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Clinical Safety Case for the Curation of National CareConnect FHIR Interoperability Standards as used in Transfer of Care and GP Connect

Document Management

Revision History

Version	Date	Summary of Changes
0.1	27/03/2018	First draft
0.2	12/04/2018	Second draft
0.3	20/04/2018	Third Draft

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
FHIR Project Team	Project Team	20/04/2018	0.3
Stuart Harrison	Head of Safety Engineering	23/04/2018	1.0
Clinical Safety Team	Safety Engineers / Clinical Safety Officers	23/04/2018	1.0

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
Amir Mehrkar		Senior Clinical Lead – interoperability and architecture	23/04/2018	1.0
Munish Jokhani		Clinical engagement lead – Programme 13	23/04/2018	1.0

Glossary of Terms

Term / Abbreviation	What it stands for
CATR	Clinical Authority to Release
CRMP	Clinical Risk Management Plan
CSMS	Clinical Safety Management System
FHIR	Fast Healthcare Interoperability Resources
PRSB	Professional Record Standards Body

Document Control:

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Related Documents

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

Ref	Doc Reference Number	Title	Version
1.	NPFIT-FNT-TO-TOCLNSA-0949.01	Clinical Safety Management System	1.1
2.	SCCI 0129 Amd 39/2012	Clinical Risk Management: its Application in the Manufacture of Health IT Systems.	4.0
3.	NPFIT-FNT-TO-TOCLNSA-1999.01	National CareConnect FHIR Interoperability Standards Mapping Clinical Risk Management Plan	1.0
4.	https://drive.google.com/drive/folders/1jJPmKi7qyk7V4aKaDRZ8KUQJY-ephHbh	Location of the Clinical Safety Case Report in the FHIR INTEROPen google drive	1.0
5.	https://drive.google.com/drive/folders/1jJPmKi7qyk7V4aKaDRZ8KUQJY-ephHbh	Location of FHIR curation documents INTEROPen google drive	
6.	https://drive.google.com/open?id=1PkdrXAML4z6attSrSnWF450DFBZrjLA5PZw1R9q3Ttg	INTEROPen Master Design Decision Matrix (DDM) STU3 CareConnect Curation Google Sheet	
7.	https://drive.google.com/drive/folders/1jJPmKi7qyk7V4aKaDRZ8KUQJY-ephHbh	Location of the FHIR Interoperability Standards Mapping_Transfer of Care and GP Connect_Hazard Log v1.0 in the FHIR INTEROPen google drive	1.0
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1 Executive Summary

FHIR® – Fast Healthcare Interoperability Resource – is a next generation standards framework created by HL7. FHIR combines the best features of HL7's v2 , HL7 v3 and CDA product lines while leveraging the latest web standards and applying a tight focus on implementability.

FHIR solutions are built from a set of modular components called "Resources". These resources can easily be assembled into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, and much more.

The curation of National CareConnect FHIR Interoperability Standards Mapping (Transfer of Care and GP Connect) project was set up to curate the FHIR profiles for the Transfer of Care and GP Connect use cases. All FHIR profiles for the identified use cases have completed curation on 16/03/2018 as planned. The project has met its objectives and delivered the scope identified in the resource plan.

Several face-to-face workshops and WebEx curation calls were held to get agreement on the mapping of PRSB clinical information models to FHIR resources; the resultant mappings creates a “profile” of the resource for use in the UK, which are being referred to as UK CareConnect profiles to support interoperability. The classification of CareConnect is found [here](#).

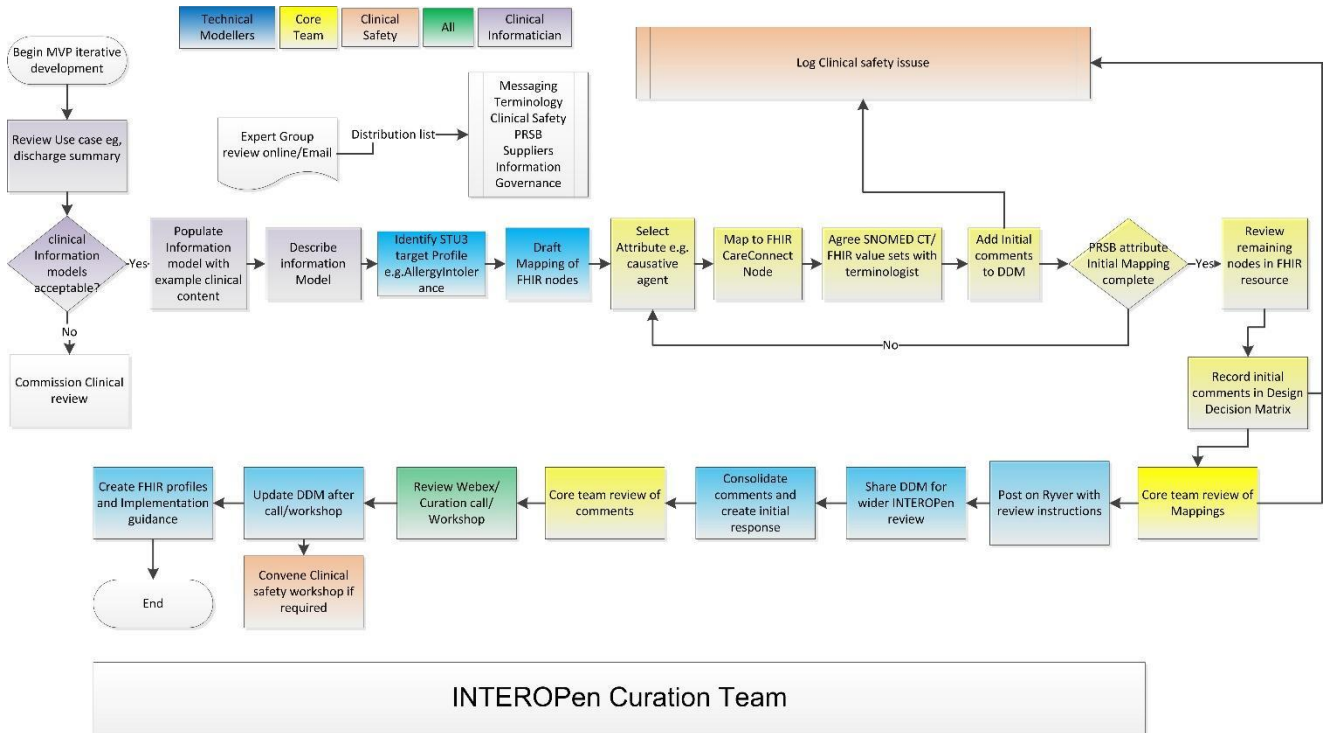
The following 16 CareConnect profiles were curated:

- Patient
- Encounter
- Organization
- Practitioner
- PractitionerRole
- Location
- MedicationStatement
- MedicationRequest
- Medication
- AllergyIntolerance
- Condition
- Observation
- Immunisation
- Procedure
- Composition
- List

The curation process has led to significant changes to initial FHIR standards for how Medications and Problem Lists are represented, in large part influenced by the expert input of clinical informaticians, PRSB, and terminologists, supported by technical experts, clinical safety team and INTEROPen vendor members. The process was endorsed by NHS Digital Domain C and Domain D programme boards.

Everyone worked together as part of the INTEROPen interoperability collaborative, using its RYVER communication platform to manage the process.

The curation mapping methodology has iterated during the process, and is summarised here:



Clinical hazards of mapping PRSB information model headings to FHIR artefact elements were captured during these sessions.

Table 1 Summary of Hazards Risk Scores below, summarises the findings of the clinical risk management activities. A total of ten (10) hazards were identified and assessed with mitigations and residual scores.

The programme safety team consider the overall risk of the National CareConnect FHIR Interoperability Standards (initially being used for Transfer of Care and GP Connect) as acceptability safe.

Table 1 Summary of Hazards Risk Scores

Initial	Residual	Risk rating	Definition
0	0	5	Unacceptable level of risk.
0	0	4	Mandatory elimination or control to reduce risk to an acceptable level
6	1	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.
4	9	2	Acceptable where cost of further reduction outweighs benefits gained.
0	0	1	Acceptable, no further action required

There are number of other projects e.g. Reasonable Adjustments Flag, Digital Medicines and Child Health which will benefit from the curation. The curation of National CareConnect FHIR Interoperability Standards project is ready to transition its methodology/process and resourcing requirements to a Business as Usual (BAU) function. A feedback review with curation members has been undertaken to improve the methodology, and it is expected the methodology will over as requirements and technologies change.

The feedback received is found at:

[<https://docs.google.com/document/d/1N2Exj2MsRimH2wwwY34WpIWyNlikOihvdeNHqyo62il/edit>]

A summary presentation of the feedback at:

[https://docs.google.com/presentation/d/1Wc_AT06ahxIWhBHiWjDDvjWnBuB_dIDQxn0fj9lf6zo/present?ueb=true#slide=id.g3576ca51cb_1_1]

2 Introduction

The purpose of this document is to identify, assess and manage any clinical safety hazards arising from the creation and implementation of FHIR standards and the parts of the process where NHS Digital has direct control. It demonstrates that hazards associated with the programme have been identified and managed wherever possible to ensure they do not give rise to unacceptable risks to patients.

3 System Definition and Scope

The scope of phase 1 from December 2017 to March 2018 included curation of 16 CareConnect profiles as below:

- Patient
- Encounter
- Organization
- Practitioner
- PractitionerRole
- Location
- MedicationStatement
- MedicationRequest
- Medication
- AllergyIntolerance
- Condition
- Observation
- Immunisation
- Procedure
- Composition
- List

The output of the curation process for the above 16 generic care connect profiles with agreed value sets were reviewed for the 4 transfer of care use cases, i.e.,

- Inpatient Discharge Summary;
- Mental Health Discharge Summary;
- Emergency Care Discharge Summary;
- Outpatient Letters; and
- GP Connect.

This also created constraints (either profiles or implementation guidance) for the Transfer of Care and GP Connect use cases but these do not apply to generic Care Connect profiles. The classification of generic/parent profiles and, child or use case specific is found [here](#)

The scope excludes any gap analysis with the US version of the FHIR which is constrained for the Argonaut project for the meaningful use. Extra messaging team resources will be required if this is included in the scope.

4 Clinical Risk Management System

See also National CareConnect FHIR Interoperability Standards Mapping Clinical Risk Management Plan (Ref 3) which defines more details on the scope and resourcing of this programme of work.

4.1 Clinical Risk Analysis, Evaluation and Control

The approach to Hazard identification took two forms:

1. Identification and reviewing hazards identified during the scheduled workshops and curation calls. These have been identified as part of the development and use of PRSB and FHIR standards by numerous subject matter experts (including Technical and Clinical) and so are considered a tried and tested source of information. The list of attendees to each workshops/curation calls is maintained by the CareConnect FHIR Interoperability Standards (Transfer of Care and GP Connect) project manager; and
2. Perform Structured What If Technique (SWIFT) method of hazard identification. SWIFT considers deviations from normal operations identified by brainstorming, with questions beginning “What if...?” or “How could...?”. It includes functions, information and users and takes the form of a brain storming exercise with participation of a cross section of relevant expertise.

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.

Refer to Appendix B for list of workshops/calls.

Identified hazards are recorded in the hazard log, see: FHIR Interoperability Standards Mapping_Transfer of Care and GP Connect_Hazard Log v1.0.

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

4.2 Hazard Log

Of the thirteen (10) hazards identified, six (6) hazards were initially scored at a risk rating of three (3) and four (4) hazards at a risk rating of two (2). These hazards were then mitigated with relevant controls, and nine (9) hazards and one (1) hazards were re-scored with a residual risk rating of two (2) and three (3) respectively.

It is considered that this risk profile is acceptable as the programme is an ‘interoperability and standards’ programme and not patient facing. The hazards will then be reviewed during the deployment of the service.

The table below summaries the findings of the clinical risk management activities.

Summary of hazards risk scores

Initial	Residual	Risk rating	Definition
0	0	5	Unacceptable level of risk.
0	0	4	Mandatory elimination or control to reduce risk to an acceptable level
6	1	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.
4	9	2	Acceptable where cost of further reduction outweighs benefits gained.
0	0	1	Acceptable, no further action required

The Hazard Log is attached below:



FHIR Interoperability
Standards Mapping_T

4.3 Test Issues

As this is a curation process no testing activity has been undertaken.

5 Summary Safety Statement

The FHIR Interoperability Standards Programme has agreed with the Clinical Safety Team to subject the FHIR Standards Mapping project to the clinical safety process. The NHS Digital Interoperability Senior Clinical Lead has concluded that the programme is acceptably safe (Refer to Appendix C) but wishes to impress on all programmes and services that they will need to undertake their own clinical safety work under SCCI 0129 before being accepted as a user of the standards.

The safety arguments above demonstrate that there is a body of evidence that substantiates that the CareConnect FHIR Interoperability Standards for Transfer of Care and GP Connect are fit-for-purpose and suitable for live use, subject to implementation risk management SCCI 0160. However, programmes and services using these defined standards will need to undertake their own clinical risk management activities as defined by SCCI 0129 or SCCI 0160 for the services in which they implement, that utilise these FHIR profiles.

This document and attachment demonstrate that all the clinical hazards identified have been recognised and mitigated to as low as reasonably practical (ALARP). All required curations have been completed with a demonstration of mitigating actions against hazards identified by those engaged with the service. There have been no concerns expressed by the CareConnect FHIR Interoperability Standards Mapping (Transfer of Care and GP Connect) project team concerning the move into the live environment.

All reasonable measures have been taken to ensure the transition to and use of CareConnect FHIR Interoperability Standards (Transfer of Care and GP Connect) is clinically safe. This clinical safety report concludes that it has not identified any reason as to why the CareConnect FHIR Interoperability Standards (Transfer of Care and GP Connect) functionality should not be deployed to the wider health and social care organisations.

Dr Amir Mehrkar has approved the Clinical Safety Case and Hazard Log with the following statement, *“I confirm it is safe to release the FHIR Interoperability Standards for Transfer of Care and GP Connect from the curation process into the next stage of FoT testing into the service.”*

6 Quality Assurance and Document Approval

The Clinical Safety Closure Report and all other clinical safety documentation is stored in and managed in the CareConnect FHIR Interoperability Standards (Transfer of Care and GP Connect) Programme located at the INTEROPen google drive (Ref 5). 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 CareConnect FHIR Interoperability Standards (Transfer of Care) and GP Connect core capabilities, as outlined within Section 3, to ensure that relevant clinical safety implications are considered by all parties.

7 Configuration Control / 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.

8 Appendix A – Risk Classification Matrix

Table 2 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
		Severity				

Table 3 Risk Matrix key

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 4 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 5 Hazard Severity definitions

Severity Classification	Interpretation	Number of Patients Affected
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma.	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term.	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity	Single

9 Appendix B – List of workshops/calls

The milestone sheet is available from the link:

https://drive.google.com/open?id=1gpFvnRbzEGzrreVPHX__uMXhN10e7Pu-aptLqfw9AFo

Below is the link to the January workshop presentation:

https://docs.google.com/presentation/d/13zOXxUu2n10szsE_Bbm2rRVDO41PLguAYHIEX42OT1I/edit#slide=id.p3

10 Appendix C – Clinical Lead confirmation

From: MEHRKAR, Amir (NHS DIGITAL)
Sent: 20 April 2018 15:59
To: BICKHAN, Zak (NHS DIGITAL) <zak.bickhan@nhs.net>; JOKHANI, Munish (NHS DIGITAL) <munishjokhani@nhs.net>; PERRY, Andrew (NHS DIGITAL) <andrew.perry8@nhs.net>; BARNET, David (NHS DIGITAL) <david.barnet@nhs.net>
Cc: GARRITY, Sandy (NHS DIGITAL) <sandy.garrity@nhs.net>
Subject: RE: FHIR Interoperability Standards for Transfer of Care and GP Connect - In preparation for Clinical Safety Group on Wed 25th of April 2-3pm [a 15-20 mins slot]
Importance: High

Dear Zak,

Attached is my track changes. I doubt much else need – Munish (Andrew) do confirm with Zak by lunchtime Monday if you want to change anything in my document.

Ive added hyperlinks too.

Munish is finalising the HL and will send to Andrew, Dave and I before we send to you by Lunchtime Monday.

My safety statement: I confirm it is safe to release the FHIR Interoperability Standards for Transfer of Care and GP Connect from the curation process into the next stage of FoT testing into the service.

BW
Amir