Professional Record Standards Body

Better records for better care

Nursing Care Needs Standard

CLINICAL SAFETY CASE REPORT

October 2023

Document Management

Revision History

Version	Date	Summary of Changes
0.1	07/09/2023	First draft
0.2	12/09/2023	Updated following feedback on hazard log by CSO
O.3	02/10/2023	Updated following feedback from PRSB's Assurance Committee

Reviewed by

This document must be reviewed by the following people:

Reviewer	Version	Date
Clinical Safety Officer - Steve Bentley	0.1	08.09.23
PRSB Assurance Committee	0.2	12.09.23
Project Board	0.2	27.09.23

Approved by

This document must be approved by the following people:

Name	Version	Date
Clinical Safety Officer - Steve Bentley	0.2	29.09.23
NHS England Clinical Safety Group	0.3	

Glossary of Terms

Term / Abbreviation	What it stands for
ANP	Advanced Nurse Practitioners
CNS	Clinical Nurse Specialists
CSCR	Clinical Safety Case Report
CSG	Clinical Safety Group
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
IT	Information Technology
NHSE	National Health Service England
PRSB	Professional Record Standards Body

Related Documents

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

1. Introduction

Background and Context

The pandemic has accelerated the adoption of digital tools and systems among frontline health and care staff, along with a surge in citizen engagement with digital services. These changes highlighted the importance of standards, guaranteeing that digitally exchanged information is unequivocal, timely, and supports high-quality care. Co-producing these standards with frontline health and care workers, along with service users, guarantees that they remain person-centred. This standardised approach not only enhances interoperability but also streamlines workflows, affording more time for care provision.

Crucially, patient and citizen involvement at every level, in every stage, and across all workstreams in this national endeavour is paramount. This approach ensures that citizens are equal partners in their care, fostering self-care and enabling them to drive and evaluate outcomes that matter most to them. A collaboratively developed national standard promises to improve interoperability, promote collaborative working, and facilitate shared decision-making. The potential benefits, spanning patients, nurses, and the broader healthcare system, are manifold, ultimately translating to a substantial enhancement in care quality and safety over the long term.

Addressing the need to refine nursing information architecture, the National Health Service England (NHSE) Digital Nursing Programme entrusted the Professional Record Standards Body (PRSB) with a comprehensive discovery project. The findings, submitted in July 2021, underscore the pivotal role of nursing documentation and communications within a person's circle of care. The project underscored that achieving integrated care hinges on concurrent consideration of documentation practices, information needs, and integration of both social care and healthcare.

In August 2022, NHSE commissioned the PRSB for the scoping phase, with a clear goal: to establish a nursing documentation standard that addresses key areas of nurse-led care, with a focal point on patient/person nursing care assessments – a pivotal aspect of nursing documentation. This phase ran concurrently with other nursing documentation standardisation projects, all converging towards the creation of a unified framework for standardised nursing documentation.

Following a thorough review of the three strands of Nursing standardisation projects, NHSE, in consultation with key nursing stakeholders, concluded that the core of the Nursing Care Needs Standard should revolve around the functional care needs of individuals, enabling them to lead their best lives. Thus, NHSE commissioned the PRSB to develop a Nursing Care Needs Standard based on the functional needs of individuals, building upon the work completed thus far in relation to the Nursing Care Needs Standard.

Purpose of the Clinical Safety Case Report

This Clinical Safety Case Report (CSCR) for the Nursing Care Needs Standard addresses the requirements of DCB0129 V2.0 Clinical Risk Management: it's Application in the Manufacture of Health IT Systems [Ref.1].

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. The hazards identified here, along with proposed mitigations, are for system

suppliers and providers implementing the standards to pick up and consider when implementing the standard and doing their own assurance.

2. Scope

The scope of this project was defined based on the previous phases, which included a review of key literature, and conversations with professionals and citizens.

In Scope

The nursing led care in scope is the first nursing care contact assessment. The standard focuses on eating and drinking, mobility, elimination (toileting and continence), personal hygiene and dressing, skin, and medication self-management. 'Must haves' for the standard will also be developed.

The care settings in scope are:

- Hospital
- Community
- Care homes with Nursing

Out of scope

Mandating which specific risk assessment tool should be used for an assessment.
Nurse treatment plans used by Clinical Nurse Specialists (CNS) and Advanced Nurse Practitioners (ANP) and in non-inpatient care settings.

The following clinical specialities and their patients' needs have not been considered when developing this standard:

- Midwifery
- Neonatal care
- Mental health nursing

Although the inclusion and exclusion criteria are short, they are not exhaustive. Discussion identified that there will be many care settings that assess functional needs, including mental health. This standard should be used in care settings where it is relevant.

3. Clinical risk management system

The NHS England Clinical Safety Group (CSG) operates a full Clinical Safety Management System (CSMS) that encompasses integration with health organisations and professional bodies. The CSMS considers the integration with the Data Alliance Partnership Board (DAPB) and the process in which professional standards are developed in the CSMS framework. The essential structures of a CSMS have been implemented in this project through the consultation with healthcare professionals, patients, informaticians and clinical system suppliers, during the development of the standard. Governance structures, project methodology and stakeholder engagement are described in the Nursing Care Needs Standard final report. The PRSB remit, organisational structure, roles and responsibilities of key personnel are fully described on the PRSB website at: www.theprsb.org.

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 to fully apply

DCB0129. Organisations involved in the deployment of such software will still be expected to fully apply DCB0160.

The role of a Clinical Safety Officer (CSO) was to review the Clinical Safety Case using his/her clinical experience to judge the appropriateness and effectiveness of the risk management strategies and mitigating actions. The CSO monitored the execution of the Clinical Safety Case and ensured that clinical safety obligations were discharged.

The clinical safety case documentation is reviewed and approved by the NHS England Clinical Safety Group. The clinical safety case report is published on the PRSB website. Updates to the clinical safety case is the responsibility of PRSB.

4. Hazard identification & Clinical Risk Analysis

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

- Potential clinical safety issues identified during consultation events and other activities during the development of the standard.
- Safety issues identified by a team of the clinical and patient leads, informaticians and clinicians participating in a series of 3 hazard workshops run using 1 hour team meetings over a period of about 3 weeks.
- Production and review of a hazard log for the standard.
- Review of the hazard log and any associated safety risks.
- Review of mitigation of risks.
- Clinical safety mitigation and confirmation of risks to be passed to implementation / maintenance stages identified.
- Drafting of safety case (approaches to mitigating the risks identified).
- Final draft of hazard log and clinical safety report.
- NHS Digital clinical safety case review.

5. Clinical risk evaluation and clinical risk control

Patient safety risk assessment approach

The patient safety risk assessment approach followed the new approach and template for hazard logs from the NHSE Clinical Safety Group and was as follows:

- Identify the hazard effect.
- Identify the actual hazard and the potential harm.
- Detail the possible causes.
- Assess the severity and likelihood and overall initial risk score for each possible cause. Derive an overall risk score for the hazard based on the worst case of the individual causes.
- Consider the mitigation controls which could be applied to reduce the risk for each possible cause.

- Consider the residual risk score based on revised severity and likelihood for each possible cause, and overall for the hazard based on the worst case cause.

Hazard log composition

The Hazard log is contained in an Excel Spreadsheet which follows the NHSE Clinical Safety Group template.

Risk assessment methodology

Risk assessment was undertaken using the risk matrix and scoring tool shown in Appendix A. Note that severities were interpreted in terms of impact on outcomes including the person's experience of care.

The new way of working and template means that each effect, hazard and harm can have multiple possible causes. The approach used was to risk assess and consider controls for each possible cause.

6. Hazard log

The full hazard log is attached as a separate Excel document.

In total there are 5 hazards, but with each having several possible causes (36) which are risk assessed with additional controls at the cause level. In addition, each hazard has an overall risk score based on the worst-case cause.

The breakdown is as follows:

- 1 hazard have an initial risk of 4, reducing to 3 after additional controls.
- 4 hazards have an initial risk of 3, all staying at 3 after additional controls.

The 1 hazard with an initial risk score of 4 has 1 possible cause with an initial risk of 4 with the risk reduced to 3 with additional controls.

Full details of the hazards and causes are in the hazard log.

7. Training

Training of the end users of the systems implementing the Nursing Care Needs Standard is offered as a mitigation for a number of the possible causes of the hazards identified. This should be considered, when developing these systems. Users should understand the limitations of any system and how to use them to best understand the context and provenance of data. They should also understand that they are not designed to replace consulting the patient, which is an important mitigation in any clinical system.

Implementation guidance is provided as a part of the Nursing Care Needs Standard and PRSB provide a support service (support@theprsb.org) where implementors can get advice about implementing the standard.

8. Test Issues

As the Nursing Care Needs Standard is a conceptual model and, as yet, has not been implemented in any systems, it has not been possible to test the model in vivo. It is therefore dependent on those developing systems doing full end to end clinical safety testing. Any issues with the standard identified during testing should be raised with the PRSB through the support service (or by email to support@theprsb.org). All enquiries will be responded to, and issues requiring changes to the standard will be put on the maintenance log and the standard updated at times in accordance with the urgency of the issues identified as detailed in PRSB's release policy.

9. Summary safety statement

Five potential hazards were identified with a total of 36 possible causes. All hazards were identified through the consultation processes carried out to develop and assure the standard. The consultation process is described in detail in the project final report.

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

A. mitigated by the development of the standard (residual risk of 2 or less)
B. or the residual risk (level 3) has been transferred (with guidance) to the implementers.

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

The residual risk of the hazards and their possible causes after additional controls are all level 3 or 2. There are 26 possible causes across 4 hazards at residual risk level 3 and the mitigations for the level 3 risks are outside the control of PRSB and these risks are therefore handed on to the implementors and deployers of this standard. There are 10 possible causes (across 4 hazards) rated at level 2 and considered acceptable.

10. Quality Assurance and Document Approval

The hazard log and clinical safety case have followed the DCB0129 Risk Management standard and approach. The overall development of the Nursing Care Needs Standard has followed the PRSB methodology, proven and trusted by our members and stakeholders, overseen by a project board and the PRSB's independent assurance committee. Both the project board and the assurance committee have reviewed the hazard log and safety case with final approval residing with the NHSE Clinical Safety Group.

11. Configuration Control / Management

The hazard log and clinical safety case are both version-controlled documents held in the PRSB project files and managed under the PRSB information management policy.

Future governance of the development and maintenance of the Nursing Care Needs Standard is the responsibility of the PRSB.

12. 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
		Severity				

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

Severity Classification	Interpretation	Number 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 consequence	Single

	Risk Acceptability
5	Unacceptable level of risk.
4	Mandatory elimination or control 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