Professional Record Standards Body

Clinical Safety Case Report: Ambulance Handover to Secondary Care – Standard Revision

04 March 2020

Document Management

Revision History

Version	Date	Summary of Changes
0.1	15.03.19	First draft created by Darren Wooldridge (Royal College of Physicians, Health Informatics Unit, Project Manager)
0.2	07.08.19	Updated with details from hazard log
0.3	16.08.19	Updated after discussion with project clinical safety officer
0.4	08.11.19	Updated following comments from the NHSD Clinical Safety Group
0.5	03.01.20	Updated following comments from the NHSD Clinical Safety Group
1.0	21.02.20	V1 after approval by NHSD Clinical Safety Group

Reviewers

This document must be reviewed by the following people:

Name	Status	Date
Tom Hughes (Clinical Safety Officer)	complete	05/02/20
PRSB Assurance Committee	complete	14/10/19

Approved by

This document must be approved by the following people:

Name	Status	Date
Project Board	Approved	29/08/19
Tom Hughes (Clinical Safety Officer)	Approved	05/02/20
NHS Digital Clinical Safety Group	Approved	19/02/20

Contents

1 Introduction

In 2016, the Professional Record Standard Body (PRSB) was commissioned by NHS Digital to develop standards for ambulance transfers of care to emergency departments. This standard was endorsed by ten professional bodies, including the College of Paramedics (CoP). However, the Royal College of Emergency Medicine (RCEM) were unable to endorse the standard as it didn't have a detailed dataset to underpin it and they believe the standard included too much information which would not be pertinent to busy emergency care staff.

In 2018 NHS England commissioned a new project to deliver a set of national standards and national capabilities to enable the electronic transfer of an ambulance report from the ambulance service to a hospital. As part of this project, the PRSB have been requested to do a revision of the standards for ambulance handover to emergency care, which is able to be endorsed by key stakeholders, including the RCEM.

The PRSB have collaborated with the Royal College of Physicians Health Informatics Unit on this project. Clinical leadership has been provided by clinicians from the RCEM and the CoP.

1.1 Purpose

The purpose of this Clinical Safety Case Report (CSCR) is to evaluate identified hazards associated with the implementation of the standard developed as part of the PRSB Ambulance Handover to Emergency Department. Where the initial risk was judged to be unacceptable, appropriate controls have been agreed to reduce residual risk to a tolerable level.

1.2 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 standard. 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[1] and DCB0160[2] respectively.

2 Clinical Risk Management

2.1 Clinical Safety 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 gives particular consideration to the integration with the approval of Information Standards and the process in which professional standards are developed in the

[1] 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] 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

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 Ambulance to ED project.

3 Hazard Identification and Risk Analysis

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 assessment
- Production of a hazard log for the project
- Review of hazards log with the clinical safety officer
- Final draft of hazard log, standard headings and clinical safety report
- Drafting of safety case report (approaches to mitigating the risks identified)
- NHS Digital clinical safety case review and approval.

The patient safety assessment explored the following questions:

- What could go wrong (hazards), how often (likelihood) and how bad could it be (severity)? (severity and likelihood tables are included at Appendix A);
- What are the hazard causes?
- What risk controls/mitigation is already in place?
- What (if any) additional risk controls should be put in place?

Agreement was also reached relating to the transfer of risk (where applicable) to external organisations e.g. those bodies responsible for implementing the standards

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4 Clinical Risk Evaluation

The scope of the patient safety assessment and subsequent hazard analysis is restricted to those hazards which relate directly to the implementation of the standards. Further hazard identification and hazard analysis work will be required prior to the development and deployment of any supporting technical solution, software or other system in accordance with the requirements of DCB0129 and DCB0160 respectively.

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 standard is 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.

Output from the patient safety assessment was reviewed by the NHS Digital Clinical Safety Group on 19 February 2020, and approval was provided in writing.

4.1 Risk Evaluation Process

The clinical risk associated with each hazard was scored based on two factors; the severity of harm (if the hazard were realised) and the likelihood of occurrence of that harm. For each of these factors the presence or otherwise of existing risk controls/mitigation was considered.

Risk Estimation Matrix

The criteria that were used for scoring are provided at Appendix A. The values obtained for severity and likelihood were then applied to the following matrix to obtain an overall risk score from 1 to 5, where 5 represents the greater risk.

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
		Severity				

Risk Acceptability Criteria

	Risk Acceptability
5	Unacceptable level of risk
4	Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level
3	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
2	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

Of the 7 hazards identified, 6 were initially scored greater than 2 and hence it was agreed that additional risk controls should be put in place.

5 Clinical Risk Control

Full details of each hazard, the potential consequences and risk controls/mitigation can be found in the attached hazard log (Section 6), however a summary of the risk reduction claimed is provided below:

Summary of Risk Controls and Mitigation				
No	**Hazard**	**Initial Risk**	**Risk Controls/Mitigation**	**Residual Risk**
1	Misidentification of the patient	3	1) Requirement for access to the Spine 2) NHS number matching	2
2	Inaccurate/missing data	2	Recommend training/training materials in good recording practise	2
3	Suppliers presenting the information in a way which is inappropriate for end users	3	Implementation guidance has been provided to support suppliers with implementing the standards in their systems	2
4	Complexity of the standard inhibits clinician recording of clinical safety significant data	3	1) System design should reduce burden on end users e.g. use of auto-population where appropriate 2) End users have been involved in the design of the standards to ensure the content is appropriate 3) Provide training in use of the standard 4) Guidance has been provided on what should be recorded under each heading 5) The standards will be evaluated on an on-going basis by the PRSB. Consideration for free text has been incorporated into the design and provided not only at a question level but also at an overarching level for the care event	2
5	Failure to adopt record standard	3	1) RCEM and CoP provided clinical leadership for the project 2) Consistent data structures defined in ADS and ECDS 3) Communication of the standards by NHS Digital, PRSB, College of Paramedics and Royal College of Emergency Medicine 4) Championing by stakeholder organisations who have provided endorsement for the standards	2

6	Burden on clinicians	3	1) Include prompts reminding clinician to enter safety significant data 2) Clear use cases for data entry and proof of user-centred design of the user interface (e.g. measures of usability) 3) Inclusion of mandatory fields to prevent sending of messages without key information 4) Automation of as many fields as possible to avoid manual entry of information	2
7	Unsafe transmission of CPR information	5	System design must not allow any transmission of CPR decision information unless the provenance is provided. The DNACPR element was **not** included in the standard to remove the risk of wrongly **not** performing CPR. This leaves the lesser risk of doing unwanted / inappropriate CPR.	3

Summary of Risk Controls and Mitigation

On the basis that the risk controls and other mitigation identified in the above table are satisfactorily implemented, 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 one remaining hazard, hazard 7, is judged only to be acceptable as further risk reduction is impractical. Unless the provenance relating to information about **not** giving CPR is available and can be trusted, the risk of transmitting any “do not attempt (DNA) CPR” information was considered unacceptable as the consequence is catastrophic. This risk was negated by removing the DNACPR element from the standard, but the residual risk is that a patient may be inappropriately resuscitated but that is consistent with 'first do no harm'. The inclusion of CPR in the standard can be re-considered when there is a mechanism for providing trusted provenance of the information.

6 Hazard Log

A copy of the Hazard Log is attached below:

Ambulance_Transfe
r_of_Care_Hazard_Lc

7 Summary Safety Statement

A total of 7 hazards have been identified, associated with the implementation of the standards and are recorded within the Hazard Log (Section 6). Evaluation of the initial risk

associated with these hazards has led to a requirement to implement additional risk controls to reduce residual risk to a tolerable level.

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 standard is 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.

Provided that the risk controls and other mitigation identified in the hazard log (Section 6) are successfully implemented, the residual risk associated with the implementation of the standards is considered acceptable, but there is clearly opportunity to improve the risk profile further through a good implementation .

The Clinical Safety team can confirm that all identified risks and hazards have been mitigated to as low as possible. This clinical safety report and hazard log has been reviewed by the Clinical Safety Officer to ensure that all risks, hazards and strategies are addressed.

8 Quality Assurance and Document Approval

The clinical safety work undertaken to support development of this CSCR has been conducted in compliance with the NHS Digital CSMS. This report illustrates how the requirements of DCB0129 have been applied during the development of the standards in the context of an information standard, rather than a Health IT System.

9 Configuration Control / Management

Maintenance arrangements for the standard will be in accordance with the General Editorial Principles for the Development of Standards for the Structure and Content of Health Records (https://www.rcplondon.ac.uk/projects/outputs/editorial-principles-development-record-standards). Future governance of development and maintenance for all professional record standards is the responsibility of PRSB.

Appendix A: Hazard Severity and Likelihood

The following tables present the basis on which hazards associated with the implementation of the standards have been categorised in terms of severity and likelihood.

Severity of Hazard Consequences

Severity Classification	Interpretation	
	Consequence	No. of 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 severity	Single

Likelihood of Harm Occurring

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