DCB0160 Clinical Safety Case Report

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Reviewers

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Reviewer name	Title / Responsibility	Date	Version
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Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Pratyusha Mohan	Head of Care and Clinical Safety Officer	04 August 2025	1.1

Related Documents

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

Doc Reference Number	Title	Version
1	DCB0160 Clinical Risk Management System	1.0
2	Suvera Eligibility Criteria	-
3	DCB0160 Hazard Log	1.1
4	Functional and Non-Functional Testing Strategy	1.0
5	Incident Reporting Meeting Minutes	-
6	Incident Reporting Procedure	1.1
7	Governance Dashboard	-
8	Clinical Product Safety Platform Log	-
9	Configuration Plan	-
10	Training Log	-
11	Business Continuity Plan	1.1
12	Suvera Product Description	0.4
13	Suvera User Manual	-
14	Hazard Identification Workshops	1.0
15	Clinical Guidelines Policy	1.1
16	SCAL IM1	2.0
17	Suvera Clinic Eligibility Criteria	-
18	UCLP Risk Scoring	-
19	Product development lifecycle	-
20	DCB0160 Clinical Risk Management Plan	1.0
21	Standard Operating Procedure	-
22	Live referrals	-
23	DCB0160 Standard	-
24	DCB0129 Suvera Clinical Risk Management System	0.8
25	DCB0129 Clinical Product Risk Management Plan	1.7
26	DCB0129 Product Clinical Safety Hazard Log - Suvera Clinic	2.1

Contents

DCB0160 Clinical Safety Case Report
Introduction
- In Scope
- Out of Scope
- System Definition / Overview
  - Pre-deployment EHR Analysis and Eligibility Extraction
  - Patient Engagement via SMS and Web App
  - Clinician Onboarding and Dashboard Access
  - Integration with Partner EHR Systems
  - Partner Dashboard (Planner) Configuration
  - Central Coordination via “Care Team Task” Node
  - Patient-Facing Deployment Touchpoints
  - Clinical Pathways Enabled Through Deployment
  - GP Practice Partnership Workflow
  - Feedback Loops and Operational Flow
- Aims (Intended Use)
  - Key clinical benefits
  - Clinical Context
  - Current conditions and parts of care supported are:
  - Users / Scale
- System Functionality Overview
  - Software Description
  - Deployment and Technical Architecture
  - Clinician views in the dashboard
  - Planner
  - Workflow and Functionality
  - Scope / project boundaries
  - System dependencies
  - Integrations
  - Data Migration
  - IM1 Connection
  - IM1 Architecture
  - Failure in IM1

Clinical Risk Management System
Clinical Risk Analysis
Clinical Risk Evaluation
Clinical Risk Control
  - Initial Risk Evaluation
  - Residual Risk Evaluation
  - Risk Review
- Hazard Log
  - Test Issues
  - Current Testing Coverage
  - Medical Device Status
  - Summary Safety Statement

Quality Assurance and Authorisation to Proceed / Release
Configuration Control / Management
Appendix A
Definitions
- Risk Status
- Likelihood
- Consequence
- Risk Matrix
- Risk Acceptability Criteria

Abbreviations & Definitions

Term	Definitions
ALARP	As Low As Reasonably Practicable
BP	Blood Pressure
CRMP	Clinical Risk Management Plan
EHR	Electronic Health Record
QOF	Quality Outcomes Framework
SWIFT	Structured What If Technique
PWA	Patient Web Application
LTC	Long Term Conditions
GP	General Practice
BP	Blood Pressure
SMS	Short Messaging Service
Suvera Clinic	Virtual clinic including a patient web dashboard, a care team dashboard and planner
COPD	Chronic Obstructive Pulmonary Disorder
HTN	Hypertension

Introduction

The purpose of this Clinical Safety Case Report is to provide the structured clinical safety argument, supported by the referenced body of evidence, that the defined deployment of the Health IT system – the Suvera Virtual Clinic - is acceptably safe for its intended use and deployed across multiple primary care settings..

The deployment model of the Suvera platform is central to its success, enabling remote clinical management of long-term conditions at scale. The platform is not only a digital tool but a fully integrated virtual care environment that bridges patients, GP practices, and Suvera's clinical workforce through secure, efficient workflows and evidence-based clinical protocols.

It demonstrates that:

- All risks associated with the system have been identified
- Appropriate risk controls have been put in place
- There are appropriate processes in place to monitor the system on an ongoing basis.

In Scope

This Clinical Product Clinical Safety Case Report focuses on the deployment, and use of Suvera's Digital Health solutions that enable the delivery of a virtual clinic service within primary care settings.

Included within scope are:

- **Deployment and configuration of the Suvera Clinic platform**, which comprises:
  - Care Team Dashboard
  - Planner
  - Patient Web App
- **Operational deployment components**, such as:
  - Automated SMS-based patient outreach
  - Patient self-service data collection via webforms
  - Task management and routing to appropriate clinical pathways (e.g., async review, scheduled call, consultation)
  - Integration with appointment scheduling tools (Acuity) and communication systems (Twilio, Slack)
- **System view and safety assessment** of third-party digital health solutions utilised as part of deployment, including:
  - Communication platforms
  - Scheduling and calendar integrations
  - Video conferencing / telephony tools
  - IM1-linked GP EHR systems (e.g. EMIS, TPP) where deployment enables clinical documentation or data retrieval
- Processes used during deployment to onboard care teams and practice partners, and training activities related to clinical system use.

Out of Scope

The following are out of scope for this Clinical Risk Management activity:.

Information Governance and Data Privacy obligations beyond those with a direct impact on clinical safety (e.g., errors causing incorrect or missing patient data). Broader IG compliance is managed independently.

As Suvera undertakes both the development ("Manufacturing") and the deployment of its digital health solution, it is required to comply with both DCB0129 and DCB0160 Clinical Risk Management Standards. This document (DCB0160 Clinical Safety Case Report) is therefore to be read in conjunction with the Suvera DCB0129 Clinical Safety Case Report, Hazard Log, and associated Clinical Risk Management documentation, which detail the safety case from the perspective of software development and manufacturing.

System Definition / Overview

The Suvera Clinic supports the Suvera care team in delivering non-urgent management of specific long term conditions (LTC) in primary care on behalf of GP practices. The clinic is comprised of three key components; Suvera Patient Web application, Suvera Dashboard, Suvera Planner. Patient details are obtained from partner practices EHRs. Patients are then contacted via an SMS to invite them to the virtual clinic via a personalised link to their web application. Once consented the web application will ask the patient to submit their clinical data (e.g. BP). The submitted clinical data is accessible by the Suvera Care Team through the Suvera Dashboard. Care team members then invite the patient for a virtual consultation via an SMS. Tasks are generated within the Suvera Dashboard for the Care team members depending on the requirements of the patient (see conditions below). Patients are reviewed by the care team with resultant clinical decisions undertaken by qualified clinicians. Once Suvera's clinical team reviews the patients data, the consultation is coded onto the practice's EHR via IM1. The Suvera clinic is a non-urgent service however on the account where urgent information is processed through the Suvera dashboard, there is an urgent task pathway which notifies care team members to act upon this task within a timely manner. A list of tasks can be found in the Suvera Product Description. The Planner componant allows partner practices to review their patients (Suvera and non-Suvera), in addition to sending communications to Suvera clinicians via live refferals. When a live refferal is sent via Planner, it shows up on the Suvera Dashboard as a task. A care team member is allocated to these tasks and these referrals are actioned upon (see diagram below).

The deployment of the Suvera virtual clinic is designed to be modular and scalable.

Key aspects of the deployment include:

Pre-deployment EHR Analysis and Eligibility Extraction

- Deployment begins with Suvera's EHR analysts conducting an initial extraction from partner GP practices to identify eligible patients based on pre-defined clinical thresholds (e.g., BP ≥140/90 mmHg for hypertension case finding). This structured approach ensures appropriate patient identification aligned with contract requirements. If patients fit into the eligibility criteria they will then be invited to the service via an SMS.

Patient Engagement via SMS and Web App

- Eligible patients are engaged via SMS with personalised links to the Suvera Patient Web App, where they can submit clinical data (e.g., BP, ACT scores, lifestyle data). This remote engagement model is deployed with an emphasis on accessibility and patient autonomy.

Clinician Onboarding and Dashboard Access

- Suvera Care Team members—including pharmacists, GPs, and care coordinators—are onboarded and granted secure access to the Suvera Dashboard, where they manage patients' reviews. The deployment includes role-specific training and user configuration tailored to clinical function.

Integration with Partner EHR Systems

- Where available, IM1 API integrations allow for semi-automated data synchronisation with GP practice systems (EMIS and TPP). If IM1 is not enabled, manual copy-paste workflows are deployed with auditing steps to ensure accuracy. This dual-mode integration ensures deployment is flexible and does not disrupt existing GP workflows.

Partner Dashboard (Planner) Configuration

- GP practices are given access to the Planner Dashboard as part of the deployment. It enables practices to monitor referral status, discharge patients, and track patient cohorts using filters (e.g., month of birth, target area). Data refreshes every two weeks through controlled EHR extracts.

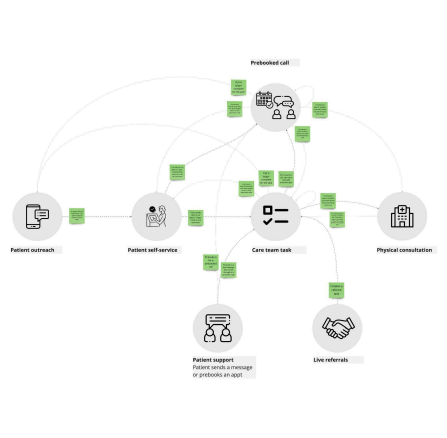


Figure 1 High level overview of the Suvera Clinic

Figure 1 illustrates the functional deployment architecture of the Suvera virtual clinic. This diagram breaks down the end-to-end patient journey and links it to clinical operations. Key components interact with the care delivery workflow to demonstrate how the platform is deployed and used in practice. Further depth is found below:

Central Coordination via “Care Team Task” Node

At the centre of the diagram is “Care team task”, which acts as the operational hub of the virtual clinic. It connects all inputs (from patients or systems) and routes them into appropriate clinical pathways.

This node represents:

- The Suvera Dashboard used by clinicians
- The task assignment system for handling patient needs
- Integration points between asynchronous data and synchronous clinical decision

Patient-Facing Deployment Touchpoints

Several patient-facing entry points are shown, demonstrating the multichannel engagement used during deployment:

- **Patient outreach**: Represents the automated SMS invitations sent via Twilio. This marks the first step in deployment when Suvera reaches out to eligible patients.
- **Patient self-service**: Shows how patients can submit health data (e.g., BP, lifestyle) via the Patient Web App, a key part of the virtual clinic's front-end.
- **Patient support**: Indicates support pathways for patients to send messages or schedule calls. This functionality is deployed via secure messaging tools and Acuity calendar integration.

These features are part of the platform's deployment bundle that gets rolled out to GP practices.

Clinical Pathways Enabled Through Deployment

Once a task is created, the care team can direct the patient to:

- **Prebooked call**: A synchronous review via scheduled video or phone call, deployed through Acuity + Google Calendar.
- **Physical consultation**: If remote care isn't sufficient, the system routes patients to an in-person GP practice review with the partner practice**, showing the safety net built into the deployment model.**

GP Practice Partnership Workflow

The Live referrals pathway shows how GP practice staff (via the Planner dashboard) can:

- Refer patients to Suvera

This supports the co-deployment model where Suvera is embedded within existing GP workflows without disrupting them.

Feedback Loops and Operational Flow

The dotted arrows suggest bi-directional communication and feedback loops, meaning data and actions can flow:

- From patient to dashboard
- From dashboard to patient or GP
- From tasks back to scheduling or messaging systems

This reflects how Suvera's deployment is interconnected, rather than linear, ensuring continuity of care.

Aims (Intended Use)

Key clinical benefits

 The Suvera virtual clinic is designed to support the non urgent remote clinical management of long-term conditions (LTCs) in partnership with GP practices. Its core aim is to enable scalable, safe, and effective deployment of digital-first healthcare pathways that maintain clinical quality while optimising resource use across primary care networks.

Clinical Context

- Seamless remote monitoring of patients with long-term conditions using digital tools, reducing the need for in-person appointments.
- Direct access for patients to communicate with clinicians via pre-booked virtual appointments**,** SMS outreach**,** or self-service clinical updates**.**
- Automated risk stratification and prioritisation, allowing care teams to focus on patients with the greatest need.
- Consistent application of national guidelines (e.g., NICE, QOF) through a digital platform deployed with built-in safety and triage protocols.

Current conditions and parts of care supported are:

The Suvera virtual clinic is deployed to enable the Suvera care team to deliver delegated clinical services on behalf of GP practices, focusing on the proactive management of high-impact LTCs. The deployment includes patient engagement tools, clinician dashboards, and EHR integration, supporting the following clinical workflows:

- **Hypertension Case-Finding**
  Patients with elevated BP (≥140/90 mmHg) but not yet diagnosed are invited to submit readings via the Patient Web App. Reviews lead to diagnosis or discharge and are managed via the Care Team Dashboard. This flow is deployed as part of the case-finding onboarding cycle.
- **Hypertension Routine Review**
  Patients already on the QOF register complete digital reviews through the app or a care team call. Care plans are developed and monitored asynchronously, with tasks routed via the dashboard. This service is deployed alongside practice referral criteria.
- **Hypertension Urgent Review**
  Triggered automatically when a submitted BP is ≥175/115 mmHg. These patients are flagged through Slack and reviewed immediately. This alert-driven workflow is part of the deployed high-risk response layer.
- **Diabetes Routine Review**
  Type 2 diabetic patients complete digital submissions; bloods and foot checks are done in-practice. The Suvera care team integrates data from both sources, documents plans, and follows up remotely, using the deployed IM1 (if implemented) and dashboard systems.
- **Diabetes Case Finding**
  Patients with HbA1c between 42–47 are onboarded via the Patient Web App and triaged by clinical rules embedded in the platform. Their care is initiated and documented via the dashboard.
- **Cholesterol Review**
  Conducted as part of a hypertension or diabetes pathway. EHR values are reviewed and addressed via the dashboard. This supports medication review workflows embedded during deployment.
- **Structured Medication Reviews (SMRs)**
  Suvera pharmacists conduct SMRs as part of scheduled reviews using Acuity booking and dashboard documentation. These are deployed as discrete task flows assigned by the care team lead or GP.
- **Frailty Reviews**
  Care team members complete digital frailty assessments using EHR templates and the Suvera Dashboard, as part of the broader LTC workflow.
- **Asthma Reviews**
  Patients complete pre-assessment via the Web App, followed by structured reviews by clinicians. Suvera's digital deployment ensures validated tools (e.g., ACT) are consistently applied.
- **Chronic Kidney Disease (CKD)**
  GFR, ACR and other CKD data are extracted from the EHR and reviewed in Suvera's Dashboard. Deployment ensures data is presented in a structured review format, enabling longitudinal monitoring.
- **Asynchronous (Async) Reviews**
  Patients previously onboarded can be reviewed without appointments if within validated clinical thresholds. This model is deployed to reduce unnecessary contacts while maintaining safe follow-up. Automated SMS notifications and pharmacist sign-off are included in the deployed workflow.

Users / Scale

- Patient Web App users include:
  - Patients using the web app to submit their Blood Pressure Readings and Lifestyle information.
- Dashboard users include:
  - Suvera Care Team (GPs, IPPs (Prescribing Pharmacists & Care Coordinators).
- Partner Dashboard (Planner software):
  - Staff (GPs, IPPs, Nurses, Administrators) at all/any of our partner GP practices ○ These users are limited to live referrals functionality, as described below.

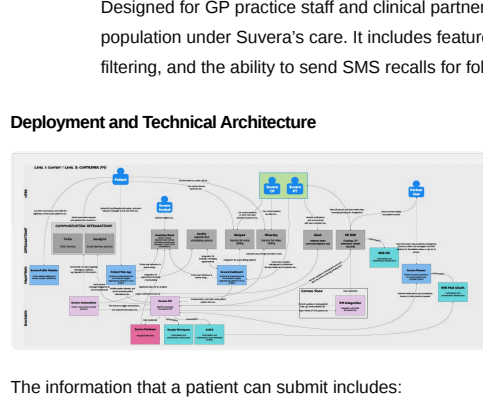
System Functionality Overview

Software Description

The Suvera platform is composed of three integrated components, each designed to support a different aspect of the virtual clinic service:

- **Patient Web App**
  Patients use the web app to securely submit clinical data, such as blood pressure readings and lifestyle information. Once submitted, this information is automatically linked to the patient's profile and made available for review within the Suvera Dashboard.
- **Suvera Dashboard**
  This is the central workspace for clinicians, enabling them to review patient-submitted data, conduct virtual consultations, document clinical interactions, and manage care plans. It provides a structured, condition-specific view to support safe and efficient clinical decision-making.
- **Planner (Partner Dashboard)**
  Designed for GP practice staff and clinical partners, the Planner offers visibility into the patient population under Suvera's care. It includes features such as real-time task tracking, patient filtering, and the ability to send SMS recalls for follow-up.

Deployment and Technical Architecture



The information that a patient can submit includes:

- Blood Pressure & Pulse
- BMI (height & weight)
- Lifestyle questions
- ACT questionnaire
- Consent for async medication changes

Clinician views in the dashboard

A list of patients

- Name, age, average BP, max bp,
  - Information submitted by the patient from the webform as above both as a dashboard and as a more detailed complete review.
  - History of encounters with the patient
  - Ability to Log an Interaction
  - Ability to send an SMS to the patient
- Ability to update the action for that patient.

Planner

Core features:

- Finding Patients under Suvera's care
- Finding a Patient under the Practice care
- Export the designated practice patient list
- Viewing Patient interactions with Suvera
- Referring a patient to Suvera
- Discharging a patient from Suvera

The patient list can be filtered by the following categories:

- Target area
- Date of birth
- Suvera status (this is the reason the patient is showing as 'Your Patient' rather than a 'Suvera Patient)
- Show the Target area register patient list
- Sorted by default using
  - Partner EHRs tag patients with their UCLP risk score, once patients are extracted onto planner they sorted with highest risk presented first.
  - Patients without a UCLP risk score are presented at the bottom of the patient list.
- Use filters to switch between Suvera led vs Practice led patient lists
- Ability to filter by
  - Month of birth of patients
  - Practice / Suvera
  - Target area complete/incomplete
- Ability to export filtered data as a csv file. CSV files will not be password protected. However all those with access to patient data will have DBS checks and therefore IG risk is transferred to the practices.
- Data is updated every two weeks in line with EHR extracts
- Show data update notice - see screenshots below - information to show last update of EHR extracts.

Workflow and Functionality

This section can be found in the Suvera Product Description. It summarises the workflow diagrams relating to the main functions of the Suvera Clinic System. It maps expected outcomes by the system and has been used in part to help identify hazards during workshops. The hazard identification workshops consider conditions which may cause deviations to the expected outcomes and possible risks to patient safety. Hazards are evaluated using an agreed categorisation tool and added to the hazard log. This process is explained in more detail later in this document.

Scope / project boundaries

The Suvera Virtual Clinic uses Role based Access control (RBAC) within its deployment.

- Patient Web App users include:
  - Patients using the web app to submit their Blood Pressure Readings and Lifestyle information.
- Dashboard users include:
  - Suvera Care Team (GPs, Clinical Pharmacists, Care coordinators, pharmacy technicians and operations.
- Planner users include:
  - Staff (GPs, Clinical Pharmacists, Nurses, Administrators) at all/any of our partner GP practices
  - These users are limited to live referrals functionality as described below.

System dependencies

Integrations

Integrated with the Suvera Platform

- Google Workspace: Authentication for Care Team User Authentication
- Twilio: SMS Notifications / Messages. Prompting the patient to make an appointment or complete assigned tasks
- Acuity: Schedule & view Appointments. Acuity is integrated with Google Calendar for Care Team users to use for scheduled appointments with patients.
- Twilio Send Grid Email API: Send Emails (One-way personalised messages from Care Team to patient via an email button in the platform)
- Slack: for High Risk Alerts / Notifications (i.e. patients submitting S3 blood pressure readings)

Third Party Applications used by Suvera Platform:

- Mongo DB / AWS Stores Data for / from Suvera Platform

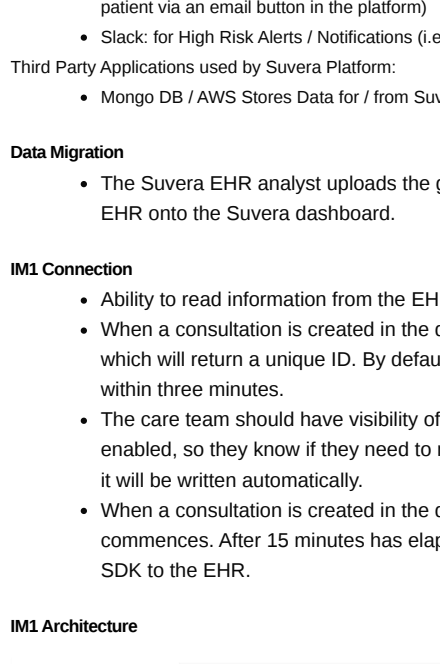
Data Migration

- The Suvera EHR analyst uploads the generated list of eligible patients from the GP's EHR onto the Suvera dashboard.

IM1 Connection

- Ability to read information from the EHR (EMIS and TPP)
- When a consultation is created in the dashboard, it will be sent via the core SDK, which will return a unique ID. By default, it will be visible in the GP practice's EHR within three minutes.
- The care team should have visibility of which GP practices have IM1 integration enabled, so they know if they need to manually copy and paste the consultation or if it will be written automatically.
- When a consultation is created in the dashboard, a grace period of 15 minutes commences. After 15 minutes has elapsed, the consultation gets sent via the core SDK to the EHR.

IM1 Architecture



Failure in IM1

Data manually transferred bidirectionally:

- GP EHR - currently manual:
  - See below section for patient registration and sync.
  - Suvera's Care Team members update the EHR in real time to:
    - Document in the clinical notes
    - Add any necessary coding
    - Record patients as discharged from Suvera - this is also communicated to the partner according to agreed local policy - either via task within the GP EHR or by
    - NHS email

Clinical Risk Management System

This product and the safety documents created will follow the risk management processes that are detailed in the existing Clinical Risk Management System.

This approach will ensure compliance with the clinical risk management standards DCB0160 which are mandated under the Health and Social Care Act 2012.

The Suvera team and its clinical safety officer are responsible for the creation and the maintenance of this document, the hazard log and meeting records held as input and assessment of the hazards identified.

As Suvera also manages the manufacturing of the product, a separate DCB0129 Clinical Risk Management System and associated documentation have been developed. Cross-referencing is maintained between these two safety cases to ensure continuity and traceability of clinical risk management throughout the product lifecycle.

Clinical Risk Analysis

To simplify the document, a number of decisions have been made related to the way clinical safety is progressed throughout the project and these are:

- Identification and analysis to identify the hazards will primarily use the SWIFT method
- Assessments of all hazards will be periodically reviewed, and outcomes documented
- Any hazard with an overall rating of “Moderate” or above will need to be examined and acceptable control measures identified to bring the overall risk rating to as low as reasonably practical.
- Any hazard with an overall rating of “Low” that has not required a control measure will be accepted
- Definitions of Risk Status, Consequence and Likelihood are documented in the Clinical Risk Management Plan.
- Risk Acceptability Criteria is documented in Risk Acceptability Criteria
- Risk Matrix is documented in this document's Risk Matrix section

The clinical risk matrix, evaluation and management process used is found in the appendix.

Identified hazards captured in the SWIFT workshop meeting notes were transferred to, described and risk rated in the Hazard Log and the following information was defined, recorded and summarised:

- Hazard number;
- Hazard scenario name;
- Hazard description (Cause, Sequence of events, Effect, and Harm). The Hazard is used to classify the hazard scenario equating to the main root cause.
- Existing controls – if any, these are identified existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation against the hazard

Clinical Risk Evaluation

For each identified hazard, an estimation was made of the clinical risk. This included the severity of the hazard, the likelihood of the hazard and the resulting clinical risk. The estimation process followed is established by the safety processes defined in DCB 0160. A copy of the risk assessment matrix and risk acceptability criteria is provided in Appendix A.

All identified hazards were evaluated from the perspective of patient safety consequences using a Cause, Effect, Hazard, Harm approach to explore potential consequences. Contributory factors were considered, in addition to identifying existing mitigating controls from a Health IT design, User Training and Business Process perspective.

Based on all of the above and using the pre-defined criteria in Risk Matrices (Appendix A) an estimation of Clinical Risk was completed.

Clinical Risk Control

Initial Risk Evaluation

This table shows the initial risk rating prior to sufficient control measures.

Risk Level	Risk Acceptability Definition	No. of Hazards from Initial Assessment
5	Unacceptable	0
4	Mandatory elimination of hazard	0
3	Undesirable level of risk	0
2	Acceptable where cost of reduction outweighs benefits	8
1	Acceptable	1
	TOTAL	9

Residual Risk Evaluation

Following confirmation of completion of controls outlined in the hazard log, the number residual risks are summarised below:

Risk Level	Risk Acceptability Definition	No. of Hazards from Residual Assessment
5	Unacceptable	0
4	Mandatory elimination of hazard	0
3	Undesirable level of risk	0
2	Acceptable where cost of reduction outweighs benefits	8
1	Acceptable	1
	TOTAL	9

Current Status of Residual Hazards

Status	Status of Residual Hazards				
	Acceptable	Acceptable where cost of reduction outweighs benefits	Undesirable level of risk	Mandatory elimination of hazard	Unacceptable
Accepted	0	0	0	0	0
Monitored	1	6	0	0	0
Transferred	0	2	0	0	0
Subtotal	1	8	0	0	0
Total	9				

Clinical Risk Category	Initial Risk (count)	Residual Risk (count)
Low	2	2
Moderate	14	11
Significant	-	-
High	-	-
Very High	-	-

Risk Review

As part of the deployment of the Suvera platform, a total of 9 clinical hazards have been identified and documented. These represent known risks associated with virtual care delivery, third-party integrations, patient communication, and clinical data handling in a remote environment.

Of the 9 hazards:

- 6 hazards are being actively monitored by the technical team, primarily related to software bugs, interoperability connection issues, and the risk of missing or incomplete data. These are considered undesirable but manageable due to the presence of control measures such as automated alerts, backend monitoring, and rigorous testing protocols.
- 2 hazards have been transferred to third-party suppliers, including EHR system providers and integrated communication platforms. Responsibilities for mitigation are clearly defined in partnership agreements, and Suvera maintains oversight to ensure timely resolution of any incidents.
- 1 hazard is accepted and remains under ongoing monitoring, where the residual risk has been assessed as low and outweighed by the clinical benefits of the system.

Mitigations in place include custom-built software tests, real-time Slack alerts, role-based access controls, incident reporting procedures, and clinician training through standard operating procedures. All hazards are reviewed as part of Suvera's clinical risk management cycle. Any changes in functionality, service scope, or user interaction that could affect the clinical safety profile will trigger a re-evaluation.

Full details of each hazard, including their current status and mitigation measures, are available in the deployment hazard log.

Hazard Log

The Hazard Log can be accessed here. This hazard log references and builds upon the DCB0129 Product Clinical Safety Hazard Log, which captures development-related hazards and risk controls.

Test Issues

As part of the Suvera platform deployment, all known test issues with potential clinical safety impact have been resolved. At present, there are no outstanding issues that would affect the safe operation of the platform in a live clinical environment. Risk mitigations identified through the clinical hazard log have been implemented and verified prior to deployment.

The platform is supported by a robust and mature automated testing framework, ensuring that all functionality is validated continuously throughout the development and release cycle. This framework plays a critical role in maintaining clinical safety and service integrity during and after deployment.

Automated testing comprehensively covers the following areas:

- **Security Testing:** Verifies that users cannot access protected data or functionalities without proper authentication and authorisation.
- **Functionality Testing:** Confirms that all key user workflows—such as logging consultations or submitting patient data—perform as expected and that data is correctly stored.
- **Safety Testing:** Validates clinical parameters and thresholds (e.g., blood pressure classification) to ensure that all edge cases and clinical safety boundaries are respected.
- **Sequence (End-to-End) Testing:** Simulates complex patient and clinician journeys over multiple days to ensure sustained and accurate system performance.

Current Testing Coverage

The deployment is underpinned by the following automated test suite:

- **4,224** tests for the shared application backend
- **1,710** tests for the care dashboard UX
- **670** tests for the partner dashboard UX
- **285** tests for the patient web app UX

These tests are collaboratively designed by Suvera's product, clinical, and engineering teams to align with clinical workflows, safety standards, and technical requirements. Tests are developed using a test-driven development (TDD) approach: tests are written before new functionality is built, serving as specifications and automated checks for completed features.

Critically, all deployments are governed by a no-pass, no-release policy. If any test fails, the version is automatically blocked from progressing to release. Additionally, all code releases undergo manual peer review by an engineer independent of the original author to ensure unbiased validation.

This testing and governance framework ensures that the deployed platform meets Suvera's safety, functional, and clinical standards and remains compliant with internal and external safety expectations.

Further information on testing can be found here.

Medical Device Status

Suvera has considered whether this application would come into scope for the Medical Device Regulations (MDR). Following guidance from MHRA's Medical device stand-alone software including apps guidance this software component is not classified as a medical device.

This computer program does not have a medical device intended purpose. It does not function to prevent, diagnose, monitor or treat disease. It has no in vitro functionality.

This position will be reviewed periodically.

Summary Safety Statement

The Suvera platform is being deployed to support the Suvera care team in delivering non-urgent remote management of specific long-term conditions (LTCs) in primary care, on behalf of GP practices. The service is delivered through a virtual clinic model that uses SMS communications, webforms, and clinical templates.

As part of the deployment workflow, patients are invited via SMS to engage with the platform and may complete structured assessments through a secure web app. Clinical data submitted by patients is reviewed by the care team, and follow-up decisions are made as appropriate.

During deployment, the platform integrates with GP practices' EHRs to retrieve patient clinical data remotely. Suvera's technology compiles this data and presents it on a clinician-facing dashboard for review. The clinical team codes relevant data into the practice's electronic health record (EHR) system, and care team tasks are generated where further dialogue with patients is indicated. The Suvera clinic is a non-urgent provider, urgent clinical data may pass through the system, via the live referral route. The Suvera clinic dashboard has built in functionality to process urgent clinical data, in addition to the Suvera care team being trained in acting on urgent queries within a timely manner to mitigate any risk surrounding urgent queries.

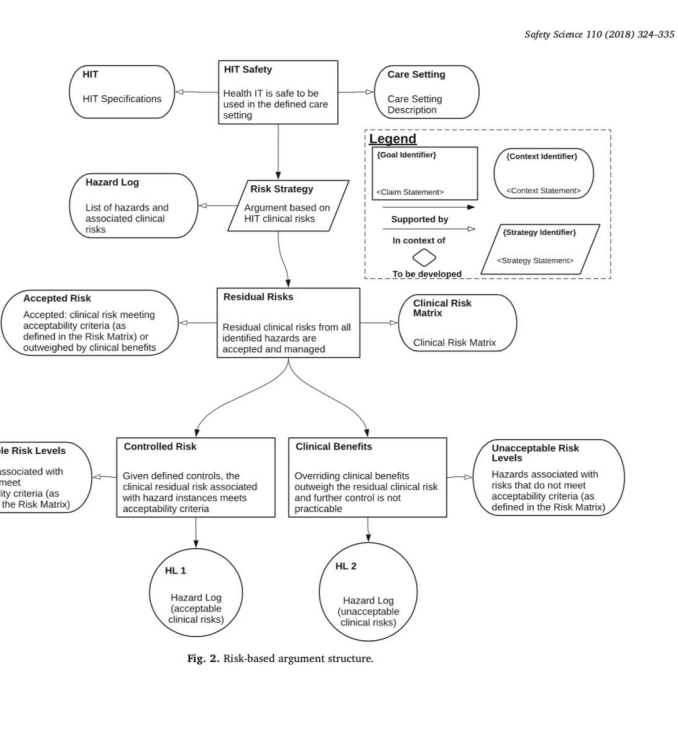
Prior to deployment, the intended use of the Suvera platform and its associated clinical hazard log were reviewed thoroughly. Comprehensive hazard identification, risk evaluation, and implementation of safety controls have been completed. These measures have undergone both internal verification and external validation, including structured system and integration testing.

As part of the deployment process, the platform has been subject to formal witness testing with system supplier(s). No issues were raised during this testing phase, and all critical functions performed as expected.

Post-deployment, the majority of identified hazards continue to be monitored in accordance with the Clinical Risk Management Plan. This ensures that clinical safety remains a dynamic and responsive process.

In conclusion, sufficient clinical risk management activities have been undertaken to support the safe deployment of the Suvera platform. Ongoing monitoring and governance will continue following deployment, with this document subject to review in the event of changes in service scope, incidents, or at routine intervals, in line with clinical safety standards.

Dr Pratyusha Mohan | Head of Care | Clinical Safety Officer | GMC: 7134032



I. Habli et al.
Safety Science 110 (2018) 324–335
HIT
HIT Specifications
HIT Safety
Health IT is safe to be used in the defined care setting
Care Setting
Care Setting Description
Legend
Supported by
In context of
To be developed
Hazard Log
List of hazards and associated clinical risks
Risk Strategy
Argument based on HIT clinical risks
Accepted Risk
Accepted: clinical risk meeting acceptability criteria (as defined in the Risk Matrix) or outweighed by clinical benefits
Residual Risks
Residual clinical risks from all identified hazards are accepted and managed
Clinical Risk Matrix
Clinical Risk Matrix
Acceptable Risk Levels
Hazards associated with risks that meet acceptability criteria (as defined in the Risk Matrix)
Controlled Risk
Given defined controls, the clinical residual risk associated with hazard mitigation meets acceptability criteria
Clinical Benefits
Overriding clinical benefits outweigh the residual clinical risk and further control is not practicable
Unacceptable Risk Levels
Hazards associated with risks that do not meet acceptability criteria (as defined in the Risk Matrix)
HL 1
Hazard Log (acceptable clinical risks)
HL 2
Hazard Log (unacceptable clinical risks)

Fig. 2. Risk-based argument structure.

Quality Assurance and Authorisation to Proceed / Release

All new system requirements follow the change management process as outlined in the DCB0160 Clinical Risk Management Documentation. Suvera follows a stringent development methodology to ensure new features are risk assessed, tested and evaluated prior to release, in addition to post marketing surveillance undertaken through governance and platform support portals.

Configuration Control / Management

An implementation / deployment strategy, including configuration guidance and control management has been developed and adhered to as per company documentation.

Reference Documents

The referenced documents collectively form a comprehensive framework for ensuring the safety, and effective operation of Suvera's digital clinical product. Risk identification and management is covered in the following documentation: DCB0160 Clinical Risk Management System,DCB0160 Clinical Safety Hazard Log ongoing safety monitoring is focussed within the Incident Reporting Procedure. Governance and oversight are supported by the Governance Dashboard. The Business Continuity Plan addresses operational resilience and staff preparedness. User-oriented resources such as the Suvera Product Description, User Manual, and Eligibility Criteria ensure clarity and usability, and the Product Development Lifecycle and Hazard Identification Workshops demonstrate a proactive approach to continuous improvement and safety-by-design. Overall, these documents reflect a robust clinical governance and product safety infrastructure.

Appendix A

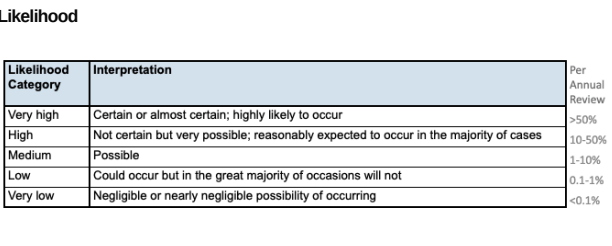
Definitions

The following details the definitions used through the hazard log and are key in the categorisation of the hazard. When reviewing hazards, it is useful to have this view. This information is also in the hazard log.

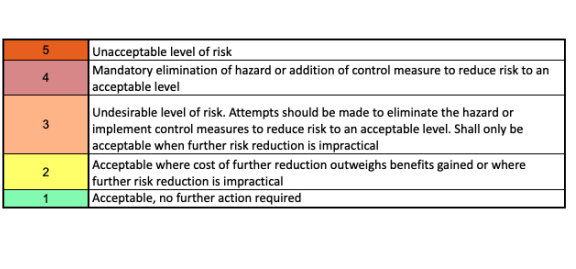
Risk Status

Status Category	Interpretation Status
Accepted	Clinical risk meets acceptability criteria (as defined in risk matrix) or is outweighed by clinical benefits. Risk is 'as low as reasonably possible (ALARP)'
Monitored	Clinical Risk continues to be monitored, with additional controls yet to be introduced or still under testing
Transferred	Sufficient risk controls have been applied during design and deployment of the system. Further risk management will be undertaken by users specified hazard log.

Likelihood

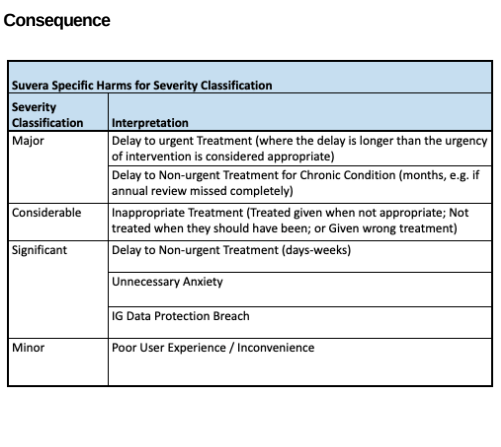


Likelihood Category	Interpretation	Per Annual Review
Very high	Certain or almost certain; highly likely to occur	>50%
High	Not certain but very possible; reasonably expected to occur in the majority of cases	10-50%
Medium	Possible	1-10%
Low	Could occur but in the great majority of occasions will not	0.1-1%
Very low	Negligible or nearly negligible possibility of occurring	<0.1%



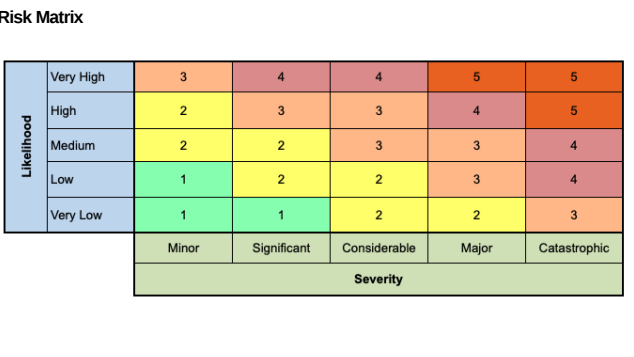
5	Unacceptable level of risk
4	Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level
3	Undesirable level of risk. Attempts should be made to eliminate the hazard or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical
2	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

Consequence



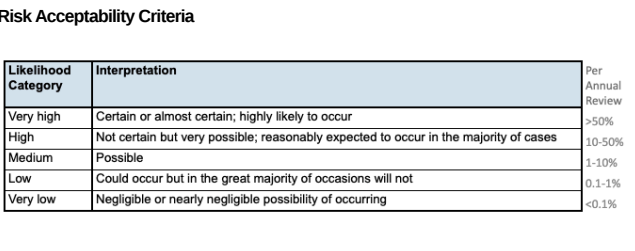
Suvera Specific Harms for Severity Classification	
Severity Classification	Interpretation
Major	Delay to urgent Treatment (where the delay is longer than the urgency of intervention is considered appropriate)
	Delay to Non-urgent Treatment for Chronic Condition (months, e.g. if annual review missed completely)
Considerable	Inappropriate Treatment (Treated given when not appropriate; Not treated when they should have been; or Given wrong treatment)
Significant	Delay to Non-urgent Treatment (days-weeks)
	Unnecessary Anxiety
	IG Data Protection Breach
Minor	Poor User Experience / Inconvenience

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 Acceptability Criteria



Likelihood Category	Interpretation	Per Annual Review
Very high	Certain or almost certain; highly likely to occur	>50%
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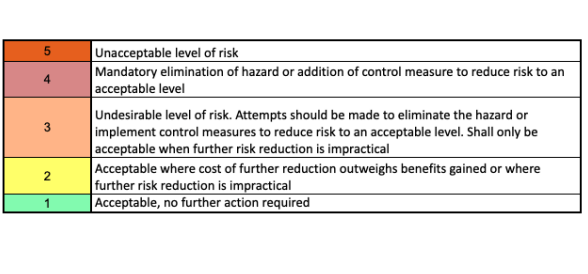

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2	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

Clinical Risk Category	Initial Risk (count)	Residual Risk (count)
Low	2	2
Moderate	14	11
Significant	-	-
High	-	-
Very High	-	-