Comments on
How Standards Will Support Interoperability

Version	Status
1.0	For publication (minor editorial changes from version 0.3 submitted to FCI)

Contents

1 Introduction

This document consists of comments from HL7 UK on the Draft Standards and Interoperability Strategy *How Standards Will Support Interoperability* dated April 2022[1].

HL7 UK and associated HL7 organisations internationally are non-profit bodies that provide open interoperability standards for health and social care. It is assumed that readers of comments in this

[1] https://facultyofclinicalinformatics.org.uk/web/content/4767

document are familiar with HL7 UK and in particular its responsibilities for FHIR in the UK. No further background information is provided here but can be found, if needed, at the HL7 UK website: https://www.hl7.org.uk.

Some familiarity with the HL7 UK FHIR Board (or just the 'FHIR Board') is also assumed but, as a reminder, it represents all key FHIR stakeholders including:

- the four countries;
- suppliers of both health and social care systems together with associated trade bodies;
- CIOs (chief information officers) and CCIOs (chief clinical information officers) from front-line NHS organisations; and
- professional and standards bodies.

A full list of member bodies and further information on the Board is available from: https://confluence.hl7.org/display/HL7UK/HL7+UK+FHIR+Board.

2 Overall comments

The importance of interoperability between systems used in health and social care is indisputable as is the role of standards in this context. We therefore welcome any developments which lead to progress in this area and it is our view that the draft strategy is a useful step forward.

Interoperability and related standards are highly complex areas involving multiple stakeholders and considerable multidisciplinary working. For this reason joint working is essential. Accordingly we also welcome the consultative approach that is being taken to the development of the strategy and the commitments within it to work with stakeholders in the future.

However, there are some parts of the text where (inadvertently or otherwise) the impression given is that some decisions will be made unilaterally.

As previously stated, HL7 UK and associated HL7 organisations internationally develop open standards and we are therefore pleased to see the commitment to open standards in general.

3 HL7 standards and FHIR

Within many UK hospitals there is a high degree of system interoperability using HL7v2 and this has been the case for some years. FHIR and other HL7 standards are also being used at local level and to provide central services such as Care Connect, PDS (Personal Demographics Service), and the millions of prescriptions exchanged every day via EPS (Electronic Prescription Service). Furthermore, in many countries FHIR is being used successfully for a wide range of use cases. In other words, HL7 standards are proven solutions.

As noted, a considerable amount of interoperability has largely been achieved within UK hospitals. In contrast there is a major issue with interoperability of hospital systems with external systems, and GP systems in particular. As a result, for example, it is not unusual for patients to attend outpatient appointments with very little of their information that is held in primary care being available to hospital doctors (other than a referral letter or equivalent).

Appropriate standards exist in this space and are ready to be used.

However, the draft strategy places considerable emphasis on defining a model care record and an overall architectural approach. Even if these initiatives should be pursued as advocated, they will take a considerable amount of time and resource.

Significant levels of interoperability can be achieved using FHIR or other HL7 standards, and that is without the proposed initiatives. We therefore strongly recommend that greater, overriding, priority is given to implementing interoperability solutions that are proven and can be deployed in the short term.

The long-standing issue of information not flowing as required between the NHS and social care should also be a priority.

Any solution needs to be based on modern proven standards from accredited organizations. Some of the solutions mentioned are outdated or are not recognized standards.

4 Funding

Existing systems will inevitably need to be modified and/or upgraded, if not replaced, to support increased interoperability. Although the strategy refers to funding in a number of places and we recognize that the strategy is in draft form, there is no indication of possible amounts nor how these might be determined.

Even if the many other actions that the Centre proposes to take are all achieved, that will be of limited use if there is insufficient funding either for deployments at local level or for central development. If the revised version of the document does not address funding in greater detail, there is a significant risk that the strategy will not have the support or engagement that it would otherwise deserve.

We do not need huge shift in the architecture of currently deployed systems. We just need to deploy the available standards for interoperability.

5 Systems and data in scope

5.1 Clinical information systems

A considerable amount of the document is concerned with the model care record and/or the creation of "composite electronic health records". There is, however, little or no discussion of actual systems in scope. We would like to see at least some statement of these, particularly given the apparent omission of image exchange (as noted below). Composite electronic health records would benefit from being discussed in greater detail and, specifically, how it is envisaged they will be implemented, as that is not clear.

5.2 Radiology and imaging

The DICOM standard and related IHE products should be included with the "key" standards listed in the draft strategy. We assume that no explanation of that is needed here and that others taking part in the consultation have made the same recommendation.

5.3 Data Architecture Strategy

As the document notes it "needs to be considered in conjunction with … the forthcoming Data Architecture Strategy". It is unfortunate that the latter is not available as there are inevitably going to be many interdependencies between the two strategies (and there is a risk of significant overlap or duplication). In the meantime, it would help to delineate the two documents more clearly as some of the text on pages 4 and 5 could refer to one or the other if not, in some cases, both.

5.4 Big data, ML and AI

In connection with the forthcoming Data Architecture Strategy there are references to machine learning (ML), AI and (by implication) big data on Page 4 in the subsection *Why this matters*. FHIR is being used for the transfer of large data sets and analytics in US. The suitability of FHIR in that connection for the UK, and for example for TREs (Trusted Research Environments) could be mentioned here. Other standards, not necessarily health care specific, also have a role particularly if data from domains other than health and care is involved.

6 Organizations in scope and use cases

6.1 Four nations

The draft strategy is for England and, for all the well-known reasons, that is inevitable. It also acknowledges (in 2.13) that it does not "expect systems designed for a global health market to be highly tailored for the English NHS" and, in Section 5, that the "English market is not big enough that particular needs for England are prioritised over international standards".

In contrast:

- in the subsection *Architectural features which enable this world*, it states "We will continue to develop the FHIR UK Core";
- in the subsection *Enabling Increased use of event-based architectures* it says "We propose that …. FHIR UK Core will include definitions of national event messages"; and
- in the subsection on *Enabling Information Discovery* it says "We propose that: …New, standard national record pointer types will be created for FHIR UK Core resources".

As a UK-wide body, we are concerned that there is little reference to working with the other three nations and that the examples above could be taken to mean that certain work on the UK Core will be determined on the basis of English priorities. We hope and assume this is unintentional. If so, we suggest that a commitment to continuing with the existing arrangements would be helpful; specifically, the FHIR Board determines UK-wide priorities while the UK FHIR Delivery Senior Leadership Team (SLT) oversees development of the UK Core. INTEROPen plays an important role in running hackathons and these are not confined to clinical information. For example, recent work has addressed workforce information.

The FHIR Board, SLT and INTEROPen all have representation from the four countries, as well as other key stakeholders.

6.2 Cross-border flows and other use cases

Section 3.1 is concerned with the end-to-end model. It is stated that a framework will be created that "ensures true co-production and engagement that involves vendors, frontline staff and people who use services across all four UK nations right through the standards lifecycle and beyond". This appears to be an acknowledgement of cross-border flows and it is good that they are recognised, albeit in passing.

There is an increasing flow (in some cases funded by the NHS) of patients and service users between the independent or private health sector and the NHS. The strategy does not mention this nor other use cases where people, sometimes in significant numbers (e.g. elderly care) are not exclusively in the English NHS and social care system.

We also note 2.4 states the future NHS is one which "enables patient access to information". That is also good but suggests (perhaps inadvertently) retrieval only, whereas patients should be able to update their own records. This applies whether patient enter information themselves or, in the longer term, upload it from their own devices such as fitness trackers and commodity diagnostic equipment such as blood glucose meters.

In summary, it is not clear that the strategy has taken into account many use cases where information about patients and service users will need to be exchanged. We therefore suggest that the revised strategy should be more explicit about use cases that it intends to include.

7 Model care records

7.1 Priorities

As noted earlier, our view is that greater priority should be given to deployment of interoperability solutions that are already proven to work with heterogeneous systems.

Interoperability would be easier if the systems exchanging information have compatible logical models. However, clarification is needed about what a "model care record" means. A virtual model for fostering interoperability is very different from a mandated internal model that systems should adhere to (which is different again to an actual physical set of care records).

The mandated internal model approach has not found success anywhere in the world and is not what effective interoperability projects are based on. Commenters such as Tim Benson make this abundantly clear. It is a methodology that has been widely rejected in favour of using external interoperability models. There is plenty of evidence of success of the latter and little of the former.

Software suppliers are virtually unanimous in rejecting this approach - adopting a new internal model - because this is an area that they rightly want to be able to control and innovate with. Interoperability standards are well aware of this and not hindered by it.

On the other hand, if what is meant by a "model care record" is external to systems or is a "virtual" interoperability model, then the leading standard for this is FHIR. Other formalisms that are intended to replace the internals of a system (e.g. openEHR) are not appropriate here. ISO 13606 and its derivatives have had little impact on interoperability in decades of existence.

7.2 Proposed options

The draft strategy proposes (in Section 1) selecting either "ISO 13606-1 or openEHR". The work on these has been seminal but they have been in existence, in one form or another, for an extended period, with little take-up (for whatever reasons).

Although these are undoubtedly important, there is some resemblance to the history of ISO's OSI (Open Systems Interconnection) standards. The OSI model heavily influenced certain networking developments, but the majority of the OSI standards were never implemented. Instead, TCP/IP and related protocols predominated.

We therefore suggest that, if the concept of a model care record is pursued, approaches other than ISO 13606-1 or openEHR should be considered.

FHIR profiles are suitable for describing reusable record structures and they allow data to be physically stored in appropriate ways (including in FHIR itself if desired), without forcing a reliance on a third-party model – which is unlikely to be practical in almost all realistic cases.

The failure of openEHR to become the de-facto model in any country (even though the UK continues to be a uniquely fertile ground for it to be discussed) was part of the rationale for FHIR's external interface based model, with an option to internalize it if required. FHIR-native data storage, although not a mainstay of FHIR, has been far more widely adopted than these other approaches, even given the relatively short time it has been in existence.

As an aside and on a point of detail, it is stated in Section 1 that organisations "including National Institute for Health and Care Excellence (NICE), Professional Records Standards Body (PRSB) and Royal Colleges have described business requirements for care records". It goes on to say that these "follow the approach adopted in ISO 13606-1 and its derivative reference model from the openEHR foundation". That is not the case. Although it is then stated "The structure was adopted in the design of the HL7 V3 GP2GP specifications", the influence of ISO 13606 on GP2GP is relatively minor.

7.3 Migration and achievability

Even if a model care record could be specified/defined, there would need to be widespread if not universal adoption for it to make an impact on interoperability. In reality there will always be legacy systems that cannot conform, and also emerging systems or medical technologies (perhaps related to genomics or pharmaceuticals) that the model does not cater for. In addition there will be the challenge, as the draft strategy notes elsewhere, that the English market is a small one for many system suppliers that might be expected to adopt the record. In practice, the exceptions will be the norm, and are the primary thing that must be accommodated, which leaves the "internalised" model care record concept with an insurmountable obstacle.

7.4 FHIR Profiling

In this overall context and as an initial step, we recommend some logical modelling that then leads to FHIR profiles which are directly implementable by everyone. These logical models may be easier to understand by certain stakeholders. But experience has shown that those involved in software find FHIR profile and resource models very easy to work with. FHIR acceptance and adoption has been remarkably quick because of this ease.

We should move rapidly from models to profiles and to prototype implementation. Often the production of un-specific general purpose models leads to "analysis paralysis", which is best avoided by getting data moving early and seeing which solution and scope is appropriate on the ground.

At the end of the subsection Shared reusable record structures (top of page 7) it is stated that:

> *We shall select one or more standards for cataloguing and representing these reusable structures. The standards being considered are the health specific standards ISO 13606-2, HL7 FHIR's questionnaire resource specification and the general IT standard ISO 19763-13.*

This is in area that undoubtedly needs attention and has been overlooked for some time. However, this text is somewhat unexpected not least because it is inconsistent with a consultative approach. This is a topic that needs detailed consideration.

FHIR Questionnaire is a successful and innovative input form standard but is not primarily intended for "logical models" or for data templates. We mostly do not want to record data in terms of how it was collected, since that makes it harder to reuse. This is a flaw of existing archetype models, in which you need to know how data was captured, in order to locate it. Alternatively, if the data is then removed from the template or indexed within it (e.g. with SNOMED codes, or more generic structures than the templates) then the data capture template issue does go away. You can re-use the data in other contexts. But at that point the template has little merit. Data captured as a persisted input template is a fundamentally bad idea. And once you take away the reliance on that template you are left with no useful features of the template (other than perhaps a user interface design).

For pre-implementation design there are FHIR logical models, preferably, or plain UML (as adopted currently by the PRSB). (An easier way to switch between those two formalisms would be welcomed and is very achievable). Then of course there are the FHIR profiles themselves, which are the modern and well adopted version of archetypes and templates. For data capture there is FHIR Questionnaire. For data definition and exchange there are FHIR profiles, and for physical storage there are, optionally, the actual FHIR resources.

FHIR logical models, profiles and implementation guides have recently become even more user friendly and better supported, via the FHIR Shorthand initiative ("FSH" – see http://hl7.org/fhir/uv/shorthand/), which is further revolutionising the interoperability definition landscape.

8 Summary and conclusions

8.1 Way forward

The correct direction is identified in the document and is:

- FHIR plus REST with (mostly) SNOMED.

Better adoption of the NHS Number is a somewhat separate issue to the technicalities of interoperability, but can only enhance it.

8.2 Logical models

Logical models can help get traction in the early phases of an interoperability project, but must be project specific and not try to "model the world". This never works, although being informed by related prior art is worthwhile. But – crucially – projects must move rapidly to prototype implementation, to see what works. We need working code and moving data, not models as an end in their own right.

Do not seek to standardise all health care data (which is unfeasible even in the longer term) but seek to exchange it, in tightly specified, domain appropriate ways. Decide a data model for that exchange. Players in that space will already support that information, or they would not be successful in that arena. They don't need to reboot, just be encouraged to open up.

8.3 FHIR Profiles and Implementation Guides

FHIR Profiles undoubtedly help interoperability, but profiles without specific use cases are of less benefit. Don't wait for profiles to exist for a use case, because 90% of what you need is already there in FHIR. A profile is a useful but relatively thin layer on top of the vast utility that already exists in FHIR. Start with FHIR.

FHIR Implementation Guides (IGs) are the de-facto way to document interoperability definitions (see http://fhir.org/guides/registry/ for a small subset of these). Use FSH to democratize and speed up authoring of FHIR Logical Models, Profiles, IGs and example instances of FHIR resources for exchange.

8.4 FHIR versions

Do not let relatively minor issues such as variations in the FHIR standard over time be a blocker. The differences between, for instance, FHIR STU3 and R4 are insignificant compared to the effort of getting any interoperability project off the ground. Conversation between these standards (assuming the business needs are properly understood – the harder part) is usually trivial compared to implementing either of them. Somehow this minor issue strikes fear into project leads.

8.5 The international FHIR community

Reach out to the International FHIR Community. The NHS is very parochial and tends to think it is a special case and a world of its own. We have our own issues, but the technical solutions are common. There are over *twenty thousand* FHIR developers on the FHIR Community chat at https://chat.fhir.org, all pursuing similar goals, and we need to engage, at scale. An example international Implementation Guide (from Denmark) can be found at: https://docs.ehealth.sundhed.dk/latest-released/ig/index.html

Instead of looking to a new model care record we need to be looking at how the rest of world actually achieves interoperability. One only needs to pay attention to the sheer number of FHIR projects, Implementation Guides, software deployed, and the roll call of companies that have committed to it.

Shining examples exist in the UK such as at the Kings Health Partnership and the YHCR (Yorkshire & Humber Care Record). As another exemplar is in the Somerset region which has implemented a composite care record across both health and social care organisations using FHIR STU3 (the SIDeR programme).