Comments on: HL7 Fast Healthcare Interoperability Resources (FHIR)

DRAFT for Comment Ballot

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1. The key issue for FHIR (and by extension HL7) is “what problem are we trying to solve”? There is little value in amassing technical specifications without foundational requirements statements which:

• Scope and detail the problem space;

• Allow comparability (across Standards); and

• Can be concisely measured for fulfillment.

Requirements statements allow ready assessment of FHIR (as proposed), alongside HL7’s extant suite of Standards including v2, v3, CDA, RIM, EHR and PHR System Functional Models. Requirements statements also allow demonstration of how far we’ve come (v2 and on) and how far we have yet to go.

It is unclear if/how this project should proceed without explicit Requirements Statements that show fit, consistency and contrast with/among HL7’s existing suite of Standards. This is both prudent and fundamental.

2. In 2012, EHR (PHR and other) systems are being certified for record management functions. Data/record management starts at the point of origination and must be continuously (uninterruptedly) assured through each point of retention (at rest) and exchange (in motion). Data/record management encompasses:

• Lifespan: from point of origination to permanent offline archive or loss/destruction

• Lifecycle, starting at origination and at each event thereafter: attestation, amendment, access/view, transmittal/disclosure, receipt, archival…

• Identity: subject, participant, observer, author, co-author, organization, system

• Capture, origination, source, provenance

• Authorship, signature, signature binding to content

• Attestation, for accuracy/completeness

• Non-repudiation

• Amendment, preservation of prior content, audit logs and amendment history

• Retention, persistence

• Non-alteration

• Consents, permissions to access, consent binding to content

• De-Identification

• Encryption

• Transmittal, disclosure, disclosure logs

• Receipt, consumption

• Content binding: author/system signature, consent/permissions, amendment logs

As a key reference for certification programs worldwide ISO/HL7 10781 EHR System Functional Model Release 2 specifies twenty-four (24) distinct record lifecycle events. Four (4) relate directly to exchange (transmit, output/report, disclose, receive).

2a. If FHIR “resources” are intended as exchange only (transient) artifacts, then Requirements Statements should be scoped in consideration of applicable bullets above and the four EHRS FM lifecycle events.

2b. If FHIR “resources” are intended as Records Management (persistent) artifacts, then Requirements Statements should be scoped in full consideration of all bullets above and all EHRS FM lifecycle events.

3. If FHIR “resources” are intended to be transient, why aren’t extant interchange standards sufficient? This goes back to comparison exercise outlined in Comment 1.

4. Preservation of author’s signature binding to authored content is an essential requirement for virtually all primary health data/record use. Primary use includes immediate clinical intervention/care and decision making. This author/content binding requirement also extends to health data/records submitted for substantiation of claims for payment and many other uses.

In reading this FHIR specification it is unclear how author/content binding is preserved through an instance of FHIR exchange. Please clarify.

5. (Per Comment 4) If the key focus of FHIR is secondary data/record use, then we stand begging the question of whether it should be a major initiative for HL7 going forward. Needs clarity.

6. Capture and management of consents/permissions for data/record access – including explicit binding to related content – is emerging as an essential requirement. In terms of this FHIR specification it is unclear how consents/permissions and their binding to content are established and preserved. Needs clarity.

7. If FHIR is not about Records Management (full lifespan/lifecycle) and preservation of authorship and consent/permission bindings to content, how relevant it is in today’s market much less with foresight ahead 10-20 years? Needs clarity.

FHIR Introduction: *“Fast Healthcare Interoperability Resources (FHIR) defines a set of ‘resources’ for health.* *These resources represent granular clinical concepts that can be exchanged in order to quickly and effectively solve problems in healthcare and related processes. The resources cover the basic elements of healthcare - patients, admissions, diagnostic reports, medications and problem lists - with their typical participants and also support a range of richer and more complex clinical models. The simple direct definitions of the resources are based on thorough requirements gathering, formal analysis and extensive cross-mapping to other relevant standards.”*

8. What does “healthcare interoperability” mean in this context? Are we making the process (provision) of healthcare interoperable? Or are we making health/healthcare data/records interoperable? Please clarify.

9. It is stated that “resources represent granular clinical concepts” and that “these resources cover the basic elements of healthcare and related processes – patients, admissions…”. Resources related to patient and admission resources would likely include some non-clinical (e.g., demographics, finance, insurance, next of kin, guarantor). Make this explicit.

10. To what does “with their typical participants” refer? Do “resources” have typical participants? Do “basic elements of healthcare” have typical participants? Do “patients, admissions, diagnostic reports, medications and problem lists” have typical participants?

11. Assume “fast” describes some aspect of time, velocity and/or response to priority or urgency. “Healthcare” (better yet “health”) describes the domain.

“Interoperability” describes what? What makes FHIR interoperable?

The EHR WG produced a “Coming to Terms” White Paper on Interoperability, reviewing more than 100 industry sources and defining three levels: Technical, Semantic and Process. The WG also produced the EHR Interoperability Model DSTU, with 56 relevant criteria. (CDA R2 meets 51 of 56.) How does FHIR measure up to these internal HL7 “interoperability” benchmarks?