CLINICAL SAFETY CASE REPORT

Ardens Healthcare Informatics

Published on 13th June 2022

VERSIONS

Version	Date	Summary of Changes
1.0	08.02.2017	First issue
2.0	23.09.2019	Second issue
3.0	26.10.2020	Third issue
4.0	09.10.2021	Fourth issue
5.0	12.10.2021	Fifth issue
6.0	13.06.2022	Sixth issue

REVIEWERS

Name	Title	Date	Version
Dr Robert Greville-Heygate	Chief Executive and Clinical Safety Officer	13.06.2022	6.0
Dr Miles Carter	Chief Executive EMIS Web	13.06.2022	6.0
Dr Merlin Dunlop	Director	13.06.2022	6.0
Dr Nazmul Kamal	Director	13.06.2022	6.0
Dr Stephanie Greville-Heygate	Director	13.06.2022	6.0
Laura Tomlin	Director	13.06.2022	6.0

APPROVED BY

Name	Title	Date	Version
Dr Robert Greville-Heygate	Chief Executive and Clinical Safety Officer	13.06.2022	6.0

CONTENTS

1 INTRODUCTION

This report summarises the key elements of the Clinical Risk Management Plan for Ardens Healthcare Informatics and serves to communicate the Clinical Safety Case to the end users. As the underlying Clinical Safety Case continues to evolve with the Ardens resources, the Clinical Safety Case Report will be re-issued in support of key milestones. This document follows the structure recommended to support the interpretation of the requirements presented in DCB0129.

2 SYSTEM DEFINITION / OVERVIEW

Ardens Healthcare Informatics is a Health IT System that is comprised of two products for use by Primary Health Care Professionals in England.

Ardens Clinical is a clinical decision support tool for Primary Care for GP practices who us EMIS Web and/or SystmOne. It achieves this via supplying Users with numerous standardised resources all based upon national and local guidance including alerts, formularies, protocols, referral forms, reports, templates and views.

Ardens Manager is a cloud-based data analytics platform that allows practices, PCNs and CCGs to monitor, aggregate and benchmark Primary Care activity. It achieves this via providing Users with numerous dashboards including activity reports, alerts, case finders and performance indicators. It also support both national and local contract management.

3 CLINICAL RISK MANAGEMENT SYSTEM

The Clinical Safety Officer is Dr Robert Greville-Heygate who is a General Practitioner, holds a current registration with the General Medical Council and has previous experience as a Chief Clinical Informatics Officer and a Health Informatics Post Graduate Certificate. Dr Robert Greville-Heygate holds a Clinical Safety Assessment Certificate and has in-depth experience, knowledge and skills in risk management and its application to clinical domains.

The Top Management are all aware of their responsibilities and are suitable experienced and trained in clinical safety. This team includes:

Dr Robert Greville-Heygate	Chief Executive and Clinical Safety Officer
Dr Miles Carter	Chief Executive EMIS Web
Dr Merlin Dunlop	Director
Dr Nazmul Kamal	Director
Dr Stephanie Greville-Heygate	Director
Laura Tomlin	Director

All key documents including this Clinical Safety Case Report, the Clinical Risk Management Plan and the Hazard log are all stored in a Clinical Risk Management File on Microsoft SharePoint.

4 CLINICAL RISK ANALYSIS

Existing hazards have been reviewed including their description, potential clinical impact, possible causes and existing risk controls. The hazard description, severity and likelihood five-stage qualitive scales and risk rating interpretation score can all be found on the References worksheet of the hazard log, as well as in the Clinical Risk Management Plan. used can be found in the resources

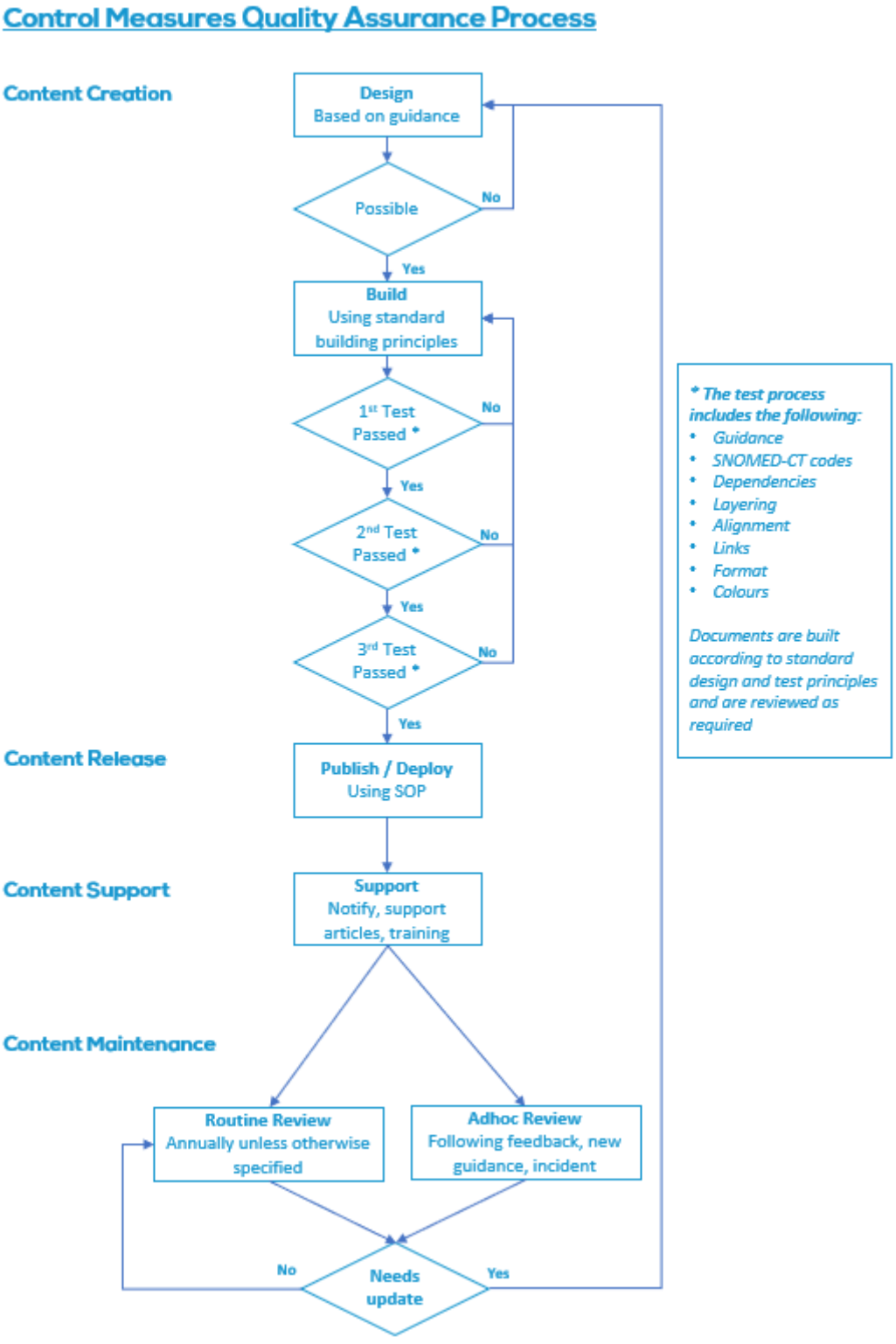
A new hazard has been added to the hazard log for version control which is particularly relevant for the Ardens EMIS Web product for practices using Template Manager.

5 CLINICAL RISK EVALUATION

The initial risk of all hazards documented in the hazard log have been re-evaluated using the pre-defined risk rating score.

6 CLINICAL RISK CONTROL

Every Ardens resource goes through a rigorous set of control measures at all stages to reduce the likelihood of the hazard occurring or reduce the severity of the impact if the hazard arises. All current control measure options have been reviewed with some being further expanded in the updated version of the Clinical Risk Management Plan. The risk control mechanisms are summarised in the Quality Assurance Process (QAP) below and below.



6.1 Content Creation Controls

All resources are created using a standardised 'design, build and test' approach. Where risks and problems are identified at any point in the process, a clinical safety discussion with the clinical safety

officer is initiated and documented. Where necessary, a formal clinical safety process will be implemented.

Design Controls - Resources are developed in response to national or local requirements or in response to feedback based on the latest, up-to-date guidance from an approved organisation (for example NICE). Resources are designed by clinicians and health informaticians with experience and expertise in the relevant field for the new resource and are reviewed for approval by a Clinical Director.

Existing clinical system resources will also be reviewed during the design stage and will not be replaced or duplicated without discussion by the development team and appropriate justification. User behaviour (based on primary care User experience of EMIS Web, SystmOne and Ardens Manager) is considered during the design phase.

Where calculators are required, these must always only use simple arithmetic functions (addition or subtraction) and they must have their outputs tested against various input scenarios. If a calculator is required that uses additional arithmetic functions with a complex equation, these will not be built but a link to an approved and validated online calculator can be provided.

Build Controls - Resources are built based upon code sets that are held and maintained by the senior development team with oversight by top management. These lists are updated in response to horizon scanning, identified gaps in information and the publication by NHS Digital of new codes when available on EMIS Web or SystmOne.

Where information and guidance is displayed, the source guidance from which that information is derived will be made accessible. The use of automated actions will always be minimised and any automated action must be justified and must include a User confirmation action where appropriate.

Test Controls - To ensure a rigorous test process, 3 tests by different staff members are completed. If any test stage is failed, the process starts again and the reasons for failing the test are reviewed and discussed with the content creation team. The test controls are an iterative process involving both clinical and technical members of the development team.

The 1st test is completed by the builder on the development environment of EMIS Web, SystmOne or Ardens Manager. A set of test criteria are followed which can be viewed in the Quality Assurance Process above. The 2nd test is completed by a different staff member who was not involved directly in the build process on the development environment of EMIS Web, SystmOne or Ardens Manager. The 3rd test is completed by a further different member of staff on test data on a live environment of EMIS Web, SystmOne or Ardens Manager.

6.2 Content Release Controls

Version and Deployment Controls - When publishing new content, version control is considered with previous versions being decommissioned as necessary. During the deployment stage for Ardens EMIS Web, clinical safety is ensured by the expert installation with regular spot accuracy checks occurring. A client portal exists to enable Ardens EMIS Web Users to download the latest versions of resources which tracks this on the Ardens client database should a recall need to occur.

6.3 Content Support Controls

Notification Controls - When any new content is released, Users will be notified if necessary via appropriate mechanism including noticeboards, emails and social media. Ardens provides Users with an online support knowledge base that contains support articles and videos to ensure the User is competent at using the content resource types.

Training Controls - Training is provided routinely either remotely or in person. An amount of training is provided as standard and as part of the setup fee, with additional training available as required. Training is also delivered to a wider audience via webinars

Helpdesk Controls - Ardens provide Users a helpdesk for support, feedback and request mechanisms via; online contact forms, email or via phoning the helpdesk Monday-Friday 8.30-18.30 (excluding bank holidays). Contact details can be found at www.ardens.org.uk/contact

User Controls - Ardens is not intended to replace the clinical judgement of an autonomous healthcare practitioner in the care of individual patients. Whilst every control measure will occur to ensure the safety of the resource, Users are reminded appropriately that they must always exercise their own clinical judgement when deciding to use or follow guidance on a resource.

Users are encouraged to feedback any questions, comments or concerns via the online support desk, email, telephone or on social media where these will be responded to by an appropriate member of the team. Whilst proactive processes exist, the User is also made aware of their responsibility for notifying Ardens of any changes to local referral forms, local contracts or other local content as soon as they become aware.

The User will be reminded that copying and editing Ardens clinical content creates a clinical safety risk. If users wish to a resource to be amended, they are encouraged to submit a development request to Ardens via the support desk where this will be considered with all control measures in place.

Should the User wish to cease their subscription to any of the Ardens resources, the User will be reminded of the potential clinical safety risk due to no longer having access to Ardens. The User will be encouraged to perform a hazard risk assessment and to have an alternative clinical decision tool that can be implemented without any gap in provision.

6.4 Content Maintenance Controls

Routine Review Controls - Routine reviews on each resource occurs annually as a minimum. Each resource is reviewed by a staff member who is adequately experienced and trained in the medical field for which the resource applies. Following a routine review, if any updates are required to the resource the control process will start from the beginning with the design control measure stage.

Adhoc Review Controls - Adhoc reviews may occur following newly published guidance or following User feedback. Following an Adhoc review, if any updates are required to the resource the control process will start from the beginning with the design control measure stage.

Decommissioning Controls - If any content is to be decommissioned, Ardens will provide adequate information and notification to users about this, along with signposting users to alternative content to be used instead.

7 HAZARD LOG

The hazard log has been updated and reviewed, with separate worksheets for Ardens Clinical and Ardens Manager hazards. This can be accessed via the link below.

Hazard Log.xlsx

8 TEST ISSUES

There are no known outstanding test issues that may impact on clinical safety.

9 SUMMARY SAFETY STATEMENT

On review of the Ardens Clinical Risk Management Systems, all appropriate measures have been taken to identify and evaluate any hazards and review all potential control measures to reduce the residual clinical risk to an absolute minimum. There are no known outstanding test issues or defects. The DCB0129 Compliance Assessment has been used to re-assessed Ardens Healthcare Informatics and all elements have been passed.

Ardens Clinical and Ardens Manager are therefore considered clinically safe for use in Primary Care.

10 QUALITY ASSURANCE AND DOCUMENT APPROVAL

The Control Measures Quality Assurance Process flow diagram above has been updated within the Clinical Risk Management Plan which has been approved by the Clinical Safety Officer on 9th September 2021.

11 CONFIGURATION CONTROL / MANAGEMENT

Within the Clinical Risk Management File is a 'Test Evidence' folder. Of most recent note is the spreadsheet used during the testing of the NICE NG12 Cancer Symptom Analyser. This includes 90 typical clinical scenarios of symptom presentation for the input, with the output being compared directly against the NICE NG12 guidance, the EMIS Web tool output and the SystmOne tool output.