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i	Template guidance This is a draft CRMP prepared by Suvera in accordance with DCB0160 to support partner practices deploying Recall. It is intended as a starting point for the deploying healthcare organisation's own clinical safety documentation. The deploying organisation's CSO should review, amend as necessary to reflect their local deployment context, and formally approve this document before Recall is deployed. Sections requiring organisation-specific input are indicated throughout. Steps to take • Read through this generated document and make changes as appropriate. We suggest you keep the language at a high enough level such that is stays representative for at least a year. • Send to others to review. Ensure all relevant stakeholders have reviewed the document. • Once reviewed, approve the first version of this document and save a versioned copy, which is readily accessible. Text in grey italics gives examples for you to follow, and should be deleted or replaced with the appropriate information. Text highlighted in yellow requires particular attention. Delete this information callout once you have reviewed the document.



Clinical Risk Management Plan - DCB0160

The Clinical Risk Management Plan (CRMP) outlines the processes in place to assess and mitigate clinical risks and assure clinical safety of products, during the development, design and deployment phases of the product life cycle.

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Clinical Risk Management Plan - DCB0160

The Clinical Risk Management Plan (CRMP) outlines the processes in place to assess and mitigate clinical risks and assure clinical safety of products, during the development, design and deployment phases of the product life cycle.

Introduction

The Clinical Risk Management Plan (CRMP) outlines the processes in place to assess and mitigate clinical risks and assure clinical safety of the Recall health IT product during the deployment phases of the product life cycle.
This CRMP provides a framework that promotes effective risk management of potential health IT hazards and operational incidents. It describes how clinical risk management will be conducted to ensure patient safety. This CRMP identifies the means by which the product life

cycle shall be controlled to ensure that the safety work is of high quality. This CRMP addresses the requirements of DCB0160 and acknowledges the related requirements of DCB0129 as applicable to the manufacturer. This CRMP follows best practice as promoted by NHS England (previously NHS Digital).

Purpose

The purpose of the Clinical Risk Management Plan (CRMP) is to define the implementation of, and any variation to, the Clinical Safety Management System. It describes how clinical risk management will be conducted to ensure patient safety with respect to services provided and the interrelated and interactive activities that will occur to ensure that the requirements of DCB0129 and DCB0160 are met.

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 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 Clinical Safety Officer and/or Team.

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.

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.

Programme Overview and Clinical Safety

Recall is a cloud-based clinical tool developed by Suvera to support GP practice teams in delivering effective recall of patients with specific long-term conditions (LTCs) in primary care, including associated high-risk drug monitoring where relevant. Recall integrates with existing GP clinical systems (EMIS and TPP SystmOne) and uses an algorithmic rules engine, informed by recognised national clinical guidance and standards, to identify when recommended investigations or reviews are due for individual patients.

Practice staff can initiate recall actions within Recall, and the corresponding activity is documented back into the patient's electronic health record.

The aim of this deployment is to use Recall to improve the consistency, efficiency and completeness of our patient recall processes. By presenting a holistic view of each patient's outstanding investigations, reviews and target areas, Recall enables practice teams to proactively manage their patient cohorts and reduce the risk of patients being lost to follow-up.

The current phase of the programme is the deployment phase. Any future phases involving new clinical conditions, medication monitoring rules, or significant changes to existing functionality will be addressed through a revised CRMP.

In relation to clinical safety, the scope of this plan covers all clinical functions of Recall that have the potential to impact patient safety. The primary clinical safety considerations relate to the accuracy, completeness and availability of the data presented to users, specifically, the risk that missing, incorrect or inaccessible data could lead to delayed, unnecessary or inappropriate clinical action. Additionally, as Recall writes recall activity back to the EHR, the accuracy and integrity of data recorded in the patient record is also within scope.

Recall does not replace clinical judgement or existing clinical workflows; rather, it supplements them by surfacing information from the patient's existing EHR record and supporting the recall process. Clinical decisions remain the responsibility of the practice clinician.

This context has informed the scope of the hazard identification and risk assessment activities described in this plan, which focus on data integrity, system availability, the accuracy of algorithmic recall recommendations, and the integration between Recall and GP clinical systems.

For further detail on Recall's intended use, clinical context, supported conditions and software functionality, refer to the Service Overview section of this document.

Impact of DCB0129 and DCB0160 on Recall

Suvera is classed as a ‘Manufacturer’ of Recall 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.’

Recall is intended for use by healthcare organisations. The DCB0160 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.

Suvera, as manufacturer, will ensure compliance with DCB0129. We, as the deploying organisation, are responsible for meeting the requirements of DCB0160 in relation to our deployment of Recall.

Scope

This document refers to our deployment and use of Recall in its current deployment phase. The policy also applies to any subsequent updates or upgrades, or any local customisations or specific configurations made to a healthcare IT system. Any changes in phase scope, content and future phase development will be addressed in this document by a revised CRMP document. The revised documentation will be agreed with the Clinical Safety Officer and Suvera, as manufacturer, to ensure correct governance and control is in place.
If clarification is required of whether any system falls within scope of this CRMP this should be raised with a member of the Clinical Safety team.

Abbreviations and Definitions

CSO: Clinical Safety Officer - the person responsible for ensuring that the healthcare IT Clinical Risk Management System is applied to all clinical systems.
DCB: Data Coordination Board

Service Overview

Manufacturer background
Suvera is a digital health technology company that develops and maintains Recall software for NHS primary care. Recall looks across a practice's patient population, identifies gaps in required care such as overdue investigations, reviews, or medication monitoring, and enables practices to bring those patients in for recall. Recall integrates directly with existing GP clinical systems, including EMIS and TPP SystmOne, so that patient data flows into the platform without duplicate record-keeping, and recall and monitoring activity is coded back into the patient's electronic health record.
Clinical context
Give a brief overview of clinical practice prior to the introduction of the new digital health technology.
Give a brief overview of how clinical practice and workflows or pathways will change as a result of introduction of the new digital health technology, and the clinical context in which it will be used.
Development lifecycle
The current phase of the product life cycle is the deployment phase.

Existing systems
Describe any existing IT systems the product replaces or interfaces with

Intended use

- Intended purpose:

Recall supports practice teams to deliver effective recall and ongoing management of specific long-term conditions (LTCs) in primary care, including associated high-risk drug monitoring

where relevant.

The solution enables patients with eligible LTCs to be viewed holistically. It presents a complete picture of each patient's needs, allowing practices to recall patients for investigations and reviews more efficiently and consistently.

The service includes:

1. Pre-go-live setup: An EHR data analyst from the Suvera team works closely with the practice to ensure EHR integration is correctly configured and that all relevant data is visible within Recall.
- Ongoing support: Once live, practices receive continued technical support to ensure smooth and effective use of the system.
- Patient cohort identification: Practice users can identify and review cohorts of patients who require recall. Recalls are carried out using the Recall platform, with activity reflected through relevant coded entries in the patient record.

- Intended users (primary, secondary, tertiary):
  - Staff at the GP practice (GPs, Clinical Pharmacists, Nurses, Administrators)
  - Describe who will manage the system (e.g. clinical or administrative staff in GP practices)

- Use environment:
  - Recall is a cloud based web app that is used by healthcare practitioners in their browser on GP practice computers

- Operating principle:
  - Recall analyses coded data in the patient's electronic health record against national and local clinical guidance to identify when a recommended investigation, review, or medication monitoring check is due or approaching. Patients meeting these criteria appear in Recall's dashboard, where practice staff can review the outstanding items, initiate recall actions individually or in bulk, and track progress through to completion. Once an action is carried out, the corresponding activity is coded back into the patient's electronic health record, keeping Recall's view of each patient current.

Key Clinical Benefits:
Identification of patients with long-term conditions (see list below) and patients requiring medication monitoring, and support for associated investigations, clinical review and patient recall for both groups.

Clinical Logic:
Recall incorporates an algorithmic rules engine to determine which investigations a patient may require and the appropriate monitoring frequency. The rules are informed by recognised national clinical guidance and standards including:

- QOF
- NICE
- SPS

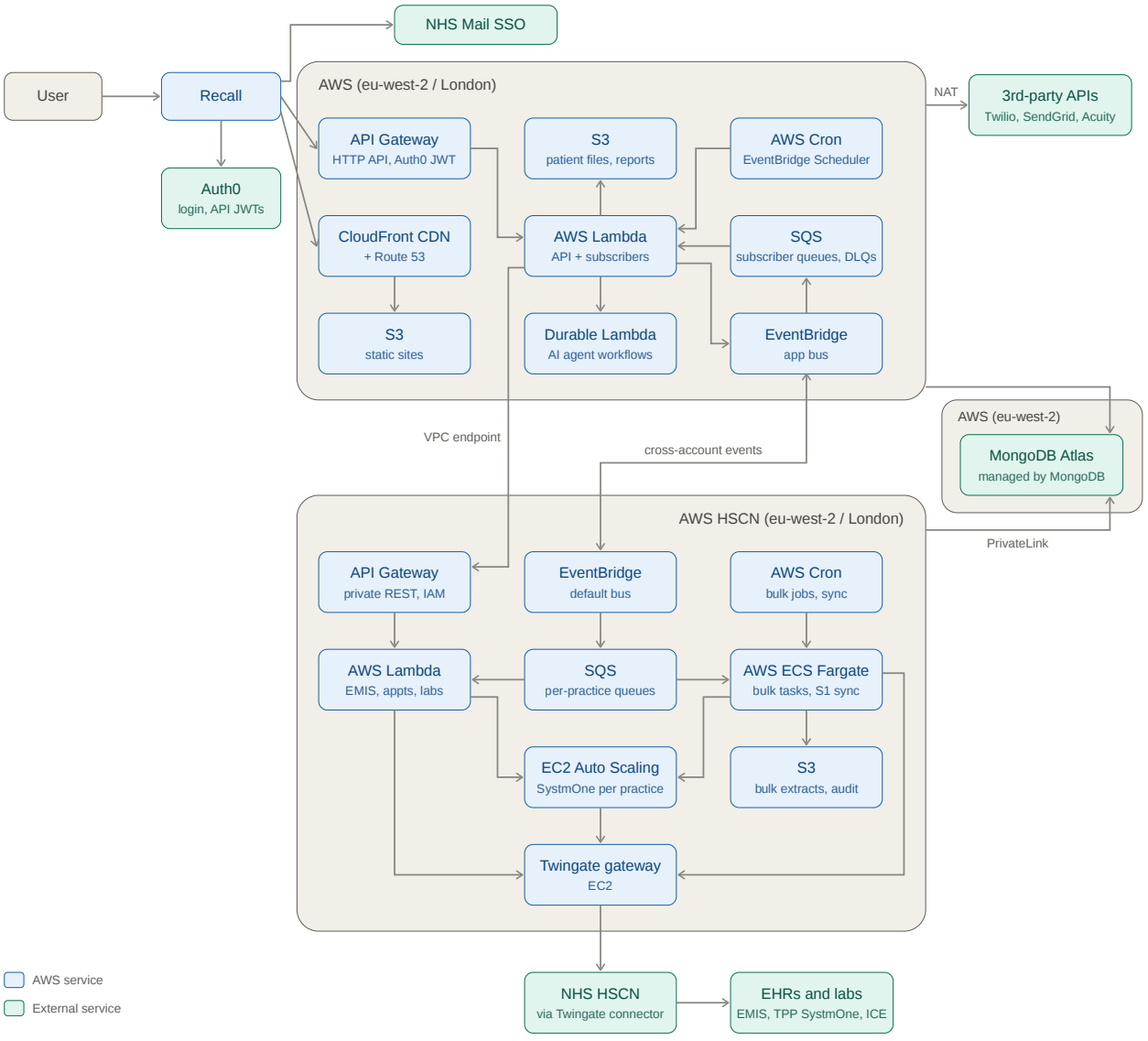
- NHSE
- BNF
- BSG
- MHRA

The system analyses coded data within the patient record to identify when recommended investigations are due or approaching their due date. The logic used is listed here. Any changes to clinical logic or rules are subject to the product development lifecycle, with appropriate clinical team review and input throughout.

Software Description:

Recall allows partners to have visibility of national and local targets, and to efficiently manage recall to achieve those targets.

Deployment and Technical Architecture:



Features

- View all patients at the practice who require recall for supported long-term conditions, as well as any high-risk medication monitoring required for those patients.

- Distinguish between:
  - Patients under Suvera care
  - Patients under practice care
- Search for individual patients using NHS number
- For each patient Recall displays:
  - investigations required
  - reviews required
  - target areas
- Patients are sorted by default according to furthest from completion.
  - Alternative sorting options include:
    - UCLP/CCLP risk score
    - Closest to completion
- Users are able to filter patient lists using multiple criteria, including:
  - Target area / condition
  - Month of birth
  - Care ownership (Suvera-led vs Practice-led)
- The interface provides dedicated tabs or views to support operational workflow, including:
  - All patients
  - Recall not started
  - Recall in process
  - Review (1+ area has been reviewed, or the review is booked)
  - Complete
- Recall actions can be Initiated:
  - Individually for a single patient
  - In bulk for multiple patients, either by multi-select or “select all” within a filtered list
- Progress Indicators
  - Visual indicators ie. a progress/completion bar is displayed for each patient to show the proportion of recall activity completed versus outstanding

Scope of deployment

Describe the scope of deployment that this report refers to. It could be the number of healthcare organisation sites and/or the number of patients affected.

This document, as well as the Hazard Log and Clinical Safety Case Report, will be updated as a result of progress through subsequent phases of the development lifecycle. It will be specified how clinical risk activities are applicable at each particular lifecycle phase.

Clinical Risk Management (CRM) Governance Arrangements

The CRMP will be executed by the Clinical Safety Team. The list below identifies the key people responsible for clinical safety within our organisation. The Clinical Safety Team includes representatives from our Top Management. All members of the safety team integrate an awareness of clinical safety into every aspect of their work.

Key personnel

The list below identifies key people responsible for clinical safety within our organisation, making up the Clinical Safety team.

Clinical Safety team

Name	Role	Responsibilities
Example 1	*Clinical Safety Officer*	*Create clinical risk management processes* *Review clinical risk management documentation* *Approve clinical risk management documentation* *Lead hazard identification reviews* *Lead regular, episodic clinical risk management reviews*
Example 2	*Practice Manager / Clinical Lead / GP Partner*	*Coordinate local implementation and configuration* *Identify local risks arising from deployment* *Communicate practice-level feedback and incidents to the CSO* *Join hazard identification reviews and regular clinical risk management reviews*

Clinical Safety Officer

Name	Professional qualifications	Professional Body	Competency/Skills/Experience	Clinical Safety Training
[Insert]	[Insert]	[Insert]	[Insert]	[Insert]

The Clinical Safety Officer is responsible for ensuring the clinical safety of deploying and using Recall 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;
- 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;
- escalating any unacceptable safety risks.

All documents created as part of the Clinical Safety Management System are maintained, version controlled and managed by the Clinical Safety Team and authorised by the Clinical Safety Officer. Documents are stored in the Clinical Risk Management File, which has appropriate access control measures in place.

Delegation of authority

Describe here any delegation of authority (DOA) to allow for sign off and changes to this document and the Clinical Safety report in the absence of the named Clinical Safety Officer.

Governance

Governance for patient safety is provided through the following forums:

- Clinical Risk and Safety Meetings

The Clinical Safety Team will meet for Clinical Risk and Safety Meetings once every [insert your desired review frequency], to review the clinical safety approach, the hazard logs, mitigations and residual risks associated with our deployment and use of Recall.
The clinical safety team will maintain a Clinical Safety Incident Management Log.
All documents created as part the our Clinical Safety Management System are maintained, version controlled and managed by our Clinical Safety Team, and authorised by the Clinical Safety Officer.

Clinical Risk Management Deliverables

Clinical Risk Management File

We will establish a Clinical Risk Management File (CRMF) for our deployed health 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 each safety-related deployment of a health IT system, the following deliverables will be produced:
1. Clinical Risk Management Plan (CRMP, this document)
2. Hazard Log (HL)
3. Clinical Safety Case Report (CSCR)
4. Safety Incident Management Log (SIML)

The deliverables will be kept up to date to reflect the scope of the live deployment. They will be subject to version control so that the status and most up to date version is clear and will be stored in the Clinical Risk Management File.

Clinical Risk Management Plan

We will establish a Clinical Risk Management Plan (CRMP) (this document) for our deployment of Recall. The purpose of the CRMP is to identify the clinical risk management activities that are to be undertaken and the phasing of these activities. The CRMP will also identify the resources required to discharge these clinical risk management activities.

Hazard Log

We will establish and maintain a Hazard Log (HL) for our deployment of Recall. The HL is made available within the CRMF. The purpose of the HL is to manage the effective resolution and communication of hazard risk.

Clinical Safety Case Report

We will establish a Clinical Safety Case Report (CSCR) for our deployment of Recall, recording our own risk assessment of the deployment, configuration, and local use of the system. The CSCR will reference Suvera's Clinical Safety Case Report as evidence supporting the manufacturer-side safety argument. The CSCR will be issued to support initial deployment and updated during the lifecycle of our use of Recall should the safety characteristics change. The CSCR will be made available within the CRMF.

Clinical Risk Management Plan Review process

This CRMP will be reviewed and updated periodically, as decided by our safety teams, and the Clinical Safety Officer, to ensure that:

- changes in working practices are incorporated
- issues identified through 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.

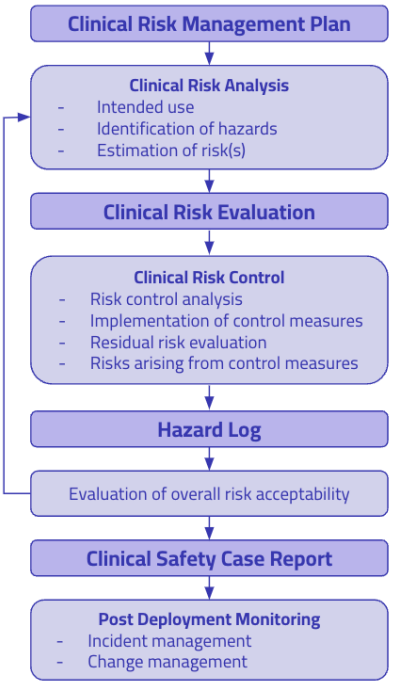
The current CRMP review frequency is: [insert your desired review frequency]
Review of the CRMP may be also triggered by a transition to the next phase in the Health IT System lifecycle, a change of resource or in line with existing governance arrangements. It may also be triggered by a modification of the product or in response to an incident, as outlined by our **Clinical Safety Change Management Procedure**, and our **Clinical Safety Incident Management Procedure**.
The CRMP will be maintained throughout the life of the health IT product.

Clinical Risk Management Activities

Clinical Risk Management Process

The purpose of the clinical risk management process, outlined in the adjacent diagram, is to identify and document known and foreseeable credible hazards that could impact on patient safety, related to our use of Recall, in both normal and fault conditions. A hazard is defined as a condition or event in which harm to a patient could theoretically occur. The clinical risk management process will also establish the controls which are already present or need to be put in place to mitigate the risk to acceptable levels. The clinical	

risk matrix (see Appendix) determines the risk score based on the severity and likelihood of an identified hazard.
The following diagram (right) sets out the overall Clinical Risk Management process.



CRM Review Process

The clinical risk management process will be formally reviewed [insert your desired review frequency], with representatives including key stakeholders, the clinical safety team and CSO. The review examines whether any changes are needed as a result of greater experience, best practice or lessons learnt from previous releases to support a process of continual improvement. Any changes to the clinical risk management process will be captured in future updates to the Clinical Risk Management Plans.

Hazard Identification

Hazards can be identified at any stage of the product lifecycle and the hazard log will be continually maintained and updated as required.

Hazard identification methodology

A Structured What-If Technique (SWIFT) will be used to perform the hazards analysis. The Structured What-If Technique 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. The clinical or system business process is broken down into individual tasks. ‘What If’ questions will be tested against each task to generate ideas for hazards, causes and controls. Should the SWIFT technique be found to be inappropriate for the subject matter or additional rigour be required, other structured techniques can be employed such as Failure Modes and Effects Analysis (FMEA), Bow-Tie diagram or Fishbone diagram.

HAZID workshops

In line with best practice, to maximise hazard identification, when appropriate we will conduct hazard identification (HAZID) workshops to identify potential hazards associated with the deployment and use of Recall. These will be attended by representatives from relevant practice functions, including clinical staff, practice management, IT/information governance, and the CSO. We will endeavour to ensure a representative from Suvera, as manufacturer, is also in attendance where relevant, subject to availability.
Minutes of any HAZID workshops will be taken and a copy stored in the CRMF. If a healthcare IT solution is deemed not to be safe then this decision will be formally recorded.

Additional hazard identification
Hazards may be identified in other ways outside of HAZID workshops, during the deployment and use of Recall such as:

- Discovery during deployment or use of a solution;
- Testing of amended functionality;
- Ad hoc testing of live service functionality;
- Reporting of an incident or problem within the live service;
- Identification by a member of staff within the Manufacturer or Healthcare Organisation

Our **Clinical Safety Change Management Procedure**, and our **Clinical Safety Incident Management Procedure** have been designed to enable new hazards to be identified and the HL to be updated as appropriate. All newly identified hazards will be recorded in the HL.

Hazard log

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

- Hazard ID or number;
- Hazard name or 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
- Controls – these are identified controls or measures that are in place and will remain in place post implementation that provide mitigation against the hazard.

Each Hazard will be discussed by the Clinical Safety team and any other appropriate people. They will perform the following tasks and record the outcome in the Hazard Log:

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

Risk Analysis

For each identified hazard estimation will be made of the clinical risk. Clinical risk will be determined based on the description of patient harm, severity, causes and contributory conditions. The estimation process will follow that established by the safety processes defined

in DCB0160. See Appendix for copies of the Risk Assessment Matrix, and definitions of Hazard likelihood and Hazard consequence.

The HL will be updated to capture the risk analysis.

Risk Evaluation

Each identified hazard will be evaluated and attributed a level of clinical risk according to the criteria set out in the Appendix. Together the hazards and their associated clinical risk will comprise the safety profile. A project may only proceed if the clinical risk associated with the identified hazards are acceptable.

A hazard will be deemed acceptable if:

- The Residual Clinical Risk is 1: Acceptable, with no further action required.
- The Residual Clinical Risk is 2: Acceptable where the cost of further reduction outweighs the benefits gained.
- The Residual Clinical Risk is 3: Undesirable, but acceptable only when further risk reduction is demonstrated to be impractical and the hazard has been mitigated to As Low As Reasonably Practicable (ALARP).
- The Residual Clinical Risk is 4 or 5: Unacceptable, unless exceptionally justified based on a clinical risk-benefit analysis and approved by the Clinical Safety Officer.

Should the Residual Clinical Risk be deemed Unacceptable (4 or 5), and this cannot be justified by the clinical benefits, the assessment will conclude that additional means of risk control must be implemented before the project can proceed.

The HL will be updated to capture the risk evaluation.

Risk Control

Where the initial risk evaluation is deemed unacceptable, further risk controls will be required. Adequate additional clinical risks controls will be identified, justified, implemented and verified. Details of the risk control measure and evidence of effective implementation will be captured in the HL.

Third Party Products

As part of the clinical risk management process, any third party products used within our deployment of Recall will be identified and considered in the scope of hazard identification activities and subsequent risk assessment. Where none are used, there will be a positive declaration to this effect. Details of any third party products used and any associated risks will be outlined in the **Clinical Safety Case Report**.

Pre-deployment review

Prior to deployment, we will complete a formal review of the Health IT system and Hazard Log, which will be recorded in the **Clinical Safety Case Report**. The Health IT System configuration for the specific release will be specifically recorded in the **Clinical Safety Case Report**. The **Clinical Safety Case Report** will require approval by the Clinical Safety Officer

prior to deployment. This will ultimately ensure that all of the requirements of the Clinical Safety standard have been addressed.

Post-deployment Monitoring

Incident Management

Post-deployment, we will maintain a process to collect and review reported safety concerns and incidents, and will assess the impact of any such information on the ongoing validity of the Clinical Safety Case. If gathered evidence undermines the safety case, appropriate corrective action will be taken. Any reported safety incidents will be assessed and resolved in a timely manner.

A record of safety incidents, including their resolution, will be maintained in the **Clinical Safety Incident Management Log**. Any reported incidents will be managed appropriately with requirement for CSO assessment if the severity dictates. These incident management procedures are detailed in our **Clinical Safety Incident Management Procedure**.

Change Management

Post-deployment, we will maintain a process to apply clinical risk management processes to any modifications or updates of the deployed health IT system. The application of this process will be commensurate with the scale and extent of the change and the introduction of any new clinical risks. Any changes will result in the issue of an updated **Clinical Safety Case Report** to support any modification to the health IT system that changes its clinical risk. The change management procedure is currently defined in our **Clinical Safety Change Management Procedure**.

Clinical Safety Competency and Training

The clinical safety activities described in this **Clinical Risk Management Plan** shall be undertaken by competent staff. Suitable training shall be undertaken by staff to maintain and expand their level of competence.

Competency

All of the staff identified in the organisation chart, shall be sufficiently competent for the roles and tasks 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 (for example, a HAZOP or FFA) 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. Thereafter, competence shall be monitored through the organisation's established appraisal scheme. Any perceived deficiencies identified during the course of the work or at the appraised stage, especially during probation, shall be addressed immediately, for example, through the assignment of a competent supervisor or the provision of suitable training.
Staff competency will be reviewed periodically, and records of staff competency will be maintained. All registered clinicians involved in safety roles shall, as a minimum, have completed an accredited training course.

Training

As part of the employment process and thereafter through the appraisal scheme, clinical safety personnel will 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, and/or 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 individual on the annual appraisal form.

Audits

Overview

Audits shall be undertaken to ensure that projects are adhering to the defined safety requirements. We will maintain an audit trail of all versions and patches released for deployment.

Internal Safety Audits

We shall undertake regular internal safety audits to ensure that projects undertaken within the organisation are compliant with this Clinical Risk Management System. These audits shall be conducted and recorded in accordance with internal quality management procedures.

Appendix

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**
		Severity				

Risk Matrix key - Acceptability

5 4	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
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

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 severity	Single