X-on
Clinical Safety Case Report

Software and Version

X-on Surgery Connect v9.22

Purpose

This document summarises all the elements of the Clinical Safety Case for X-on Surgery Connect for DCB0129 compliance.

This document should be read in conjunction with the attached supporting documentation: the Clinical Risk Management Plan, the Hazard Log and the Responsibilities and Resources RACI documentation. Together these documents constitute the Clinical Safety Case for X-on Surgery Connect. .

Scope

Applies to the X-on Surgery Connect development and delivery

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Document Author	Derrick Measham/Dr Geoff Schrecker
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Document history

Amendment History

Version	Date	Amendment history
0.1	01 September 2022	First draft
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Approval

Name	Title/Responsibility	Date	Version
Dr Geoff Schrecker	Clinical Safety Officer	14 September 2022	1.0

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version in the Clinical Risk Management File is the controlled copy. Any printed copies of the document are not controlled.

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Introduction

This Clinical Safety Case Report outlines the X-on Surgery Connect , the Clinical Risks presented by the system, additional control measures put in place to minimise the Clinical Risks, the verification that such controls are in place and the conclusion about the Clinical Safety of the solution.

System Definition and Scope

The scope of this report is for the X-on Surgery Connect V9.22.

Primary Care currently undertakes a large workload via a variety of communication channels in addition to the traditional face to face consultation. These channels include telephone communication and consultation, SMS text messaging , video messaging, plus monitoring and reporting . This way of working adds some additional challenges and carries some risks, for example calling the wrong number for a patient, or consulting without visual evidence.

The X-on Surgery Connect seeks to mitigate a range of these risks by integrating with the practice's electronic health record. This enables the practice to call a patient directly using the verified contact details stored in the practice record , or to identify the record of an inbound caller from these details. .

In addition to this the X-on Surgery Connect also provides a secure messaging system for patients to submit photographs which the practice can view and incorporate into the patient's record rather than requesting them to be sent via email or other such insecure method. The patient interface allows for appropriate confirmations and verification with the patient and the integration with the electronic health record also reduces risks associated with misfiling .

The X-on Surgery Connect also enables integration with video consulting, where the integration brings the same safety benefits as for the communication of photographs.

More information regarding the Surgery Connect v9.22 offering can be viewed here regarding the Active Patient process:
https://help.x-onweb.com/en/articles/7814-making-a-call-from-the-active-patient-window

The full platform offering comes with help guides for the users and clearly outlines the user set up process, integration and reporting https://help.x-onweb.com/en/

As an enabler for current communication mechanisms which are already established within primary care, which provides no clinical input or direction, the intrinsic risks for this

application are very low as is reflected in the risk scoring within the Hazard Log within this clinical safety case.

Clinical Risk Management System

Clinical Risk Management System

X-on's approach to Clinical Risk is detailed in the attached Clinical Risk Management Plan, section 2.3.

Clinical Risk Management Plan

Key Personnel, Roles and Responsibilities are detailed in the attached X-on Clinical Risk Management RACI matrix.

Clinical Risk Assessment

X-on Clinical Risk Assessment records are stored in a centralised attached Hazard Log.

Hazard Identification & Description of Patient Safety Impact

The method of Hazard Identification is explained in the Clinical Risk Management Plan.
SWIFT methodology was applied to the current list of software features.
Identified hazards are presented in the Hazard Log. Descriptions of potential patient safety impacts and the possible causes of the identified hazards are likewise presented in the Hazard Log.

Clinical Risk Evaluation

Clinical Risk Evaluation has been undertaken following the methodology detailed in the Clinical Risk Management Plan (section 2.3.2). The risks have been stratified according to the Risk Matrix, presented in the Hazard Log.
The Initial Clinical Risk Evaluation for each identified clinical risk is detailed in the Hazard Log.

Clinical Risk Control

Where Clinical Risk Evaluation shows a risk above the defined risk appetite threshold, therefore requiring the application of additional controls, such controls have been considered and applied. As described in section 2.3.4.
The further control measures are outlined for each Clinical Risk cause in the Hazard Log.

Evaluation of Residual Risks

Following the application of additional control measures, the residual Clinical Risks have been analysed using the same methodology as that used for initial Clinical Risk Evaluation, as detailed in the Clinical Risk Management Plan (section 2.3.2). The same Risk Matrix and associated risk appetite/acceptance criteria have been used to assess and stratify residual risk values.
Residual clinical risk after the application of all relevant controls are presented in the Hazard Log.

Cost/Benefit Analysis of Residual Risks

Where residual risks are greater than the lowest score on the Risk Matrix, further analysis has taken place to determine whether further controls are desirable and/or practicable weighted against the impact and likelihood of the risk itself. This analysis is presented in the worksheet section of the Hazard Log, entitled 'Risk/Benefit Analysis' and documented in column R of the Hazard Log

Verification of Risk Controls

All risk controls have been audited to ensure that they are both present and functioning as intended. The verification that these risk controls are operating correctly is presented within the Hazard log.

Many of the Clinical Risk Controls, particularly in terms of business processes, were audited at the same time as wider and more general Information Security controls through a defined Internal Audit process aligned to the ISO27001:2013 Standard (forming part of X-on's ISO27001:2013 Certification). The ISO 27001 certification is attached.

Summary of control status

Status Summary	
Open	0
Transferred	14
Closed	20

Controls requiring action from the client

Where there are risk controls are transferred (requiring action from the client) these are fully detailed in the deployment and training materials.

Hazard Log

The Hazard log contains a relatively small number of hazards and at low risk levels, This reflects the low clinical risks inherent in the scope of the X-on Surgery Connect.

Test Issues

There are currently no outstanding Test issues. X-on is currently working in GP Practices across England. We have no outstanding issues, and no clinical safety issues, specifically.

Summary Safety Statement

The X-on Surgery Connect represents an enhancement to clinical safety for a variety of practice communication channels with patients, where there are risks, these are minor and significantly out-weighed by the benefits.
Having reviewed the evidence supplied in the attached Hazard log, clinical risk management plan and ISO 27001 documentation it is clear that deployment of this solution has minimal risk attached and delivers a significant overall reduction in clinical risk for patients.

I am fully satisfied that X-on Surgery Connect system is compliant with DCB0129 and is a clinically safe solution for healthcare organisations to adopt and deploy.

Dr Geoff Schrecker
MA MB BChir MBCS FRCGP FFCI
Clinical Safety Officer

Quality Assurance

Section 5 of the Clinical Risk Management Plan outlines the frequency within which X-on's Clinical Risk Management activities will be formally reviewed. Said reviews, as well as any interim amendments or updates, will be documented within the X-on document review log in line with ISO27001 policies.
All materials presented in this Clinical Safety Case Report have been examined for DCB0129 compliance by the Clinical Safety Officer.

Configuration Control / Management

We ensure that our solution is designed, tested, and deployed in partnership with the practices who will use them. Any changes are clearly documented, and only implemented with prior agreement with those practices wanting them.