Re-Envisioning HL7 – Taking Another Perspective

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Given the objective to re-envision HL7, here's what I would consider:

1. Cross-consistency of data and exchange standards. HL7 Standards will be designed and specified in such manner as to maximize commonalties.
   - Transformation of data content and context between HL7 exchange standards (v2 messages, CDA documents, FHIR resources) will be without data loss.

2. Cross product tooling support. The HL7 Toolkit will be designed to support and integrate the entire HL7 Standards family, from requirements statements to implementable specifications including:
   - Data and exchange standards (content, context, data types, format, ranges...)
   - Functionality standards, including EHR and PHR System Functional Models and Profiles
   - Terminology/vocabulary standards for classification, code and value sets
   - Implementation guides
   - Profiles and extensions

3. Patient safety. HL7 Standards will be designed to recognize and address patient safety as an explicit objective.

4. Clinician assurance. HL7 Standards will be designed in recognition that clinicians are key stakeholders who act as accountable authors and end users of health data/records. Essential perspectives:
   - Looking downstream, where the clinician is author (originator) of health data/record content subsequently transmitted via HL7 exchange artifacts;
   - Looking upstream, where the clinician is user (consumer) of health data/record content authored by others and received via HL7 exchange artifacts.

HL7 Standards must focus on key characteristics of health data/records, specifically to support and benefit the clinician. The following enumeration is derived from assessments of the HL7 EHR WG's Reducing Clinician Burden Project...

5. Truth and trustworthiness of data. HL7 Standards will be designed to ensure health data/record content is:
   - True: authentic, accurate.
   - Trustworthy: assured, accountable.
   - Traceable and transparent: following chain of trust from source to use.

6. Data usability. HL7 Standards will be designed to ensure key qualities of health data/records (and thus data usability) including provenance. These qualities encompass health data/records that are:
   - Known to be true and trustworthy [per #5].
   - Known to include assured identity of subject of care (patient).
   - Known to include assured identity of accountable provider (individual, organization).
   - Known to include assured identity of source: system, software, device ID, network address.
   - Known to be composed by human author or rather assembled by software algorithm.
   - If composed by human author, known to include his/her assured identity: author's name/ID, author's role and credentials.
   - Known to be tied to actions taken: who did what, when, where and why.
     - Actions are taken to support individual health, to provide healthcare...
     - Data resulting from actions taken includes facts, findings, observations...
   - Known as to chronology and time of clinical relevance – date/time of capture.
   - Known to be relevant + pertinent – for purposes of end use and end user.
   - Known to be comprehend-able + digestible – for purposes of end use and end user.
   - Known to be action-able – for purposes of end use and end user (e.g., clinical care, interventions, decision making).

- Known to have content bound to context or not (i.e., clinical content bound to clinical context).
  - Clinical context includes vital inter-relationships among/between (as applicable): problems, conditions, diagnoses, complaints, symptoms, encounters, history and physical findings, allergies, medications, vaccinations, assessments, goals/objectives, clinical decisions, orders, results, diagnostic procedures, interventions, observations, treatments/therapies, referrals, consults, outcomes, protocols, care plans and status...
- Known to include source and authorship bound to data content/context or not.
  - If bound, maintains linkage to "source of truth".
- Known to be unaltered from (maintaining fidelity to) source or known to be transformed.
  - If transformed, known to carry original content alongside or not.
- Known as to purpose and method of data capture or not.
- Known as to anticipated purpose of data use or not.
- Known to be complete or known to be incomplete, partial or pending.
- Known if original content was subsequently updated (e.g., corrected, revised or supplemented), with the date/time of such update.
  - If updated, known as to prior content (i.e., non-destructive update).
- Known if content has been reviewed and verified, with date/time of such verification.
  - e.g., automated device data verified by human; student data verified by preceptor.
- Known as to whether content has been formally reviewed and attested, with the date/time of such attestation.
- Known as to whether original content was structured or unstructured (at source).
- Known to be consistent with standard data definition(s) or not:
  - Element name(s), data type(s), range(s) (including normal or reference range), unit(s) and scale of measure, vocabulary/ terminology scheme, codes and value sets...
- If recipient and end use and/or end user are known, data provision is consistent with principles of "minimum necessary" and "need to know" or not.
- Known as to whether data provision is consistent with authorization and consent permissions or not.

7. Data instances. HL7 Standards will be designed with recognition that there can be multiple health data/record instances in the flow from source to use:
   - Instance as originated and viewed by author in source system
   - Instance as retained/maintained in source system datastore
   - Instance as viewed in source system
   - Instance as verified in source system
   - Instance as attested in source system
   - Instance as created in (transformed to) exchange artifact (e.g., HL7 v2 message, CDA document or FHIR resource), as transmitted from source system
   - Instance as maintained by exchange intermediary (e.g., HIE system)
   - Instance as captured by receiving system
   - Instance as retained/maintained in receiving system datastore
   - Instance as accessed/viewed for purposes of end use/end user

8. Sanctity of clinician intent with regard to health data/record content and context. HL7 Standards will be designed to ensure end-to-end consistency and fidelity to source:
   - Point of origination/data capture – authoring clinician: Content and context view is as intended
   - Point of review – same clinician: Content and context view is equivalent
   - Point of end use – another clinician or end user: Content and context view is equivalent

9. Functional usability. HL7 Standards will be designed to maximize functional usability of EHR/HIT systems – to include:
   - ISO/HL7 10781 EHR System Functional Model (currently balloted/published at HL7 as Release 2.1, awaiting finalization of ISO/HL7 Partnership SDO Agreement to be advanced to ISO)
   - HL7 EHR System Usability Functional Profile (currently balloted at HL7 as Release 1 but not yet published)

10. Work flow accommodative. HL7 Standards will be designed to facilitate variant work flow needs and patterns.

11. Burden reduction. HL7 Standards will be designed to enable burden reduction (for clinicians and other accountable authors and end users of health data/records).

With regard to Items 5-11 above, this detail is (should be) part of trusted health data/record infrastructure maintained by the source/receiving EHR/HIT system(s) and facilitated through exchange itself. It should not require additional input by the clinician or other end user. Further, as part of this infrastructure, the details do not need to be part of the “top” view but rather can be made available through “drill-down” views when needed for confirmation/verification of health data/record content and context.