IPLATO HEALTHCARE

Clinical Safety Case Report

January 2025

Version 1.8 – External

iplato
a HUMA company

Contents

Version Control

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About this Manual

This Manual is a compilation of all Clinical Safety policies.

The policies stated are subject to change at any time and are at the sole discretion of iPlato.

The policies as detailed in this manual supersede any other published versions of iPlato policies (including the Employee Handbook).

Executive Summary

This Clinical Safety Case Report (CSCR) is provided by the manufacturer, iPlato to support the safety of the myGP system. UK NHS Clinical Safety standards are mandatory to those manufacturers providing digital health solutions (including medical devices) to NHS organisations. The UK NHS Clinical Safety standards comprise of organisational and product safety requirements based on the principles of risk management. This document, together with the Clinical Risk Management Plan (CRMP) [10] and associated hazard log, provide evidence to support compliance with DCB 0129 [1].

It is essential that the health organisation is cognisant of the product safety claims made by manufacturers of Health IT. Care must be taken to review these documents in line with the source material from which key evidence is taken:

- Quality Management System [6]

- Training documents [9-11]

- Help site [12]

- Corporate Policy Manual [13]

Note – access to this information is subject to approval and agreement of iPlato.

Introduction

Purpose

The purpose of the Clinical Safety Case Report (CSCR) is to communicate and evidence that hazards associated with the intended use of the myGP®/iPlato System have been identified and the associated risks evaluated. In doing so, the CSCR also evidences compliance with NHS Clinical Safety requirements [1-3]. This CSCR summarises the key elements of the Clinical Safety Case and highlight iPlato's commitment and adherence to its defined Clinical Risk Management (CRM) principles, processes, and activities.

The production of CSCRs (with supporting evidence) is considered best-practice as:

- A clinical safety assessment with risk at its core, facilitating the prioritisation of effort.

- Compliance with DCB 0129 and DCB 0160 is mandatory under the Health and Social Care Act 2012

- Structured, written records of safety decisions (the CSCR and supporting documentation) mitigate against patient safety issues if considered by the health organisation.

- Information developed within CSCRs can be shared and reused, facilitating feedback of lessons learnt, open safety culture and economies of scale.

- CSCRs together with efficient organisational risk/safety management systems and a robust culture of safety reduce whole-life costs, facilitate better change management and Business-As-Usual (BAU) processes, business improvement, improved morale, and efficiency by reducing the harm caused by hazards.

- Quality Clinical Risk Management allows innovative approaches and facilitates the incorporation of both Health IT engineering and clinical judgement (e.g., as a contribution into design), where decisions can often be complex and value judgements are often required.

Scope

This CSCR applies to iPlato designed and built Healthcare IT systems and to all subsequent updates or upgrades to systems. The policy also applies to any local customisations or specific configurations made to the iPlato IT systems by iPlato.

The following iPlato solutions are included in this version of the CSCR:
- iPLATO Connect platform
- Messaging
- myGP® App
- iPLATO Toolbar
- preGP®
- iPLATO Triage
- Patient Questionnaires
- NHS App API

CSCR are software product, version, and development stage specific. That is, a CSCR may be produced at a stage of product development, to outline the safety case at that point in time, eg. prior to entering a technology evaluation or beta testing (pre-market); for the purposes of testing prior to entering the market; or post market as part of ongoing change management and maintenance.

System Lifecycle Phase

- iPLATO Connect platform 4.11
- Messaging
- myGP® App IOS:8.25.0, Android 8.25.0
- iPLATO Toolbar 3.11
- preGP
- iPLATO Triage
- Patient Questionnaires
- NHS App API

As Messaging, Triage and Patient Questionnaires all sit within the Connect Platform they retain the same version number as the Connect Platform as a whole.

If clarification is required on whether any System component or linked 3rd party component fall within the scope of this CSCR, the CSO for the project will be consulted.

The scope of this report extends to all clinical risk management linked activities undertaken during the myGP system life cycle. All clinical functions and use cases that have potential to cause harm to patients and or system users are incorporated. This document defines the boundaries of the process of CRM within iPlato for the system, including the roles and responsibilities of the personnel tasked to oversee the development, implementation, and maintenance. These encompass:

- A thorough understanding of the technical requirements of the components of the system, both in regard to hardware and software and the underlying architecture required to implement and maintain the system; and,

- A thorough understanding of:

    - The clinical functionality that the myGP®/iPlato System is intending to provide (or replicate)

    - system usability issues which may result in unintended consequences to patients.

    - The (front-ended) assessment of any known deficiencies in the system and / or supporting business activities.

    - An awareness of how CRM aligns with any wider governance processes and the significance and importance of clinical risk assessment being carried out completely and competently, and

    - A fully defined clinical risk assessment process which incorporates the application of NHS Digital recognised and rigorous methodologies and good CRM practice.

The CRM activities summarised in this CSCR have been completed in alignment with the Clinical Risk Management System (CRMS)[14], the iPlato system CRMP [13] and QMS [6]. These documents extend to cover the full life cycle of the myGP®/iPlato System and the configuration variations that may be implemented within healthcare settings.

The CSCR will be produced and maintained in alignment with each configuration variation, incorporating changes in deployment and use scope and context. Deploying Health Organisations are responsible for the DCB0160 clinical safety CSCR which should incorporate clinical risk associated with local configuration and use decisions.

System Overview

iPlato/myGP® solutions are used in the UK by patients and GP practices. The solutions do not replace any existing systems but replace manual processes, for example, appointment booking, reminders and cancellations; ordering prescriptions and viewing medical records. The solutions have direct API integration with TPP (SystmOne), EMIS and Vision that supports the delivery of integrated healthcare. The interface is managed via the Connect Platform. This allows clinicians and patients to correspond via data messages / SMS / myGP App. The practice user can send a message to any patient and select to have this written-back to the patient record using SNOMED CT codes. They can also attach files or documents for the patient's attention and receive attachments in return using the Toolbar messaging widget. Patient responses are displayed in the Remote Consultation Inbox. The practice can also use Toolbar to provide video consultations.

The system allows GPs and clinical administrators to configure / administer the setting up of appointment slots that can be booked via the myGP App, as well as define appointment types and how far ahead they can be booked. The Triage system combines the use of the Connect platform and myGP App to offer patients a triage option when booking an appointment. pre-GP allows practices or PCNs to configure and signpost patients to alternative services.

iPlato products are a cloud-based solution (AWS) however the myGP Application uses IM1 patient facing services (NHS Login) to verify patients' identity. This ensures submissions made using Triage are verified correctly.

Integration with the NHS Application (NHS APP API) – Patients registered on the NHS app are automatically picked up using the NHS APP API, this means messages can also be delivered via this channel if appropriate, this ensures maximum cost saving to the NHS. This newest addition to the Connect platform means informational messages that don't require a free-text response from patients can be sent via this channel.

The below diagram (Diagram 1) shows the relevant architecture being used within the iPlato product suite.
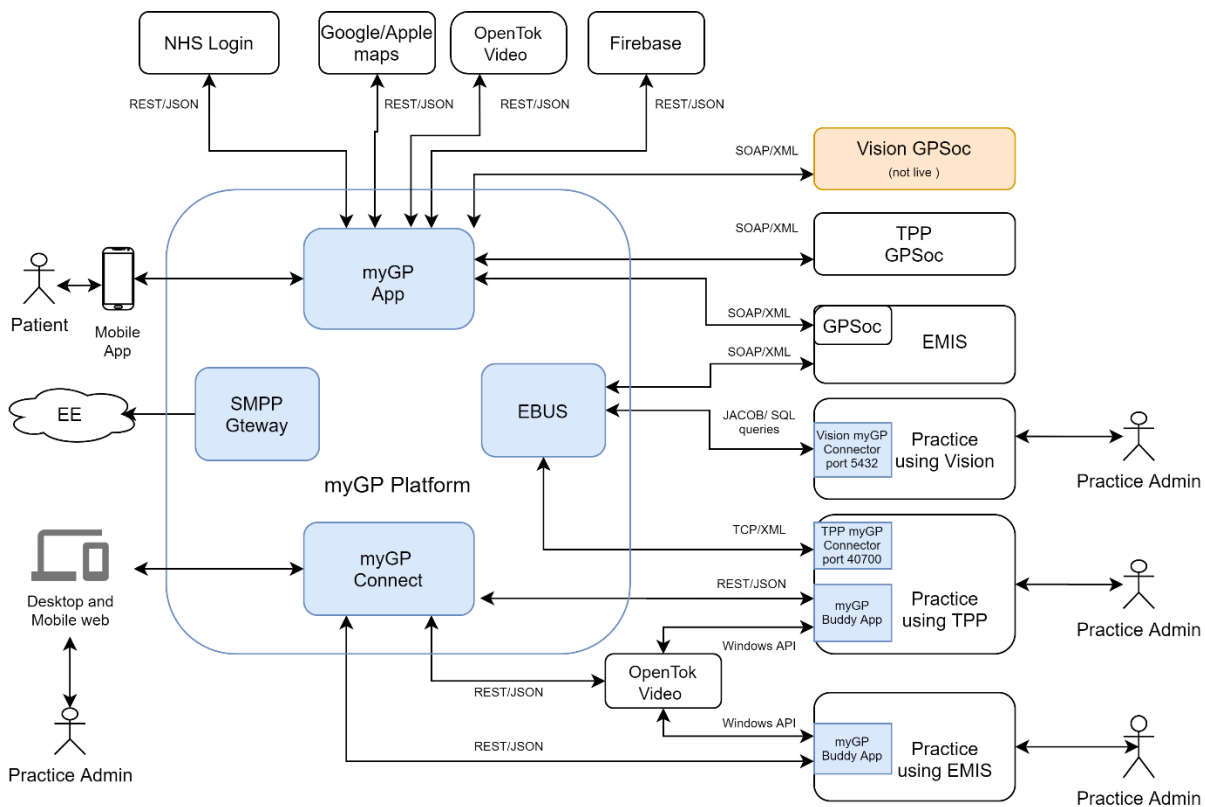
Diagram 1: System Overview

iPLATO Platorm

Intended Use

The iPlato Platform is a healthcare communication platform. It facilitates communication between patients and their health care providers. The iPlato Platform is intended to be used by GP practice staff (clinical and non-clinical) in primary care settings to support engagement with their patient population. Engagement and communication can be facilitated by several mechanisms such as SMS or data messaging (via the myGP app or NHS App), digital patient questionnaires, or online consultation channels. Additionally, it can be used by patients who want to contact or send data to their GP practice.

The iPlato platform can be broken down into several modules/components:

- **iPLATO Connect** – this component designed for GP practices to conduct mass communication to patients via bulk SMS or data messages. Messages can include links to external websites or various digital questionnaires. Structured data/information returned from patients via questionnaires is securely transferred to a practice inbox and saved to the Electronic Patient Record using IM1 integrations.
- **Selfbook** – allows GP practices to offer self-serve online appointment bookings via an invitation (web link) sent in an SMS or data message. Booking made by the patient are instantly made in the clinical system via our IM1 integration.
- **iPLATO Toolbar** – a floating remote consultation product that can read patient demographic data from the clinical system in real-time, supporting 1-to-1 patient messaging and Selfbook invitations.

- **iPLATO Triage** – provides patients with the ability to contact their GP practice online via a web form or mobile app (myGP or NHS App). Requests are split into three categories – admin, medical and prescription. Data/Information is displayed to GP practices via an inbox that allows them to prioritise, allocate and respond to requests appropriately.

The platform is where most of the features are configured, and users are managed. Users require access to the platform to access the features/solutions.

Additional tools

In addition to the above components the platform enables users to access other tools, the main example of this is the ability to send patients clinical questionaires (**Patient Questionnaires**). These questionnaires can be a standalone information gathering exercise or make up part of a clinical pathway.

A further example is the ability to gather and report on patient experience (**Patient Survey**). This survey enables a practice to gain anonymous feedback from their patients about the service and provides reports which complies with NHS England requirements.

Data sent to patients from GP practices can be instructional, promotional, or general in nature. Data sent to GP practices from patients can me medical or general. The data is used by GP practices to determine care processes, prioritise treatment, action administrative requests and improve service offerings.

Core Capabilities

- SMS and data messaging – bulk (**Connect**) and individual/1-to-1 (**Toolbar**)
- Automated appointment reminders - SMS or data message
- Patient driven online appointment booking (**Selfbook**)
- Clinical system integration – transferring medical and administrative data/information to Electronic Patient Records (EPRs)
- Online **patient questionnaires** – the collection and reporting of structured data/information (medical and administrative)
- Online consultation forms for medical, administrative and prescription requests (**Triage**) accessible via:
  - a website
  - the myGP app
  - the NHS App

General Description – Messaging

Messaging is an SMS messaging solution, improving appointment attendance and QOF performance. The solution's flexibility enables a practice to conduct individual ad-hoc instant messaging through to bulk CCG-wide health campaigns e.g. flu immunisation. Our solution spans the spectrum. As a 24/7/365 cloud-based solution, a real-time dashboard is available.

Features benefiting practices encompass:

1. Automated SMS appointment reminders, automatic appointment cancellation from patient responses

2. Manual/Campaign messaging to individuals and groups e.g. information on COVID-19

3. Campaign management: Import patient groups and/or searches from principal system

4. Campaign coding: auto coding based on patient response

5. Customisable templates (including auto personalisation) and delivery options

6. Patient consent management, including blacklists. GDPR compliant

7. Real-time message status and delivery reporting

8. Downloadable app-based messaging, intuitive solution.

General Description – Patient Survey

Patient Survey is an automated patient experience collection and reporting tool. Patients anonymously provide feedback on service quality via SMS, Tablet, Online, myGP app and paper. At month-end, the system provides a report which complies with NHS England requirements and also provides additional information on how to improve services.

This product is not referenced further within the CRM processes as it does not have a clinical purpose.

General Description – iPLATO Toolbar

Toolbar allows practices and patients to communicate via video, audio and asynchronous messaging based on the input from appointment reasons gathered from the patient themselves. Clinicians can simply start a video session from within the clinical system. Appointments can occur without the need for participants to travel. Features benefiting stakeholders encompass:

1. Facilitates remote video and audio consultation between a practice and a patient.
2. Coding of patient information directly to IT system workflow
3. Allows GPs to attach documents and images and send to the patients, fully coded into the clinical systems.
4. Allows patients to attach documents and images and send to the GP, fully coded into the clinical systems.
5. Authenticate user's identity using their Date of Birth
6. Reporting, including CCG and practice system uptake and utilisation.
7. Ability to review a patient without face-to-face appointment.
8. Secure patient's consent during set-up to enable camera and audio.

General Description – preGP

preGP is a signposting solution that can direct a patient to relevant national or local services as an alternative to an appointment with a GP or nurse. This aims to reduce the volume of appointments being booked which could be dealt with by pharmacies, charities or other organisations. The signposting can take place after the appointment has been booked (preGP) or before the appointment is booked. GP practices are responsible for the configuration of available services, including their contact information.

General Description – iPLATO Triage

Triage enables patients to send in requests directly from the myGP app and via the web, delivered into the Connect inbox. Triage is not for emergency or immediate medical needs, and the product makes it clear to the patient to not pursue this route of seeking medical help. Simple Triage options are available for patient's Admin queries, Medical Issues and repeat Prescriptions.

Features encompass:

1. Automate patient journey direct patient to send admin, medical and repeat prescription requests.

2. Total Triage enables a member of practice staff to complete a Triage request on the behalf of a patient, these requests enter Connect for review.

3. Requests sent to Connect for review and action by the practice, the messages are categorized by type and can be flagged for action. Inbound messages can also be sent to a dedicated email inbox.

4. Ability to turn triage off and on as appropriate directly from the Connect Platform

5. Default automatic coding of inbound messages with a generic SNOMED code (eConsultation via online application) with associated patient generated message. A user can switch the coding to manual if required.

6. The user has the option to add additional codes on review, for example, codes which relate to the content of the request.

7. Set up redirection for all patients to be redirected to a URL of your choice (Third party triage).

Amendment NHS Login

With the introduction of NHS login as another method of Authentication into the app and for web services which, the Patient can choose to use. Choosing NHS login will give them access to all the features of the app and for web Triage.

Should the user choose to login using NHS login, NHS Digital will take over the Authentication into myGP App and for web Triage with all their security practises enforced.

General Description – Patient Questionnaires

Patient Questionnaires are quick and simple browser-based questionnaire that you can send out to patients and have their results recorded into their clinical system, either via Connect manually or automatically. Each

patient will be required to authorise prior to completing the questionnaire using date of birth. The system has been designed with ease of use in mind, all read-codes are pre-defined and ensures each response can be coded if required.

1. Web-based link to enable access via mobile/desktop/tablet.
   Patient authentication to ensure the correct patient completes the questionnaire.
2. Automatic or Manual coding dependant on configuration settings.
3. Dedicated questionnaires inbox
4. Easily send questionnaires in bulk to large volumes of patients.

General Description –NHS APP API

Integration with the NHS Application (NHS APP API) – Patients registered on the NHS app are automatically picked up using the NHS APP API, this means messages can also be delivered via this channel if appropriate, this ensures maximum cost saving to the NHS. This addition to the Connect platform means informational messages that don't require a response from patients or key word response messages can be sent via this channel.

myGP App

Intended Use

The myGP application (**myGP App)** is designed to enhance patient engagement and streamline access to primary healthcare services. It serves as a comprehensive digital health platform intended to simplify and improve the interaction between patients and their GPs. At its core, myGP App enables patients to manage their healthcare needs efficiently. One of its primary functions is facilitating the booking, cancellation, and rescheduling of GP appointments. This reduces administrative burden on GP practices and provides patients with the convenience of managing appointments anytime and anywhere.

The myGP app also supports medication management, allowing users to order repeat prescriptions and set reminders for taking their medications. This feature is particularly beneficial for patients with chronic conditions who require ongoing medication. Health tracking is another significant aspect of myGP App. Patients can monitor various health metrics, such as blood pressure and weight. This data is self-collected by the user and remains within their app, it is not currently shared with the GP or medical records.

Integration with NHS patient facing services is a key advantage of myGP App enabling patients to view medical records, prescriptions and coming soon the myGP App enable users to support family members with the same functionality. Secure messaging between patients and GP practices allows queries to be addressed without potentially needing a physical appointment, enhancing communication efficiency. Overall, the myGP App aims to empower patients by providing them with the tools and information needed to manage their health proactively and efficiently. The overarching goal is to simplify access to healthcare via the myGP App.

The myGP app also enables users to access other health services, these may either be local or national NHS funded programmes for which a patient is eligible, or private health services which users are able to choose

and self-refer themselves to. These services may vary over time or by region or user demographic. Current examples include: home blood tests, private physiotherapy, and orthopaedic services.

List of Capabilities:

- Appointment Booking - Allows patients to book, cancel, and reschedule GP appointments directly through the app.
- Medication Management - Enables patients to order repeat prescriptions and set medication reminders.
- Health Tracking - Provides tools for tracking various health metrics, such as blood pressure and weight.
- Secure Messaging - Facilitates secure communication between patients and their GP practice.
- Health Information - Allows patients to view their medical records, test results etc
- Appointment Reminders - Sends reminders and notifications for upcoming appointments and important health related campaigns.
- Access to health services – enables a user to view a range of health services to which they are able to self-refer. These services may be NHS funded or private.

General Description – myGP® App

myGP is a native smartphone mobile application that is downloaded and installed from either the Google Play app store or the Apple Store. It is specifically used by patients in the following way:

1. Individual patients book and cancel GP and Nurse appointments at their registered GP practice.

2. Individual patients order repeat prescriptions, and view and update their nominated pharmacy.

3. Individual Patients see future appointments that they have booked on their app.

4. Individual Patients enter and track their weight and blood pressure data within the app.

5. Individual Patients can set up in app reminder notifications to remind them to take medication on time.

6. Individual Patients are able to track adherence to medication, by responding to the medication reminder, select to record whether they took the medication or not. This information is then displayed back to the patient in the form if useful graphs and tables within the app.

7. Individual Patients are able to view details of their practice address.

8. Individual patients are able to View and save their medical records stored on the Clinical system.

9. Individual patients can explore and use self-paid health products and services.

10. Individual patients can send & receive messages from their GPs (Remote Consultation).

11. Individual patients can receive and partake in remote consultations by their GPs (Remote Consultation).

12. Individual patients can submit queries to their GPs (**Triage**).

13. Individual patients can add/manage their dependants within the app.

Amendment NHS Login

With the introduction of NHS login as another method of Authentication into the app which, the Patient can choose to use. Choosing NHS login will give them access to all the features 1 through to 8 in the above list and are now included in the submission.

Should the user choose to login using NHS login, NHS Digital will take over the Authentication into myGP App with all their security practises enforced.

iPlato's App Denotations

Locking the app

The app if locked will hold only nonclinical data such as appointments, reminders, and medications.

Closing the App

If the app is closed, then all data will be removed from the phone and users will have to re-authenticate with NHS login.

Session expired

If user does not login to the myGP app for a given time (this session time out is denoted by NHS Digital), they will again have to log back into NHS login.

No Mobile data or Wi-Fi signal

Should a Patient of the myGP app find themselves in a place with no mobile data or Wi-Fi they will only be able to see what is held on the phone such as appointments and reminders.

Once they get back in a position where there is Mobile data or Wi-Fi signal then they will again be able to see all data including medical records as long as the session time out has not come into force.

General Description – Partner Organisations

myGP App enables direction of patients to relevant partner organisations via the Health Marketplace (Health Services, Health Products). All partner organisations are reviewed prior to acceptance into the marketplace to ensure they meet high standards of clinical governance and clinical safety (where applicable). Where partner software products are integrated into the app a full hazard identification process is followed as per iPlato products.

Intended Users

The iPlato system is intended to be used in UK primary care by patients and GP practices. The iPlato Connect platform and associated products: Toolbar, preGP, Triage, Patient Questionnaires and the NHS APP API are designed to be managed and used by clinical or administrative staff in GP practices with the support of the iPlato support team as required. The myGP app is designed to be used by patients. Its functionality can vary depending on the practice set up of access via the app, for example appointment management, within Connect.

Clinical Risk Management System

The iPlato CRMS and CRMP describe how iPlato:

- Conduct Clinical Risk Management (CRM) to ensure patient safety with respect to the System.

- Align with the existing SMS, documenting any warranted variations to standard practice.

- Complete interrelated and interactive activities that constitute the SMS.

- Meet the requirements of Data Coordination Board (DCB) 0129 [1] and enable Healthcare Organisations (HCOs) deploying the System to meet the obligations of DCB 0160 [2].

The clinical risk management process involves:

- Ongoing involvement of the Clinical Safety Officer (CSO), in all appropriate product development activities

- Quarterly product review between the CSO and Product Management (PM) team to facilitate the discussion of configuration management metrics; further review of any reported clinical hazards / clinical safety incidents; review of clinical risk management processes and systems; and review of clinical risk management regulatory changes

- Passive monitoring of customer feedback for clinical hazards / clinical safety incidents

- Active monitoring of all iPlato customers for clinical hazards / clinical safety incidents (

- Reporting of clinical risk management activities and clinical risks or incidents to the board on a monthly basis

- Audit of clinical risk management activities and clinical incidents annually

- The iPlato CSO is responsible for reviewing the clinical safety / risk documentation. The Chief Technology Officer and PM are responsible for leading the clinical risk management processes and documentation with input from other key individuals in the iPlato team such as the CEO.

Clinical risk management activities and clinical risks or incidents are submitted to the board in the form of a summary report on a monthly basis. Results of audit of clinical risk management processes are reported to the board on an annual basis. The iPlato CFO has authority for final approval of all clinical risk management documentation and process changes.

Risk Management Team

Role	Designee	Responsibilities
Chief Financial Officer/ SIRO	Martin Rowden	Perform 'top management' functions. Approve clinical risk management documentation. Join clinical risk management reviews (regular and episodic)
Clinical Safety Officer	Dr. Harriet Leyland	Create clinical risk management processes. Review clinical risk management documentation. Approve clinical risk management documentation. Lead hazard identification reviews Lead clinical risk management reviews (regular and episodic)
Product Team Lead	Jak Moore	Set up clinical risk management process. Co-ordinate clinical risk management across iPlato. Act as main point of contact with Clinical Safety Officer. Create risk management reviews. Join hazard identification reviews. Join clinical risk management reviews (regular and episodic)
Chief Technology Officer (Interim)	Jirka Orlik	Support clinical risk management process (tech) Join hazard identification reviews. Join clinical risk management reviews (regular + episodic) Management of Product and Product Managers
Product Managers		Product development identification of risk and appropriate controls for identified risk. Communicate product development with the PTL and/ or CSO. Communicate user feedback with PTL and/ or CSO. Join hazard identification reviews. Join clinical risk management reviews (regular + episodic).

Clinical Hazard Assessment

Two methods have been combined to identify hazards.

A top-down approach based upon known hazards and a bottom-up approach relating to foreseeable hazards that can occur in operation. Hazard identification used a combined HAZID (hazard identification) and SWIFT (structured 'what-if' technique).

Qualitative probability (likelihood) of Hazards occurring (table 1) and clinical severity (consequence) of Hazards levels (table 2) were then used for risk analysis.

Qualitative Probability Levels

The defined levels for the probability of harm are described as follows:

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur

Likelihood Category	Interpretation
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

Table 1: Likelihood (Probability) Descriptors

Qualitative Severity Levels

The defined levels for the severity of harm are described as follows:

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

Table 2: Severity (Consequence) Descriptors

Description of Patient Safety Consequences

Despite the fact that the myGP®/iPlato System cannot cause direct harm to patient, it may cause indirect harm derived from the following hazardous situations which are typical of any clinical software platform:

- Inconvenience / confusion about appointments, health status or health services including delivery of incorrect health service information.

- Wasted clinical resources e.g. unfilled GP appointments due to patients missing appointments due to failed / incorrect appointment reminders. This resource waste may have an indirect impact on patient care but is not a direct threat to patient safety.

- Potential delay in ordering and fulfilling a patient's medication or delay in the processing and fulfilling of administrative queries due to the Prescription ordering feature or the Triage feature not working as designed.

- Potential delay in receiving clinical care or administrative support if messaging, triage or remote consultation products do not function efficiently as intended either due to technical issues or business process on the practice side.

Residual Risk Acceptance

The severity and likelihood scores for each Hazard are matched to the Clinical Risk Classification Matrix (Table 3) this gives the Hazard a Clinical Risk Estimation value. This classification matrix applies to the myGP/iPlato System in the context of this CSCR and associated DCB 0129 compliance. The acceptance criteria are defined as follows:

Likelihood		Minor	Significant	Considerable	Major	Catastrophic
	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				

Table 3: Clinical Risk Classification Matrix

Following the application of additional mitigations, Residual Risk Scores will be determined, these scores will be reviewed against the Residual Risk Acceptance Criteria (Table 4). Where the acceptability level is defined as follows.

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

Clinical Risk Evaluation and Control

The Hazard Log will be managed in line with the iPlato CRMS and stored in the CRMF.

A table for each hazard analysed is shown with the following information:

- Hazard No.: identifier

- Hazard: The potential cause of harm.

- Effect (Hazardous situation): The injury or damage to the health of people, or damage to property or the environment

- Initial probability before applying mitigations.

- Initial severity before applying mitigations.

- Initial risk before applying mitigations.

- Risk control measure: Measures identified to reduce unacceptable risks and acceptable risks as far as possible.

- Residual probability after applying mitigations.

- Residual severity after applying mitigations.

- Residual risk after applying mitigations.

The evaluation of the overall residual risk posed by the product, considering the contributions of all residual risks in relation to the benefits of the product's intended use is provided here. The evaluation table provided in this section summarise the total count of risks of each category, after applying risk control measures. The overall risk is then compared with the risk of similar products and balanced with the product benefits to determine the overall risk score.

Risk Classification	No of Risks	Status		AFAP	
Class 5 – Very High	0	N/A		N/A	
Class 4 – High	0	N/A		N/A	
Class 3 – Medium	12	Open	12	Transferred	12
Class 2 - Low	51	Open	51	Tolerable	50
				Transferred	1
Class 1 – Very Low	14	Open	14	Acceptable	14
Total	77				

Table 5: Hazard Status for iPLATO Products

A residual risk evaluation has been carried out considering that:

- All hazardous situations have been considered and included in the present document.

- All risk control measures (mitigations) have been specified.

- All complaints/ incidents with a direct or potential effect on the myGP/iPlato system have been reviewed.

- The training documentation [9-11] and help site [12] provide information for the safe use of the system.

Those controls which are required to be implemented by deploying practices are highlighted in the hazard Log and referenced in Appendix A

Hazard Log

The Hazard Log is provided in the NHS Digital format. This document, together with the Clinical Risk Management Plan and associated CSCR (this document), provide evidence to support compliance with DCB 0129.

It is essential that the health organisation is cognisant of the product safety claims. Care must be taken to review these documents in line with the source material from which key evidence is taken.

Existing Mitigating Controls

The majority of mitigation for identified risks relate to system design measures ensuring the products are logical to use, and used as intended. In addition, effective user training and support with ongoing routine system surveillance / monitoring provides an appropriate level of control.

Undesirable Hazards

Despite application of software based, and training provision controls it is not always possible to mitigate hazards to a tolerable level. There are 12 hazards which fall into this category, 8 of relevance to this excerpt. In these instances either the functionality will not be released until appropriate mitigation can be implemented or where this is not possible or the use case makes release desirable these risks will be highlighted to those who deploy and use our solutions with suggestions for further business process mitigations that can be implemented at the point of use (see Appendix A for controls which are required to be implemented by deploying practices).

No.	Products	Hazard	Initial Risk	Residual Risk	Status
13	Connect Platform 4.11 Messaging NHS App API myGP App (iOS 8.25.0, Android 8.25.0) Toolbar 3.11 Patient Questionnaires	Patient reply not received or delayed	3	3	Open
14	Connect Platform 4.11 Triage	The triage request is not received by practice or not actioned	3	3	Open
15	Connect Platform 4.11 Triage	The patient selects the incorrect category of triage/ "medical query" is not switched on/ available	3	3	Open
18	Connect Platform 4.11 Messaging Patient Questionnaires Toolbar 3.11	Replies not actioned appropriately	3	3	Open
35	Connect Platform 4.11 Triage preGP myGP App (iOS 8.25.0, Android 8.25.0) Patient Questionnaires	Inappropriate use of online resource to access help. A patient accesses an inappropriate service or unable to access an appropriate service	3	3	Open
55	Connect Platform 4.11 Triage myGP App (iOS 8.25.0, Android 8.25.0)	User not presented with appropriate triage category	3	3	Open
56	Triage myGP App (iOS 8.25.0, Android 8.25.0)	User misunderstanding about triage categories	3	3	Open
57	Connect Platform 4.11 Triage myGP App (iOS 8.25.0, Android 8.25.0)	Response to triage request not completed in a timely manner	3	3	Open
58	Connect Platform 4.11 Triage myGP App (iOS 8.25.0, Android 8.25.0)	User sends triage request due to urgent problem	3	3	Open
59	Connect Platform 4.11 Triage myGP App (iOS 8.25.0, Android 8.25.0) Toolbar 3.11 Patient Questionnaires	Misdiagnosis based on quality/ quantity/ scale of information	3	3	Open

No.	Products	Hazard	Initial Risk	Residual Risk	Status
60	myGP App (iOS 8.25.0, Android 8.25.0)	A patient fails to make an appointment after accessing signposting information provided	3	3	Open
63	Patient Questionnaires	Further output or next steps not triggered as expected	3	3	Open

Table 6: Undesirable Hazards Summary

These risks all relate to the combination of a patient using the service misunderstanding the intended use e.g. for non-severe health conditions, with the requirement for robust process to manage incoming queries from the practice side. As the manufacturers of this Health IT iPlato cannot mitigate against some aspects of this risk. The business process management within the healthcare system where this product is deployed needs to ensure that they have appropriate controls in place to ensure safe use.

Test Issues

The iPlato Quality Assurance team follow the standard testing procedures outlined below with each project. All products and new releases pass through the test process and must pass prior to release. This process is tracked via Jira.

Test Process that QA follow:

Test Strategy		
Automation Strategy	Test Schedule	Resource Planning
	↓	
Test Development		
Test Plans	Test Scripts	Test Data
	↓	
Test Execution		
Defects	Test Reports	Test Metrics
	↓	
Defect Management		
Bug Fixing	Bug Verification	Bug Tracking
	↓	
Delivery		
UAT	Installation Testing	Requirement Verification

Testing Techniques:

Specification based testing techniques	Structured based testing techniques	Experience based testing techniques
Equivalence Partitioning	Unit Testing	Error Guessing
Boundary Value Analysis	Branch Coverage testing	Exploratory Testing
Decision table	Statement Coverage testing	Checklist based testing

State transition	Integration testing	Fault attack testing
Cause effect graphing		
Configuration Testing		
Classification Tree Method		
Use case testing		

All planned verification activities were completed. There are no outstanding test issues. All products and new releases pass through the test process and must pass prior to release.

Summary Safety Statement

Clinical Risk Management activities have been completed in alignment with the Clinical Risk Management Plan. It should be noted that the myGP/ iPlato system is designed to mitigate a number of known hazards and potential safety risks existing within delivery of primary care services. The risk reflected by the Hazard Log and this report is not necessarily considered greater than the risk of non-digital workflows. The responsibility for the implementation and use of the myGP/iPlato system is with the Health Organisation. The iPlato training [9-11] and help website [12] provide clear guidance to operating the system as designed and intended. It is the assessment of Clinical Safety Officer that this Clinical Safety Case Report provides a compelling body of evidence to support the system and that Residual Risks can be considered acceptable where the deploying organisation has put in place additional controls [Appendix A] to manage risk further.

In the context of its present intended deployment (UK primary care), the iPlato / myGP solutions are effective and safe with few clinical hazards and no outstanding test issues.

The product is fully compliant with UK NHS Clinical Safety standards, and the supporting evidence is stored in the CRMF. Access to detailed information relating to this evidence is only provided under the strict approval of iPlato.

Appendices

Appendix A - Suggested Mitigations for Healthcare Organisations

iPLATO Connect Platform

- Practices should have local processes for running detailed clinical searches which may be used in messaging campaigns.

- Practices should have systems in place for monitoring the Connect inbox.

- Practices should have systems in place to monitor the system status.

- Practices should be aware that some inbound message types are not automatically saved to the patient record - consequently they will not be available for future management.

- Practices should have a process in place to monitor appointments booked via digital platforms.

- Practices should be aware that if they exclude appointment slots they need to check if patient shave already booked them and reschedule the appointment.

- Practices should ensure they have a process to keep patient contact details up-to-date on the clinical system.

- Practices should have systems in place for managing PQ, the triage service and triage requests

- Practices may need to put processes in place to prevent muliple users working on a single inbound contact

myGP App

- Practices should have a process for managing prescription requests whether come in from triage or via app.
- Practices should be aware that if they do not allow access to certain features their patients will not be able to access them via myGP App.

iPLATO Toolbar

- Practices may develop standard process around saving triage and PQ automatically. They may also develop policies around the saving of video consultation to a patient record.
- Practices should have processes in place to manage the use of remote management tools and video consultations, including the selection of appropriate patients.
- For Toolbar backend update:
  - For self-installed users: Update whenever you see the pop-up when starting Toolbar or check the provided link.
  - For IT team-deployed users: Your myGP Buddy should update automatically. Check your version number, and if it's not 3.11, please contact support.

iPLATO Triage

- Practices should have systems in place for managing the triage service and triage requests, including checking details when submitting a triage request on the patients behalf.

- Practices should be aware that they can manage the triage settings to meet their needs, and whichever they switch on they should be able to service.

- Practices should have a process for managing prescription requests whether come in from triage or via app.

- Practices may develop standard process around saving triage and PQ automatically. They may also develop policies around the saving of video consultation to a patient record.

- Practices should have processes in place to manage the use of remote management tools and video consultations, including the selection of appropriate patients.

- Practices are made aware that they should regard information collected from patients via Triage or PQ as having the potential to contain inaccuracies.

- Practice should have safeguarding policies and processes which may alert to situations where patients may be at risk.

- Practices should recognise that remote management tools should be used with caution and any concern should prompt direct patient contact.

Patient Questionnaires

- Practices should have processes around their choice of questionnaire, which patient groups are eligible to receive questionnaires and how the information received is managed. This may be particularly relevant where a questionnaire which was designed to be delivered by a clinician is now utilised as remote management and filled in by the patient/ carer.

- Practices should have processes in place to manage any questionnaires that form part of a patient pathway.

- Practices may develop standard process around saving triage and PQ automatically. They may also develop policies around the saving of video consultation to a patient record.

- Practices are made aware that they should regard information collected from patients via PQ as having the potential to contain inaccuracies.

- Practices should have a process in place to monitor responses from PQ and follow up appropriately.

- Practices are advised that they should be aware that some clinical terms may be altered in the patient facing questionnaire to support patients understanding, in this case both terms will be referenced in the clinical coding.

- Practices may require processes for users to access scoring for PQ when they are assessing responses

- Practices should be aware of the automated configuration for PQ responses and decide if they want to leave it switched on or switch it off.

- Practices are advised that they should be aware that some clinical terms may be altered in the patient facing questionnaire to support patients understanding, in this case both terms will be referenced in the clinical coding.

PreGP

- Practices are advised to employ a checking process for any local services which are added to Pre GP, the information which is provided for each service and include regular review of details.

Appendix B – Glossary

Term	Definition
Clinical Safety Officer (CSO)	Person in a Manufacturer's organisation responsible for ensuring the safety of a Health IT System in that organisation through the application of Clinical Risk Management as required by the DCB 0129 & DCB 0160 standards.
Clinical Risk	Combination of the severity (consequence) and likelihood (probability) of harm to a patient and the likelihood of occurrence of that harm.
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 File (CRMF)	Repository of all records and other documents that are produced by the Clinical Risk Management process. Referred to in this document as the Risk Management File (RMF).
Clinical Risk Management Plan (CRMP)	A document that defines the implementation of, and any variation to, the iPlato Safety Management System. It describes how iPlato 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 the requirements of DCB 0129 are met.
Clinical Risk Management (CRM) Process	A set of interrelated or interacting activities, defined by iPlato. to meet the requirements of this standard with the objective of ensuring Clinical Safety in respect to the development, deployment, and use of Health IT Systems.
Clinical Safety	Freedom from unacceptable Clinical Risk to patients.
Clinical Safety Case	Accumulation and organisation of product and business process documentation and supporting evidence, through the life cycle of a Health IT System.
Clinical Safety Case Report (CSCR)	A report that presents the arguments and supporting evidence that provides a compelling, comprehensible, and valid case that a system is safe for a given application in each environment.
Client Organisation	A Health Organisation which has deployed, or will be deploying the Health IT System
Data Coordination Board (DCB)	The Data Coordination Board assures the quality of information standards.
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.

Term	Definition
Hazard Log	A mechanism for recording and communicating the on-going identification of system Hazards associated with a Health IT system.
Healthcare Organisation (HCO)	Organisation within which a Health IT System is deployed or used for a healthcare purpose.
Health IT System	Product used to provide electronic information for health or social care purposes. The product may be hardware, software, or a combination.
Initial Clinical Risk	The Clinical Risk derived during Clinical Risk estimation taking into consideration any retained risk control measures.
Intended use	Use of a product, process, or service in accordance with the specifications, instructions and information provided by the manufacturer to clients.
Issue	The process associated with the authoring of a document. This process includes reviewing, approval, and configuration control.
Likelihood (Probability)	Measure of the occurrence of harm.
Lifecycle	All phases in the life of a Health IT System, from the initial conception to final decommissioning and disposal.
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.
Patient	Person who is the recipient of healthcare.
Patient Safety	Freedom from harm to the patient.
Post-deployment	That part of the life cycle of a Health IT System after it has been manufactured, released, deployed and is ready for use by the Health Organisation.
Procedure	Specified way to carry out an activity or a process.
Process	Set of interrelated or interacting activities which transform inputs into outputs.
Release	A specific configuration of a Health IT System delivered to a Health Organisation by the Manufacturer because of the introduction of new or modified functionality.
Residual (Clinical) Risk	Clinical risk remaining after the application of risk control measures.
Safety incident	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients' receiving healthcare.
Safety Incident Management Log	Tool to record the reporting, management and resolution of safety incidents associated with a Health IT System.
Severity (Consequence)	Measure of the possible consequences of a Hazard.
Third party product	A product that is produced by another organisation and not by the Health IT System manufacturer. Examples include operating systems, library code, database and application servers and network components.
The Organisation	The generic term used for the organisation that is the prime owner and responsible for the Clinical Safety of the Health IT System. It is used whenever a formal statement or clarity is required.
Top Management	Person or group of people who direct(s) and control(s) an organisation and has overall accountability for a Health IT System.

Appendix C - Related Documents

These documents provide additional information and are specifically referenced within this document. The current version of each document is stored and accessible via the iPlato SharePoint and access to these files will require approval by the iPlato Team.

Ref	Title	Version
1	Data Coordination Board (DCB) 0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems Accessible via: https://digital.nhs.uk/services/clinical-safety	n/a
2	Data Coordination Board (DCB) 0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems Accessible via: https://digital.nhs.uk/services/clinical-safety	n/a
3	Data Coordination Board (DCB) 0129: Implementation Guidance Accessible via: https://digital.nhs.uk/services/clinical-safety	n/a
4	ISO 9001 - Quality Management Systems – Requirements	n/a
5	Medical Devices: Software Applications Accessible via: https://www.gov.uk/government/publications/medical-devices-software-applications-apps.	n/a
	iPlato Reference Documents	
6	Quality Management System	
7	Corporate Policy Manual	2.3
8	Data Protection and Security Policy	3.0
9	myGP – Induction and myGP app setup	
10	myGP – Appointment Reminders	
11	myGP - Campaign Messaging	
12	Help Centre: https://www.mygp.com/help/connect/	
13	Corporate Policy Manual	2.3
12	Hazard Log – Triage Excerpt	1.4
13	Clinical Risk Management Plan	1.0
14	Clinical Risk Management System	2.6