Professional Record Standards Body

NHS Digital

Clinical Safety Case Report: DCB3009 – PRSB Healthy Child Record Standard ISN (Phase 1 of 2)

Published 07 December 2018

Information and technology for better health and care

Executive Summary

This document provides the clinical safety case to support implementation of the healthy child record standard [Ref. 1]. The standard provides information models and implementation guidance which will be used by NHS Digital (NHSD) to develop technical standards for structuring and coding to facilitate the sharing of information in support of the healthy child programme. The aim is to incorporate [Ref. 1] into standard clinical Information Technology (IT) contracts to facilitate better access and interoperability.

A total of 7 hazards have been identified associated with the implementation of [Ref. 1] and are recorded within the DCB3009 Phase 1 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.

Provided that the risk controls and other mitigation recorded in the hazard log (Section 6) are successfully implemented, the residual risk associated with the implementation of [Ref. 1] is considered tolerable.

Document Management

Document filename: Clinical Safety Case Report: DCB3009 – PRSB Healthy Child Record Standard (Phase 1 of 2)			
Directorate / Programme	Integrating Care	**Project**	DCH
Document Reference			
Director		**Status**	Final
Owner		**Version**	1.0
Author		**Version issue date**	07.12.2018

Revision History

Version	Date	Summary of Changes
1.0	07.12.2018	First Issue

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Chris Dickson	Clinical Safety Officer (Assurance)	07.12.2018	1.0
Andy Spencer	Clinical Lead (PRSB)	04.12.2018	1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
PRSB	Professional Records Standards Body	07.12.2018	1.0
NHS Digital	Clinical Safety group	04.12.2018	1.0

References

These documents provide additional information and are specifically referenced within this report.

Ref	Doc Reference Number	Title	Version	Status
1	Report Dated October 2017	Record Standards for the Healthy Child Programme	2.0	Issued
2	NHS England Publications Gateway 05454	Healthy Children: Transforming Child Health Information	Nov 2016	Published
3	DCB0129	Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Specification	4.2	Approved
4	DCB0160	Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems – Specification	3.2	Approved
5	NPFIT-FNT-TO-TOCLNSA-0949.03	Clinical Safety Management System	1.2	Approved

Abbreviations and Acronyms

CHIS	Child Health Information Service
CSCR	Clinical Safety Case Report
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
DCB	Data Coordination Board
DCH	Digital Child Health
ePCHR	electronic Personal Child Health Record
GP	General Practise/Practitioner
HAZAN	Hazard Analysis
HAZID	Hazard Identification
HDO	Healthcare Delivery Organisation
ISB	Information Standards Board
ISN	Information Standards Notice
IT	Information Technology
NHS	National Health Service
NHSD	NHS Digital
NPSA	National Patient Safety Agency
PRSB	Professional Records Standards Body

Contents

Figures

1 Introduction

In November 2016 NHS England published a new digital strategy [Ref. 2] describing how making child health information more accessible can support parents and professionals in their care for children and young people and how that same information can be used to promote their health and wellbeing.

The first step in the journey towards modern, responsive services is to ensure that key health information can be shared safely by introducing standards. The healthy child record standard [Ref. 1], co-produced by the Professional Records Standards Body (PRSB) and NHSD in consultation with a wide variety of health and care professionals, is that first step.

1.1 Purpose

The purpose of this Clinical Safety Case Report (CSCR) is to demonstrate that hazards associated with the implementation of [Ref. 1] have been identified and the associated risk evaluated. 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 [Ref. 1]. 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 [Ref. 3] and DCB0160 [Ref. 4] respectively.

2 Clinical Risk Management

2.1 Clinical Safety Management System

[Ref. 5] presents the extant NHSD Clinical Safety Management System (CSMS) which recognises the requirement to adopt an integrated approach to clinical risk management, including the involvement of Healthcare Delivery Organisations (HDO) and professional bodies. In particular, [Ref. 5] considers integration with the Information Standards Board (ISB) and the processes under which professional standards are developed. Development of this CSCR has been supported through engagement between the Digital Child Health (DCH) programme and the following bodies, to whom [Ref. 1] also applies:

- Principal clinical suppliers (e.g. GP and other Primary Care Services);
- Child Health Information System (CHIS) suppliers;
- Health visitor and school nursing system suppliers;
- Screening service suppliers;
- System suppliers providing solutions for NHS England commissioned immunisation services;
- Digital electronic Personal Child Health Record (ePCHR) suppliers.

Additional resource from the DCH programme has also been utilised to support safety assessment activities, for example during Hazard Identification (HAZID) and Hazard Analysis (HAZAN).

3 Hazard Identification and Risk Analysis

In order to minimise the risk of harm to patients through the implementation of [Ref. 1] the following activities have been undertaken:

- A patient safety assessment based on a comparison with the implementation of other Information Standards Notices (ISN) similar to [Ref. 1];
- Development of a hazard log following formal consultation on the ISN headings and any associated safety risks; and
- Review of the implementation status and effectiveness of risk controls.

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 [Ref. 1].

4 Clinical Risk Evaluation

It was agreed that the scope of the patient safety assessment and subsequent hazard analysis would be restricted to those hazards which relate directly to the implementation of [Ref. 1]. Further HAZID and HAZAN 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 [Ref. 3] and DCB0160 [Ref. 4] respectively.

Output from the patient safety assessment was formally reviewed during a hazard workshop held 5th November 2018. During the workshop the attendees agreed that the 7 hazards identified during the patient safety assessment were bounding and should be analysed in further detail. For each individual hazard a list of possible causes was agreed, and details of any existing risk controls/mitigation were recorded for consideration during the risk evaluation process described below.

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.

Hazard Workshop Implementation of the Healthy Child Records Standard			
Date	5th November 2018	**Time**	09:00 – 12:00
Location	Meeting held by WEBEX		
	Name	**Role**	
Attendees:			
Chair	Chris Dickson	Clinical Safety Officer (CSO)	
Secretary	Mark Thomas	Safety Engineer	
	Neill Jones	Senior Clinical Advisor / GP	
	Silas Collinge	Business Analysis Manager	
	Andy Spencer	Senior Clinical Advisor / Paediatrician	

Figure 1 Hazard Workshop: Implementation of the Healthy Child Records Standard

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				

Figure 2: Risk Estimation Matrix

The risk score for each hazard was then assessed against the following 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

Figure 3: Risk Acceptability Criteria

Of the 7 hazards identified, 5 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			
Hazard	**Initial Risk**	**Risk Controls/Mitigation**	**Residual Risk**
Clinical safety significant data missing or inaccurate	**4**	Inclusion of headings and fields to capture safety significant data. Include prompts reminding clinician to enter safety significant data. The National Patient Safety Agency (NPSA) recommends that the NHS number is used to correctly identify a person. Provide training in good recording practise. Clinicians routinely cross check patient demographic details before delivering care.	**3**
Headings difficult to understand/interpret by the child or their parent/guardian	**3**	Public representatives involved in the records standard and eRed Book providers to ensure that headings use terms that are comprehensible to parents/guardians. Provide training in good recording practise.	**2**

Incorrect patient identified and given treatment	**4**	The National Patient Safety Agency (NPSA) recommends that the NHS number is used to correctly identify a person. System should be linked to the Patient Demographic Service (PDS) to obtain NHS number. Clinicians encouraged to use the Patient Demographic Service to identify the individual.	**3**
Detailed data model inhibits the recording of clinical safety significant data	**3**	The healthy child record standard will be evaluated on an on-going basis. 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. Guidance has been provided on what should be recorded under each heading and examples.	**2**
Failure to adopt record standard	**4**	Communication of the ISN by PRSB. Transfer of responsibility. Contractual obligation for service suppliers to comply. Local service providers are being supported to adopt ISN through incentivisation.	**3**

Figure 4 Summary of Risk Controls and Mitigation

On the basis that the risk controls and other mitigation identified in Table 4 are satisfactorily implemented, the residual risk associated with 4 of the 7 hazards was scored 2 or less and is hence considered broadly acceptable.

The residual risk score of 3 for the remaining hazards is judged only to be acceptable where further risk reduction is impractical. A brief justification relating to the impracticality of further reducing the risk associated with these hazards is provided below:

Tolerability of Residual Risk		
Hazard	**Residual Risk**	**Argument for Tolerability**
Clinical safety significant data missing or inaccurate	**3**	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework of [Ref. 3]. Hence the overall risk score cannot be reduced further.
Incorrect patient identified and given treatment	**3**	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework of [Ref. 3]. Hence the overall risk score cannot be reduced further.

Failure to adopt record standard	**3**	Adoption of standards through PRSB is an established process that has in this case been strengthened by formal contract and through supplier incentivisation. The only realistic additional measure that could be taken to further increase adoption would require statute, which is judged to be impractical.

Figure 5 Tolerability of Residual Risk

6 Hazard Log

A copy of the DCB3009 Phase 1 Hazard Log is attached to this CSCR.

DCB3009 Phase 1 Hazard Log.xlsx

7 Summary Safety Statement

A total of 7 hazards have been identified associated with the implementation of [Ref. 1] and are recorded within the DCB3009 Phase 1 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.

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 [Ref. 1] is considered tolerable.

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 [Ref. 5]. This report illustrates how the requirements of [Ref. 3] have been applied during the development of [Ref. 1] in the context of an information standard, rather than a Health IT System.

9 Configuration Control / Management

Maintenance arrangements for the headings that constitute these standards are specified in the General Editorial Principles for the Development of Standards for the Structure and Content of Health Records. 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 [Ref. 1] have been categorised in terms of severity and likelihood.

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

Figure 6: Severity of Hazard Consequences

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

Figure 7: Likelihood of Harm Occurring