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Clinical Risk Management Plan

Interweave Products

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Reviewers

This document must be reviewed by the following people:

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| Name | Title | Date | Version |
| Rebecca Wilson | Clinical Safety Officer | 09.09.2022 | 1.0 |
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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 | 0.4 |

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| **Glossary of Acronyms** | |
| Clinical Risk Management System | CRMS |
| Clinical Safety Officer | CSO |
| Clinical Risk Management | CRM |
| Clinical Risk Management File | CRMF |
| Clinical Risk Management Plan | CRMP |
| Clinical Safety Case Report | CSCR |
| Data Co-ordination Board | DCB |
| DCB 0129 | Clinical Safety Standard- Clinical Risk Management: its application in the manufacture of Health IT Systems |
| DCB 0160 | Clinical Safety Standard- Clinical Risk Management: its application in the Deployment and Use of Health IT Systems |
| Integrated Care Board | ICB |
| Hazard Log | HL |
| Shared Care Record | SChR |

# Introduction

The purpose of this Clinical Risk Management Plan (CRMP) is to define the manufacture of the Interweave Exchange products.

It describes how the Interweave programme 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 Interweave platform meets the requirements of DCB0129 (1).

In fulfilling this purpose, any variation to the standard practices and procedures to be followed, as defined by the Clinical Risk Management System (CRMS) (3), when performing the activities of the programme are documented in this document.

This CRMP identifies how the Interweave products shall be controlled to ensure that the safety work is of high quality, conforms to the requirements of the CRMS 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. This will be decided by the Programme Lead and the Clinical Safety Officer.

# Background.

# Clinical Risk Management Purpose

## 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 Clinical Safety Standards related to patient safety described below. These standards can be found at:

[DCB 0129 Clinical Risk Management: its Application in the Manufacture of Health IT platforms](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)

[DCB 0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT platforms](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)

## DCB 0129: Clinical Risk Management: its Application in the Manufacture of Health IT platforms

This standard sets clinical risk management standards for manufacturers of Health IT platforms. It requires the manufacturer to establish a structure within which clinical risks associated with the design and development of a new platform 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 during the manufacture of the Health IT platform [Ref 1]. This plan supports safe deployment of the Interweave products and its associated configurations or software.

## DCB 0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT platforms

This standard requires health and care organisations deploying and using new or modified Health IT platforms to have a structure to manage clinical risks associated with that deployment. Many of the requirements in DCB 0129 are repeated in DCB 0160 for the health organisations [Ref 1 & 2]. Interweave is approaching this standard with a proactive, best practice approach to ensure patient safety throughout the product deployment and decommissioning pathway.

## ISO 14971: Risk Management: its Application to Software as a Medical Devices

ISO 14971 is an international standard aimed at those products whose intended purpose falls within the scope of the Medical Device Regulation. The scope of the standard encompasses harm not just to patients, but also to healthcare staff, property, and the environment. The Interweave CRMP will only be concerned with clinical risk management as the products are not registered as a medical device.

## Compliance with the DCB 0129 Safety Standard

The Standard requires that manufacturers of software or products undertake a formal risk assessment of the system and conduct clinical risk management activities. This process ends with the production and issuing of three Clinical Risk Management (CRM) related deliverables:

* The Clinical Risk Management Plan (CRMP)
* The Clinical Safety Case Report (CSCR)
* Supporting Hazard Log.

Interweave obtain all relevant clinical safety documentation in the programme’s Clinical Safety Teams Folder. This will perform the function of the Clinical Risk Management File (CRMF). This folder will be managed by the Clinical Safety Officer(s) and other clinical personnel who have an active role in clinical safety activities. In terms of the shared care record (SChR) deployment the programme with any external subject matter experts will complete the required clinical safety activities and documentation. This will be shared with the partners within the Integrated Care Board (ICB) where required and consumers of Interweave. The end users may request, review and adapt the clinical safety documentation locally where required as to comply with individual workflow process compliance.

## Intended Audience

This Clinical Risk Management Plan (CRMP) will be made available to key stakeholders involved in the design, build, test, and deployment of the Interweave products to inform their own clinical risk management activities. This Clinical Risk Management Plan, together with CSCR and supporting Hazard Log will be made available where requested in support of the CRM process.

## Naming Conventions used in this Clinical Risk Management Plan Document

* The Clinical Risk Management Plan (this document), subsequently referred to as **the document**
* Synanetics, subsequently referred to in this document as **the Manufacturer**
* Consumers of the SChR referred to as the **Health Organisation(s)**
* Interweave, subsequently referred to in the document as **the System.**

# Overview

## Scope

The scope of the CRMP extends to all static and dynamic functionality, including any operational use and potential misuse of the product in the specific Interweave product configurations, which has the potential to cause harm to patients or service users or carers. This document defines the process of clinical risk management within Interweave with a focus on its analytical boundaries, and to the role and responsibilities of the personnel tasked to oversee its implementation.

Clinical risk assessment and management applies to all aspects of the Interweave products and considers any third-party hardware or software being used as part of the deployment, by provider companies.

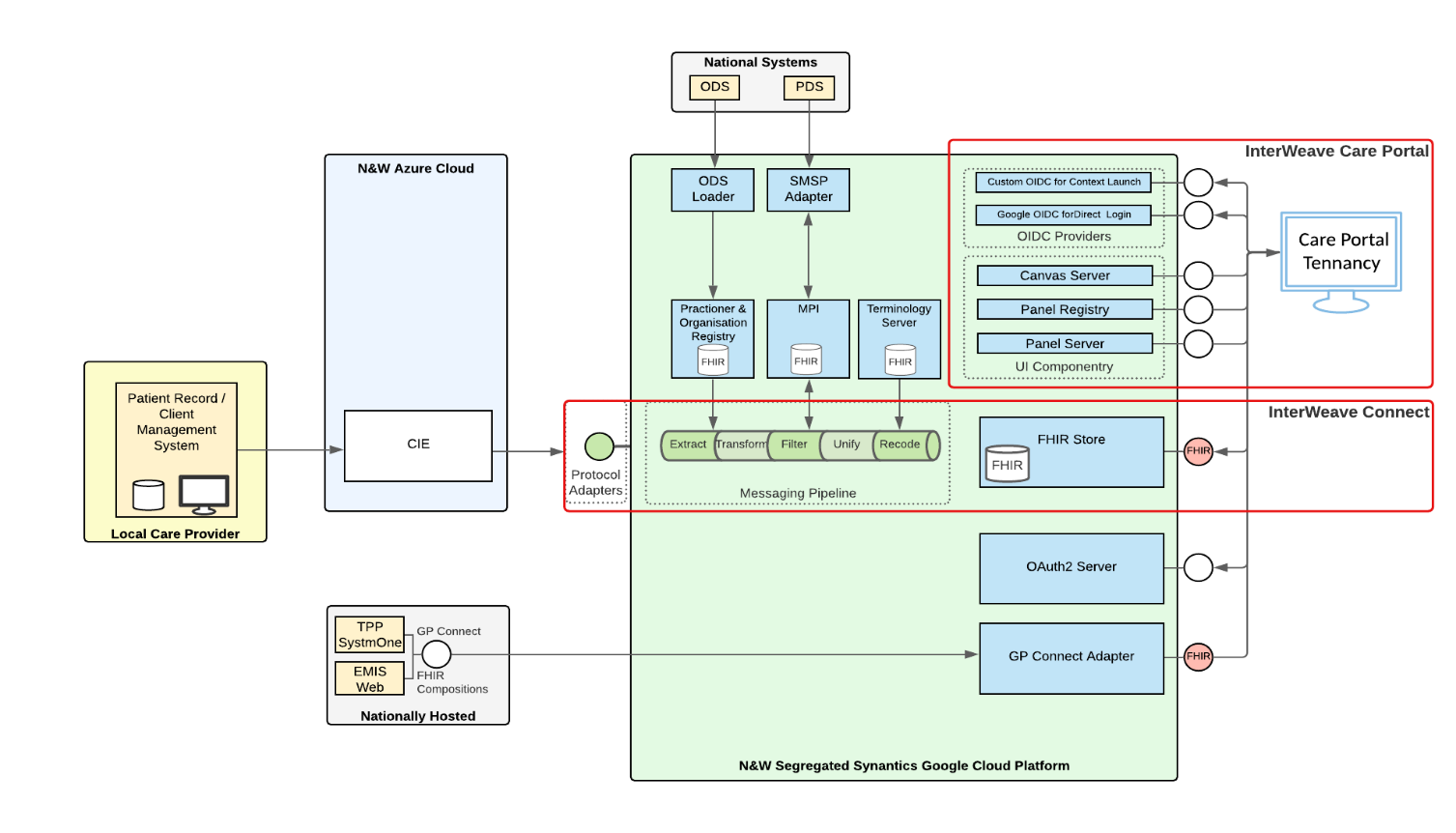
The configuration adheres to this scope. It takes the following users into consideration:

* Primary care users
* Secondary Care users
* Social care Users
* Other

## Product Overview

The ICP is mainly web hosted, it uses simple panel design and structure to display data provided by a number of on-boarded sites. The portal can be opened in TPP’s context launch with ongoing developments with EMIS emerging.

The Portal is a standalone multi-tenant web-app, hosted within the same cloud instance as the Exchange, which provides a blended view of the data aggregated by the Exchange, and thereby provides a holistic view of the patient. Data is currently presented using panels to show information for specific FHIR resources, as well as demographics validated against national NHS services, and unstructured data such as documents. It is important to note that only data which is provided by the providing sites is available. Providers do provide various data resources with various timeframe limitations, therefore not all the available data for the patient may be shared into the exchange. Users are made aware of this on logging in with the portal disclaimer.



The Portal is an evolving product as the programme learn about usability during testing with health and care workers, currently the data resources which are available includes:

* Appointments
* Allergies
* Encounters
* Episode of Care
* Documents
* Medications
* Related Persons
* Tasks
* Referrals
* Procedures
* Conditions
* Flags

Future data resources will be available, these include but is not exhaustive of:

* Observations and Results
* End of Life Care plans
* Diagnostic Report

In addition to the resources been provide by provider sites, the Portal also displays GP Connect HTML data directly from NHSD.

# Methodology

The clinical risk management activities to be subject to analysis and clinical risk evaluation are set out in the following sub-sections.

### Establishing a Baseline

Identification of the hazards produced by the products, creating the required clinical safety documentation to evidence the logic and theory.

### Design Analysis

Considerations of hazards and the identification of suitable controls focused on design. Where functionality features of the products have been modified to mitigate clinical risk, these will be captured as design controls. Interweave plans to identify design hazards when forming the requirements specification with the manufacturer. The design will then be reviewed and further hazards identified and assessed.

### User Interface Analysis

Review of the product user interface as part of Clinical Safety Officer (CSO) due diligence.

### Human Factors Analysis

Considerations in respect to any product controls identified which relied on users operating the product in a particular manner. Any administrative and clinical workflow processes can be analysed for potential hazards highlighting those mitigation areas which need to be satisfied to reduce the risk to an acceptable level.

### Third Party Component Analysis

The System may use third-party components to enable message flow solutions and Application Programme Interfaces (APIs) and any such third-party component analysis should consider the End-to-End System dependency of third-party products in respect to the potential for such third-party products to introduce unintentional clinical risk. For example, such third-party considerations in relation to:

* The purpose of the third-party product and how failure might impact the overall end-to-end product.
* Whether the third party has a time limited license which could cause it to fail should the license unexpectedly expire.
* Whether functioning of the component was dependent on the availability of another service, and the potential for the third party to be upgraded or changed without the system Manufacturer being aware.

### Assurance by Stakeholders

Where it has been identified that stakeholders will need to own and implement certain controls, that these have been characterised, identified, and appropriately communicated.

### Clinical Risk Management Activities

The DCB 129 Safety Standard clinical risk activities supported by the document are defined below.

* Deconstruct the key functions of the product into its constituent parts
* All supporting business processes and functions to be deconstructed into individual tasks
* Subject each task to a Structured What-If (SWIFT) analysis in respect to system operations in normal, fault conditions and reasonably foreseeable misuse
  + From the SWIFT analysis, generate ‘candidate’ hazards, with due consideration as to cause, effect, and potential harm
  + Consider appropriate hazard controls
  + Assemble this information in the supporting Hazard Log
  + The clinical risk for each candidate hazard will be estimated and evaluated based on a combination of the hazard’s severity and the likelihood of a patient coming to harm of the stipulated
  + Where the clinical risk is unacceptable or undesirable, undertake a control option analysis to examine opportunities for further hazard mitigation
  + Where further controls are required, ensure appropriate prioritisation strategies which are most likely to be effective (i.e., through training or business process controls). Ensure that only where these measures were deemed to be impractical, were less effective means of control (such as information provision) considered
  + Evaluate any additional clinical risk associated with the implementation of new controls
  + Validate that where the proposed controls require deploying organisation’s end users to act to mitigate the risk that these will be highlighted to support the training guides, and
  + That the proposed controls are realistic, viable and likely to be effective in the intended clinical setting.

Only when each component, function, screen, or business process discussed above has been considered and worked through and all the system elements (key functions and supporting business processes) had been subject to analysis will the clinical risk management activities be deemed complete.

### SWIFT

The Structured What-If Technique (SWIFT) is a systematic method of hazard identification. The technique, carried out as a brainstorming activity, employs an analysis of potential deviations from the expected business process using ‘guidewords. In relation to the ‘system’ the application of SWIFT will consider whether the supporting task could be:

* Performed incorrectly
* Performed incompletely
* Performed inappropriately or for the wrong reasons
* Performed at the wrong time
* Performed against the wrong patient
* Performed more than once
* Performed but resulted in confusion, or
* Not performed.

# Hazard Identification.

Hazards may be identified in other ways during the development and use of the products 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 programme Clinical Safety team 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.

## Clinical Risk Management Deliverables

The following Clinical Risk Management deliverables will be produced:

* The Clinical Risk Management Plan (this document)
* The Clinical Safety Case Report, and
* Hazard Log.

The deliverables will be signed off by the Clinical Safety Officer(s) and Clinical Lead and through the correct clinical approving board.

## Acceptance Criteria

The appendices section of this document details the risk acceptability criteria against which the level of clinical risk associated with each hazard will be tested. If the clinical risk is found to be Acceptable or Tolerable, then no further action will be taken other than to monitor the controls during live service.

Where the clinical risk is deemed Undesirable, options for further risk control will be explored and a remediation plan put in place. If the clinical risk is found to be Unacceptable, this will be escalated to the ICB, stakeholders and Health Organisation’s where required. Deployment of the product will be suspended until further controls are implemented.

## Assumptions and Constraints

### System Assumptions

* Clinicians and supporting administrative staff will apply judgement in interpreting information provided by the products
* If they have any concerns regarding the correctness or completeness of information communicated by the product, it is assumed that alternative sources of information will be consulted.

## Constraints

* End users are responsible for the deployment clinical safety activities as documented in the DCB0160 safety standard. Interweave rely on feedback if any further hazards are identified or issues which are not communicated back into the programme.
* Provision of data from providers is of a good quality

### 

### Testing Analysis

**Exchange**- The Interweave programme has a robust testing strategy and assigned test manager. In essence the test manager engages with the end users and performs a series of testing. These tests vary between providers depending on the data resource types been provided. Once User Acceptance Testing (UAT) has been completed a test report is produced which highlights any issues. These are reviewed and any issues agreed to be fixed and a timeline assigned. Daily/weekly calls are initiated between all parties to ensure durability and efficiently. Several further testing sessions may take place before the UAT is signed off. The UAT is performed in the sandpit environment. They may be occurrences when the issue log is reviewed by the CSO at this point to determine if an issue needs be fixed before moving on to the next stage. The test manager and CSO work closely together to identify, monitor and evaluate any issues and the testing. The data standards manager is also involved in the review of the testing to ensure the providing sites have aligned and mapped their data correctly to the FHIR resources and are complaint with the specification the Interweave programme team have developed.

Once in staging further tests are performed similar to that in the sandpit environment. No further issues should be detected at this stage however it can happen and therefore the test managers and CSO’s work together to ensure these are fixed and safe before proceeding. The test reports and Data Quality Reports are reviewed by the CSO and then a ‘Assurance Gateway’ meeting is scheduled with the organisations involved. Once approved and a date set the provider/consumer is connected to the Exchange. On the day further testing is performed by the CSO/Clinician/responsible person at the end site to ensure information is flowing correctly and safely in the production environment. After the initial one day assessment the service continues and is monitored in early life.

With regards to GP Connect robust testing has been driven by NHS Digital in the form of conformance testing. The test team have tested GP Connect as directed by the document set and provided evidence to the level directed by NHS Digital. This testing for the exchange provides assurance that the data displayed within the portal is assured and correct.

**Portal-** Designs and changes are discussed in sprint planning, these are then developed by Synanetics and reviewed at the sprint review meetings. This gives opportunity to identify any hazards and make comments or further changes. Once agreed the developments are released from the test environment into sandpit. These changes are tested by Synanetics then by the interweaves test manager and assured by the CSO. This occurs in each environment from sandpit, staging and through to production. If any issues are identified these are raised on tickets using JIRA. These are then actioned, fixes applied and retest completed before In pushing into live.

From a Synanetics developers perspective on testing:

* automated testing routines which run against units of functionality in the portal, written in a testing framework called Playwright (<https://playwright.dev/>)
  + This is limited by the quality (or lack thereof) of the static data currently available in sandpit – this will be improved when they get a static set of test records in a dedicated provider in the sandpit
  + This also functions as automated regression testing as it runs against all units of functionality at every deployment and we keep tests for all units of functionality
* The developers test their units of functionality as they are developing it
* code reviews where another developer will review the code written before a development branch is merged into what will be deployed
* run manual functional unit testing on new functionality (time permitting) at various stages in dev, test, sandpit, and staging
* run smoke tests after deployments on sandpit, staging and production in all environments

## Resourcing/ Governance

| Role | Name |
| --- | --- |
| Programme Director | Lee Rickles |
| Clinical Lead | Dr Jason Broch |
| Product Manager | Ian Clucas |
| Project Manager | Hollie Harrison |
| Project Manager | Adam Brown |
| Data standards manager | Sophie Lowsley |
| Data Service Manager | Chintan Chokshi |
| Clinical Safety Officer | Paul Warwick |
| Lead Technical Architect (Synanetics) | Robert Hickinbotham |
| Head of Applications (Synanetics) | Emma Smith |
| Applications Developer (Synanetics) | Greg Kekesi |
| Senior Applications Developer (Synanetics) | Richard Brown |

These personnel will:

* approve 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;
* ensure 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;
* review evidence in the Clinical Risk Management File to ensure it is complete and supports the Clinical Safety Case Report;
* providere commendation to GP Connect Programme whether the Service is safe to release; and
* escalate any unacceptable safety risks.

# Summary

This CRMP sets out the activities and responsibilities in the analysis, evaluation and control of hazards during the Interweave project deployments.

# 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 in 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 |

# Glossary of Terms

|  |  |
| --- | --- |
| AFAP | As Far As Possible – The level risk acceptability criteria as per Clinical Safety Standards |
| Clinical Risk Analysis | Systematic use of available information to identify and estimate a clinical risk. |
| Clinical Risk Control | Process in which decisions are made and measures implemented by which clinical risks are reduced to, or maintained within, specified levels. |
| Clinical Risk Estimation | Process used to assign values to the severity (consequence) of harm to a patient and the likelihood (probability) of occurrence of that harm. |
| Clinical Risk Evaluation | Process of comparing a clinical risk against given risk criteria to determine the acceptability of the clinical risk. |
| Clinical Risk Management (CRM) | Systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, and controlling clinical risk. |
| Clinical Risk Management (CRM) Process | A set of interrelated or interacting activities, defined by the ETHOS Ltd. Clinical Safety Officers to meet the requirements of the DCB 0129 Standard with the objective of ensuring clinical safety in respect to the development, deployment and intended use of the Health IT System. |
| Clinical Safety | Freedom from unacceptable clinical risk to patients. |
| Clinical Safety Officer | NHS Digital accredited clinician responsible for ensuring the safety of the Health IT System through the application of clinical risk management as set-out in the NHS Digital DCB 0129 and DCB 0160 Standard requirements. |
| Clinical Safety Case Report (CSCR) | A report that presents the arguments and supporting evidence that provides a compelling, comprehensible, and valid case that the Health IT System is safe for intended use. |
| Digital Health Platform | A platform comprising hardware, software, and third-party components. |
| ETHOS Ltd. | Clinical Risk Management Health IT subject Matter Experts (Clinical Safety Engineers and Clinical Safety Officers) contracting to the Health Organisation, providing Health IT Clinical Safety assurance in respect of the Health IT System as set out in the NHS Digital DCB0129 and DCB 0160 Standard requirements. |
| Harm | Death, physical injury, psychological trauma and / or damage to the health or well-being of a patient. |
| Hazard | Potential source of harm to a patient. |
| Hazard Log | A mechanism for recording and communicating the on-going identification of hazards associated with the Health IT System. |
| Initial Clinical Risk | The clinical risk derived during clinical risk estimation. |
| International Organisation for Standards (ISO) | The organisation that develops and publishes International Standards.  Link at: <https://www.iso.org/home.html> |
| Intended Use | Use of the Health IT System in accordance with the specifications, instructions and information provided by the manufacturer to its clients for its intended use. |
| Likelihood (probability) | Measure of the occurrence of harm. |
| Manufacturer | 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. |
| Service User Safety | Freedom from harm to the patient. |
| Residual Clinical Risk | Clinical risk remaining after the application of risk control measures. |
| Severity (Consequence) | Measure of the possible consequences of a hazard. |