UK Core Fast Healthcare Interoperability Resources (FHIR) Release 4 (R4) Governance

Specification and Guidance

DAPB4020 Amd 33/2021

Improving lives with data and technology

Data Alliance Partnership Board

The Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, has approved a new information standard for publication under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and endorsed by the Data Alliance Partnership Sub Board (DAPSB).

This information standard comprises the following documents:

- Specification and Guidance

An Information Standards Notice (DAPB4020 Amd 33/2021) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

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Contents

Glossary

Term or Abbreviation	Definition
Apache License, Version 2	The Apache License Version 2 is an open source software license.
BCS Health and Care	British Computer Society Health and Care was formed to cover all aspects of informatics in support of health and care, a sector of particular relevance and importance to BCS.
CareConnect	Care Connect assets were developed in HL7 FHIR STU3 collaboratively by HL7 and the INTEROPen community with NHS Digital as the development partner.
CASPA	The Care Software Providers Association is an independent association representing the views and interests of social care software providers.
CCIO Network	The CCIO Network promotes the development of Chief Clinical Information Officers across the NHS. The rapidly growing best practice and expert end user community is delivered through regular meetings and online events and collaboration community. The network is open to all current and aspiring clinical information leaders.
CIO Network	The UK CIO Network gathers the UK's most influential IT Leaders from the UK's largest organisations to network, share best practice and discuss the upcoming challenges and opportunities arising from the latest technology.
CodeSystems	Many elements in the FHIR resources have a coded value. CodeSystems define concepts and give them meaning through formal definitions and assign codes that represent the concepts. The HL7 FHIR standard includes detailed discussion about CodeSystems.
Data types	Explanation of data types can be viewed online.
Coded datatypes	Further information about the use of terminologies in HL7 FHIR can be viewed online.
ConceptMaps	A concept map defines a mapping from a set of concepts defined in a code system (commonly referred to as the "system") to one or more concepts defined in other code systems. Further information about ConceptMaps can be viewed online.
Configuration management	This is a systems engineering process for establishing and maintaining consistency of a product's performance, functional, and physical attributes with its requirements, design, and operational information throughout its life. Further information about Configuration management can be viewed online.
Data Alliance Partnership Board (DAPB)	The Data Alliance Partnership Board (DAPB) has been established as part of a system-wide information and technology governance model. The DAPB acts with delegated authority from the Secretary of State for Health and Social Care as the main governance route through which all requirements for information standards and data collections are agreed and priorities assigned.
Data models	A model that organizes elements of data and standardises how they relate to one another and to the features of real-world entities. In the case of HL7 FHIR data models (resources), these are entities relating to healthcare e.g. Patient, Condition, Medication.
DHCW	Digital Health and Care Wales is a new Special Health Authority created to take forward the digital transformation needed for better health and care in Wales, making services more accessible and sustainable while supporting personal health and well-being. Read more about DHCW.
dm+d	The dm+d is an approved national standard for the NHS in England and comprises of a dictionary of descriptions and codes which represent medicines and devices.

FCI	The Faculty of Clinical Informatics is the multi-disciplinary professional body for all health and social care qualified individuals working as informaticians across the UK.
HL7 FHIR	FHIR is a standard for health care data exchange, published by HL7. The version of the UK Core referred to in this standard is HL7 FHIR R4.
HL7 FHIR terminologies	HL7 FHIR uses standard healthcare terminologies. Many data elements in resources have coded datatypes. These use sources such as HL7 terminologies or terminologies like SNOMED CT. Read more about the standard healthcare terminologies used in HL7 FHIR.
HL7 FHIR version	FHIR version information appears on the HL7 website alongside details of change management.
HL7 UK	HL7 UK looks after HL7 activities in the UK.
HL7 UK ballot process	Information about the ballot process can be viewed online.
HL7 FHIR US Core	The US Core defines HL7 FHIR profiles customised for US use and guidance for implementers.
HSCNI	Health and Social Care in Northern Ireland is provided as an integrated service, incorporating several organisations which work together to plan, deliver and monitor Health and Social Care in this country. Relevant links are available online.
Implementation Guide	An implementation guide is a set of rules about how HL7 FHIR resources are used (or should be used) to solve a particular problem, with associated documentation to support and clarify the usage.
INTEROPen	INTEROPen is an action group to accelerate the development of open standards for interoperability in the health and social care sector.
IOPS	NHS Digital Interoperability Standards Team
JSON	This stands for JavaScript Object Notation and is a lightweight, straightforward and readable language used for open data exchange.
NHS Data Model and Dictionary	The NHS Data Model and Dictionary provides a reference point for approved Information Standards Notices to support health care activities within the NHS in England.
NHS Digital	NHS Digital teams design, develop and operate the national IT and data services that support clinicians at work, help patients get the best care, and use data to improve health and care. Read more about NHS Digital.
NHSE&I	NHS England and NHS Improvement (NHSE&I). The Transformation Directorate of NHSE&I supports local NHS and care organisations to digitise their services, connect the health and social care systems through technology and transform the way patients' care will be delivered at home, in the community and in hospital. This work was previously undertaken by NHSX, which closed in January 2022.
NHS Health Scotland	NHS Health Scotland is a national Health Board working to reduce health inequalities and improve health. Read more about NHS Health Scotland.
NHS Long Term Plan	The NHS Long Term Plan is drawn up by frontline staff, patient groups, and national experts and sets direction and strategy for the NHS for the next ten years.
NHS Wales	The NHS in Wales.
NHS Wales Data Dictionary	The NHS Wales Data Dictionary is a guide to the definitions, collection and interpretation of nationally agreed data standards adopted by the NHS in Wales.
PRSB	The Professional Record Standards Body is a collaboration of groups representing those who receive and provide health and social care across the UK, as well as those providing the IT systems that support care. Read more about the PRSB.
Ryver	Ryver is an online chat tool which also includes functionalities such as posts and comments.

Simplifier	Simplifier.net is a FHIR registry where FHIR resources can be published and managed. It is also a collaboration platform with a news item functionality. Further information about Simplifier and its features is available.
Simplifier packages	Simplifier packages contain FHIR assets present in a Simplifier Implementation Guide and can be downloaded by implementers who can use them to verify that their messages conform to the UK Core standard.
Semantic Versioning Standard	The Semantic Versioning Standard offers simple set of rules and requirements that dictate how version numbers are assigned and incremented.
SNOMED CT	SNOMED CT is an approved national standard for the NHS in England. It comprises of an international clinical terminology that provides the vocabulary for use in systems to support the recording of information in relation to the direct management of the health and care of an individual.
techUK	techUK is a trade association which brings together people, companies and organisations to realise the positive outcomes of what digital technology can achieve. Read more about techUK.
Transfer of Care	A term used to describe the exchange of inpatient discharge summary documents and outpatient letters from hospitals to GP practices. FHIR specifications for these uses cases can be viewed.
UK Core assets	UK Core assets is a group term for all the things (files/content) that make up an implementation guide. They are all capable of being validated against the FHIR specification. Read more about UK Core assets.
UK Core Clinical and Technical Assurance process	A team of subject matter experts map use case specific clinical information models, for example, allergies and adverse reactions, to the AllergyIntolerance FHIR resource. This mapping produces a “profile” or customisation of the international base resource. Further information about UK Core Clinical and Technical Assurance can be viewed online.
UK Core Development team	This team is comprised of individuals who are involved in UK Core FHIR assets’ development and/or authoring guidance contained in the UK Core Implementation Guide.
UK Core extensions	UK Core extensions add additional data elements to or “extend” the UK Core profiles. Further information is available relating to extensions.
UK Core profiles	UK Core profiles are FHIR assets which are customised models of FHIR resources, hence making them more suitable for relevant UK use cases. Further information about FHIR profiling is available.
UK Core resources	The list of HL7 FHIR R4 resources is available online.
UK Core statuses	The HL7 FHIR standard has five descriptive terms which explain levels of stability and implementation readiness.
ValueSet	A ValueSet specifies a set of codes drawn from one or more code systems, intended for use in a particular context. Further information about ValueSets is available online.
XML	XML (eXtensible Markup Language) is a mark up language designed for storing and transporting data.
Zulip	Zulip is an online chat forum for distributed teams.

Introduction

Purpose of Document

The purpose of this specification and guidance document is to formally introduce the UK Core governance process. This process will establish the UK Core as the principal mechanism for data exchange using FHIR across the NHS, health services and adult social care in England.

Mandated as DAPB4020 by the Data Alliance Partnership Board, this standard describes the governance under which UK Core resources are developed, assured, approved and published.

At the core of this governance structure is the HL7 UK FHIR Board; this Board is the primary governance body regarding UK FHIR development and deployment, providing strategic oversight, direction and leadership of the development of UK-wide FHIR assets, including implementation guides and profiles.

The DAPB has accepted these governance arrangements and will receive regular reports on implementation progress. Individual UK FHIR resources will not be submitted to the DAPB for approval; however, changes to the HL7 UK FHIR governance structure (this information standard) will be presented to the DAPB.

What is the UK Core?

Background

HL7 FHIR

All assets in the UK Core are based on the FHIR standard, version R4, published by HL7.

HL7 FHIR is the global industry standard for sharing healthcare data between systems.

The HL7 FHIR standard uses the latest web standards and focuses on making implementation as simple as possible. It is suitable for use in a variety of contexts including mobile phone apps, cloud communications, Electronic Health Record-based data sharing and electronic communication in large healthcare provider organisations.

Any FHIR solution is built using an appropriate selection of building blocks called FHIR resources. These are data models of common healthcare entities such as Patient, Practitioner, Organisation, Location, Medication, Condition, Procedure, etc. They can be put together to build working systems which solve real life healthcare problems.

Terminologies used in HL7 FHIR

HL7 FHIR uses standard healthcare terminologies. Many data elements in resources have coded datatypes. These use sources such as HL7 terminologies or terminologies like SNOMED CT.

CareConnect

Prior to the development of the UK Core, HL7 UK and INTEROPen collaborated with NHS Digital as a development partner to create a library of nationally defined HL7 FHIR assets in FHIR version STU3. This was called the CareConnect initiative and the assets were then formally reviewed by different stakeholders to make them suitable for implementation. An example of successful use of CareConnect assets has been in transfer of care scenarios, for example for the exchange of inpatient discharge summary documents and outpatient letters from hospitals to GP practices.

However, issues were identified with the CareConnect landscape, for example

- there was a need for a more robust version control and change management process
- there was a need to streamline the process for creation and change of CareConnect assets
- the scope of CareConnect was England only.

The UK Core initiative aimed to address these issues, but also to build on the useful work already done. Therefore, where they existed, CareConnect assets were used as input for the initial UK Core development.

UK Core Governance Overview

UK Core Governance Summary Description

Standard	
Unique Identifier	DAPB4020
Title	UK Core Fast Healthcare Interoperability Resources (FHIR) Release 4 (R4) Governance
Version Number	Amd 33/2021
Version Title	Initial standard
Description	The UK Core governance process is an information standard which underpins the development, maintenance and publication of the UK Core. The UK Core is fundamental to other standards which use FHIR where there is a need to communicate an individual's health and care data securely and consistently between providers. **UK Core Governance Structure** The governance structure consists of two main bodies: ▪ The HL7 UK FHIR Board - To set strategy, policy and priorities for all stakeholders ▪ The UK FHIR Delivery Senior Leadership Team (SLT) – Overseeing the creation and management of changes to FHIR assets. Each body contains representatives from organisations involved in health and care IT in the UK, both in the area of policy and strategy and in delivery as shown below in Figure 1. **Development** UK Core assets will be developed by the UK Core Delivery Team and will adhere to clearly defined design principles to ensure consistency and quality. **Assurance** The standard's defined Clinical and Technical Assurance process involves a team of subject matter experts who apply relevant use cases to selected FHIR resources to produce a "profile" or customisation suited to the UK context. This process ensures consistency and quality of resources. **Approval** The approval process has two stages: ▪ Clinical and Technical Assurance This ensures an asset is clinically and technically assured and can move on to development. ▪ HL7 UK Ballot

	The ballot allows for issues to be raised and resolved collaboratively and is an official HL7 UK process. **Publication** The use of the standard gives consistent version control and release processes which enhances quality control in the UK Core. All UK Core resources are available through one publication mechanism, providing transparency and ease of access. **Change Control and Maintenance** Any stakeholder can request a change to UK Core assets. Once logged, the request will be assessed by the governance bodies. **Other Governance** Further supporting strategies are: ▪ Risk management ▪ Communication and engagement. **Presentation of the UK Core Governance Process** An alternative view of this document, with full supporting processes, is presented online as webpages using the Simplifier platform. **Publisher and Licensing** This version release will be published by HL7 UK. It is licensed under the Apache License, version 2.0.
Applies to	Health and care providers in England which are using FHIR R4.

Supporting Documentation

Version 1.0 (FHIR Version R4) of the UK Core Design and Development Approach webpages provide detailed supporting information for this standard.

Why is it important for health and care in England?

Context

The NHS Long Term Plan was published in January 2019 and Chapter Five describes a "*wide-ranging and funded programme to upgrade technology and digitally enabled care across the NHS*". Key areas of work relating to this digital transformation include the provision of "*digital services and tools to give people more control over their own health and the care they receive from the NHS*" which will be underpinned by "*standards that keep information secure and make sure NHS IT systems talk to each other to provide health and care staff with complete access to joined up patient records.*" A standard like the UK Core is thus key to realising government digital policy objectives for healthcare.

Vision and Objectives

The vision for this standard is:

"To create a consistent governance structure for the UK Core, resulting in the clinical and technical assurance of UK Core FHIR assets."

This will ensure a unified approach to interoperability using HL7 FHIR across the four nations which will enable information to flow across countries to improve health and care outcomes for all citizens. Implementers of UK Core assets can also be confident that they are technically sound and safe to use.

The standard's objectives are to ensure that the UK Core succeeds in:

- facilitating the exchange of coded clinical data in a safe and consistent way
- mapping to older or alternative standards used by existing IT systems to be done once, then agreed and shared across the UK
- better facilitation of secondary use of data allowed by consistent format of exchanged information

Benefits

Interoperability

Health and social care interoperability is the ability of health and social care information systems to work together within and across different organisations to advance the effective delivery of healthcare for individuals and communities, through shared data.

There are many benefits to improving interoperability in both health and social care, such as:

- informed decision making - the right information available at the right time
- efficient care - reduce duplication, save time, share data
- person level data - a Shared Care Record for patients which is up-to-date, accurate and widely available and which supports better patient care
- improved patient experience - by joining up care through different settings
- better data re-use - to inform research and developing trends (secondary purposes).

Consistent, structured governance of the UK Core will mean it is capable of underpinning information systems throughout the UK which will greatly improve the interoperability and exchange of data between those systems.

Interoperability Benefits of the UK Core

The UK Core's governance structure and processes are expected to ensure that it can deliver significant interoperability benefits as below:

- a common approach to UK wide HL7 FHIR developments, for use by Health and Social Care services and vendors, implementing supporting IT systems
- a common set of HL7 FHIR assured assets and supporting implementation guidance that have undergone Clinical and Technical review, suitable for UK wide use
- FHIR assets that are common through the UK once, to be reused by many, to ensure they can establish interchange of data either now or in future scenarios
- establishment of a common approach across the Four Nations of the UK that will allow interchange of data between their systems where they use the UK Core
- reduction of development costs and time by building these common assets once and allowing developers to reuse these assets
- increased interoperability between vendors, services and health and social care programmes by providing common reusable HL7 FHIR assets
- reduction of independent and localised HL7 FHIR developments in the UK that cause extensive duplication of effort, produce dissimilar solutions and create technical debt where differing systems are required to interact

- uptake and adoption of HL7 FHIR as the common way to develop UK systems and services and build in interoperability for current and future needs
- simplification of the development landscape by encouraging movement to a common set of open HL7 FHIR standards for the UK and progress from legacy standards with limited development and benefit.

UK Core governance structure

In order to make sure that processes to manage the UK Core, a robust governance structure has been put in place while making sure that the interests of all stakeholders are represented (this is shown below in Figure 1)

UK Core Governance structure and contributing organisations

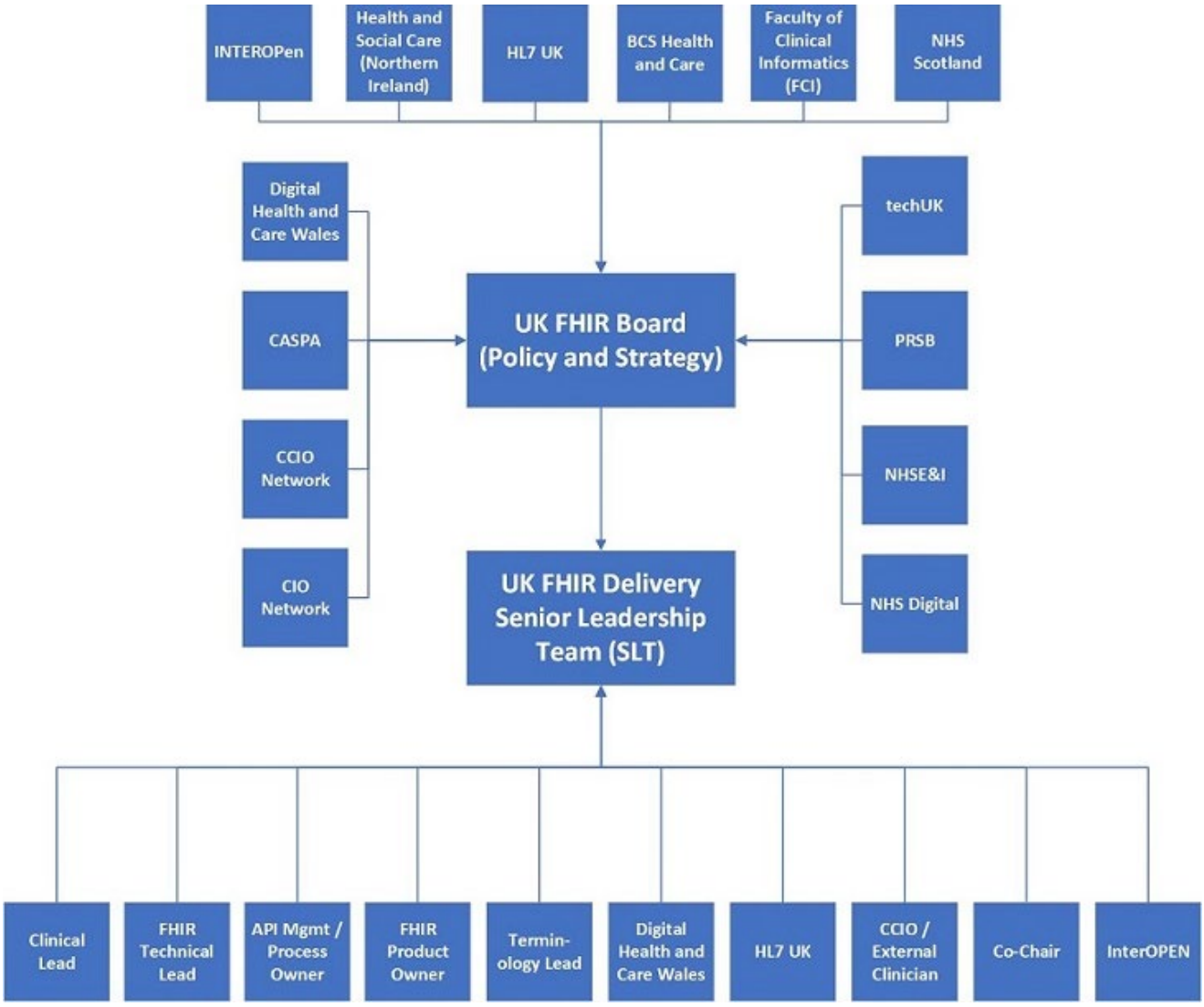

Figure 1

The UK-wide governance structure has been established at two levels -

- HL7 UK FHIR Board - to set strategy, policy and priorities for all stakeholders
- UK FHIR Delivery Senior Leadership Team (SLT) – overseeing the creation and management of changes to FHIR assets.

This UK governance structure will support the roadmap, priorities, development and progress of the UK Core (as well as other and future FHIR versions). NHSE&I is a co-chair of the HL7 UK FHIR Board and as such will seek to ensure the development of the standard is funded and delivered on behalf of the representatives of the Board.

To deliver the UK Core assets and guidance that make up the UK Core, the UK FHIR Delivery SLT will take its development priorities from the HL7 UK FHIR Board and will authorise cycles of Clinical and Technical Assurance, to consult on and establish the UK Core assets, along with the related guidance in the form of published Implementation Guides.

Further information about the HL7 UK FHIR Board and the UK FHIR Delivery Senior Leadership Team (SLT) is available online.

Development

UK Core assets will be developed by the UK Core Delivery Team, currently the Interoperability Standards Team (IOPS) within NHS Digital.

The development of assets will adhere to design principles for each asset type. All principles are reviewed and agreed through the Clinical and Technical Assurance process and/or by other stakeholders represented in the HL7 UK FHIR Board or the UK FHIR Delivery Senior Leadership Team.

It is also intended that UK Core design principles will conform to future relevant DAPB standards.

The key UK Core design principle is:

"FHIR assets must not be England specific and must be capable of representing the requirements of each UK nation identified during collaboration."

Further information about the design principles can be viewed online.

Full details of the development cycle are available online in diagrammatic format.

Assurance

The standard’s Clinical and Technical Assurance process involves a team of subject matter experts who map use case specific clinical information models, for example, allergies and adverse reactions or medications, to the relevant FHIR resource(s). This mapping produces a “profile” or customisation of the HL7 FHIR base resource which is suited to the relevant UK use case(s).

From a clinical assurance perspective, the resulting FHIR assets are reviewed for:

- accuracy (clinical knowledge and clinical practices)
- validity (designed correctly for the purpose of clinical practice and clinical use)
- usability (useful and usable for the clinical story tested against).

From a technical assurance perspective, the FHIR assets are reviewed for:

- conformance to the HL7 FHIR Standard
- adherence to the UK Core asset development guidance
- correct usage of the assets for the use case
- usability of assets by suppliers and vendors.

This process has been shown to ensure:

- robust requirements definition
- FHIR asset consistency
- engagement with stakeholders
- clinical risk reduction through consultation with clinicians during the assurance process.

Further information about the UK Core Clinical and Technical Assurance process can be viewed online.

Approval

Approval of any release of the UK Core is done in stages as below:

1. Clinical and Technical Assurance

Once a UK Core asset has passed through this process, it has been clinically and technically assured and can be handed over for development.

2. HL7 UK Ballot

Once the required asset development is completed and associated implementation guidance produced, the standard is put to ballot. The ballot allows for issues to be raised and resolved as part of a collaborative process.

Further information about the HL7 UK Ballot process can be viewed online.

Publication

The UK Core Development team is responsible for publication and follows a documented version management and release cycle agreed by the UK FHIR Board and the UK FHIR Delivery SLT to ensure the quality of published items.

Levels of versioning

UK Core individual asset level

The internal versioning for published assets will follow the Semantic Versioning Standard.

UK Core Release level

The version history and statuses of the UK Core releases are documented.

Further details of version management and the UK Core release cycle with a diagrammatic overview are available online.

Change control and maintenance

This process allows any stakeholder to request a change via the Create Issue option in Simplifier. Once logged, the request will be assessed by the governance bodies in line with the process.

Further textual detail about the standard's change control process is available online alongside a diagrammatic representation.

Other Governance

The standard has additional robust governance processes as outlined below:

Risk Management Strategy

The overall Risk Management approach for the UK Core is divided into several levels:

1. Simplifier Issues

   The development of the UK Core is publicly accessible at the HL7 UK Simplifier account which hosts all releases of the UK Core. Simplifier allows the raising of issues against any asset in development and this approach is used throughout the Clinical and Technical Assurance process.

2. Clinical Safety log

   The Clinical Safety log is updated and maintained throughout the Clinical and Technical Assurance process and is modified and reviewed as needed between Clinical and Technical Assurance cycles. It is maintained by the Product Owner of the Clinical and Technical Assurance process in agreement with the Technical Lead and Clinical Lead for the UK Core. The latter ensures clinical safety is considered throughout development.

3. UK Core Risk and Issues Log

   Where Risks and Issues extend beyond the remit of the Clinical and Technical Assurance process and the UK Core Development Team, a separate log is maintained on the UK FHIR Delivery SLT Google Drive, to document and progress risks and issues at a higher level. This is accessible to the members of the UK FHIR Delivery SLT and is managed on behalf of the UK FHIR Board.

Communications and Engagement

UK Core communication can be defined in two areas of scope:

1. UK Core specific communication
   a. Publicly developed and published by HL7 UK on their Simplifier platform
   b. UK Core Clinical and Technical Assurance process

   This communication will be covered using the owners and outlets described in the following Communication Matrix, maintained by the UK FHIR Delivery SLT:

Outlet	Owner Organisation
Ryver	INTEROPen
HL7 UK membership	HL7 UK
Zulip	FHIR Community
Simplifier news	HL7 UK
PRSB email shot	PRSB
Wales	DHCW (Wales)
Scotland	NHS Health Scotland
Northern Ireland	HSCNI
techUK Email/Interop working group	INTEROPen/techUK

UK Core development and the Clinical and Technical Assurance consultations are shared and communicated as illustrated in the above matrix.

2. As part of the wider Interoperability 'Community'
    a) NHSE&I Community of Interest
    b) NHSE&I Standards Portal (under development)
    c) UK Wide Governance and representation (See UK Core Governance)

The above outlets are expected to grow and develop as required to deliver Interoperability in its broadest sense and will include the work being done to develop and establish the UK Core.

Supporting Technology

Simplifier

The Simplifier platform has been chosen to host the UK Core. Simplifier is an online collaboration tool and has been chosen for the following reasons:

- Simplifier is FHIR aware
    - it is based on FHIR server
    - supports validation
    - interfaces directly with the FHIR profiling tooling.
- subscribers can track development progress and news items
- subscribers can leave feedback and raise issues
- stakeholders may be familiar with Simplifier as it is used for thousands of FHIR projects.

Any interested party can create a Simplifier account and begin to collaborate.

Contact

For information relating to the UK Core ballot process: HL7 UK Secretariat: secretariat@hl7.org.uk

For information relating to Clinical and Technical Assurance and the development and release of UK Core assets: NHS Digital Interoperability Standards Team (IOPS): interoperabilityteam@nhs.net

Appendices

Appendix One

Overview of the FHIR UK Core

Overview

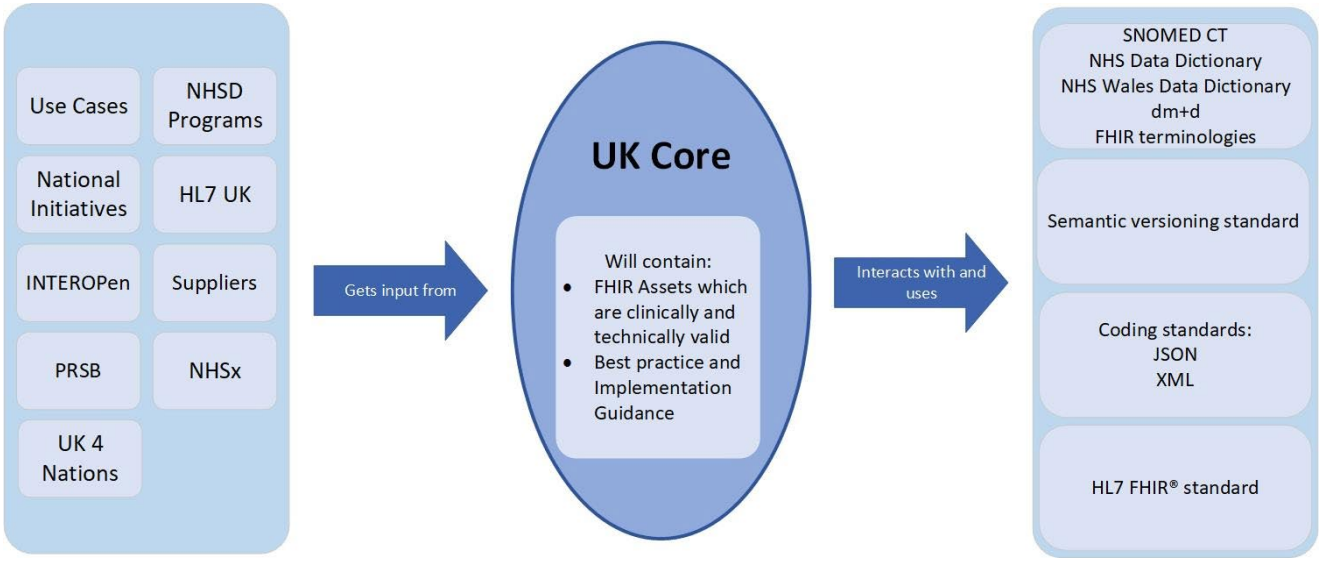

Figure 2

The UK Core can be viewed online.

Appendix Two

Use of the UK Core FHIR R4 Governance process

The standard has been effective in producing 21 clinically and technically assured profiles which have been used in specifications in England.

A version history for these profiles can be viewed online.

The change history for the profiles is available via the audit log provided in Git and a history of changes for each profile in Simplifier.

Use in England

Use cases listed in the specifications listed below have been a central feature in the Clinical and Technical Assurance process for this release of the standard.

This first release of the UK Core is the standard used for the following interoperability specifications:

- Electronic Prescription Service
- NHS Digital FHIR Medicines

Appendix Three

UK Core Related Standards

The UK Core is based on or uses the following standards:

Base standard

- HL7 FHIR R4 – the UK Core is based on this standard and it is used for the profiles, extensions and value sets, code systems and concept maps.

Standards used in the UK Core

Terminology Standards

- SNOMED CT (for terminology)
- dm+d (for terminology)
- NHS Data Model and Dictionary (for terminology in England)
- NHS Wales Data Dictionary (for terminology in Wales)

Note that discussions are being initiated in relation to other terminology standards used in Northern Ireland and Scotland.

Coding Standards

- XML
- JSON

Versioning Standard

Semantic Versioning Standard