Clinical Risk Management Plan

Clinical Risk Management Plan TEMPLATE

|  |  |
| --- | --- |
| Version Number: | 2.0 |
| Author (name) | Paul Warwick |
| Name of approving committee | Interweave Management Board |
| Date Issued: | 12.02.2024 |

**Updates**

|  |  |  |
| --- | --- | --- |
| New Version Number | Date | Change |
| V1 | 13 09.2021 | Independent quality review of draft document to include consistency, branding changes and alignment to local ICS programme methods |
| V2 | 12.02.2024 | Review of template, change of branding and lay out to reflect consistency across all CS documentation |
|  |  |  |
|  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Document filename:** | | | |
| **Directorate / Programme** |  | **Project:** |  |
| **Document Reference:** | |  | |
| **Director:** |  | **Status:** |  |
| **Owner:** |  | **Version:** |  |
| **Authors:** |  | **Version issue date:** |  |

**Document Management**

**Revision History**

|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Summary of Changes** |
|  |  |  |
|  |  |  |

**Reviewers**

This document must be reviewed by the following people:

|  |  |  |  |
| --- | --- | --- | --- |
| **Reviewer name** | **Title / Responsibility** | **Date** | **Version** |
|  |  |  |  |
|  |  |  |  |

**Approved by**

This document must be approved by the following people:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Title** | **Date** | **Version** |
|  |  |  |  |
|  |  |  |  |

**Related Documents**

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

| **Ref** | **Doc Reference** | **Title** | **Version** |
| --- | --- | --- | --- |
| 1 | DCB 0129 | Clinical Risk Management: its Application in the Manufacture of Health IT Systems - Specification | 3.2 |
| 2 | DCB 0160 | Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - Specification | 4.2 |
| 3 | CRMS | Clinical Risk Management System (organisations own- please see Interweave version as an example) |  |

**Contents**

[Introduction 4](#_Toc490472093)

[Purpose of Document 4](#_Toc490472094)

[Background to clinical safety standards and requirements 4](#_Toc490472095)

[DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems 4](#_Toc490472096)

[DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems 4](#_Toc490472097)

[Programme Overview & Clinical Safety 5](#_Toc490472098)

[Impact of DCB0129 and DCB0160 on Programme 5](#_Toc490472099)

[Clinical Risk Management File 6](#_Toc490472100)

[Programme Individual project areas and associated assurance approaches 6](#_Toc490472101)

[Resources / Personnel 6](#_Toc490472102)

[Clinical Risk Evaluation and Management 7](#_Toc490472103)

[Appendix – Risk Classification Matrix 9](#_Toc490472104)

# Introduction

## Purpose of Document

The purpose of the Clinical Risk Management Plan (CRMP) is to define the implementation of, and any variation to, the *Insert Organisation Name* Clinical Safety Management System. It describes how the project team will conduct clinical risk management to ensure patient safety with respect to services provided and the interrelated and interactive activities that will occur to ensure that the project meets the requirements of DCB0129 and DCB0160

In fulfilling this purpose, any variation to the standard practices and procedures to be followed, as defined by the Clinical Risk Management System (CRMS), when performing the activities of the programme are documented here in this document.

This CRMP identifies the means by which the project shall be controlled to ensure that the safety work is of high quality, conforms to the requirements of the CSMS and any specific programme requirements.

This document will be updated when the plan changes in any way as to deviate from what has been committed to deliver.

## Background to clinical safety standards and requirements

Information standards provide the mechanism for introducing requirements to the NHS, those with whom it commissions services and its IT system suppliers. There are two Information Standards related to patient safety described below. These Standards can be found at:





## DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems

This standard sets clinical risk management standards for manufacturers of Health IT systems. It requires the manufacturer to establish a structure within which clinical risks associated with the design and development of a new Health IT system or the modification of an existing system are properly managed. It also ensures that outputs are clearly documented to provide evidence of compliance. Compliance with the standard ensures that the manufacturer has instigated a best practice clinical safety programme during the manufacture of the health IT system.

## DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems

This standard requires health organisations deploying and using new or modified health IT systems to have a structure to manage clinical risks associated with that deployment. Many of the requirements in DCB0129 are repeated in DCB0160 for the health organisations.

# Project Overview & Clinical Safety

Provide an overview of the programme or project in which this document relates to. Include a high-level summary of the aims and scope only. Any detailed information can be referenced out to existing documentation held in the programme document files. Part of the summary should highlight the timeline for delivery of any part of the programme and also the scope in relation to clinical safety with any reasoning behind decisions being made.

**Note:** any change in phase scope, content and future phase development will be addressed in this document by a revised CRMP document. This revised documentation will be agreed by theclinical safety officer to ensure the correct governance and control is in place.

# Impact of DCB0129 and DCB0160 on Project:

Whilst the project may not physically be manufacturing the service itself, it may classify as a ‘Manufacturer’ as defined in DCB0129:

‘Person or organisation with responsibility for the design, manufacture, packaging or labelling of a Health IT System, assembling a system, or adapting a Health IT System before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.’

Within the safety standard DCB0160 we can also assume partial responsibility in the role of a Health Organisation. This standard is addressed to those persons in Health Organisations who are responsible for ensuring clinical safety in the deployment of Health IT Systems through the application of clinical risk management.

The project will therefore adhere to all applicable requirements of DCB0129 and DCB0160 in this regard.

Note: this section provides guidance for those organisations who may fall within the scope of both safety standards. If this does not apply then please delete this section.

# Clinical Risk Management File

The project SharePoint/Intranet/file location site contains all relevant clinical safety documentation and will perform the function of the Clinical Risk Management File. This folder will be managed by the Clinical Safety Officer and Clinical Safety Engineer. The location of the SharePoint site is:

[*provide reference here*]

## Individual project areas and associated assurance approaches

Highlight any individual areas where assurance processes differ from the normal within the organisation. Document any assumptions or constraints that may provide detail to the CRMP and overall delivery and compliance to the safety standards.

## Resources / Personnel

The Clinical Safety Officer is responsible for ensuring the clinical safety of the project through the application of clinical risk management. The Clinical Safety Officer is a suitably qualified and experienced clinician who holds current registration with their relevant professional body and has had appropriate training for this role.

Key responsibilities include:

* approval of the Clinical Risk Management Plan to confirm that the plan is appropriate and achievable in the context of the Health IT System development and modification;
* ensuring that clinical risk management activities are completed in accordance with the Clinical Risk Management Plan (this document);
* reviewing and approving of all safety documentation including Clinical Safety Case Reports and Hazard Logs;
* reviewing evidence in the Clinical Risk Management File to ensure it is complete and supports the Clinical Safety Case Report;
* providing recommendation to GP Connect Programme whether the Service is safe to release; and
* escalating any unacceptable safety risks.

**Table 1 Roles and responsibilities**

|  |  |  |  |
| --- | --- | --- | --- |
| Development Team | | Assurance Team | |
| Safety Engineer |  | Safety Engineers |  |
| Clinical Safety Officer |  | Clinical Safety Officers |  |

**Note:** This is an example of where roles and responsibilities can be summarised simply or referenced out to more suitable and detailed documentation if available.

## Clinical Risk Evaluation and Management

The clinical risk matrix, evaluation and management process used is defined below and can also be found in more detail within the appendix. The hazard assessment process will follow the standard *Clinical Risk Management System* [*provide reference*] approach.

Hazards may be identified in other ways during the development and use of the system such as:

* Discovery during design of a solution by supplier or NHS Organisation;
* Testing of amended functionality;
* Ad hoc testing of live service functionality;
* Reporting of an incident or problem within the live service; and
* Identification by a member of staff within the supplier or NHS Organisation

For each identified hazard, the following information will be defined and recorded on the Hazard Sheet and summarised on the Hazard Log:

* Hazard number;
* Hazard name;
* Hazard description;
* Potential clinical impact – this will describe the effect of the hazard in the care setting and potential impact on the patient;
* Possible causes – these may be technical, human, error etc. A hazard may have a number of causes; and
* Existing controls – these are identified existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation again the hazard, i.e. will be used as part of the initial Hazard Risk Assessment.

Each Hazard will be discussed by the Clinical Safety Officer for the project and any other appropriate people. They will perform the following tasks and record the outcome in the Hazard Sheet and a summary in the Hazard Log:

* Estimation of clinical risks;
* Clinical risk evaluation; and
* Clinical risk control option management.

Estimation of clinical risks.

For each identified hazard estimation will be made of the clinical risk. This will include the severity of the hazard, the likelihood of the hazard and the resulting clinical risk. The estimation process will follow that established by the safety processes defined in DCB0129. A copy of the risk assessment matrix is provided in the appendix.

**Note:** Any valid approach to hazard assessment and associated risk assessment matrices can be used. The sample provided in this document is to highlight documentation requirements only and does not provide a recommendation on any specific methodology to be used. This decision must be made by the organisation and its clinical safety team.

# Appendix – Risk Classification Matrix

**Clinical Risk Management 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 Matrix key - Severity**

|  |  |
| --- | --- |
| 5 | Unacceptable level of risk.  Mandatory elimination or control to reduce risk to an acceptable level |
| 4 |
| 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 | Acceptable where cost of further reduction outweighs benefits gained. |
| 1 | Acceptable, no further action required |

**Hazard likelihood definitions**

|  |  |
| --- | --- |
| **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 on the great majority of occasions will not |
| Very low | Negligible or nearly negligible possibility of occurring |

**Hazard Consequence definitions**

| **Consequence 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 severity | Single |