



**Professional
Record
Standards
Body**

**Better records
for better care**

Wound Care Information Standard

CLINICAL SAFETY CASE REPORT

September 2023

Document Management

Revision History

Version	Date	Summary of Changes
0.1	20/3/2023	First draft
0.2	04/07/2023	Revised after changes to hazard log (v0.5) and in response to comments from the NHSE CSG
1.0	27/09/2023	V1 after NHS Clinical Safety Group approval

Reviewed by

This document must be reviewed by the following people:

Reviewer	Version	Date
Clinical Safety Officer - Steve Bentley	0.1	28/03/23
PRSB Assurance Committee	0.1	31/03/23
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Approved by

This document must be approved by the following people:

Name	Version	Date
Clinical Safety Officer - Steve Bentley	0.1	28/03/2023
NHS England Clinical Safety Group	0.2	21/09/2023

Glossary of Terms

Term / Abbreviation	What it stands for
CIS	Core Information Standard
CSCR	Clinical Safety Case Report
CSG	Clinical Safety Group
CSMS	Clinical Safety Management System
CSO	Clinical Safety Officer
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GUI	Graphical User Interface
IG	Information Governance
NHS	National Health Service
NHSD	NHS Digital
NHSE	NHS England
NWCSP	National Wound Care Strategy Programme
PDS	Patient Demographic Service
PRSB	Professional Record Standards Body
RBAC	Role Based Access Control
SNOMED CT®	Systematized Nomenclature of Medicine – Clinical Terms

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

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1 Introduction

1.1 Purpose of Wound Care Information Standard

The Professional Record Standards Body has been commissioned by the National Wound Care Strategy Programme to produce a wound care record information standard that will support the programme's strategic aims to

- Reduce patient suffering.
- Improve healing rates.
- Prevent wounds occurring and recurring.
- Use clinical time and other health and care resources in the most effective way.

Wound care is provided by a wide range of professionals working as a care team that can include doctors, nurses, podiatrists and others, as well as people themselves and their carer(s). As such it is vital that information is shared so that care is maximised. However, there is currently no recognised standard for recording the details of the provision of wound care in a person's care record and documenting the assessments, observations and treatments that have been delivered in a way that can be shared between care professionals that provide wound care. The NWCSP has identified the creation of an information standard as a key enabler to improving wound care services for people. The PRSB working with its member organisations, representing the health and care professions and people who use services, set out to develop a standard to support sharing information digitally to deliver safe and effective care.

The PRSB information record standard on wound care provides a framework for clinicians to record the clinical assessment, observations and treatments delivered, based on professional guidance and the relevant NICE guideline, evidence review, and extensive consultation with healthcare professionals, people and carers.

The information standard is a record standard and defines what items should be recorded: a very few are mandatory, some are required to be used where the information is available, and some are optional. The standard will also enable the wound care information to be shared between professionals and their different record systems.

1.2 Purpose of the Clinical Safety Case Report

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

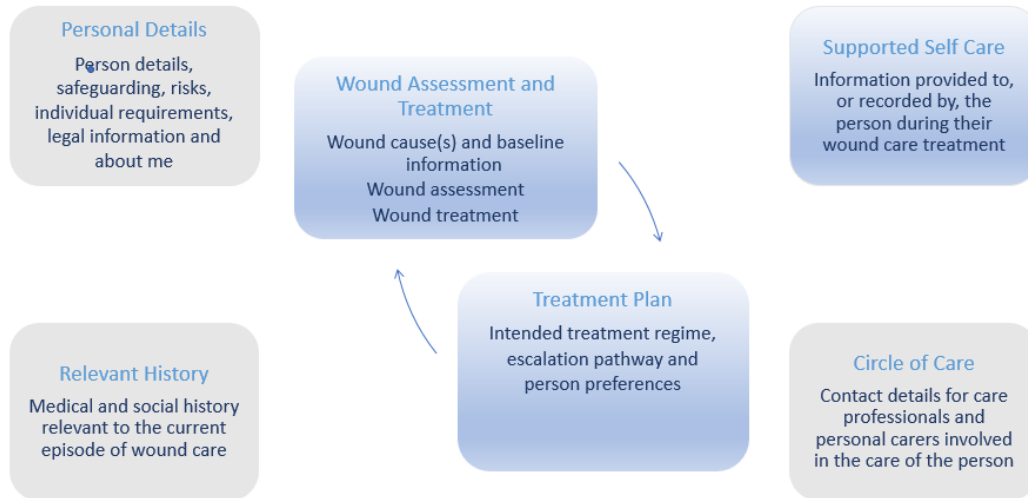
The full application of DCB0129 cannot be applied, as the professional standard itself is not a manufactured health IT system. However, the guidance within DCB0129 concerning clinical risk management and appropriately governed hazard assessment has been considered. The hazards identified here, along 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. System Definition/ Overview/ Scope

The standard comprises 3 domains which are specific to wound care; wound assessment and treatment, treatment plan and supported self care; and 3 domains

which for information which should be available to the professionals but are not specifically part of the wound care standard; personal details, circle of care and relevant history. These are shown in the diagram below.

Structure of the draft standard



The standard doesn't define what systems should contain the wound care information and it is recognised that this will vary between local implementations and it is possible this could be fulfilled by either a specialist wound management system or a general electronic patient record, or more likely a combination of both.

2.1 In Scope

The scope of the standard includes:

- Applicable to all UK nations
- All ages including children.
- Alignment with NWCSP and NICE guidance
- The standard should be developed as far as is reasonably possible to be generic for wide use for wound care, but its scope is specifically:
 - Lower limb (leg & foot) wounds
 - Pressure ulcers
 - Surgical wounds
- The standard will cover the assessment, management, maintenance and prevention of the wound types listed above and will cover all settings including acute and community.

2.2 Out of scope

- Wound types not specified above, including those caused by external factors such as new trauma and burns.
- Prevention for peripheral arterial disease. While leg wounds often result from vascular or peripheral arterial disease, prevention of peripheral arterial disease is beyond the scope of wound care.
- Conditions associated with lymphoedema are also out of scope.

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 Wound Care Information 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 [Ref. 1]. Organisations involved in the deployment of such software will still be expected to fully apply DCB0160. [Ref.2].

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 from the National Wound Care Strategy Programme participating in a series of 4 hazard workshops run using 1 hour team meetings over a period of about 8 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

5.1 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.

5.2. Hazard log composition

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

5.3 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 6 hazards, but with each having up to 16 possible causes, leads to a total 48 possible causes 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:

- 3 hazards have an initial risk of 4, all reducing to 3 after additional controls.
- 2 hazards have an initial risk of 3, all staying at 3 after additional controls.
- 1 hazard has an initial risk of 2, staying at 2 after additional controls.

The 3 hazards with an initial risk score of 4 each have 1 cause with an initial risk of 4, 1 of which reduces to 3 with additional controls, 2 of which reduce to 2 with additional controls.

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

7 Training

Training of the end users of the systems implementing the wound care information 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 Wound Care Information Standard and PRSB provide a support service (support@theprsb.org) where implementors can get advice about implementing the standard.

8 Test Issues

As the Wound Care Information 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

6 potential hazards were identified with a total of 48 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. It included patient and carer representatives as well as professionals from Royal Colleges, specialist societies, allied health professions, health informatics professionals, social care professionals and system suppliers.

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 5 hazards and 29 possible causes 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 is 1 hazard, and 19 possible causes (across 5 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 wound care information 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 Wound Care Information Standard is the responsibility of the PRSB.

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