Professional Record Standards Body

Better records for better care

CLINICAL REFERRAL INFORMATION STANDARD:

CLINICAL SAFETY REPORT

JANUARY 2019

Document Management

Revision History

Version	Date	Summary of Changes
0.2	12.11.2018	First draft adapting transfers of care hazard log
0.3	22.11.2018	Second draft following a clinical safety meeting
0.4	26.11.2018	Updated compliance matrix
0.5	03.12.2018	Updated hazards
0.6	12/12/2018	Incorporated feedback from Dr Michelle Durham
1.0	08/01/2019	Final version

Reviewed by

This document must be reviewed by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr Neill Jones	03/12/2018
Clinical Safety Officer, NHS e-Referral Service Programme	Dr Michelle Durham	13/12/2018
NHS Digital Clinical Safety Group representative	Bruno Tchek	08/01/2019

Approved by

This document must be approved by the following people:

Name	Signature	Date
Clinical Safety Officer	Dr Neill Jones	03/12/2018
NHS Digital Clinical Safety Group	Bruno Tchek	08/01/2019

Glossary of Terms

Term / Abbreviation	What it stands for
BMA	British Medical Association
e-RS	e-Referral Service
HIG	Health Informatics Group (of the RCGP)
HIU	Health Informatics Unit (of the RCP)
PID	Project initiation Document
PRSB	Professional Record Standards Body
RCGP	Royal College of General Practitioners
RCP	Royal College of Physicians

Related Documents

Ref no	Title
[1]	Clinical Referral Information Standard Final Report
[2]	NHS e-Referral Service https://digital.nhs.uk/services/nhs-e-referral-service/
[3]	Outpatients Letter Record Standard https://theprsb.org/standards/outpatientletterstandard/

Table of Contents

1. Executive summary and safety statement

34 potential hazards were identified with risk controls and mitigation also identified. Of the 34 potential hazards, 11 were generic, 3 were specific to mental health, 11 were specific to clinical referrals, 9 were deemed implementation issues. The mitigated hazards include information that should be addressed by implementers.

Of the 11 hazards specific to clinical referrals, the residual risk associated with all of the hazards was scored 2 or less and is hence considered broadly acceptable.

For generic and mental health related hazards, the residual risk associated with 7 of the 14 hazards was scored 2 or less. The residual risk score of 3 for the remaining 7 hazards is judged only to be acceptable where further risk reduction is impractical.

All hazards were identified through the consultation steps carried out to develop these standards. The consultations consisted of a multidisciplinary workshop, online survey, review of draft information models and implementation guidance (by clinical informaticians and system suppliers) and an expert user group review. These workshops, surveys and communications included patient representatives as well as professionals from Royal Colleges, specialist societies, nursing, midwifery, social care, allied health professions, health informatics professionals 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 Digital commissioned the Professional Record Standards Body (PRSB) to develop the clinical referral information standard. 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 from the RCP and a clinical lead from the Royal College of General Practitioners (RCGP).

The project has built on the information models developed in the previous PRSB transfer of care projects (which include diagnoses, procedures, allergies and medications) and is aligned with the referral headings in the Standards for the Structure and Content of Patient Records [1], published in 2013. The project was carried out in collaboration with the e-Referrals Service [2] to build on the work already undertaken by the e-RS on requirements for a minimum data set for GP clinical referral information.

The following approach was taken to develop the project deliverables:

- A multidisciplinary consultation workshop was held to discuss the acceptability of the initial draft deliverables. Outputs from the meeting were used to inform an updated version of the draft deliverables.
- An online survey was used to gain patient and professional consensus on a number of identified issues.

- The draft information models and implementation guidance were reviewed by clinical informaticians and system suppliers.
- Outstanding issues were consulted on by an expert user group. The outputs of this meeting informed the final draft deliverables.
- Final draft deliverables were disseminated to the project board for their official sign off.

This document provides the final report of the work done to manage identified clinical safety risks associated with the clinical referral information standard project. The project has produced professional standard, as such 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
- RCP
- RCPsych
- Royal College of Surgeons
- RCEM
- RCGP
- Project boards, for each project
- Expert user groups, for each project, together with wider consultation through PRSB, professional body and patient networks
- NHS Digital terminology team (UKTC)
- NHS Digital messaging team
- NHS Digital clinical safety group
- Other Royal Colleges and specialist societies
- The professional bodies of nursing, midwifery and the Allied Health Professions
- The professional bodies for social care
- Involvement of patient representatives

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 assessment carried out with input from stakeholders attending project workshops
- Production of a hazard log for the project
- Review of the hazard log following national consultation on the headings and any safety risks associated with any of the headings
- Review of mitigation of risks as part of the development of the standard headings and the implementation guidance
- Clinical safety mitigation of the project deliverables and confirmation of risks to be passed to implementation / maintenance stages identified
- Final draft of hazard log, standard headings and clinical safety report following final consultation.
- Drafting of safety case (approaches to mitigating the risks identified)
- 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? (likelihood and consequence) [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 for these standards, consequences were interpreted in terms of impact on outcomes including the person's experience of care.

6. Consultation stakeholders

Hazard Workshop			
Date	19th November 2018	**Time**	10:00 – 11:30
Location	Meeting held by WEBEX		
Attendees:			
	Name	**Role**	
	Neill Jones	Clinical Safety Officer (CSO) / GP / Clinical adviser	
	Julian Costello	GP / Clinical informatician	
	John Robinson	GP / Clinical informatician	

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 headings. 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

Those applying to all clinical records are listed first, followed by specific additional headings related to clinical referrals.

Hazard Id:	1
Hazard Name	Critical data absent as not recorded
Hazard Description:	Critical data absent because it is not recorded.
Hazard Causes:	Critical data not entered in the system, e.g. because clinician is not prompted for it or forgets to record it.
Potential Clinical Impact:	Incorrect treatment or advice may be given based on incomplete clinical information
Mitigation:	Include headings and fields to capture critical data. Include coded text to indicate the absence of information eg allergies and adverse reactions, if none are recorded, clinician must record 'no known allergies' or 'no information available'. Guidance to Implementers: This issue/risk might arise in use or misuse of our product. Mitigated By Design Training in good recording practice
Residual risk:	2
Hazard Id:	2
Hazard Name	Inconsistent use of headings
Hazard Description:	Inconsistent use of headings. i.e. The names and definitions of headings need to match between primary/secondary care/social care etc.
Hazard Causes:	Inconsistencies in data transfer between systems
Potential Clinical Impact:	Incorrect data transfer, so that the data is presented under an inappropriate heading, resulting in it being missed or misinterpreted by the care professional
Mitigation:	Include heading and data field definitions. Guidance to Implementers: Implementers have to ensure they have the most up to date version of the headings, and that the headings are correctly implemented in their system(s). Mitigated By Design
Residual risk:	2
Hazard Id:	3
Hazard Name	Too many headings

Hazard Description:	Too many headings will be time consuming and burdensome and may result in omission of key clinical information.
Hazard Causes:	Headings design issue.
Potential Clinical Impact:	Critical clinical information may be omitted, having an adverse effect on patient safety.
Mitigation:	Although the requirement is for IT systems to support all the headings, not all headings will be mandatory for implementers. It is anticipated that local trading agreements will determine the optional headings to be used by a particular community, but that where they are used they must match those in the record standard. Also pre-population will be used wherever possible to reduce burden on user. Logical grouping for the practice setting. The headings have gone through several levels of consultation to make sure there are not too many headings. Pre-population where appropriate. Users trained to use headings appropriately. Complete only fields relevant to individual patient/specialty
Residual risk:	2
Hazard Id:	4
Hazard Name	System does not support headings
Hazard Description:	Clinicians unable to add information because the headings are not in the system.
Hazard Causes:	System design issue.
Potential Clinical Impact:	Critical clinical information may be omitted having an adverse effect on patient safety.
Mitigation:	Include requirement for headings in system procurement and configuration. Test that the system can support the headings Test that the system can support the headings
Residual risk:	3
Hazard Id:	5
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.
Mitigation:	Implementation guidance states for optional fields that if a 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. System design should reduce this.
Residual risk:	3
Hazard Id:	6
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.
Hazard Causes:	Inappropriate auto population of information
Potential Clinical Impact:	The recipient may miss important information and not provide appropriate treatment.
Mitigation:	Headings specify "relevant" where there is danger of superfluous information e.g. "relevant past medical, surgical, mental health history". Headings specify that only relevant information should be recorded. System design should reduce this. Clinicians encouraged to review autopopulated information to make sure it is relevant.
Residual risk:	3
Hazard Id:	7
Hazard Name	Misidentification of patient
Hazard Description:	Correct patient may not be identifiable from the information provided.
Hazard Causes:	Unique identifier unknown or entered incorrectly e.g. NHS number entered incorrectly
Potential Clinical Impact:	If patient is misidentified, they may not receive appropriate treatment.

Mitigation:	The NPSA recommends that the NHS number is used to correctly identify a patient. 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 patient.
Residual risk:	3
Hazard Id:	8
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:	Lack of standardisation across health/care records used in different sites, resulting in insufficient information to make decision about 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.
Residual risk:	3
Hazard Id:	9
Hazard Name	Lack of clarity about required actions
Hazard Description:	Recipients are unclear about what is expected of them for the ongoing care of the patient.
Hazard Causes:	Clinicians completing the referral do not clearly specify who is responsible for required actions.
Potential Clinical Impact:	Patient receiving incorrect or no treatment as clinician fails to act upon the required actions described.

Mitigation:	Use of headings and sub-headings to specify contents of plan section should include the action to be taken and who should be responsible (eg hospital or GP). Mitigated by system design. Training in good recording practice
Residual risk:	3
Hazard Id:	10
Hazard Name	Legal issues
Hazard Description:	Users may not be able to adequately complete the legal information headings.
Hazard Causes:	Lack of understanding about medicolegal issues.
Potential Clinical Impact:	The patient may not get the care needed. Eg if a patient has made an advance directive but care professionals do not know where to look for this under the legal headings and thus do not meet the patients' needs.
Mitigation:	The descriptions under the legal headings provide clarity about what is to be recorded. Training on medicolegal issues.
Residual risk:	2
Hazard Id:	11
Hazard Name	Coded data which is not human readable
Hazard Description:	If coded information is carried without associated text it may not be comprehensible.
Hazard Causes:	Sending organisation using codes other than SNOMED CT or using SNOMED CT codes which are not in the set supported by recipient system.
Potential Clinical Impact:	Incorrect diagnosis or treatment.

Mitigation:	Include associated text with any coded field. Only use SNOMED CT in communications (eg not READ, OPCS etc,) Guidance to Implementers: This issue/risk might arise in use or misuse of our product. Mitigated By Design
Residual risk:	2
Hazard Id:	12
Hazard Name	Key information may be overlooked.
Hazard Description:	Certain information of particular importance may be overlooked (e.g. Mental Health Act status, key worker/ care coordinator contact details, safety alerts.) causing patient harm.
Hazard Causes:	Headings are not prominent enough.
Potential Clinical Impact:	Clinicians may be unaware of this key clinical information and therefore do not take these into consideration when treating the patient.
Mitigation:	Mandation and 'required' for key headings. These items to have a prominent position on the system template. Guidance to implementers. System design so reduce this. Users trained to use headings appropriately.
Residual risk:	3
Hazard Id:	13
Hazard Name	High risk conditions
Hazard Description:	Failing to identify a critical clinical condition e.g paranoid schizophrenia, borderline personality disorder, suicide risk.
Hazard Causes:	Lack of a place to clearly recognise the condition.
Potential Clinical Impact:	If the underlying conditions are not recognised and appropriate care given the patient may become a safety risk to self and/ or others.

Mitigation:	Clinical headings were developed from consultations with experts in mental health. They support the ability to record and communicate the pertinent information required to identify and evaluate criticality and high risk conditions e.g. diagnoses, clinical summary, safety alerts, actions and requested actions. Implementation guidance provided. Existing methods for identification of high risk patients should continue to be used, eg patient held information, care plans.
Residual risk:	3
Hazard Id:	14
Hazard Name	Different statutory and legal requirements across the four UK countries
Hazard Description:	Certain headings will have different statutory and legal requirements and applications in the four UK countries e.g. Mental Health Act, Deprivation of Liberty Safeguards, Mental Capacity Assessments, Care planning arrangements etc.
Hazard Causes:	Confusion by clinicians about which headings are relevant to the country in which they work.
Potential Clinical Impact:	Confusion for clinicians who are not aware of the correct requirements, which may result in the patient receiving inappropriate care.
Mitigation:	The clinical descriptions under the legal and statutory requirement headings provide clarity about what is to be recorded. Implementation guidance refers to the relevant legislation and statutory requirements in each country. System design should reduce this. Clinicians know what is required in their practice. Training on country specific issues.
Residual risk:	2

Hazard Id:	15
Hazard Name	Referral never arrives
Hazard Description:	Recipient doesn't receive the clinical referral
Hazard Causes:	1) Referral was not sent 2) Referral was sent but did not arrive due to failure in delivery mechanism
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result

Mitigation:	Involve patient in the process Mitigated by system design e.g. built in dashboards, read receipts, delivery reports Training in good practice Patient awareness of following up referrals and being able to review online
Residual risk:	2
Hazard Id:	16
Hazard Name	Un-read clinical referrals
Hazard Description:	Recipients of the clinical referral do not read them.
Hazard Causes:	1) Clinical referrals not opened and unread. 2) Recipients may be unaware that the clinical referral has been sent to their system. 3) Clinical referral may not have arrived at the recipient system
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result
Mitigation:	Implementation guidance states no automatic upload and audit trail to ensure individual review of clinical referral contents. Mitigated by system design e.g. built in dashboards, read receipts, delivery reports at hospital end Audit trail to identify reviewer Training in good practice Process within GP practice to handle shared inbox.
Residual risk:	2
Hazard Id:	17
Hazard Name	Unactioned clinical referral
Hazard Description:	Recipients of the clinical referral do not act upon them.
Hazard Causes:	1) Clinical referrals not opened and not acted upon 2) Clinical referrals opened but unactioned 3) Recipients may be unaware that the clinical referral has been sent to their system. 4) Clinical referral may not have arrived at the recipient system
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result

Mitigation:	Implementation guidance states no automatic upload and audit trail to ensure individual review of clinical referral contents. Mitigated by system design e.g. built in dashboards, read receipts, delivery reports at hospital end Audit trail to identify reviewer Training in good practice Process within GP practice to handle shared inbox.
Residual risk:	2
Hazard Id:	18
Hazard Name	Attached information is out of date
Hazard Description:	There would be a time period between referral and admission and this information may be out of date
Hazard Causes:	Out of date investigations, medication list at time of referral may be taken for current list without checking
Potential Clinical Impact:	May result in the patient receiving inappropriate care or medication
Mitigation:	Implementation guidance. Summary Care Record for current medication list. Clinician knowledge of the time period between referral being sent and attendance Mitigate by system design e.g. medication at time of referral, access current medications Training Ensure hospitals are able to access current medication list
Residual risk:	2
Hazard Id:	19
Hazard Name	Delay in communicating clinical referral
Hazard Description:	Delay in the time period between referral and its receipt and therefore associated actions
Hazard Causes:	Decision made to refer but the time is extended due to process or system
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result

Mitigation:	Involve patient in the process Mitigated by system design e.g. built in dashboards, read receipts, delivery reports Training in good practice Patient awareness of following up referrals and being able to review online
Residual risk:	2
Hazard Id:	20
Hazard Name	Referral to incorrect department
Hazard Description:	Referral is sent to incorrect department
Hazard Causes:	Decision made to refer but the time is extended due to process or system
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result Organisational risk Risk to other patients due to inappropriate use of resource
Mitigation:	Involve patient in the process Mitigated by system design e.g. redirect Training Patient awareness of the correct department being referred to
Residual risk:	1
Hazard Id:	21
Hazard Name	Referral to inappropriate Clinician
Hazard Description:	Referral is sent to inappropriate clinician. Clinician unable to perform the right procedure
Hazard Causes:	Lack of awareness of a suitable clinician to refer to
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result Organisational risk Risk to other patients due to inappropriate use of resource

Mitigation:	Involve patient in the process Mitigated by system design e.g. redirect Training Awareness of resources and capability
Residual risk:	1
Hazard Id:	22
Hazard Name	Patient non-attendance due to not understanding importance of the problem
Hazard Description:	Referral being made without collaboration with the person and not adequately explaining the problem
Hazard Causes:	Lack of patient engagement Lack of patient activation Lack of adequate explanation of the problem and reason for referral
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result
Mitigation:	Involve patient in the process Mitigated by system design e.g. online referral letter Sending patient reminders Training in good practice Patient education on the reason for referral
Residual risk:	2
Hazard Id:	23
Hazard Name	Incorrect patient demographic
Hazard Description:	Incorrect patient demographic information resulting in appointment missed
Hazard Causes:	1) Patient moves, doesn't inform practice 2) Incorrect patient record open
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result or incorrectly performed
Mitigation:	Mitigated by system design Training in good practice

	Patient education to keep their details up to date
Residual risk:	2
Hazard Id:	24
Hazard Name	Individual requirements not met
Hazard Description:	Individual requirements for attendance not communicated or met eg. lack of translator, wheelchair access, or other needs
Hazard Causes:	Not identified at referral Not actioned at attendance
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result
Mitigation:	Involve patient in the process Individual requirements actionable Mitigated by system design Training in good practice
Residual risk:	1
Hazard Id:	25
Hazard Name	Repeat investigations incomplete data
Hazard Description:	Information not updated or not included in referral letter
Hazard Causes:	Information not updated or not included in referral letter
Potential Clinical Impact:	Clinicians unaware of the patient's care needs Investigations, treatments, diagnoses are delayed as a result or incorrectly performed Waste of resources
Mitigation:	Patient access to records Mitigated by system design e.g. information is always available Training
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:	26
Hazard Name	Unavailable information
Hazard Description:	Information missed out as system already implemented is too structured/ inflexible to include headings.
Hazard Causes:	E.g. Already structured systems, which cannot be changed or only at high cost.
Potential Clinical Impact:	Incorrect treatment as a result of insufficient information.
Residual risk:	3
Hazard Id:	27
Hazard Name	Electronic system failure
Hazard Description:	If the headings are only designed for use in electronic systems, there is a risk that there is no fall back if the system is not available.
Hazard Causes:	Critical problem of system.
Potential Clinical Impact:	Inability to record patient data. Incorrect treatment as a result of insufficient information.
Residual risk:	5
Hazard Id:	28
Hazard Name	Information sharing
Hazard Description:	There may be some information (such as sexual health information) that patients do not want recorded on a shared record.
Hazard Causes:	Autopopulation of sensitive information or failure of clinician to discuss what information was acceptable to be included.
Potential Clinical Impact:	Violations of privacy may cause great distress to the patient.
Residual risk:	3
Hazard Id:	29
Hazard Name	Cross boundary interpretation
Hazard Description:	Incorrect interpretation/ translation of clinical information.
Hazard Causes:	Incorrect interpretation/ translation of clinical information between IT systems.
Potential Clinical Impact:	Incorrect clinical information resulting in incorrect treatment.
Residual risk:	3
Hazard Id:	30
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.
Residual risk:	4
Hazard Id:	31
Hazard Name	Inability to exchange information
Hazard Description:	Different coding systems used in different sites will limit exchange and re-use of data.
Hazard Causes:	Different coding systems used in different sites.
Potential Clinical Impact:	Incorrect clinical information resulting in incorrect treatment.
Residual risk:	4
Hazard Id:	32
Hazard Name	Policy/statutory evolution
Hazard Description:	As policy/statutory requirements change the current headings will be obsolete.
Hazard Causes:	Statutory requirements change all the time.
Potential Clinical Impact:	Use of obsolete headings mean required information may not be captured and communicated resulting in potential inappropriate treatment.
Residual risk:	4
Hazard Id:	33
Hazard Name	Use of diagnosis qualifiers
Hazard Description:	Using diagnosis qualifiers to indicate certainty of diagnoses. If the qualifier indicating 'working diagnosis' is separated from the diagnosis code it may be taken to be 'final diagnosis'.
Hazard Causes:	Separation of diagnosis qualifier from diagnosis SNOMED CT code.
Potential Clinical Impact:	Inappropriate treatment as clinical decision support may indicate an inappropriate medication e.g. working diagnosis of ischemic heart disease (IHD) may trigger prescription of statins.
Residual risk:	4
Hazard Id:	34
Hazard Name	Recording allergies as diagnoses
Hazard Description:	If allergic causative agents are recorded using SNOMED CT diagnosis codes, the IT system will not be able to use the code in prescribing decision support.
Hazard Causes:	If IT system prescribing decision support uses allergic agents rather than diagnosis codes.
Potential Clinical Impact:	Risk of allergic reaction as clinicians are unaware of the allergic agent.
Residual risk:	5

10. Summary safety statement

34 potential hazards were identified with risk controls and mitigation also identified. Of the 34 potential hazards, 11 were generic, 3 were specific to mental health, 11 were specific to clinical

referrals, 9 were deemed implementation issues. The mitigated hazards include information that should be addressed by implementers.

Of the 11 hazards specific to clinical referrals, the residual risk associated with all of the hazards was scored 2 or less and is hence considered broadly acceptable.

For generic and mental health related hazards, the residual risk associated with 7 of the 14 hazards was scored 2 or less. The residual risk score of 3 for the remaining 8 hazards is judged only to be acceptable where further risk reduction is impractical.

All hazards were identified through the consultation steps carried out to develop these standards. The consultations consisted of a multidisciplinary workshop, online survey, review of draft information models and implementation guidance (by clinical informaticians and system suppliers) and an expert user group review. These workshops, surveys and communications included patient representatives as well as professionals from Royal Colleges, specialist societies, nursing, midwifery, social care, allied health professions, health informatics professionals 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.
1	Acceptable, no further action required

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