Clinical Safety Case Report - Clinical Decision Support (CDS) API Implementation Guide Release 2.0 v2.0

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Document Management

Revision History

Version	Date	Summary of Changes
0.01	25 Nov 2019	Initial draft for peer review
0.2	05 Dec 2019	Updated following Hazard Workshop held 02122019
0.3	08 Jan 2020	Updated following peer and CSG review
0.4	08 Jan 2020	For CSO approval
1.0	08 Jan 2020	CSO approved version for CSG
1.0	15 Jan 2020	CSG endorsed
1.1	02 Mar 2020	Draft with input from CSO
1.2	06 Mar 2020	Updated with comments from CO and BT
1.3	24 Mar 2020	Updated with comments from ZB, additional comments from BT and CO and scope changes
1.4	26 Mar 2020	Updated with UECDI Team Comments
1.5	27 Mar 2020	Updated with CSG comments
2.0	30 Mar 2020	Submitted for Endorsement. Endorsed 8th Apr 2020

Reviewers

This document must be reviewed by the following people:

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
Lee Montgomery	Clinical Safety Officer and Clinical Lead UEC	30/03/2020	2.0

Related Documents

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

Ref	Doc Reference Number/URL	Title	Version
1	https://developer.nhs.uk/apis/	Clinical Decision Support (CDS) RESTful Fast Healthcare Interoperability Resource (FHIR) STU3 'Read Only' API implementation guide	2.0
2	FHIR-PUB-04	FHIR API Maturity 'Publication Requirements' section of the NHS FHIR Policy.	1.60
3	DCB0129	Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Implementation guidance	3.2
4	NPFIT-FNT-TO-TOCLNSA-0949.03	Clinical Safety Management System	1.2
5	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**,	
6	DCB0160	Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems	4.2
7	http://hl7.org/fhir/STU3/clinicalreasoning-module.html	International FHIR STU3 Clinical Reasoning Module	STU3
8		UECDI Clinical Risk Management Plan	2.0
9		Hazard Workshop minutes 06/06/2019	1.0
10		Hazard Workshop minutes 10/07/2019	1.0
11		CDSS Proof of Concept Report – Supplier 1	1.0
12		CDSS Proof of Concept Report – Supplier 2	1.0
13		CDSS Proof of Concept Report – Supplier 3	1.0
14		UEC Curation Workshop minutes 19/09/2019	1.0
15		UEC Curation Workshop minutes 01/10/2019	1.0
16		UEC Curation Workshop minutes 16/10/2019	1.0
17		UEC Curation Workshop minutes 05/11/2019	1.0
18		UEC Curation Workshop minutes 13/11/2019	1.0
19		CDS API Design Decision Matrix	1.0
20		CDS API Conformance Approach	1.0
21		CDS API usage guide	1.1
22	https://digital.nhs.uk/about-nhs-digital/our-work/nhs-digital-data-and-technology-standards	NHS Digital Data and Technology Standards	
23	https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance	NHS Data Security and Information Governance guidelines.	
24		Hazard Workshop minutes 02/12/2020	1.0
25		Clinical Safety Case Report – CDS API Implementation Guide Release 1.1	1.0

Ref	Doc Reference Number/URL	Title	Version
26	NPFIT-FNT-TO-TOCLNSA-2166.01	NHS Digital Clinical Safety Group (CSG) Endorsement - Clinical Decision Support (CDS) API Implementation Guide Release 1.1	1.0
27		ITK 111 Report	2.0
28		ITK Ambulance Request Report	2.1
29		Clinical Safety Assessment - CDS API Implementation Guide Patch Release 1.1.1	1.0
30		Hazard Workshop minutes 20/02/2020	1.0
31		CDS API Implementation Guide v2.0 Design Decision Matrix	1.0
32		Triage Outcome Mapping Report	1.0
33		111 Online to Online Consultation Alpha Report	1.0
34	https://developer.nhs.uk/apis/uec-tech-standards/cds-api-conformance-overview.html	CDS API Implementation Guide Conformance Approach	1.0

Glossary of Terms

A glossary of terms relating to the CDS API is provided in the implementation guide.

Additional terms required for this document are provided below.

Term / Abbreviation	What it stands for
ALARP	As Low As Reasonably Practicable
API	Application Programme Interface
CAD	Computer Aided Dispatch
CAS	Clinical Assessment Service
CCG	Clinical Commissioning Group
CDS	Clinical Decision Support
CDSS	Clinical Decision Support System
CPR	Cardiopulmonary resuscitation
dm+d	Dictionary of Medicines and Devices
ED	Emergence Department
EMS	Encounter Management System
ERR	Encounter Report Receiving System
FHIR	Fast Healthcare Interoperability Resource
GP	General Practitioner
IOPS	Interoperability Standards (team)
ITK	Interoperability Toolkit
ODS	Organisation Data Service
OOH	Out of hours
OTOC	111 Online to Online Consultation project
PDS	Personal Demographics Service
POC	Proof of Concept
RCS	Repeat Caller Service
UEC	Urgent and Emergency Care
UEC DI	Urgent and Emergency Care Digital Integration (programme)
UECDI	Urgent and Emergency Care Digital Integration
UTC	Urgent Treatment Centre

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Contents

Introduction

This Clinical Safety Case Report is applicable to the NHS Digital Clinical Decision Support (CDS) RESTful Fast Healthcare Interoperability Resource (FHIR) STU3 'Read Only' Application Programme Interface (API) implementation guide version 2.0 [Reference 1], subsequently referred to as this 'Release' in this report.

The maturity label of this Release, as defined in the NHS FHIR Policy [Reference 2] is Alpha, an initial test API, likely to change substantially, or be discontinued as the project develops

Whilst the specifying of the CDS API implementation guide is not strictly in scope of DCB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems [Reference 3], the principles of this standard are being adopted to ensure safety by design.

This clinical risk assessment is being undertaken in accordance with the NHS Digital Clinical Safety Management System [Reference 4] and addresses requirements of DCB0129 [Reference 3].

This report is an uplift to the Clinical Safety Case Report - CDS API Implementation Guide Release 1.1 v1.0 [Reference 25] which was endorsed by the NHS Digital Clinical Safety Group (CSG) on 15th January 2020 [Reference 26]. It also builds on the Clinical Safety Assessment - CDS API Implementation Guide Patch Release 1.1.1 v1.0 [Reference 29]. It includes the assessment of new scope introduced in version 2.0.

The purpose of this document is to identify, assess and manage clinical safety hazards arising from the creation and implementation of the CDS API specified in this Release. It demonstrates that associated hazards have been identified and managed, where possible, to ensure they do not give rise to unacceptable risks to patients.

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 3] and other in scope standards or regulations e.g. Medical Device Regulations [Reference 5].

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 6].

This report is intended to inform those activities.

System Definition / Overview

The NHS CDS API implementation guide specifies the interactions for the following UEC systems:

- Clinical Decision Support System (CDSS)
- Encounter Management System (EMS)
- Directory Services
- Encounter Report Receiving system (ERR)

Version 1.1 focuses on the implementation of an interface between a CDSS and an EMS and provides resources and operations to enable the representation, distribution, and evaluation of clinical decision support (CDS) rules. This supports the ability to:

- request decision support guidance

- impact clinical workflow, and
- retrospectively assess quality metrics.

Version 2.0 introduces new interactions to support the ability to:

- identify a service instance from Directory Services that can meet the need identified in the triage outcome ($CheckServices)
- build and communicate an encounter report (Encounter Report)
    - to hand the patient journey over to a different EMS/ERR
    - to make available for information

Identify whether a CDSS has a contractual relationship with a patient's Clinical Commissioning Group (CCG) ($IsValid).

This Release is a refinement of the International FHIR STU3 Clinical Reasoning Module [Reference 7] which was developed by international experts to meet a generic Clinical Reasoning use case. The refinement is necessary to meet the specific use case of **triage in Urgent and Emergency Care (UEC) settings**.

Examples of where the CDS API might be used include:

- Triage of patients by non-clinical call handlers (e.g. NHS 111, 999)
- Triage of patients by Clinicians (Integrated Urgent Care Clinical Assessment Service IUC CAS), Walk-in centre, Emergency Department (ED).
- Patient self-triage using online applications (e.g. 111 Online, Online consultation systems, Symptom checker apps).

The CDS API developed by system suppliers using this Release would replace:

- proprietary interfaces between EMS and CDSS
- Interfaces between EMS and Directory Services
- UEC Interoperability Toolkit (ITK) messaging e.g. Ambulance Request, 111 Report, Report to Repeat Caller Service (RCS) and proprietary messaging between EMSs.

It is likely that the CDS API will be initially adopted by greenfield implementations before appropriate drivers are in place to promote extensive change across the UEC landscape. Therefore, the numbers of users and patients affected by suppliers implementing version 2.0 of the API will be very low. It will be the suppliers'/ providers' responsibility to develop their own safety cases and hazard logs and address any information Governance issues to this effect.

CDS API in a patient journey

This section is provided to set the context for where the CDS API is used in a patient journey.

Patient journeys through UEC Services may take several different routes. An example of a simplified journey is provided in figure 1 below.

Figure 1 A simplified patient journey through UEC

A patient (or their representative) contacts the UEC service via an appropriate channel e.g. telephony, face to face, online. The patient (or representative) will either use an EMS directly (e.g. online) or indirectly through a healthcare professional e.g. NHS 111 Call handler.

When applicable the EMS will access data to identify the patient (e.g. PDS search) and whether they meet repeat caller criteria (called 3 x in 72 hours).

If the EMS user has the appropriate access rights, they may be able to view clinical records held locally on the EMS. Subject to the technical solution they may be able to access clinical records held remotely e.g. Summary Care Record, Local Health Care Record, GP record, Special Patient Notes.

The patient then undergoes triage which is the process of determining the priority of the patient's treatments based on the severity of their condition. This is usually undertaken with the support of a CDSS which is interfaced to the EMS.

The triage outcome is used to query Directory Services to identify a service that can provide the required activity to manage the patient's condition within an appropriate timescale.

An encounter report is sent to the receiving care service and, where appropriate, the patient's GP.

Triage outcomes are analysed with the resultant patient outcomes, at the end of the patient's journey, to inform continuous improvement to CDSS logic and service provision.

The CDS API is utilised in the following segments of this journey:

- Triage and Consult
- Access to services
- Report Triage

Level of complexity and risk

The CDS API has an increased level of complexity and risk when compared to other published NHS Digital API implementation guides due to the following:

- This Release is the first time that NHS Digital has published an API Implementation Guide that uses a FHIR Operation. Operations are used:

  a) where the server needs to play an active role in formulating the content of the response, not merely return existing information, or

  b) where the intended purpose is to cause side effects such as the modification of existing resources, or creation of new resources.

- The CDS API utilises ServiceDefinition.$evaluate which is an 'evaluate' operation performed by the EMS against the Service Definition resource to request clinical decision support guidance from a selected Clinical Decision Support System (CDSS).

- The use case of triage in Urgent and Emergency Care (UEC) settings is more complex than the generic clinical reasoning use case for which the refinement of the International FHIR STU3 Clinical Reasoning Module [Reference 7]. was developed.
- If the CDS API Implementation guide is not designed with an appropriate level of rigor clinical decision support (CDS) rules assured by CDSS suppliers may be misrepresented.
- EMS/CDSS end users include patients and non-clinical care professionals who are less likely to notice if they are given inappropriate clinical advice.

Whilst the clinical risk lies with the system suppliers developing against this Release and the Service Providers deploying those systems, this Release warrants a level of clinical risk analysis commensurate with the increased level of complexity and risk to ensure that the principle of ‘safety by design’ is upheld.

Scope

The use case for this Release is a patient journey for unscheduled care triage – for example, during an NHS 111 call, through service section and reporting the encounter to the recipient healthcare provider. This assessment will consider all potential channels (telephony, web, app, etc.) and any unscheduled care setting (111, 999, walk into ED or Urgent Treatment Centre). It includes interactions between:

- a CDSS and a user facing Encounter Management System (EMS)
- EMS and Service Directories; and
- EMS and Encounter Report Receiving system (ERR)

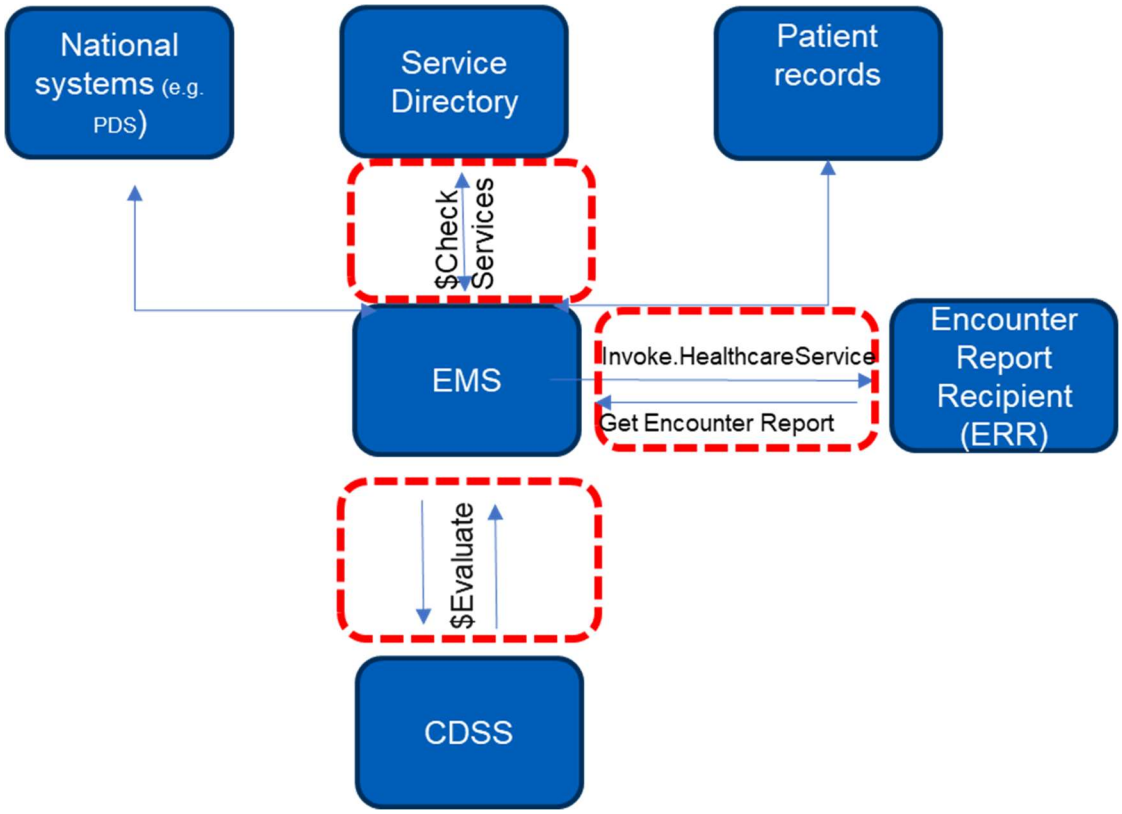

Figure 2 Scope of this Release

This Release also introduces some ValueSets for the Resources used in the $evaluate operation in the guidance [Reference 1].

$Check Services

$CheckServices details how Directory Services identify and return details of a service instance that can meet the need identified in the triage outcome (chief concern, next activity and acuity).

The Encounter Report

On completion of a patent's triage encounter the EMS builds a report that contains all the resources collected during the $evaluate interactions plus additional data required by a downstream service provider to provide safe clinical care to that patient. This provides conformant Encounter Report Receiving Systems (ERRs) with structured Triage Information to drive business processes e.g.

- Posting to specific queues e.g. based on chief concern, acuity, skillset required
- Avoiding unnecessary duplication of triage questions already asked, where clinically appropriate, to provide continuity of triage
- Display of customised human readable Encounter Report that supports the receiving Service Providers processes

The aim is for the Encounter Report to be suitable for communicating Triage information between any Care Setting. Within the current UEC landscape there is no single standard for

a UEC Encounter Report, so a number of existing messaging standards were used to inform the initial development of the CDS API Implementation Guide Encounter Report:

- ITK 111 Report [Reference 27]
    - Used to communicate triage information from NHS 111 to :
        - Receiving services for action e.g. ED, OOH, Pharmacy, Clinical Assessment Service, Primary Care, UTC
        - Patient's registered GP (copy)
- ITK Ambulance Request [Reference 28]
    - Used by 111 services to place an Ambulance Dispatch Request directly on the Ambulance Service Trusts' Computer Aided Dispatch (CAD) system.
    - Used by 999 Services for Cross Border Transfers

The EMS pushes a notification to the receiving Service Provider's ERR endpoint (the details of which were returned by Directory Services in the $CheckServices operation) and the ERR requests the Encounter Report. This mechanism was chosen as patients are often signposted to Service Providers but may not attend. It also allows Service Providers who have not been notified to request the Encounter Report if the patient attends their service unexpectedly.

$Is Valid

$IsValid is a custom operation to identify whether a CDSS has a contractual relationship with the patient's CCG. The requirement for this operation was identified in the 111 Online to Online consultation Alpha project [Reference 33] so that 111 Online would only search for Service Definitions on Online Consultation systems that had been purchased by the patient's registered GP via their CCG. The EMS passes the CCG Organisation Data Service (ODS) code from the Patient resource to the CDSS in $IsValid and the CDSS responds with a Boolean response as to whether it is valid for that patient or not. This operation would only be undertaken when an EMS can call multiple CDSSs prior to undertaking a Service Definition search to perform a patient triage. $IsValid does not introduce any new FHIR resources.

FHIR Resources in scope

FHIR® – Fast Healthcare Interoperability Resource – is a standards framework created by HL7. FHIR combines the best features of HL7's v2, HL7 v3 and Common Document Architecture (CDA) product lines, is aligned with latest web standards with a view to improving implementation.

FHIR solutions are built from a set of modular components called "Resources". These resources are assembled into working systems to solve real world clinical and administrative problems. FHIR is suitable for use in a wide variety of contexts including mobile phone apps, cloud communications, EHR-based data sharing and server communication in large institutional healthcare providers.

The resources are detailed in table 1 below:

FHIR Resource	Details
Appointment	Carries appointment detail in the Encounter Report
Bundle	Used to define a "document" that represents a triage journey, this document holds a bundle of resources that are collected throughout the triage process i.e. All Questionnaire, QuestionnaireResponse and Observation resources collected during the triage process. Patient and Practitioner (Patients GP) resources. A Composition resource that provides a summary of what the document is about in the form of an Encounter resource.
Care Plan	Carries the care advice recommendation given by the CDSS May also carry a recommendation of self-care
Composition	Used to represent the Human Readable summary of the triage journey for a patient. Will also contain all the resources used to build the human readable Encounter Report.
Condition	Used to carry the Chief Concern element of the triage outcome (also secondary concerns).
Consent	Patient consent of different types can be carried in this object. This has been constrained to consent to share the Encounter Report for this release.
Co-ordinate	Used to carry the co-ordinates in a QuestionnaireResponse to an image Questionnaire
Encounter	Used to carry information arising from an interaction between a patient and healthcare provider(s) for the purpose of providing healthcare service(s) or assessing the health status of a patient. In the CDS context, an encounter occurs for the duration of a patient's interaction with a single service provider. This is the root resource for the Encounter Report used to represent a summary of the triage encounter. This references 'patient' and 'practitioner' which will be CareConnect profiles, and will follow the rules for those profiles
Flag	Used to carry information about a patient that is not a clinical assertion e.g. Scene Safety, transport requirements, accessibility requirements, patient preferences and reasonable adjustments
Guidance Response	Used to represent the result of invoking a decision support service. Provides a container for the status of the response, any warnings or messages returned by the service, as well as the output data of the module and any suggested actions to be performed.
HealthcareService	Once a provider organisation is selected from a directory, the instance is populated as a HealthcareService

FHIR Resource	Details
List	Used to represent the structured summary of the triage journey for a patient. The List associated with an encounter is linked through the List.encounter element. The Encounter resource does not contain a reference to the List. There may be more than one List per Encounter, for example, where a CDS is managing multiple ServiceDefinition interactions with the EMS for the same patient at the same time.
Location	Used to carry the location of a patient or organisation
Observation	The Observation resource is used to carry a clinical assertion in a CDS context and is created and populated by a CDSS, which will work from clinical assertions to reach decisions. Due to the nature of triage in unscheduled care, these assertions are often time-bounded and limited, so are appropriate to capture as Observations. The assertions are normally based on input from the patient, captured as QuestionnaireResponses. A single QuestionnaireResponse can drive a single assertion, or multiple assertions. An assertion may need multiple QuestionnaireResponses to be validated.
Organisation	Used to carry details of a healthcare organisation
Patient	Used to carry the details of the patient to whom the triage journey pertains.
Practitioner	Carries details of person who is directly or indirectly involved in the provisioning of healthcare
Procedure	Used to carry details of procedures undertaken in the EncounterReport
ProcedureRequest	Carries the ‘next’ activity’ in the triage outcome which is used to search Directory Services.
Provenance	Used to carry the relevant history of the triage journey. The full history of the journey will be available in the GuidanceResponse.outputParameters and the ServiceDefinition.$evaluate.inputData, but the key steps in the journey will be carried as the relevant history. It will be the decision of the CDSS which assertions are most relevant, and only these will be added to the Provenance resource.
Questionnaire	Used to send one or more questions from the CDSS to the EMS. The EMS present the question and the set of possible responses received from the CDSS to the user during an ongoing clinical evaluation process.

FHIR Resource	Details
Questionnaire Response	The responses to a Questionnaire sent by the CDSS are communicated back by the EMS using the QuestionnaireResponse resource. The EMS will present the question and the set of possible responses received from the CDSS to the user during an ongoing clinical evaluation process and any answers from the user will be used to populate a QuestionnaireResponse.
ReferralRequest	Used to carry the triage outcome of recommendation to another service for a patient. MAY reference a ProcedureRequest, where there is a known requested procedure which the referring service is intended to perform. RequestGroup.action.resource MAY also carry a reference to one or more CarePlans to carry accompanying care advice (not self-care) for the patient. Used to communicate directions to an actual service to which the patient has been referred.
Request Group	Used to group related requests that can be used to capture intended activities that have inter-dependencies.
SearchParameter	Specifies a search parameter that may be used on the RESTful API to search or filter on a resource.
ServiceDefinition	Published by the CDSS, describing what decisions the CDSS can provide support for. Describes in what circumstances the CDSS is valid, and what information is needed to render the decision.
Task	Used to communicate a task to be performed at the end of triage - either by a professional, or the patient e.g. For a Pharmacist receiving a Community Pharmacy Contractual Framework referral request to contact the patient.

Table 1 FHIR Resources in scope for this Release

FHIR interactions in scope

The FHIR interactions in scope of this Release are described in table 2 below.

FHIR Interaction	Details
Select ServiceDefinition	This action is performed by the EMS in order to get a ServiceDefinition from a CDSS
Evaluate ServiceDefinition	This is a FHIR operation performed by the EMS. It is an evaluate operation performed against the Service Definition resource to request clinical decision support guidance from a selected CDSS

Result interaction	The GuidanceResponse is the primary message generated by the Clinical Decision Support System (CDSS). It is returned by the CDSS in response to the EMS's ServiceDefinition.$evaluate operation. It carries the status of the response, any warnings or messages returned by the service, as well as the output data of the module and the result in the form of any suggested actions to be performed
$Check Service	This FHIR operation supports the ability to identify a service instance that can meet the need identified in the triage outcome.
Get Encounter Report	This enables ERR to pull down the Encounter Report from the originating EMS.
$IsValid	A custom operation to identify whether a CDSS has a contractual relationship with a patient's CCG

Table 2 FHIR Interactions in scope for this Release

The FHIR interactions in scope of this Release are detailed the CDS API Interaction diagram below (Figure 3).

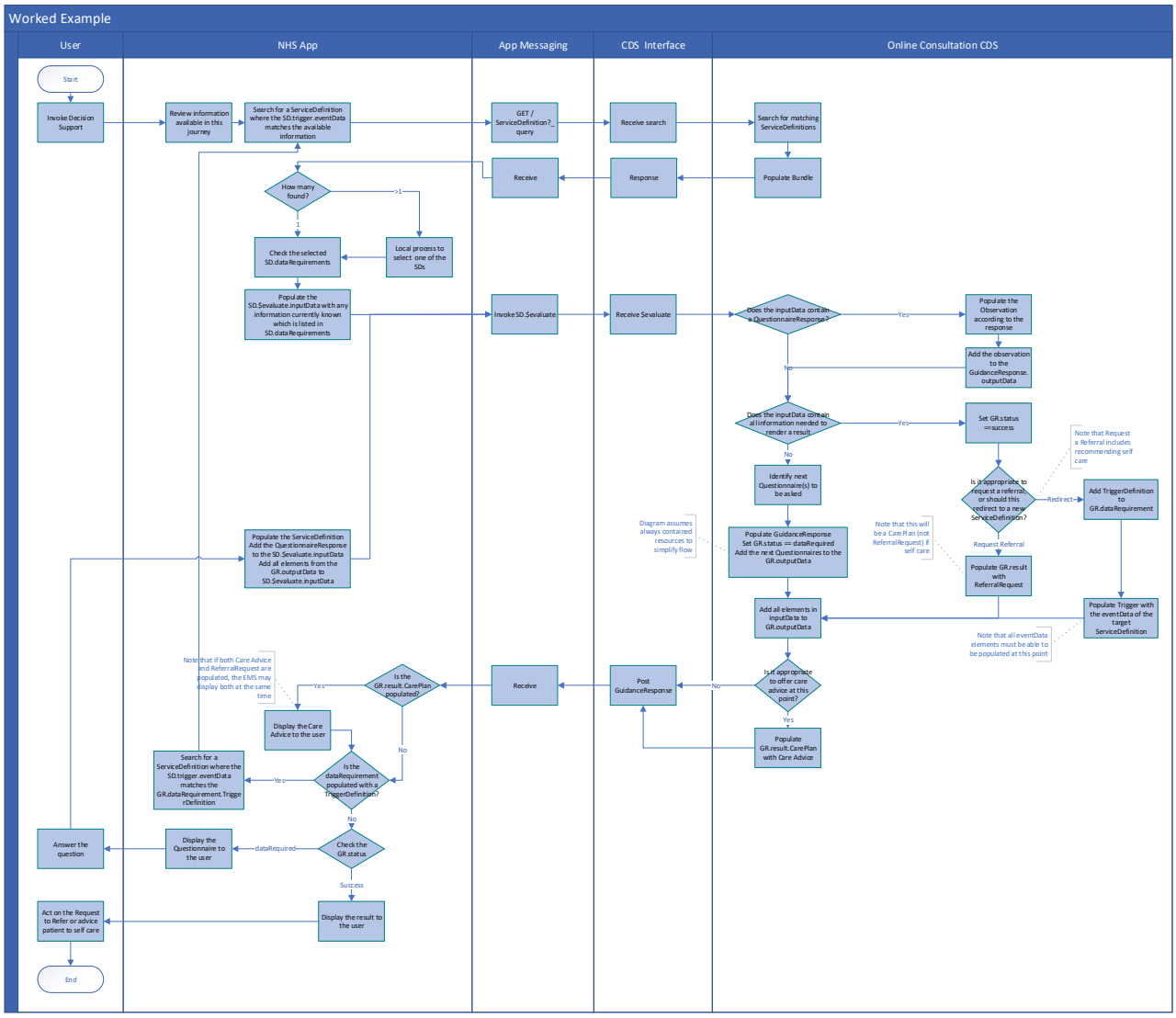

Figure 3 CDS API Interaction diagram

Out of scope for this Release

The following functions are out of scope for this Release and consequently out of scope of this assessment:

Out of scope	Rationale
CDSS clinical content	The CDSS supplier is responsible for the clinical content of their product and will have appropriate clinical governance arrangements in place to ensure that it is aligned with current best practice and conformant with relevant standards and regulations (e.g. Medical Device Regulations if in scope).
EMS/CDSS Infrastructure	This Release does not specify the infrastructure for hosting the EMS and CDSS. The organisation hosting the EMS/CDSS is responsible for ensuring that the architecture is designed to be fault tolerant, resilient, scalable and compliant with NHS Digital Data and Technology Standards [Reference 22]. It is assumed that the Healthcare Provider Organisation will assess the clinical impact of the chosen infrastructure for their deployment as part of their DCB0160 compliance activities.
EMS communication with national services (e.g. RCS. PDS)	Causes relating to EMS communication with national services (e.g. RCS. PDS) are out of scope for this assessment. System suppliers are responsible for ensuring they are conformant with the relevant message standards. It is assumed that the deploying Healthcare Provider Organisation will assess EMS communication with national services as part of their DCB0160 compliance activities.
Information governance	The CDS API does not specify the storage or sharing of information between organisations. The EMS supplier will comply with NHS Data Security and Information Governance guidelines.[Reference 23]
EMS functionality	The functions of the EMS beyond its interaction with the CDS API are not considered in this assessment. EMS suppliers will undertake clinical safety activities in accordance with DCB0129 for their product.
Level 3 FHIR Profiles	A decision has been taken by NHS Digital NOT to define FHIR profiles at Level 3 (Programme specific) but instead to provide textual implementation guidance for each resource and operation element.
Clinical Safety activities for projects using the CDS API implementation guide.	There are several projects that are implementing the CDS API based on this Release. Clinical Safety activities will be undertaken by the manufacturers of the systems implementing the CDS API in accordance with DCB0129.
Triage of patient groups	This Release is focused on the triage of individual patients and the triage of patient groups (e.g. an incident with an unknown number of casualties) is out of scope.

Table 3 Items out of scope for this Release

Version 1.1.1

Four (4) bugs were identified in version 1.1 of the CDS API Implementation Guide and a minor Release v1.1.1 was published to address these. The UEC DI Clinical Safety Officer 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 4]. This was documented in an addendum to the CDS API Implementation Guide v1.1 Clinical Safety Case Report [Reference 29] and stored in the Clinical Safety File.

No updates were made to the Hazard Register in light of the v1.1.1 Patch Release.

ID	Issue	Clinical Risk if this bug was developed in a Live Product	Rationale
UECI-09 Referenced resources	https://developer.nhs.uk/apis/cds-api-1-1-0/api_general_guidance.html#referenced-resources "This guide is agnostic about passing references by reference or by value within a Bundle" Should say "This guide is agnostic about passing resources by reference or by value within a Bundle	No clinical impact	Cosmetic issue
UECI-10 Doubled Phrases	There is a doubled phrase on the Security page (https://developer.nhs.uk/apis/cds-api-1-1-0/api_security.html#process) on the first bullet point.	No clinical impact	Cosmetic issue
UECI- 11 Doubled phrase in release note	The 1.1.0 release notes (https://developer.nhs.uk/apis/cds-api-1-1-0/overview_release_notes.html#110-alpha) include a duplicate line: "Further guidance and updates added on searching for a ServiceDefinition using additional customised SearchParameters." This can be removed.	No clinical impact	Cosmetic issue
UECI-14 inputData Cardinality	An existing issue, the inputData parameter provided in the body of the call to $evaluate is marked as 0..1 in the CDSS guide, but it is necessary to have multiple instances of it in order to add multiple Observations or QuestionnaireResponses. The FHIR spec also marks it as 0..*, we assume that the guide should be updated to reflect this.	Acceptable, no further action required (1)	Provides a mitigation to HAZ01 Absent or incomplete triage

It was agreed with NHS Digital Clinical Safety Group that there would be no uplift to the CDS API Implementation Guide v1.1. Clinical Safety Case Report or Hazard Log [Reference 26].

Clinical Risk Management System

This clinical risk assessment is being undertaken in accordance with the NHS Digital Clinical Safety Management System [Reference 4]. It relates to the UEC Digital Integration (UEC DI) Programme Clinical Risk Management Plan [Reference 8].

The Hazard log will develop alongside each release the CDS API Implementation Guide and will reflect the maturity of the latest version.

A Clinical Safety Case Report will be issued for the major CDS API implementation guide version and will be updated for each subsequent major version. If a minor version of the CDS API implementation guide changes the clinical risk profile significantly the Clinical Safety Case Report will be updated and reissued. Each Clinical Safety Case Report will include a snapshot of the Hazard Log in accordance with DBC0129.

Whilst the Clinical Safety activities for future releases of the CDS API Implementation Guide will be undertaken as part of a broader clinical assurance process, which is detailed in the UEC DI) Programme Clinical Risk Management Plan [Reference 8], it was determined that organisation level clinical safety activities were appropriate for this Release given that it has a maturity level of Alpha.

The EMS is responsible for all personal information relating to patients as the CDSS is stateless.

Staffing and Responsibilities

Clinical safety activities have been undertaken in accordance with the following table:

	Safety Engineer	**Clinical Safety Officer (CSO)**
Programme	Julie Harris	Lee Montgomery/ Martin O'Keeffe
Assurance	Charles Olowosuko Bruno Tchek	Zak Bickhan

Responsibilities are described in the UEC DI Clinical Risk Management Plan [Reference 8].

Additional programme resource has been utilised to support safety assessment of key clinical functionality, for example during Hazard workshops. For attendees of Hazard Workshops please see the related meeting minutes [References 9-10 and 30].

CDS API Implementation guide products

CDS API implementation guide

An implementation guide is a set of rules about how FHIR resources are used (or should be used) to solve a problem. The CDS API Implementation guide (this Release) is intended to provide all the technical resources needed to successfully develop the CDS API and is published on developer.nhs.uk. Its intended audience is EMS and CDSS development teams.

Design controls within NHS Digital's boundary identified in the Hazard Log are implemented through this product.

CDS API Usage Guide

The CDS API Usage Guide is associated documentation to support and clarify the usage of the CDS API implementation guide. It provides broader guidance and implementation examples for EMS and CDSS Product teams and is published on developer.nhs.uk.

Training controls within NHS Digital's boundary identified in the Hazard Log are implemented through this product.

CDS API Conformance Approach

The Conformance Approach [Reference 34] describes the requirements for EMS and CDSS assurance teams to achieve certification of technical conformance with the CDS API implementation guide. These requirements will be a combination of centrally managed conformance testing and supplier managed testing with self-declaration of conformance. It is published on developer.nhs.uk. Details of the Conformance Approach are provided later in this report.

Test controls within NHS Digital's boundary identified in the Hazard Log are implemented through this product.

Supporting activities

The CDS API products have been informed by several activities which are summarised in figure 4 below.

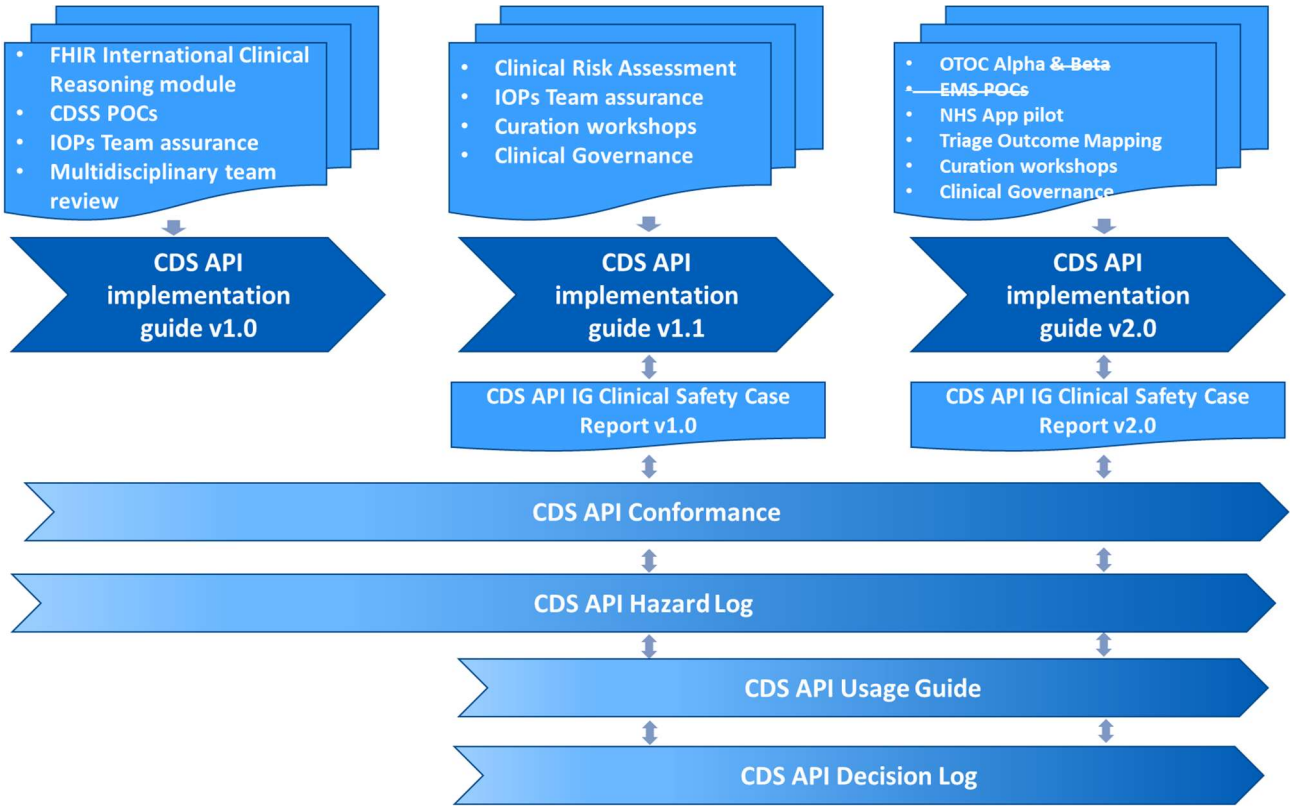

Figure 4 CDS API products and informing activities

Clinical Risk Analysis, evaluation and control

Hazard identification was undertaken during the following activities:

- Clinical attendance (supplier and NHSD) at CDSS Proof of Concept Sprint Ceremonies

- Clinical review of End of CDSS POC Supplier Reports [References 11 to 13]
- Hazard workshop attended on 06/06/2019 by a multidisciplinary team from UEC DI and NHS Digital Clinical Safety Group [Reference 9]
- Hazard workshop attended on 10/07/2019 by a multidisciplinary team from UEC DI and NHS Digital Clinical Safety Group [Reference 10]
- Multidisciplinary team curation workshops to agree updates to Release 1.1 and record the design rationale for key decisions [Reference 14-18].
- Contribution to and review of CDS API Conformance Approach [Reference 20] to ensure identified test controls within NHS Digital's boundary are implemented.
- Contribution to and review of CDS API Usage Guide [Reference 21] to ensure identified training controls are implemented.
- Hazard workshop attended on 02/12/2019 by a multidisciplinary team from UEC DI and NHS Digital Clinical Safety Group [Reference 24]
- Hazard workshop attended on 20/02/2020 by a multidisciplinary team from UEC DI and NHS Digital Clinical Safety Group [Reference 30]
- Multidisciplinary team curation workshops to agree updates and record the design rationale for key decisions in the CDS API Design Decision Matrix [Reference 31]
- Clinical Review of Triage Outcome Mapping report [Reference 32]
- Clinical Review of 111 Online to Online Consultation Alpha Report [Reference 33]

Once clinical hazards had been identified and recorded in the Hazard Log in the next section. Initial Likelihood and Consequence scorings for each hazard were performed and a Risk Rating derived using the definitions defined in Appendix A – Risk Classification Matrix. Each hazard was re-assessed to ensure that the proposed mitigations reduce the risk to acceptable levels.

Throughout the programme lifecycle implementation feedback will inform any changes required (e.g. control measures) to the Hazard Log.

It should be noted that Hazards have been identified at the patient interface in accordance with the latest NHS Digital Clinical Safety Group training. This leads to fewer Hazards with more causes than earlier methods.

Hazard Log

This release introduces three (3) new hazards and provides two (2) additional causes and related controls to an existing hazard.

Of the seven (7) hazards identified in total, four (4) hazards were scored at with an initial risk rating of three (3) and three (3) hazards scored at with an initial risk rating of two (2). Following control option analysis and the implementation of control measures all seven (7) hazards were assessed having a residual risk rating of two (2) in accordance with the Risk Classification Matrix in Appendix B of this report.

The risk profile of this Release is therefore assessed as Acceptable where cost of further reduction outweighs benefits gained.

The table below summarises the findings of the clinical risk management activities. Seven (7) hazards were identified and assessed.

Hazard	Initial Risk			Residual		
	Conse-quence	Likelihood	Risk Class	Conse-quence	Likelihood	Risk Class
H01 Absent or incomplete triage	Major	Medium	3	Major	Very Low	2
H02 Inappropriate triage	Major	Medium	3	Major	Very Low	2
H03 Triage outcome misleads HCPs	Significant	Medium	2	Significant	Low	2
H04 Failure to identify an appropriate service using the CDS API triage outcome	Considerable	Low	2	Considerable	Very Low	2
H05 Encounter report content incomplete or incorrect	Considerable	Medium	3	Considerable	Low	2
H06 Encounter Report is not retrieved by the relevant service provider or service	Significant	Medium	2	Significant	Low	2
H07 Human readable version of the Encounter Report is rendered in a way that misleads	Considerable	Medium	3	Considerable	Low	2

A snapshot of the Hazard Log is provided as a separate document to this report.

Hazard 1 – Absent or incomplete triage

This hazard relates to the absence of triage in a patient UEC journey. This includes incomplete triage that does not lead to an outcome and the absence of care advice either at the end of or during triage of a patient.

Clinical Assessment

In the absence of triage there is likely to be a delay in the delivery of care whilst the patient or HCP seeks alternative advice. The severity of the consequence will have a direct relationship to the acuity of the patient's clinical need.

As care advice may be included for acute events, such as CPR instructions for calls relating to cardiac arrest, absence of this advice may lead to a major consequence.

Where an HCP is present (e.g. NHS 111, ED, OOH, UTC) they may triage the patient using their clinical knowledge or follow local policies and procedures for business continuity.

In the situation of online self-triage, a patient may use an alternative triage site, call NHS 111/999 or directly contact/ visit a UEC care service (e.g. GP, OOH, ED)

Initial Risk Assessment

Consequence: Major

The consequence was assessed as Major as it was felt the absence of interim care advice relating to cardiopulmonary resuscitation (CPR) may not be detectable and may contribute to an outcome of death.

Likelihood: Medium

Risk category:

3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.

Evidence/Safety Argument

In order to reduce the risk of absent or incomplete triage due to message failure, this Release defines error codes, provides guidance on alerts, timeouts and retry mechanisms for both initiating and responding systems to ensure that messaging failures are detected and managed appropriately. It also specifies pre-requisites for CDS API FHIR servers. The design decision to use a restful API means that an EMS can recover from a temporary interruption to messaging and continue from where it left off because when it invokes a ServiceDefinition.$evaluate operation it references a QuestionnaireResponse and all previous assertions (Observation resources) for the CDSS to evaluate. The CDS API Conformance Approach provides the route to implementation of test controls and includes verification of the pre-requisites for CDS API FHIR servers, appropriate use of error codes due to messaging failure and verification that the ServiceDefinition.$evaluate operation is conformant with this Release. The external control that deployment organisations are to put service desk processes in place to manage failed message queues is communicated in this report.

To reduce the risk of absent or incomplete triage due to malicious attack this Release provides guidelines for system suppliers and hosting organisations relating to the NHS

Digital approach to security. The responsibility for a secure deployment lies with the deploying organisation who should undertake an appropriate level of security testing. This external control is communicated in this report.

There is a risk that clinical decision logic to support the triage of a given presenting complaint cannot be found and this may lead to absent or incomplete triage. The main control provided by this Release is it provides guidance to ensure that each CDSS can cope with situations where nothing is known about the patient at the start of triage. i.e. states that each CDSS must publish a ServiceDefinition with a 'NULL' Trigger. It also specifies how an EMS can search for and select an appropriate ServiceDefinition for the patient's presenting complaint and other known clinical information. In order to support this all live Service Definitions URLs must be populated with the address at which the ServiceDefinition is published which must be globally unique. The CDS API Conformance Approach provides the route to implementation of test controls and includes verification that each CDSS has published a ServiceDefinition with a 'NULL' Trigger, that all CDSS ServiceDefinitions are conformant with CDS API guidance and EMSs can select and evaluate Service Definitions. Deploying healthcare organisations will need to ensure through clinical integrity checking that deployed CDSS(s) cover presenting complaints appropriate for the care setting in which they are deployed. They will also need to implement a governance process for the publishing of ServiceDefinitions.

There are several scenarios where a triage may fail to complete due to errors in the implementation of ServiceDefinition resources. Guidance is provided to CDSS suppliers to ensure that all Service Definitions end in a Result or to point to another ServiceDefinition and that that Service Definitions that end with a redirection do not point to Service Definitions that redirect to the initiating Service Definition either directly or indirectly (to avoid getting into loop). Additional guidance describes error codes and expected EMS or CDSS behaviour.

There is the potential for a CDSS to erroneously return a ‘false’ response to an $IsValid query. This means the EMS would not proceed to search for Service Definitions on this CDSS which may lead to absence of triage CDS for a patient. An external control of implementation testing undertaken by the Service Provider must ensure that $IsValid returns all CDSS’s that should be valid for that patient. If no CDSSs are valid for a patient Service Providers would revert to previous processes. For Example, in the 111 Online to Online Consultation scenario, 111 Online would signpost the patient to their registered GP.

Residual Risk Assessment

Consequence: Major

Likelihood: Very Low

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

Hazard 2 - Inappropriate triage

This hazard relates to an inappropriate triage outcome for the patient's presenting complaint. This includes a triage outcome in an inappropriate format and inappropriate advice given at the end of or during triage.

Clinical Assessment

An inappropriate triage outcome may lead to a patient being given the wrong advice which may lead to a delay in the delivery of care, or the delivery of inappropriate care which may lead to harm.

Where an HCP is undertaking the CDSS supported triage (e.g. NHS 111, ED, OOH, UTC) they MAY recognise that the triage advice is inappropriate and triage the patient using their clinical knowledge or follow local policies and procedures.

In the situation of online self-triage, a patient is less likely to recognise that the triage advice is inappropriate, but if they do they may use an alternative triage site, call NHS 111/999 or directly contact/ visit a UEC care service (e.g. GP, OOH, ED).

Initial Assessment

Consequence: Major

Likelihood: Medium

Risk category:

3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.

Evidence/Safety Argument

There is the potential for the wrong clinical decision support logic (ServiceDefinition) to be used for patient's presenting complaint. The CDSS supplier is responsible for publishing the ServiceDefinition resource which describes which decisions the CDSS can provide support for, under what circumstances the CDS is valid, and the information needed to render the decision. This must be conformant with the CDS API ServiceDefinition Implementation Guidance. It is assumed that CDSS suppliers will undertake testing to ensure that selection of a ServiceDefinition launches the expected triage logic.

This Release provides guidance to reduce errors in defining a ServiceDefinition and describes its selection and evaluation throughout the triage process. EMS suppliers are to consider system behaviour to ensure that End Users can validate that the CDS is appropriate for the patient's presenting complaint in their Clinical Safety activities

In order to reduce the risk of a Test ServiceDefinition getting into Live, this Release states that only Service Definitions with a status of 'Active' can be used in Live but it also provides other statuses for ServiceDefinitions that are still in test. It is assumed that both CDSS suppliers and deploying organisations will have governance processes that will be expanded to include the safe publication of Service Definitions.

This Release provides mitigation against causes relating to the consumption of assertions from the wrong patient or encounter by specifying responsibilities for the FHIR resource server to pass the patient and encounter context at each ServiceDefinition.$evaluate interaction and for the CDSS to consider the Observation.context in its logic.

To ensure that time dependant Observations that are no longer current are not consumed by the CDSS each Observation Resource is to include an 'effective' date/time. The CDSS logic can take the effective period into account in its logic or specify the ServiceDefinition.dataRequirements to exclude assertions that have exceeded this effective

period. Conformance testing is to ensure that Observations that have exceeded their 'effective' date/time are not consumed by CDSSs.

To reduce the risk of a CDSS consuming an assertion made from third party clinical content that is not equivalent to the same assertion recorded locally (e.g. prompted from a question with a different clinical intent to the local question), each CDSS supplier is responsible for creating coded assertions that accurately reflect the clinical meaning of the answers provided in the QuestionnaireResponse to the questions detailed in the associated Questionnaire. ServiceDefinition.dataRequirements are to be populated with the set of machine-processable assertions which the CDSS logic requires in order to render the response fully. This must include all meta data required to support the decision e.g. Codes and Values. In addition to coded assertions the CDSS will send the Questionnaire and Response that prompted that Assertion in the GuidanceResponse.

In order to achieve continuity of triage, an assertion must be coded in accordance with the Value Sets specified in the CDS API. There is the potential for CDSS suppliers to use codes outside of these Value Sets to preserve the clinical meaning of responses associated with existing question sets. Whilst this will prevent continuity of triage for these assertions it will not lead to patient harm as the associated questions will be repeated. To support this the binding strength of the ValueSets associated with Observation.code and Observation.value must support use of values outside of those Value Sets. The curation process must ensure that the Value Sets are appropriately defined to maximise the benefit of continuity of triage. This must be undertaken by a multi-disciplinary team and include a full Clinical review to ensure accuracy and completeness. As these Value Sets mature the CDS API implementation guide owner must have a process in place for healthcare providers and system suppliers to suggest additional values for value sets, for the value sets to be updated and changes communicated to stakeholders. Conformance approach to include verification that CDSS Observations (assertions) are conformant with the defined Value Sets.

The wider FHIR Curation process must include a formal change control process that ensures breaking changes are not made to published (curated) ValueSets that are used by the CDS API without agreement from the UEC DI programme team.

To reduce the risk of failing to branch to more appropriate question set (e.g. Back pain to back injury) the CDS API supports redirection to another Service Definition through the GuidanceResponse.dataRequirement element which is used to carry a description of the data required by the EMS to enable it to select the new ServiceDefinition as directed by the CDSS. Conformance approach is to include verification of logical completeness of CDSS Service Definitions. (e.g. If SD1 ends with SD3 and Result 4 they must exist).

There is the potential for the wrong version of an assertion is to be consumed by the CDS API (e.g. An observation/assertion that has been subsequently amended). To reduce this each assertion has an effective period which indicates the clinically relevant time/time-period for the observation. Assertions that are outside of this effective period should not be used to inform clinical decisions. The FHIR resource server is responsible for storing each version of an assertion within a patient encounter and for determining which version is passed to the CDS API in the ServiceDefinition$Evaluate at any point in the encounter. Service Providers will ensure this is tested in their deployment. If a response is amended the CDSS will update the associated assertion status to ‘amended’. If a question is asked again and a duplicate assertion is created the assertion will have a different Reference ID, so it is distinguishable from any previous versions.

The CDS API is dependent on the presenting complaint being coded correctly by the CDSS. There is the potential for this not to happen (e.g. CDSS codes presenting complaint incorrectly by NLP failure). The ServiceDefnition.title.description and .purpose are populated

with details about the selected CDS logic and it is assumed that EMS suppliers will assess the risk of the display of these elements to end users in their Clinical Safety activities so that they can identify when an inappropriate ServiceDefinition is being used. It is assumed that CDSS suppliers will undertake verification testing to ensure accurate coding of presenting complaint, this must include NLP testing if this is used.

There is the potential for Clinical Decision Support that is not suitable for a particular use context to be provided. This might include, but is not limited to:

- EMS user role (e.g. 111 Health Advisor, CAS clinician, Patient)
- Service type (e.g. 111 Online, IUC CAS, Walk-in centre, ED)
- Environmental factors (e.g. Localised increased pollution, heatwave, flu epidemic, Ebola outbreak, CBRN incident)

This Release reduced the risk of this by specifying that the ServiceDefinition,useContext to be populated with the context the content is intended to support. If no useContext is specified, this means the ServiceDefinition is appropriate for any useContext. The usage guide is to provide guidance about use of ServiceDefinition.useContext and/or Questionnaire.useContext to support filtering of Service Definitions or Questionnaires by user role. The EMS is responsible for setting and maintaining the user role and service type but the CDSS may set the environmental factors through the use of questioning.

In order to reduce the risk of a default response to a Questionnaire, that does not match the actual response, being inadvertently accepted by EMS user this Release states that default questionnaire responses muse not be populated by the CDSS in the Questionnare.item.initial[x]

There is the potential for secondary concerns identified in the triage process not to be recognised. Whilst communication with Directory Services is not in scope of this Release it is important to take this use case into consideration when providing guidance for use of the ReferralRequest resource. Review of the use of ReferralRequest.supportingInformation element for recording secondary concerns and how it might be used to drive Directory searches is recommended.

One advantage of the CDS API is that it supports the concurrent running of multiple ServiceDefinitions for patients presenting with multiple presenting complaints, However, questions may become ambiguous when more than one Service Definition is running concurrently. (e.g. Headache and leg pain and a question of ‘how much does it hurt’ or ‘how long have you had it?’). CDSS suppliers are to ensure that all questions and permitted responses are self-contained and self-explanatory.

EMSs often provide fields for end users to enter notes. There is no mechanism for the CDSS to take notes into consideration using this Release. Guidance is to be provided to state that notes made by EMS users are not taken into consideration by the CDSS. It is assumed control that EMS suppliers will assess the risk of providing notes fields given that that are not taken into consideration by the CDSS.

Message corruption may lead to inappropriate triage, especially if it is plausible. This Release reduces the risk of this by defining error codes and recommended system behaviour where appropriate.

A potential failure mode is that a CDSS could erroneously state that it is valid for a patient in $IsValid. This could lead to an inappropriate CDSS being used for triage. The design control for this scenario is that as $IsValid is effectively a pre-filter before the Service Definition

search, the EMS will proceed to search for valid ServiceDefinitions on the (invalid) CDSS, but it will not find any that are valid for that patient.

Residual Risk Assessment

Consequence: Major

Likelihood: Very Low

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

Hazard 3 - Triage outcome information misleads healthcare professionals (HCPs)

This hazard relates to triage information created by the CDS API misleading HCPs who may be validating triage initiated by non-clinical staff.

Clinical Assessment

If a triage outcome misleads HCPs, it may contribute to them making an inappropriate decision about the patient's clinical care. This may lead to a delay in the delivery of care or the delivery of inappropriate care.

HCPs will use their clinical judgement to inform their decision and validate any information that looks in doubt.

Initial Risk Assessment

Consequence: Significant

Likelihood: Medium

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

Evidence/Safety Argument

The coding of clinical data for communicating safely to receiving systems is one of the main challenges of interoperability. Whilst EMS to EMS communication is out of scope of this Release, design decisions relating to the coding of CDS API FHIR Resources will impact EMSs using this information. Implementation guidance will ensure that clinical meaning is preserved for all clinical resources in a consistent manner in line with NHS terminology standards e.g. SNOMED CT.

Clinical qualifiers are used to modify clinical codes to convey clinical meaning. In order to reduce the risk of clinical coding, particularly the use of qualifiers misleading HCPs, CDSS suppliers are responsible for ensuring that that:

- Assertions (generally Observation resources) are coded to preserve the clinical meaning of the response. This includes the use of relevant clinical qualifiers e.g. Observation value
- Chief and Secondary Concerns (Condition resources) are coded in a way that that conveys their clinical meaning and can be consumed by downstream systems (e.g. EMS, Directory Services). Where assertions are stored, displayed or communicated by the EMS they must include all elements required to preserve clinical meaning.

Service Providers are responsible for undertaking assurance of the CDSS to ensure that the Observation.codes created from a QuestionnaireResponse reflects its meaning.

The use of coding, including qualifiers is further discussed in the next section as the design controls for the CDS API Implementation Guide are still under discussion.

To reduce the risk of the potential lack of clarity of amended results (e.g. which version should be used to inform clinical decisions) each assertion has an effective period which indicates the clinically relevant time/time-period for the observation. Assertions that are outside of this effective period should not be used to inform clinical decisions. The FHIR resource server is responsible for storing each version of an assertion within a patient encounter and for determining which version is passed to the CDS API in the ServiceDefinition.$evaluate at any point in the encounter. Service Providers will ensure this is tested in their deployment. If a question is asked again and a duplicate assertion is created the assertion will have a different Reference ID, so it is distinguishable from any previous versions.

Causes of triage outcomes misleading HCPs include the coding of allergies and medications in a way that may either not convey their meaning or convey it in a way that may not be able to be consumed by CDSSs undertaking prescribing clinical decision support. Exploration for controls to reduce the risk of this are discussed in the next section.

Residual Risk Assessment

Consequence: Significant

Likelihood: Low

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

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Hazard 4- Failure to identify an appropriate service using the CDS API

This hazard relates to the failure of the use CDS API to search Service Directories to identify a Service that can meet the patient's needs within an appropriate timeframe. This includes the identification of an ambulance resource with the appropriate priority level.

(Note: this does not include the recommendation of a service with a higher acuity than is required as this would meet the patient's needs, albeit inefficiently for the NHS).

This Hazard was broadened for this Release to include causes related to the CheckServices Operation.

Clinical Assessment

If the CDS API cannot be used to identify a suitable service or ambulance resource to meet the patient's needs in an appropriate timeframe, there will be a delay in the delivery of care which may lead to harm. The consequence of the delay will be dependent on the acuity of the patient's need and the length of the delay.

Users could access standalone directory services and contact services directly. Patients or UEC providers can ring 999 for an ambulance.

Initial Risk Assessment

Consequence: Considerable

Likelihood: Low

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

Evidence/Safety Argument

There is the potential for Triage outcome resource elements that could be used to drive a Service Directory search not to be present or for failure to retrieve a recommended healthcare service that meets the patient's needs in response to the $CheckServices operation.

In order to reduce this risk, the CDS API design process is to include a multidisciplinary review of all triage outcome information included in the ReferralRequest to ensure it can drive a Directory search to identify a service that meets the patient's needs. This must consider cardinality and guidance to be provided to CDS API implementors regarding the presence (single and multiple) and absence of this data. Reviewers must include system suppliers, service providers and Directory Service representatives. CDS API POCs, Alpha or Beta projects are to ascertain which ReferralRequest elements are required by Service Directories in order to identify a service to meet the patient's needs. In order to adopt a standard approach to the data model required to search for Directory Services there should be a review of Directory Service standards to ensure that they are aligned with CDS API ReferalRequest elements and are not constrained to proprietary triage outcomes.

CDS API design process to also include a multidisciplinary review of all triage outcome information included in the ReferralRequest to ensure that the triage outcome information is sufficient to map to Ambulance Priority Codes. This must consider cardinality and guidance to be provided to CDS API implementors regarding the presence (single and multiple) and absence of this data. Reviewers must include system suppliers, service providers and ambulance governance bodies representatives. A review of ARP code mappings to triage outcomes must be taken to ensure that they are aligned with CDS API ReferalRequest elements and are not constrained to proprietary triage outcomes.

To reduce the risk of a failure of the $CheckServices operation, design controls in the implementation guide detail the responsibilities for this operation. Conformance testing requirements have been updated to ensure that Directory Services are able to return a bundle of Healthcare Services that match the ReferralRequest defined in the GuidanceResponse, and that EMSs can consume the bundle of Healthcare Services, returned by the Directory Service, that match the ReferralRequest defined in the GuidanceResponse.

Residual Risk Assessment

Consequence: Considerable

Likelihood: Very Low

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

Hazard 5- Encounter report content incomplete or incorrect

This hazard relates to the absence of information in the Encounter Report or the presence of incorrect information. This includes retrieval of the wrong patient's Encounter Report.

Clinical Assessment

If the Encounter report is incomplete or incorrect the receiving service provider may make decisions based on incomplete or incorrect information which may lead to a delay in the delivery of care or in the delivery of inappropriate care.

If the patients registered GP receives a copy of incomplete or incorrect Encounter Report, it may contribute to hazards relating to incomplete/incorrect information in the patient's EPR.

If the RCS receives an incomplete or incorrect Encounter Report is may mislead Service Providers who use this information to make decisions about Repeat Callers which may delay the delivery of care which may lead to harm.

If HCPs have any doubt about the validity of the Encounter Report they will validate it with the patient.

Initial Risk Assessment

Consequence: Considerable

Likelihood: Medium

Risk category:

3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.

Evidence/Safety Argument

In order to reduce the risk of the Encounter report being corrupted in transit, an implementation control has been identified for the hosting service provider to ensure that transport protocols are suitable for alerting or avoiding corruption. To mitigate the risk of the Encounter Report being corrupted at rest, Service Provider testing must ensure that their local implementation correctly builds and stores Encounter Report content.

For the Encounter Report to be effective it must contain appropriate structured content to drive the business processes of the Service Providers. To reduce the risk of this not being the case, the Triage Outcome Mapping (TOM) project was undertaken which successfully mapped the FHIR resources specified in this Release to all fields from the ITK Ambulance Request and 111 Report messaging standards currently being used. In addition, the 111 Online to Online Consultation system (OTOC) alpha showed that the Encounter Report content was sufficient to support transfer between 111 Online and Online Consultation Systems.

A design control in this Release states that the List Resource must be used communicate ALL machine-readable data from the triage journey (the $evaluate interaction) from the sending provider. In order to ensure that the control of adding a Composition resource (see H07) does not become an additional cause for this hazard, usage guidance states that resources referenced by the Composition resource must not be used to drive business processes as they may not be the complete list of resources for that triage journey.

Conformance testing will ensure that EMS can produce Encounter Report content in accordance with the CDS API implementation guidance. An external implementation control has been communicated in this report that Service Providers must ensure that the specific Encounter Report content is sufficient to drive their business processes at implementation.

An external cause for this hazard is that the receiving service provider may fail to undertake actions communicated in the Encounter Report in a clinically appropriate timescale. A design control provided in this Release is that where a receiving service provider must undertake an action (e.g. a Pharmacist receiving an NHS Community Pharmacist Consultation Service referral) this must be communicated in the Task Resource. Conformance testing is to ensure that EMSs can build Task resources and ERRs must be able to receive and consume Task resources. ERR suppliers must undertake clinical safety activities to ensure that actions communicated in Task resources are displayed appropriately and are used to drive system behaviour to support service providers in task management. Service providers must put processes in place to ensure actions communicated in Task resources are acted on within appropriate timescales.

In order to reduce the risk of the Encounter Report failing to provide enough content to support the RCS processes NHSD to include connection to the RCS in the conformance approach. EMS are to undertake conformance testing to connect to RCS.

To reduce the risk of the ERR retrieving the Encounter Report of the wrong patient Encounter Report includes the Patient resource, so the identifiers in that resource (name, NHS Number) can be verified against the expected patient details by the ERR. If the ERR gets a notification, it includes a unique id for the correct Encounter Report. If an ERR has not received a notification, it executes a query which includes the patient NHS Number which will be the primary link to ensure the correct report is retrieved. Conformance is to ensure that an ERR can execute Get Encounter Report in accordance with the implementation guide to retrieve the correct patient's report and that the EMS can create an Encounter Report in accordance with the implementation guide, to ensure that the Patient resource is present and populated to support ERR verification. Usage guidance is to be provided to advise ERRs to verify the NHS number (or other patient details if the NHS number is not present) in the Encounter Report. A Service Provider process control requires ERR users to positively identify the patient and record match before acting on it, in accordance with their organisation's Patient Identification Policy.

It is possible for a Questionnaire to be of related to an image e.g. “Show me on this image where your abdominal pain is”. In this case the expected response would be a co-ordinate, and this could be used in the CDS e.g. a co-ordinate pointing to the lower abdomen might prompt questioning about urinary problems. If the response is not managed correctly it could lead to inappropriate triage. A design control of updating the Questionaire.item.text from String to Markdown has been introduced to support adding attachments and references to the question (such as the link to an image). There is also a design control of creating a custom resource 'Co-ordinate'. This enables the recording of x and y co-ordinates by the EMS against an image presented by the CDSS in the Questionnaire. In order to ensure that the co-ordinated recorded are specifically linked to the version of the image that was presented in the questionnaire at the time of triage usage guidance is provided on up-versioning Questionnaires when changing images. This is reiterated in an implementation control stating that CDSS providers are to ensure that when a Questionnaire image is changed that a new version of the Questionnaire is created.

Residual Risk Assessment

Consequence: Considerable

Likelihood: Low

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

Hazard 6- Encounter Report is not retrieved by the relevant service provider or service

This Hazard relates to the Encounter Report not being retrieved by the service provider that the patient attends, their registered GP, or other relevant national service (e.g. RCS, NRLS). This Hazard does not include retrieval of the wrong patient's Encounter Report, which in this context is an IG issue rather than one of clinical safety (see cause 0506).

Clinical Assessment

If a service attended by the patient cannot retrieve the Encounter Report, there is the potential for healthcare professionals to act on incomplete information. This may lead to a delay in the delivery of appropriate care or in the delivery of inappropriate care which may cause harm.

Receiving service providers will restart triage without access to previous triage information via the Encounter Report.

Initial Risk Assessment

Consequence: Significant

Likelihood: Medium

Risk category: 2

2	Acceptable where cost of further reduction outweighs benefits gained.

Evidence/Safety Argument

For the sending EMS to be able to push the Encounter Report notification, it needs to identify receiving service's endpoint from Directory Services. In order to reduce the risk of failure to identify the receiving service endpoint from Directory Services the receiving Service Provider's ERR can pull the Encounter Report from known endpoints with a query based on patient details. Conformance testing will ensure that ERRs can pull the Encounter Report from known endpoints with a query based on patient details.

If a patient attends a service that is different to the one that is sent the Encounter Report push notification, then the receiving service will not have received a notification with pull down details. To mitigate this the receiving Service Provider's ERR can pull the Encounter Report from known endpoints with a query based on patient details. Conformance testing will ensure that ERRs can pull the Encounter Report from known endpoints with a query based on patient details.

Failure to identify the upstream service that created the Encounter Report would mean that the receiving Service Providers ERR could not pull down the Encounter Report. To reduce the risk of this, the CDS API implementation guide specifies how the upstream service is identified in an Endpoint resource. Conformance testing will ensure ERRs can identify upstream service Endpoints

There is the potential that suboptimal Information governance processes may lead to inappropriate denial of access to the Encounter Report. In order to provide mitigation for this the Consent resource has been included in the Encounter Report design to support the communication of consents to share data. Usage guidance to support his will provide examples of different consent types. The sending EMS is responsible for populating the Consent resource and for honouring any consent requirements regarding pushing/not pushing the Encounter Report notification or responding to a Get Encounter Report operation. Service provider testing to ensure consent is managed appropriately for their care setting. Usage guidance has been added for ERR system suppliers to consider break glass functionality for when consent is not populated in the Encounter Report and to provide guidance if Consent is not populated in the encounter Report and no other Consent is available. Conformance to validate that ERRs are compliant with Information Governance standards.

There is an external cause of this hazard where the receiving Service Provider does not act on the receipt of an encounter report notification within a clinically appropriate timescale. To reduce this risk service providers must have processes in place to ensure action is taken on the receipt of an Encounter Report notification or Encounter Report to ensure that patients receive appropriate clinical care within appropriate timescales.

Residual Risk Assessment

Consequence: Significant

Likelihood: Low

Risk category:

2	Acceptable where cost of further reduction outweighs benefits gained.

Hazard 7- Human readable version of the Encounter Report is rendered in a way that misleads

The system that receives the Encounter Report may render it in a way that misleads healthcare professionals. This includes suboptimal formatting, inappropriate filtering, misleading sorting and failure to highlight key information.

This implementation hazard assumes that the Encounter Report content received is complete and correct.

Clinical Assessment

If the ERR displays the Encounter Report in a misleading way, healthcare professionals may miss key information and make clinical decisions based on erroneous assumptions. This may lead to a delay in the delivery of appropriate care or in the delivery of inappropriate care which may cause harm.

If HCPs have any doubt about the validity of the Encounter Report they will validate it with the patient.

Initial Risk Assessment

Consequence: Considerable

Likelihood: Medium

Risk category: 3

2	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.

Evidence/Safety Argument

The Encounter Report provides the resources for the ERR to consume and build a human readable report. There is the potential that the human readable Encounter Report does not provide an appropriate level of information for receiving Service Providers to safely treat a patient. This may be due to insufficient information or too much information which may lead to healthcare professionals missing key information. To reduce the risk of this, responsibilities are defined in this Release. The sending EMS is responsible for ensuring that ALL triage journey information is included in the LIST resource and the ERR is responsible for building/rendering the human readable Encounter Report from the FHIR Resources retrieved by the GET Encounter Report Operation. It SHOULD use the structured Triage Journey information from the LIST resource which will contain ALL triage journey data sent from the upstream service provider's EMS. Usage guidance is provided on the ERR's responsibility for building and rendering a human readable Encounter Report using the LIST resource for Triage History information (in preference to the Composition Resource). Conformance to ensure that the sending EMS correctly constructs the Encounter Report LIST resource including all Triage History resources.

The ERR has control over what is displayed in the human readable Encounter Report built from the LIST resource and for undertaking a Clinical Risk Assessment to ensure that the filtered content and formatting is sufficient for the receiving Service Providers healthcare professionals to safely treat a patient . Conformance to ensure that ERR suppliers MUST be conformant with DCB0129. Service Providers to undertake a Clinical Risk Assessment to ensure that the human readable Encounter Report provides the optimal level of information to enable healthcare professionals to safely treat a patient.

To support ERRs that cannot build a human readable Encounter Report from the structured information in the LIST resource, a design decision was made that the sending EMS will ALSO send a Composition resource that includes a human readable Encounter Report. (This is in addition to the mandatory List resource containing ALL triage journey resources). The sending EMS is responsible for ensuring that ALL triage journey resources that may be required to safely treat a patient are included and suitably formatted in the human readable section of the Encounter Report Composition resource. This to be assessed as part of their 'Clinical Safety activities in accordance with DBC0129. Conformance to ensure that EMS suppliers MUST be conformant with DCB0129. Usage guidance is provided to support sending EMS's on building the composition resource.

When an ERR cannot construct a human readable Encounter Report from the Triage Journey history (List) resource it can render the human readable section of the Encounter Report Composition resource. It should be noted that this may contain more information than is required by the receiving Service Provider.

NHSD to undertake future User Research to determine if it is appropriate for the CDS API implementation guide to specify encounter report content for specific care settings.

To reduce the risk that the ERR fails to highlight key clinical information in the Encounter Report this Release defines responsibilities for rendering the Encounter Report. The ERR supplier is responsible for ensuring that key information is prominent in the Encounter Report and undertaking a Clinical Risk Assessment to ensure that relevant key information is

presented in a way that supports receiving Service Providers healthcare professionals to safely treat a patient. Conformance to ensure that ERR suppliers MUST be conformant with DCB0129.

The CDS API implementation guide provides several resources for recording key triage journey information including:

- Flags
- Provenance

Usage guidance recommends the prominent display of key information in the Encounter Report. Service Providers to undertake a Clinical Risk Assessment to ensure that the human readable Encounter Report highlights key information to enable healthcare professionals to safely treat a patient .

Residual Risk Assessment

Consequence: Considerable

Likelihood: Low

Risk category: 2

2	Acceptable where cost of further reduction outweighs benefits gained.

External Controls

There are several controls that are external to the CDS API Implementation Guidance Products that require action by CDSS/EMS suppliers developing the CDS API specified in this Release, or healthcare organisations deploying and using the CDS API specified in this Release.

These are detailed in Appendix B of this report.

System suppliers and/or deploying organisation are responsible for implementing these controls. These do not represent the totality of controls which will be identified during clinical safety activities performed by suppliers and deploying organisation in accordance with DCB0129 and DCB0160 respectively.

Functions requiring further discussion

This section discusses functions specified by this Release that require a broader discussion than that provided by the Hazard Log so that their clinical implication can be better understood by readers who are not familiar with the detail of this Release. Clinical safety activities are ongoing for these functions which are still emerging and are being informed by POCs, Alpha and Beta projects and ongoing analysis.

Continuity of triage

The CDS API Implementation Guide is being specified to support continuity of triage.

When a patient is initially triaged (e.g. by NHS 111 telephony) and is then transferred to another service provider (e.g. Clinical Assessment Service), triage questions are often repeated which can lead to a poor patient experience.

Continuity of triage allows subsequent CDSS to consume the information collected in the initial triage, where appropriate, and use it in a way to drive workflow according to its logic. For example:

- Queue management
- Skip questions where information collected previously matches a response option
- Display previous responses for validation

Safe continuity of triage relies on CDSSs creating clinical assertions from triage responses in a standard manner that preserves their clinical intent. This ensures that a downstream CDSS can consume assertions that match those required by its logic to achieve a triage outcome result. It also relies on EMSs managing assertions created during triage or from other patient information sources (e.g. GP system, Local Health Care Record) in a standard way, to ensure their clinical meaning is preserved. This enables this information to be safely displayed to end users and to be presented to subsequent CDDSs to inform the triage outcome.

If information collected in initial triage is not made available to the subsequent CDSS then continuity of triage is not possible, and the patient would be asked all the questions that the CDSS needs to determine a triage outcome. Whilst this may have a negative impact on the patient's experience it will not impact the triage outcome. This is the main mitigation for the hazard of Inappropriate Triage (H02) due to causes related to the resources and elements required to support continuity of triage.

Whilst EMS to EMS communication required for handover is out of scope for this Release, the building blocks of interoperability are being specified, in particular the FHIR Resources that carry clinical assertions and the way that they are coded.

Assertion resources

A design decision was made to use Observation resources to communicate clinical assertions in this Release. This will be further reviewed in subsequent versions when additional use cases have been considered in alpha and beta projects.

If allergic causative agents (allergens) of reported medicine allergies are recorded using Observation resources coded with SNOMED CT finding codes, other CDSS may not be able to use the code in prescribing decision support. This may contribute to patient harm. For example, a patient may state that have an aspirin allergy during initial triage and are then handed over to an Out of Hours service where they are prescribed aspirin. The aspirin allergy recorded as a Clinical Finding would not trigger a prescribing allergy alert as the prescribing CDSS requires the Dictionary of Medicines and Devices (dm+d) causative agent.

CDS API Alpha or Beta projects should explore the use of the FHIR Allergy resource coded with SNOMED CT dm+d causative agents for assertions relating to allergy. This to include a risk benefits analysis of using this as opposed to recording a SNOMED CT Clinical Finding in an Observation resource, given that the allergy is likely to be one reported by the patient rather than being a confirmed allergy.

If assertions relating to reported medications are recorded using the Observation resource coded with SNOMED CT finding codes, other CDSS may not be able to use the code in prescribing decision support. For example, a patient may state that they are taking glyceryl trinitrate during and are then handed over to an Out of Hours service where they are prescribed glyceryl trinitrate. The glyceryl trinitrate medication recorded as a Clinical Finding would not trigger a prescribing duplication alert as the prescribing CDSS requires the dm+d medication code.

CDS API Alpha or Beta projects should explore the use of FHIR Medication resources with dm+d medicine codes This to include a risk benefits analysis of using this as opposed to recording a SNOMED CT clinical finding in an Observation resource, given that the

medication is likely to be one **reported by the patient** rather than being a confirmed administration.

These should inform future versions of this Release.

Coding of assertions

In order to be interoperable assertions must be coded in a standard way. Whilst the display and utilisation of these assertions outside of the CDS API are out of scope of this Release the CDS API implementation Guide is designed to align with broader NHS data and technology standards [Reference 22] to maximise interoperability.

Observation and Condition FHIR resources capture a clinical code which may need associated context in order to be interpreted correctly.

Context includes (but is not limited to):

- Body site
- Laterality
- Temporal Context
- Absence/Presence
- Severity

For example:

A patient may provide a negative response to a question relating to blood loss. The resultant assertion may be coded with ‘Blood Loss’ with a Context of ‘absent’ and a Context of ‘Reported’.

The clinical risk associated with coded clinical information is that if the context is not considered by a receiving system, and an implicit context is used, then the meaning of the clinical information is not preserved. In the example above a system that cannot handle context may simply record ‘Blood Loss’ with an implicit context of ‘present’ and ‘proven’. This may lead to patient harm if this information is used to inform the delivery of patient care.

Many Health and Social Care IT systems do not have data models that capture all context.

Three designs were considered for the use of context modifiers:

- FHIR Modelling of Context
- SNOMED CT Modelling of Context - Post Coordination
- SNOMED CT Modelling of Context - Pre-Coordination

Following a design workshop, a decision was made to proceed by capturing all relevant context as specified elements in the FHIR resource. The argument to support this decision is detailed below.

FHIR Modelling of Context

In this option, all context is captured in the FHIR resource.

For example, the Observation resource has elements for body site, temporal context (.effective) and presence (.value). Other qualifiers can be referenced by the .related element, with a type of ‘qualified-by’.

Other resources will have different elements, which may allow the capturing of context, but each resource needs review independently.

It should be noted that context captured in this way does not use SNOMED CT codes, so may not be able to be 'reassembled' by downstream systems to create a SNOMED CT expression or concept.

This approach allows any receiving system which understands each element independently to manage the set of elements together (as they are in a single FHIR resource). This mitigates the key risk of reporting "blood loss absent" being interpreted as "blood loss".

A decision was made to proceed with this option with caution. Collaboration with other NHS Digital programmes developing API implementation guides will continue to ensure adoption of best practice and alignment of approaches.

SNOMED CT Modelling of Context – Post coordination

In this option, context is captured through SNOMED CT codes, which are post-coordinated with the core concept.

For example, the post coordination of body site and severity can be done through those SNOMED codes.

A major drawback to this option is that there is no current process for post-coordinating the temporal context which a key element of this Release. The introduction of new SNOMED CT concepts for temporal context was briefly considered but as it would have wide ranging implications outside of this Release it was not a proportionate control measure.

This option was rejected for this Release.

SNOMED CT Modelling of Context - Pre coordination

In this option, there would be different pre coordinated terms for each possible combination of core term and modifier.

For example, fever present would have a code (`103001002 Feeling feverish (finding)`) and fever absent would have a different code (`161851007 No temperature symptom (situation)`).

This option still cannot capture temporal modifiers and the volume of required pre-coordinated codes to make up the associated Value Sets would be unmanageable. This option was therefore rejected.

Default responses to triage questions

The International FHIR STU3 Clinical Reasoning Module [Reference 7] supports the concept of the CDSS defining default responses to triage questions in the Questionnare.item.initial[x] element.

Clinical assessment determined that default responses may be a cause of inappropriate triage and implementation guidance was updated in this Release to state that default questionnaire responses MUST NOT be populated by the CDSS to provide mitigation for this.

However, there may be use cases supported by CDDSs that require a default response that have not yet been identified. This should be explored in future Alpha/Beta projects and the decision revisited in a future release.

Conformance

The UECDI programme Team in conjunction with NHS Digital Solution Assurance are developing a CDS API Conformance Approach to be used to evidence that a developed product is compliant with the CDS API Implementation Guide.

It allows UEC System Suppliers to demonstrate to NHS Digital that their developed product follows guidance correctly, and therefore is likely to be interoperable with other systems using the standard. Suppliers that successfully complete the Technical Conformance process will be granted CDS API Guide Conformance certification for their product. These systems and suppliers will also be listed on NHS Digital's Conformance Catalogue.

The approach centres around suppliers referencing a requirements list and providing the required evidence to NHS Digital for assessment. Technical tooling will be provided by NHS Digital to help with the execution of test cases to demonstrate the requirements have been met. Evidence will be in the form of both test tooling log outputs and self-certifying statements.

It should be noted that for this Release NHS digital cannot mandate systems suppliers to certificate for CDS API Implementation Guide conformance nor can they mandate Service Providers to buy CDS API Implementation Guide conformant systems.

Journey process

The illustration below summarises the key stages and activities a UEC Technology supplier will go through in the conformance journey.

1. Check published conformance requirements
    - Details of the conformance process are published on NHS Digital website for Suppliers to understand the requirements and determine the feasibility of completion.
2. Access conformance resources
    - The conformance requirements list will be published on these pages of the NHS Digital developer site. The requirements list will detail all requirements that are needed to provide evidence towards a passing level of conformance.
    - Access to technical tooling will be made available with test scripts for suppliers to develop their systems to and generate conformance evidence.
3. Collect conformance evidence
    - Using the conformance requirements list Suppliers can collate their evidence. Evidence will be in the form of self-certifying statements and technical tooling log outputs.
4. Submit conformance evidence
    - Once evidence has been collected against the requirements list this can be submitted to NHS Digital for assessment.

- There may be a period of iteration where Suppliers will revise the submitted evidence until it satisfies the requirements.
- At the end of the conformance assessment process a report is generated with details of the tests.

5. Achieve conformance certificate
    - Upon passing the assessment criteria a conformance certificate is provided to the Supplier. This can be shared with provider agencies as conformance evidence.
    - Conformant systems will also be published to the Conformance catalogue on the NHS Digital website.
    - The Conformance catalogue is a way to identify all vendors and products that have been awarded Solution Assurance Conformance Certificates.
6. Tell us of any material change after go-live
    - The conformance process tests systems at a point in time. If a Supplier system has a version increment that affects the implementation of the CDS API Guide in the product, then Suppliers must work with the Solutions Assurance team to retest the affected requirements in scope to achieve an uplift of the conformance status.

Once the CDS API Implementation Guide has moved into 'Run Maintain' the Conformance process will be owned by Live Services.

Test Summary

As this is a curation process no testing activity has been undertaken but several test control measures have been identified in the Hazard Log for EMS and CDSS system suppliers. These have been added to the Conformance Approach [Reference 20] and are summarised in Appendix C.

Conformance Statement from NHSD Digital Solutions Assurance

NHS Digital are not building software or providing the end to end service and are only facilitating interoperability between third party applications. Suppliers will be required to complete a Self-certifying requirements spreadsheet that mandates they provide appropriate assurances/test evidences that their products comply with the clinical safety requirements. This document is currently being developed and will be available before a supplier makes a submission of evidence.

NHS Digital Solution Assurance (SA) and the Urgent and Emergency Care (UEC) Program team will support Private Beta suppliers in completing the requirements spreadsheet, answering any questions and ensuring suitable evidence is available.

The assurance for the UEC private beta will be conducted using the requirements spreadsheet.

A completed requirements spreadsheet submission by a supplier will capture the conformance evidence for each requirement which would be a combination of supplier self-certifying compliance statements and supplier test evidence (system screenshots, system request and response messages etc) as appropriate to each requirement.

The testing will be conducted in the UEC CDS API test engine and OpenTest test environment for message validation.

The supplier requirements spreadsheet submission including the supporting test evidence will be reviewed and signed off by Solution Assurance.

For any requirements where the supplier test evidence and/or supplier self-certifying compliance statements are found to be inconclusive to assess conformance, clarification will be sought from the UEC Program team and agreed in conjunction with the supplier.

The supplier will be awarded a conformance certificate at the end of the successful signoff of the requirements spreadsheet to be able to progress with the pilots in the live environment.

Summary Safety Statement

The NHS Digital Urgent and Emergency Care Digital Integration Clinical Lead has concluded that the CDS API Implementation Guide is acceptably safe for suppliers to build CDS APIs to support Beta projects, but wishes to impress on all system suppliers that they MUST undertake their own clinical safety work under DCB0129 before being accepted as a user of the standard.

The safety arguments above demonstrate that there is a body of evidence that substantiates that the CDS API implementation guide v2.0is fit-for-purpose and CDS APIs developed in accordance with this guide will be suitable for use **under pilot conditions**, subject to implementation risk management in accordance with DCB0160. In addition, programmes and services deploying and using CDS APIs built in accordance with this Release MUST undertake their own clinical risk management activities as defined by DBC0129 or DCB0160 for their service.

This report demonstrates that all the clinical hazards identified have been recognised and mitigated to an acceptable level of risk. All required curations have been completed with a demonstration of mitigating actions against hazards identified by those engaged with the service.

This clinical safety report concludes that it has not identified any reason as to why the CDS API implementation guide should not be used to inform the development of the CDS APIs for pilot use.

Lee Montgomery UEC DI Clinical Lead and CSO has approved the Clinical Safety Case and Hazard Log with the following statement, “I confirm that clinical safety activities in accordance with DCB0129, have reduced the clinical risk associated with the CDS API implementation Guide v2.0 to an acceptable level”.

Quality Assurance and Document Approval

The Clinical Safety Case Report and all other clinical safety documentation is stored in and managed in UEC DI Clinical Safety file located in SharePoint. Each authorised change to this document is logged and documented in the Document Control section. This document will be made available to the CareConnect FHIR Interoperability Standards (Transfer of Care and GP Connect) project board and will be incorporated into any due diligence activities undertaken by the programme in respect to future changes made to the CDS API, as outlined within Section 3, to ensure that relevant clinical safety implications are considered by all parties.

Document Control & configuration Management

This document is configured and controlled in conformance with the Clinical Safety Management System.

In future all changes to the safety documentation in this and future stages will be instigated and controlled by the programme team. Clinical review will be undertaken in accordance with the UEC Clinical Risk Management Plan (Reference 8).

Previous versions of this report will be held in the CDS API Clinical Safety file archive folder.

The latest published version of this report will be shared on the CDS API Implementation guide site to inform organisations developing an API in accordance with this Release.

Appendix A – Risk Classification Matrix

Clinical Risk Management 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
		Consequence				

Table 4 Clinical Risk Management Risk Matrix

Risk Matrix key - Severity

5	Unacceptable level of risk.
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk Attempts should be made to eliminate or control 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.
1	Acceptable, no further action required

Table 5 Risk Matrix key - Severity

Hazard likelihood definitions

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
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 6 Hazard likelihood definitions

Hazard Consequence definitions

Consequence 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 7 Hazard consequence definitions

Appendix B – External controls

There are several controls that require action to be undertaken by CDSS/EMS suppliers developing the CDS API specified in this Release, or by healthcare organisations deploying the CDS API specified in this Release.

These can be viewed using relevant filters in the Hazard Log but are also are summarised in table 9 below for ease of access.

System suppliers and/or deploying organisations are responsible for implementing these controls. These do not represent the totality of controls which will be identified during clinical safety activities performed by suppliers and deploying organisation in accordance with DCB0129 [Reference 3] and DCB0160 [Reference 6] respectively.

[Reference Num	Hazard Name	Possible Causes	Additional controls	Control type	Control owner
H01	Absent or incomplete triage	0101 Messaging failure	010102 Deployment organisations to put service desk processes in place to manage failed message queues.	Process	Deploying organisation
		0102 Malicious attack	010202 Deploying organisation to undertake security testing of their deployment.	Test	Deploying organisation
		0103 Clinical decision logic to support the triage of a given presenting complaint cannot be found.	010301 Deploying healthcare organisations to ensure through clinical integrity checking that deployed CDSS(s) cover presenting complaints appropriate for the care setting in which they are deployed.	Test	Deploying organisation
		0105 Presenting complaint is not coded correctly	010501 The CDSS is responsible for ensuring that the presenting complaint is coded in a conformant manner. This may be by use of Natural Language processing.	Design	CDSS supplier
			010502 EMS suppliers to consider system behaviour to ensure that End Users can validate the coded presenting complaint during their Clinical Safety activities in accordance with DCB0129	Design	EMS supplier
		0107 CDSS erroneously returns a false response to an $IsValid query. This means the EMS would not search for Service Definitions on this CDSS.	010701 Implementation testing to ensure that $IsValid returns all CDSS shat should be valid for that patient.	Test	Service Provider

[Reference Num	Hazard Name	Possible Causes	Additional controls	Control type	Control owner
H02	Inappropriate triage	0201 Wrong clinical decision support logic (ServiceDefinition) used for patient's presenting complaint	020101 CDSS supplier is responsible for publishing the ServiceDefinition resource which describes which decisions the CDSS can provide support for, under what circumstances the CDS is valid, and the information needed to render the decision. This must be conformant with the CDS API ServiceDefinition Implementation Guidance.	Design	CDSS supplier
		0202 Errors in Service Definition	020201 It is assumed that CDSS suppliers will undertake testing to ensure that selection of a ServiceDefinition launches the expected triage logic	Test	CDSS supplier
		0201 Wrong clinical decision support logic (ServiceDefinition) used for patient's presenting complaint	020103 EMS suppliers to consider system behaviour to ensure that End Users can validate that the CDS is appropriate for the patient's presenting complaint in their Clinical Safety activities.	Design	EMS supplier
		0203 Test Service definition gets into Live	020301 CDSS suppliers' governance processes to include the safe publication of Service Definitions.	Design	CDSS Supplier
		0203 Test Service definition gets into Live	020302 Deploying service providers' governance processes to include the safe publication of Service Definitions.	Design	Deploying organisation
		0204 Observations from another patient are consumed by the CDSS	020402 CDSS MUST only consume assertions where the Observation.subject matches the ServiceDefinition.$evaluate.patient	Design	CDSS Supplier
		0205 Assertions from a different encounter (same patient) are consumed by the CDSS in error. (This excludes intended use of assertions from different encounters e.g. Patient Medical History)	020402 CDSS MUST consider the Observation.context in its logic.	Design	CDSS supplier
		0206 Time dependant Observations that are no longer current are consumed by the CDSS	020604 CDSS MUST consider the Observation temporal meta data in its logic before consuming it to drive system behaviour (e.g. skipping questions, validating responses).	Design	CDSS Supplier

[Reference Num	Hazard Name	Possible Causes	Additional controls	Control type	Control owner
		0207 Assertion from third party clinical content consumed by CDSS is not equivalent to the same assertion recorded locally. e.g. prompted from a question with a different clinical intent to the local question	020702 The CDSS supplier is responsible for creating coded assertions that accurately reflect the clinical meaning of the answers provided in the QuestionnaireResponse to the questions detailed in the associated Questionnaire.	Design	CDSS Supplier
		0210 The wrong version of an assertion is consumed by the CDS API. E.g. An observation/assertion that has been subsequently amended.	021002 The FHIR resource server is responsible for storing each version of an assertion within a patient encounter and for determining which version is passed to the CDS API in the ServiceDefinition$Evaluate at any point in the encounter.	Design	Deploying Organisation
		0211 Presenting complaint incorrect. E.g. CDSS codes presenting complaint incorrectly by. NLP failure.	021102 The CDSS is responsible for correctly coding the presenting complaint and for the CDS logic associated with that.	Design	CDSS supplier
		0211 Presenting complaint incorrect. E.g. CDSS codes presenting complaint incorrectly by. NLP failure.	021104 EMS suppliers will assess the risk of the display of ServiceDefnition.title, .description and .purpose to end users in their Clinical Safety activities.	Design	EMS supplier
		0217 Questions may become ambiguous when more than one Service Definition is running concurrently. E.g. Headache and leg pain and a question of how much does it hurt or how long have you had it?	021702 CDSS supplier to ensure that all questions and permitted responses are self-contained and self-explanatory	Design	CDSS supplier
H02	Inappropriate triage	0218 Notes made by Clinicians are not taken into consideration by the CDSS.	021802 Assumed control that EMS suppliers will assess the risk of providing notes fields that are not taken into consideration by the CDSS.	Design	EMS supplier
H03	Triage outcome information misleads HCPs	0302 Use of clinical qualifiers mislead. E.g. If the observation code is 'Haemorrhage' and the qualifier is 'absent' and the	030201 Implementation guidance to ensure that clinical meaning is preserved for all clinical resources in a consistent manner in line with NHS terminology standards e.g. SNOMED CT SCCI034	Design	CDSS supplier

[Reference Num	Hazard Name	Possible Causes	Additional controls	Control type	Control owner
		observation code is taken in isolation, it may lead to inappropriate clinical decisions by clinicians.			
H03	Triage outcome information misleads HCPs	0302 Use of clinical qualifiers mislead. E.g. If the observation code is 'Haemorrhage' and the qualifier is 'absent' and the observation code is taken in isolation, it may lead to inappropriate clinical decisions by clinicians.	030202 CDSS suppliers are responsible for ensuring that that the assertions (generally Observation resources) are coded to preserve the clinical meaning of the response. This includes the use of relevant clinical qualifiers e.g. Observation value	Design	CDSS supplier
H03	Triage outcome information misleads HCPs	0302 Use of clinical qualifiers mislead. E.g. If the observation code is 'Haemorrhage' and the qualifier is 'absent' and the observation code is taken in isolation, it may lead to inappropriate clinical decisions by clinicians.	030203 CDSS suppliers are responsible for ensuring that that Chief and Secondary Concerns (Condition resources) are coded in a way that that conveys their clinical meaning and can be consumed by downstream systems (e.g. EMS, Directory Services) . This includes the use of relevant clinical qualifiers.	Design	EMS supplier
H03	Triage outcome information misleads HCPs	0302 Use of clinical qualifiers mislead. E.g. If the observation code is 'Haemorrhage' and the qualifier is 'absent' and the observation code is taken in isolation, it may lead to inappropriate clinical decisions by clinicians.	030204 Where assertions are stored, displayed or communicated by the EMS they must include all elements required to preserve clinical meaning.	Design	EMS supplier
H05	Encounter report content incomplete or incorrect	0501 Corruption in transit	050101 Implementation control to ensure that transport protocols are suitable for alerting or avoiding corruption	Process	Service Provider
		0502 Corruption at rest. E.g. EMS fails to build correctly or ERR fails to store correctly	050202 Service Provider testing to ensure that their local implementation correctly builds and stores Encounter Report content.	Test	Service Provider

[Reference Num	Hazard Name	Possible Causes	Additional controls	Control type	Control owner
		0503 Receiving service provider or service does not receive enough structured Encounter Report content to drive their business processes	050306 Service Providers to ensure that the specific Encounter Report content is sufficient to drive their business processes at implementation.	Test	Service Provider
		0504 Receiving service provider fails to undertake actions communicated in the Encounter Report.	050404 ERR suppliers to undertake clinical safety activities to ensure that actions communicated in Task resources are displayed appropriately and used to drive system behaviour to support service providers in task management.	Process	ERR suppliers
		0504 Receiving service provider fails to undertake actions communicated in the Encounter Report.	050405 Service providers to put processes in place to ensure actions communicated in Task resources are acted on within appropriate timescales.	Process	Service Provider
		0506 Retrieval of wrong patient's Encounter Report	050607 ERR users should positively identify the patient and record match before acting on it, in accordance with their organisation's Patient Identification Policy.	Process	Service Provider
		0507 Failure to handle image Questionnaires correctly e.g. Show me on this image where your abdominal pain is)	CDSS supplier to ensure that when a Questionnaire image is changed that a new version of the Questionnaire is created.	Process	CDSS supplier
H06	Encounter Report is not retrieved by the relevant service provider or service	0604 Failure of ERR to pull the Encounter Report using $GETENCOUNTER REPORT	060401 In the absence of the Encounter Report healthcare professionals will undertake full triage.	Process	Service Provider
		0607 Information governance processes lead to inappropriate denial of access.	060704 Service provider testing to ensure consent is managed appropriately for their care setting	Test	Service Provider

[Reference Num	Hazard Name	Possible Causes	Additional controls	Control type	Control owner
		0607 Information governance processes lead to inappropriate denial of access.	060705 ERR to consider break glass functionality for when consent is not populated in the Encounter Report.	Design	ERR suppliers
		0608 Receiving Service Provider does not act on the receipt of an encounter report notification or encounter report within a clinically appropriate timescale	060708 Service providers must have processes in place to ensure action is taken on the receipt of an Encounter Report notification or Encounter Report to ensure that patients receive appropriate clinical care within appropriate timescales.	Process	Service Provider
H07	Human readable version of the Encounter Report is rendered in a way that misleads	0701 The human readable Encounter Report does not provide an appropriate level of information for receiving Service Providers to safety treat a patient. This may be due to insufficient information or too much information which may lead to healthcare professionals missing key information.	070101 The ERR is responsible for building/rendering the human readable Encounter Report from the FHIR Resources retrieved by the GET Encounter Report Operation. It SHOULD use the structured Triage Journey information from the LIST resource which will contain ALL triage journey data sent from the upstream service provider's EMS	Design	ERR suppliers
		0701 The human readable Encounter Report does not provide an appropriate level of information for receiving Service Providers to safety treat a patient. This may be due to insufficient information or too much information which may lead to healthcare professionals missing key information.	070106 The sending EMS is responsible for ensuring that ALL triage journey resources that may be required to safely treat a patient are included and suitably formatted in the human readable section of the Encounter Report Composition resource. This to be assessed as part of their 'Clinical Safety activities in accordance with DBC0129	Process	EMS supplier
		0701 The human readable Encounter Report does not provide an appropriate level of information for receiving Service Providers to safety	070110 The ERR has control over what is displayed in the human readable Encounter Report built from the LIST resource and for undertaking a Clinical Risk Assessment to ensure that the filtered content and formatting is sufficient for	Process	ERR supplier

[Reference Num	Hazard Name	Possible Causes	Additional controls	Control type	Control owner
		treat a patient. This may be due to insufficient information or too much information which may lead to healthcare professionals missing key information.	the receiving Service Providers healthcare professionals to safely treat a patient .		
		0701 The human readable Encounter Report does not provide an appropriate level of information for receiving Service Providers to safety treat a patient. This may be due to insufficient information or too much information which may lead to healthcare professionals missing key information.	070112 Service Providers to undertake a Clinical Risk Assessment to ensure that the human readable Encounter Report provides the optimal level of information to enable healthcare professionals to safely treat a patient .	Process	Service Provider
		0702 ERR fails to highlight key clinical information in the Encounter Report.	070201 The ERR supplier is responsible for ensuring that key information is prominent in the Encounter Report and undertaking a Clinical Risk Assessment to ensure that relevant key information is presented in a way that supports receiving Service Providers healthcare professionals to safely treat a patient .	Process	ERR supplier
H07	Human readable version of the Encounter Report is rendered in a way that misleads	0702 ERR fails to highlight key clinical information in the Encounter Report.	070204 Service Providers to undertake a Clinical Risk Assessment to ensure that the human readable Encounter Report highlights key information to enable healthcare professionals to safely treat a patient .	Process	Service Provider

Table 8 External controls

Appendix C – Conformance Test safety requirements

The following test control measures have been identified for inclusion in the CDS API Conformance Approach [Reference 20].

ID	Conformance test requirement
010104	Verification of the appropriate use of error codes due to messaging failure.
010106	Verification of pre-requisites for CDS API FHIR servers.
010108	Verification that when the EMS invokes a ServiceDefinition.$evaluate operation it references a QuestionnaireResponse and ALL previous assertions (Observation resources) for the CDSS to evaluate. This to include negative testing and interruptions.
010303	Verification that each CDSS has published a ServiceDefinition with a 'NULL' Trigger
010305	Verification that all CDSS ServiceDefinitions are conformant with CDS API guidance
010307	Verification that the EMS can: • Initiate the selection of a ServiceDefinition • Initiate the evaluation of a ServiceDefinition
010402	Verification that all ServiceDefinitions end in a Result or to point to another ServiceDefinition
020201	Verification that selection of a CDSS ServiceDefinition launches the expected triage logic
020301	Verification that only Service Definitions with a status of 'Active' can be used in Live.
020603	Verification that Observations that have exceeded their 'effective' date/time are not consumed by CDSSs.
020802	Verification that CDSS Observations (assertions) are conformant with the defined Value Sets
020902	Verification of logical completeness of CDSS Service Definitions. E.g. If SD1 ends with SD3 and Result 4 they have to exist.
021004	Verification that the EMS passes the latest version of an assertion within an encounter to the CDS API in the ServiceDefinition$Evaluate.
021103	Verification that CDSS supplier has undertaken testing to ensure accurate coding of presenting complaint. This must include NLP testing if this is used.
040202	Directory Service must be able to return a bundle of Healthcare Services that match the ReferralRequest defined in the GuidanceResponse.
040302	EMS must be able to consume the bundle of Healthcare Services, returned by the Directory Service, that match the ReferralRequest defined in the GuidanceResponse.
050201	Conformance testing to ensure that the system behave consistently in accordance with the CDS API implementation Guide
050305	Conformance to ensure that ERR can produce Encounter Report content in accordance with the CDS API implementation guidance
050402	Conformance to ensure that EMSs can build Task resources
050403	Conformance to ensure that ERRs must be able to receive and consume as appropriate Task resources

050501	NHSD to have a conformance approach to connect to RCS
050502	EMS conformance testing to connect to RCS
060102 060202 060302	Conformance to ensure that ERRs can pull the Encounter Report from known endpoints with a query based on patient details
060602	Conformance testing to ensure ERR can identify upstream service Endpoints
060707	Conformance to validate that ERRs are compliant with Information Governance standards.
070104	Conformance to ensure that the sending EMS correctly constructs the Encounter Report LIST resource including all Triage History resources.
070107	Conformance to ensure that EMS suppliers are conformant with DCB0129
070111 070202	Conformance to ensure that ERR suppliers are conformant with DCB0129
070114	Conformance to ensure that the ERR can build/render the human readable Encounter Report from the FHIR Resources retrieved by the GET Encounter Report Operation