Interweave Clinical Risk Management System

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| Document filename: Interweave Clinical Risk Management System (CRMS) | | | |
| Directorate/Programme: Interweave |  | Project(s): All Clinical Safety and Healthcare IT |  |
| Document Reference CRMS | |  | |
| Director: Lee Rickles |  | Status Completed |  |
| Owner Ian Clucas |  | Version 5 |  |
| Authors Paul Warwick |  | Version issue date | 12.02.2024 |

Document Management

Revision History

|  |  |  |
| --- | --- | --- |
| Version | Date | Summary of Changes |
| 1 | 20.05.2019 | Created Document |
| 2 | 12.07.2019 | Reviewed and added comments |
| 3 | 16.07.2019 | Reviewed and actioned comments |
| 4 | 17.09.2019 | Reviewed and added context |
| 5 | 12.02.2024 | Reviewed and updated to reflect new processes |

Reviewers

This document must be reviewed by the following people:

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| Name | Title | Date | Version |
| Paul Warwick | Clinical Safety Officer | 12.02.2024 |  |
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Related Documents

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

| Doc Reference Number | Title | Version |
| --- | --- | --- |
| 3.2 | Clinical Risk Management Plan |  |
| 3.3 | Hazard Log |  |
| 3.4 | Clinical Safety Case Report SOS |  |
| 3.5 | Clinical Safety Closure Report Portal |  |
| DCB 0160 | Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems |  |
| DCB 0129 | Clinical Risk Management: its Application in the Manufacture of Health IT Systems |  |
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# Introduction

This Clinical Risk Management System (CRMS) outlines the processes to be followed to ensure that all healthcare IT is developed, implemented and used in as safe manner.

This CRMS provides a framework that promotes the effective risk management of potential health IT hazards and operational incidents.

This CRMS addresses the requirements of DCB 0129 and DCB 0160 and follows best practice as promoted by NHS Digital.

It defines the clinical safety activities that must be completed in accordance with the Clinical Safety Standards. It also outlines when the Clinical Safety Officer (**CSO**) must be involved.

This CRMS will be reviewed and maintained in accordance with the Organisation’s Document Control Policy

# Purpose

The aim of the CRMS is to ensure that all of the Interweave Team involved with the development, implementation and use of healthcare IT systems are aware of the activities that are required to be undertaken to ensure patient safety is improved rather than compromised from the introduction of healthcare IT systems.

The Organisation is required to adhere to National Information standards created and monitored via the [Data Coordination Board](https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions) **(DCB)** within NHS Information Standards frameworks.

The mechanisms used are approved process Clinical Risk Management System compliance documents.

This Clinical Risk Management System will be reviewed periodically to ensure that:

• changes in working practices are incorporated

• issues identified though an established internal audit programme are addressed

• the safety approach continues to adhere to the requirements of applicable international standards

• the system continues to protect the safety of patients in a complex and changing environment.

# Audience

This document is for anyone who is involved in ensuring the safety of healthcare IT systems, products or services.

# Scope

This applies to all Interweave products and to all subsequent updates or upgrades to systems. The policy also applies to any local customisations or specific configurations made to a healthcare IT system by Interweave.

If clarification is required of whether any system falls within scope of this CRMS this should be raised with the Clinical Safety Officer (CSO)or Clinical Lead for clarification. The Clinical lead and CSO provides clinical and organisational leadership on healthcare IT Patient Safety on behalf of Interweave.

# Abbreviations

|  |  |
| --- | --- |
| CRMS | Clinical Risk Management System |
| CSO | Clinical Safety Officer |
| DCB | Data Coordination Board |
| SCCI | Standardisation Committee for Care Information |
| DDG | Digital Delivery Group |
| HL | Hazard Log |
| CRMP | Clinical Risk Management Plan |
| CRMF | Clinical Risk Management File |
| DPIA | Data Protection Impact Assessment |
| MHRA | Medicines and Healthcare products Regulatory Agency |

Clinical Safety Officer (CSO) - the person responsible for ensuring that the healthcare IT Clinical Risk Management System is applied to all clinical systems. The Clinical Safety Officer (CSO) for the Organisation is responsible for ensuring the safety of a healthcare IT system through the application of clinical risk management. The Clinical Safety Officer must hold a current registration with an appropriate professional body relevant to their training and experience. They also need to be suitably trained and qualified in risk management or have an understanding in principles of risk and safety as applied to healthcare IT systems. The Clinical Safety Officer ensures that the processes defined by the clinical risk management system are followed.

# Healthcare IT Clinical Risk Management (CRM) and Governance Arrangements

The Interweave Management Board are responsible for the governance of healthcare IT clinical risk management.

Any new or amended processes, software or hardware involving personal confidential information will require the completion of a Data Protection Impact Assessment (DPIA). The assessment includes a section on Clinical Safety. All DPIA’s are signed off by the interweave Information Governance Team.

Clinical safety review comprises several tasks to provide assurance. The Clinical Safety Officer is responsible for the list below however it is non-exhaustive:

• Involvement in the procurement process for any new systems/software

• Engagement with various teams to develop Clinical Safety Plan(s) in relation to the Healthcare IT system/software

• Perform Hazard Workshop(s)with relevant teams in relation to system/software

• Creation of a Hazard Log for each system/software

• Creation and maintenance of Clinical Safety Closure Reports for each systems/software

• CSO should be Included in new developments

• CSO should review any release(s) before go-live

• Involved in the Incident management process and reviews

• Review Information government document’s which may have a clinical safety implication

Clinical Safety documentation is to be created and templates of these are available here.

## Clinical Risk Management Team Organisation Chart

The organisation chart provides the overview of resources and personnel involved in clinical risk management for the Organisation.

# Healthcare IT Clinical Risk Management Deliverables

## Clinical Risk Management File

Interweave has a Clinical Risk Management File (CRMF) for each safety related healthcare IT system. The purpose of the CRMF is to provide a central repository where all safety related information pertaining to the healthcare IT system is stored and controlled.

For interweave the CRMF is held on the Interweave website.

## Clinical Risk Management Plan

Interweave has a Clinical Risk Management Plan (CRMP) for each safety related healthcare IT system. The purpose of the CRMP is to identify the clinical risk management activities that are to be undertaken and the phasing of these activities in the project lifecycle. The CRMP will also identify the resources required to discharge these clinical risk management activities. This must be done at the start of any healthcare IT projects and approved by the CSO.

## Hazard Log

Interweave has a Hazard Log (HL) for each safety related healthcare IT system. The Hazard log is reviewed and amended to reflect any risk identified as part of new developments and by issues raised by partner organisations.

The Hazard log will be made available within the CRMF. The purpose of the hazard log is to manage the effective resolution and communication of hazard risk within interweave products.

## Clinical Safety Case Report

Interweave has issued a Clinical Safety Closure Report (CSCR) for each safety related healthcare IT system. The CSCR will be issued to support initial deployment and will be updated during the lifecycle of the healthcare IT system should the safety characteristics change. The CSCR will be controlled and configured in accordance with the Interweave document control policy. The CSCR will be made available within the CRMF.

# Healthcare IT Clinical Risk Management Activities

## Hazard Identification

Interweave will conduct hazard identification workshops to identify potential hazards associated with the deployment and use of a healthcare IT system. The CSO will be responsible for facilitating such workshops and ensuring attendance from appropriate representatives.

If a healthcare, IT solution is deemed not to be safety related then this decision will be formally recorded.

Where any third-party components are used to support the healthcare IT system then they will be considered in the scope of the hazard identification activities and subsequent risk assessment and reported directly to the third party for resolution All identified hazards will be recorded in the Hazard Log.

The mechanism’s used to determine the hazards will be the Structured What If Technique (SWIFT) and the ALARP system. SWIFT is a hazards analysis method that uses structured brainstorming with guide words and prompts to identify risks. ALARP, which stands for “as low as reasonably practicable” is a principle is that the residual risk shall be reduced as far as reasonably practicable by introducing controls and mitigations.



Diagram above shows the ALARP Principle

## Risk Assessment

Interweave will conduct healthcare IT system risk assessment in accordance with the Risk Management Policy.

The Hazard log will be updated to capture the risk assessment.

## Risk Evaluation

The Organisation will conduct healthcare IT system risk evaluation in accordance with the Risk Management Policy.

The Hazard log will be updated to capture the risk evaluation.

## Risk Control

Where the initial risk evaluation is deemed unacceptable, further risk controls will be required.

Details of the risk control measure and evidence of effective implementation will be captured in the hazard log.



## Deployment and Ongoing Maintenance

To support clinical safety activities undertaken during any deployment phases of a project or programme of work the following documentation will be required to form a part of the overall approval process:

Project Initiation Document– third party supplier

Project Plan

Project Business Mapping

Risk Register

Weekly highlight reports

Fallback Solution

Change Management controls

Witness Testing including test in test, user acceptance testing and any reports must be disclosed.

## Incident Management

Clinical Risk Management activities within the Organisation and the healthcare IT programmes and services offered are completed within the Risk Management Policy. As such clinical safety related incidents are dealt with in a similar manner as other incident within the organisational. All incidents are reported to the Interweave Service desk via Jira. If related to patient safety or clinical harm these incidents will be flagged to the CSO, who is required to assess the impact on patient safety if severity dictates.

# Clinical Safety Competence and Training

## Competency

All staff undertaking a clinical safety role, shall be sufficiently competent for the task which they are asked to undertake. Where an individual does not have sufficient experience or knowledge then that person shall be monitored, and his/her work reviewed, by someone who has the necessary competence. Such supervision shall prevail until it is judged that the individual has amassed the necessary experience to undertake such tasks unsupervised.

In assessing competency, the different functional roles required to fully discharge the obligations of the Clinical Risk Management System, and the necessary skills and knowledge needed for each, shall be considered. Primary functional roles may include:

* Conducting discrete safety analyses or defining the Hazard Risk Indicators for a particular project.
* Making a valid judgement on the safety tasks, activities and techniques required for a given Health Software Product in order to justify the comprehensiveness and completeness of the safety assessment and produce the safety argument with supporting evidence.
* Assurance of safety assessments and healthcare IT software products. Performance of safety techniques and development of the safety argument for a particular healthcare IT software product must be independent to any assurance activities for the same.
* Improving and refining the overall Clinical Risk Management System, for example, audit, process change, quality.
* Ownership and leadership, for example, ultimate safety accountability, culture change, influencing and strategic direction.

The first test in establishing competency shall be at the interview stage where potential staff shall be assessed against the above representative roles and agreed job descriptions. Any perceived deficiencies identified during the course of the work or at the appraised stage, shall be addressed immediately, for example, through the assignment of a competent supervisor or the provision of suitable training.

All registered clinicians involved in safety roles shall, as a minimum, have completed an accredited training course.

## Training

Clinical safety personnel should undergo suitable training to develop, maintain or enhance their competency level. Such training can comprise:

* ‘on the job’ training conducted under supervision
* Internal training courses if available
* Approved external training courses

All registered clinicians involved in clinical safety roles shall, as a minimum, have completed an accredited training course.

Completion of any safety training shall be recorded by the line managers on the annual appraisal form

# Reference to any supporting documents:

Documents are held on the Interweave website (CRMF):

* DCB0129
* DCB0160
* Hazard Log
* Clinical Safety Plan
* Clinical Safety Closure Report

## Appendix:

**Appendix 1:** Risk Classification Matrix:

Clinical Safety Framework as defined by NHS Digital

| **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 |

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