard Id:	4
Hazard Name	Lack of alignment with other standards
Hazard Description:	The standards may not be consistent with the latest version of related standards e.g. dm+d, SNOMED CT subsets
Hazard Causes:	As existing standards are updated they may be misaligned to the headings.
Potential Clinical Impact:	Patients receive incorrect treatment
Mitigation:	Maintenance of the standards is the responsibility of the PRSB and changes must be possible for integration with relevant data standards as they change. Mitigated by improving data quality in dm+d
Residual risk:	2

Dose timing specific hazards:

Hazard Id:	5
Hazard Name	Incompatible prescribing formats
Hazard Description:	Conversion from hospital (dose based prescribing) format to GP (product based prescribing) format may lead to errors, compounded by the tendency for one dose based prescription to map to more than one product based prescription. As a result the wrong product may be selected which may be hazardous or ineffective for the patient.
Hazard Causes:	A dose based medication item from hospital may be converted to the wrong product based medication item in primary care either as a result of human transcription error or as a result of automated or semi-automated conversion
Potential Clinical Impact:	Patient given inappropriate medication.
Mitigation:	Human readable rendition of original dose based prescription preserved and presented to Primary care prescriber to facilitate cross check. Primary care clinician review of the hospital prescription and decision made about future prescribing rather than dependency on fully automated conversion process Medication information model Thorough clinical safety testing of any clinical software solution both around time of developing software and around time of deployment Mandatory clinical reauthorisation of medication at transfer of care before medication is continued
Residual risk:	3
Hazard Id:	6
Hazard Name	Timing instructions are not understandable to the patient
Hazard Description:	Patients/carers with access to their records are unhappy with the content as they cannot understand it.
Hazard Causes:	Timing instructions are not understandable to the patient or patients are not happy with the clinicians population of the headings.
Potential Clinical Impact:	Patient dissatisfaction, reducing engagement with their treatment, taking incorrect dose.
Mitigation:	Dose timing instructions to use terms that are comprehensible to patients. System to produce a patient relevant version
Residual risk:	2
Hazard Id:	7

Hazard Name	Inappropriate auto calculation of information
Hazard Description:	Inappropriate auto calculation could lead to excessive doses
Hazard Causes:	Inappropriate auto calculation of information
Potential Clinical Impact:	The recipient may receive incorrect important information and not provide appropriate treatment.
Mitigation:	System design should reduce this e.g. prompts for review of auto calculated doses Clinicians encouraged to review autocalculated information to make sure it is correct
Residual risk:	2
Hazard Id:	9
Hazard Name	Complex instructions
Hazard Description:	Medication has a sequence of complicated dosing requirements
Hazard Causes:	Due to the nature of the medication e.g. Parkinson's medication
Potential Clinical Impact:	Patient receives medication at the wrong time
Mitigation:	Measures to recognise this small group of drugs
Residual risk:	1
Hazard Id:	10
Hazard Name	Do not discontinue instructions
Hazard Description:	Medicines that are dangerous to discontinue (e.g. steroids, Parkinson's medications) without discussion with specialist
Hazard Causes:	Not clear in dose timing instructions that this medication is not to be stopped without further consideration
Potential Clinical Impact:	Patient does not receive appropriate medication and their condition may deteriorate
Mitigation:	Information is transmitted in dose timing instructions Amending FHIR standard internationally
Residual risk:	2
Hazard Id:	13
Hazard Name	Errors in other dependent standards
Hazard Description:	Fault in other standards (e.g. SNOMED-CT, dm+d) regarding preparations and units of measure has an impact on dose timing instructions being communicated

Hazard Causes:	Dependent on other standards (e.g. SNOMED-CT, dm+d) which may have faults
Potential Clinical Impact:	Patients receive incorrect treatment
Mitigation:	Areas in other standards will be updated and addressed Reporting mechanism for errors in other standards
Residual risk:	2
Hazard Id:	14
Hazard Name	Initiating treatment dose not changed once stable dose achieved
Hazard Description:	Dose is not reduced after initial loading
Hazard Causes:	Poor communication with the patient
Potential Clinical Impact:	Patients receive incorrect treatment
Mitigation:	Training in communication skills
Residual risk:	2

9. Hazards transferred to implementation

These are issues that are out of scope of these projects but need to be addressed by system developers and implementers. These issues should be taken into account by system vendors and sites when implementing the headings.

Hazard Id:	19
Hazard Name	Refusal to adopt the standard
Hazard Description:	Services may refuse to use the record standard.
Hazard Causes:	Lack of support for the standard.
Potential Clinical Impact:	If some services do not adopt the standard there will remain a lack of interoperability between services. This may result in delayed or incorrect treatment.

Mitigation:	Multi professional involvement in the development of the standard to ensure it is fit for purpose. The design incorporates SNOMED CT and dm+d as an essential part of the standard, so systems will have to adopt this coding scheme.
Residual risk:	4

10. Summary safety statement

12 potential hazards were identified with risk controls and mitigation also identified. Of the 12 potential hazards, 4 were generic, 7 were specific to dose timing information, 1 was deemed implementation issues. The mitigated hazards include information that should be addressed by implementers.

For generic hazards, the residual risk associated with all of the hazards was scored 2 or less.
Of the 7 hazards specific to dose timing, the residual risk associated with 6 of the hazards was scored 2 or less and is hence considered broadly acceptable. The residual risk score of 3 for the remaining one hazard is judged only to be acceptable where further risk reduction is impractical.

All hazards were identified through the consultation steps carried out to assure dose timing solution. The consultations consisted of a clinician and clinical informatician review, online survey, consultation webinars and hazard workshops. These surveys and webinars included patient representatives as well as professionals from Royal Colleges, specialist societies, allied health professions, health informatics professionals, pharmacists and vendors.

During the consultation, 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 standards

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

Certain hazards were deemed system implementation matters. The hazard log (a separate document) however provides guidance for system developers and implementers. It is important that this guidance in relation to these hazards become requirements for implementation.

11. Document control and post standard approval maintenance

Maintenance arrangements for the headings that constitute these standards are specified in the Generic Editorial Principles for the Development of Standards for the Structure and Content of Health Records (a separate document). Future governance of development and maintenance for all professional record standards is the responsibility of the PRSB.

12. DCB 0129 compliance matrix

The table below summarises the compliance status of this safety case for the emergency care discharge summary project.

Requirement	Compliant (Y/N)?	Comments
2 General Requirements and Conformance Criteria for Clinical Risk Management	Y	See section 3
2.1 Clinical risk management process	Y	See section 3
2.2 Top Management responsibilities	Y	See section 3
2.3 Clinical Safety Officer	Y	See section 6
2.4 Competencies of personnel	Y	See section 3 & 6
3.1 Clinical risk management file	Y	This document in its entirety, including supporting evidence and the standard in full.
3.2 Clinical risk management plan	Y	See section 3 & 4
3.3 Hazard log	Y	See section 7
3.4 Clinical safety case	Y	This document in its entirety, including supporting evidence and the standard in full.
4 Clinical risk analysis	Y	See section 5
4.1 Clinical risk analysis process	Y	See Section 5
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 8
5 Clinical risk evaluation	Y	See section 5
6 Clinical risk control	Y	See section 8
6.1 Clinical risk control option analysis	Y	See section 8
6.2 Clinical risk/benefit analysis	Y	See section 8
6.3 Implementation of clinical risk control measures	Y	See section 8
7.1 Delivery	Y	This document in its entirety, including supporting evidence and the standard in

		full.
7.2 Post-deployment monitoring	N	Not required for a professional standard.
7.3 Modification	Y	See section 11

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				

	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.
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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