NHS Digital

Clinical Safety Assessment - CDS API Implementation Guide Patch Release 1.1.1 v1.0

NHS Digital

Directorate / Programme UECDI	**Project Triage Journey**
Director Tim Magor	**Status CSO Approved**
Owner Lee Montgomery	**Version 1.0**
Author Julie Harris	**Version issue date 06 Feb 2020**

Document Management

Revision History

Version	Date	Summary of Changes
0.01	05/02/2020	Initial draft for review
0.01	06/02/2020	Updated with review comments
1.0	06/02/2020	CSO Approved version

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Lee Montgomery	Clinical Safety Officer and Clinical Lead UEC	06/02/2020	1.0
Paul Gingell	Delivery Manager	06/02/2020	1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Lee Montgomery	Clinical Safety Officer and Clinical Lead UEC	06/02/2020	1.0

Related Documents

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

Ref	Doc Reference Number/URL	Title	Version
01		Clinical Safety Case Report – CDS API Implementation Guide Release 1.1	1.0
02	DCB0129	Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Implementation guidance	3.2
03	OJ No L 117/1 of 2017-05-05	The European Union Medical Device Regulation (Council Regulation 2017/745 of 5 April 2017 concerning medical devices,	
04	DCB0160	Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems	4.2
05	NPFIT-FNT-TO-TOCLNSA-0949.03	Clinical Safety Management System	1.2

Introduction

As part of the Urgent and Emergency Care Digital Integration (UEC DI) Team's Clinical Safety activities, a Clinical Safety assessment has been undertaken on the Clinical Decision Support (CDS) API Implementation Guide Patch Release 1.1.1 v0.1 ("**this Patch Release**") detailed below.

This document is an Addendum to the Clinical Safety Case Report – CDS Application Programme Interface (API) Implementation Guide Release 1.1 v1.0 [Reference 1], endorsed by CSG on 15th January 2020, and should be filed alongside and read in conjunction with this document.

This Patch Release has a maturity level of Alpha.

The responsibility for managing clinical risk in the implementation of the CDS API guidance lies with the manufacturers of Health IT systems that are developing the API, in accordance with DCB0129 [Reference 2] and other in scope standards or regulations e.g. Medical Device Regulations [Reference 3].

The responsibility for managing clinical risk in the deployment and use of the CDS API lies with the deploying Healthcare Organization in accordance with DCB0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems [Reference 4].

Summary

The UEC DI Clinical Safety Officer has assessed this Patch Release and found the incremental Residual Risk to be Acceptable, as defined in the Residual Risk Acceptance Category matrix in the NHS Digital Clinical Risk Management System (CRMS) [Reference 5].

No updates have been made to the Hazard Register in light of this Patch Release.

Scope of Maintenance Release

The scope for this Patch Release has been assessed and includes:

- Administrative updates

Assessment

ID	Issue	Clinical Risk Assessment	Rationale
UECI-09 Referenced resources	Update "This guide is agnostic about passing references by reference or by value within a Bundle" to: "This guide is agnostic about passing resources by reference or by value within a Bundle	No clinical impact	Cosmetic issue
UECI-10 Doubled Phrase	Remove duplicate phrase on the Security page 'NHS Digital authorised CDSS provider and consumer systems will be created as objects in the directory of the Health and Social Care Directory'.	No clinical impact	Cosmetic issue
UECI- 11 Doubled phrase	Remove duplicate phrase "Further guidance and updates added on searching for a ServiceDefinition using additional customised SearchParameters."	No clinical impact	Cosmetic issue
UECI-14 inputData Cardinality	Update $evaluate.inputParameter cardinality from 0 1 to 0 * as it is necessary to have multiple instances to add multiple Observations or QuestionnaireResponses	Acceptable, no further action required (1)	Provides a mitigation to HAZ01 Absent or incomplete triage

Changes to Hazard Assessment Results

No changes have been made to the Hazard Register in light of this Patch Release.

Therefore, the Residual Risk remains unchanged from that described in the Clinical Safety Case Report – CDS API Implementation Guide Release 1.1 v1.0 (Reference 1).