



HL7 EHR Guidance: Vital Data Qualities, Edition 1

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HL7 Comment-Only Ballot

**Sponsored by:
Electronic Health Records Work Group**

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HL7 EHR Work Group – Data Quality Project

Defining Data Quality – Comment Only Ballot

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Terminology	Owner/Contact
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Logical Observation Identifiers Names & Codes (LOINC®)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
NUCC Health Care Provider Taxonomy code set	American Medical Association. Please see www.nucc.org . AMA licensing contact: 312-464-5022 (AMA IP services)

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Defining Data Quality – Why a “Comment Only” Ballot?

The HL7 Electronic Health Record Work Group is working to focus and address a range of issues related to the quality of health data/records. This is prompted by our ongoing work:

- [HL7/ISO 21089:2018](#) – Health Informatics – Trusted End-to-End Information Flows
- HL7/ISO [10781:2023](#) and [16527:2023](#) – Health Informatics – Electronic and Personal Health Record System Functional Models, Record and Trust Infrastructure Sections
- [HL7 FHIR Record Lifecycle Event Implementation Guide](#) (2023)
- [Reducing Clinician Burden Project](#)
- [Artificial Intelligence Projects](#)
- [Data Quality Project](#)

Data quality is foundational and is of vital interest to ALL stakeholders in, and for ALL purposes/uses of, health data/records, including but not limited to:

- For the subject of data content (i.e., patient)
- For the author of data content
- For the end user of data content
- For primary use, secondary use and re-use of data content
- For ensuring integrity and effectiveness of the clinical process
- For assuring patient safety
- For data content ingested by artificial intelligence, including machine learning
- For data content generated by artificial intelligence, including output of AI scribes

Our quest is to understand and specify the fundamentals...

- What are “vital data qualities”, i.e., what properties or characteristics of health data/records are:
 - Constitutive of its quality?
 - Evident of trustworthiness and reliability?
- How are such properties/characteristics evidenced, i.e., made manifest by metadata bound to (carried alongside) the data itself?

On the following pages we offer:

- An enumeration of “vital data qualities”; preserving and persisting
- Evidence of those qualities alongside (or bound to) the data itself; over an
- End-to-end continuum (chain of trust) from point of data origination to each ultimate point of data access/use; while ensuring the
- Complete data lineage is preserved and available for examination/assessment at any point.

The following document comprises four pages:

- 1-2 A) Vital Data Qualities
- B) Capabilities and safeguards to ensure health data/records “show” (provide evidence of) each Quality
- 3 Immediate Context – Blood Pressure Example
- 4 Extended Context – Blood Pressure Example

Thus our inquiry for your consideration and feedback:

1. Review the “vital data qualities” we’ve enumerated (Pages 1-2, first column).
 - a. Are there any you would add?
 - b. Are there any you would revise or remove?
2. Review what we’ve specified as “show” criteria for each “vital data quality” (Pages 1-2, second column). Note that “to show” means to “provide evidence of”.
 - a. Are there additional criteria you would propose “to show”?
 - b. Would you revise or remove any criteria “to show” specific qualities?
3. Review the Blood Pressure examples on Page 3 (immediate context) and Page 4 (extended context) and offer any comments that would advance these constructs.

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Vital Data Qualities	Capabilities and safeguards to ensure health data/records...
Known and verified (verifiable) as to identity: <ul style="list-style-type: none"> • Subject: patient • Provider: individual and organization • Systems, devices and software 	Are associated with the correct identity and subject (of care/treatment)
Known and tied to actions taken: who did what, when, where, why <ul style="list-style-type: none"> • Actions are taken to support individual health, to provide healthcare... • Actions are taken by an accountable agent (person, organization, system (software/device)), at a date/time, for a period of time, at a location (physical, network, device), for a purpose • Data resulting from actions taken includes facts, findings, observations... 	Show a clear relationship/binding of datasets/data elements with actions taken – who took what action, when, where and why
Known to be oriented in time: date/time of occurrence, chronology, sequence <ul style="list-style-type: none"> • What has happened: past, retrospective • What is now in progress: present, concurrent • What is anticipated, planned: future, prospective 	Show time orientation and chronology/ sequence
Known to retain clinical context and maintain vital inter-relationships among/between (as applicable): <ul style="list-style-type: none"> • Problems, 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... [See also Immediate and Extended Context in Sections following...]	Show clear inter-relationships/ binding between datasets/data elements and their clinical context (as noted in the left-hand column)
Known as to source and provenance ("source of truth"), with traceability to point of origination: human, device, software	Show dataset/data element provenance with traceability to source/point of origination
Known as to accountable human authorship (if applicable) with role and credentials	Show dataset/data element authorship with role and credentials, as applicable
Known to be verified/attested (or not) with evidence of verification/attestation, verifier(s)/ attester(s), date(s)/time(s) and method(s), for example: <ul style="list-style-type: none"> • Human verification of data sourced by automated device • Preceptor verification of data sourced by student • Attestation of facts/findings to substantiate claim for payment 	Show evidence of dataset/ element verification, as applicable
Known to be updated (or not) with evidence of prior state(s), effective date(s)/time(s) <ul style="list-style-type: none"> • Non-destructive update(s) over time 	Show evidence of dataset/data element update, prior state(s), effective date(s)/time(s), as applicable
Known to be unaltered (maintaining fidelity to original/source content) <u>OR</u> Known to be altered/transformed from source content/ representation to another	Show evidence of dataset/data element non-alteration or alteration, as applicable

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Vital Data Qualities	Capabilities and safeguards to ensure health data/records...
<ul style="list-style-type: none"> • From one coding/classification system to another, or • From one human language to another • From unstructured to structured or vice-versa 	
Known, if altered/transformed, to carry original content/representation alongside (or not)	Carry original dataset/data element content (or not), as applicable
Known to be complete or Known to be incomplete, partial or pending or Known to be a snippet/fragment with other essential details elsewhere or Known to be a header, pointer or link to essential content elsewhere	Show notation of dataset/data element completeness (or not), as applicable
Known to be associable and congruent with like data , having same/similar context <ul style="list-style-type: none"> • Comparable, correlate-able, trend-able 	Have the same/similar context so as to be comparable, even/especially if sourced by separate EHR/HIT systems
Known to be consistent and uniform – in terms of data definition – with corresponding data: <ul style="list-style-type: none"> • Common element name(s), common data type(s), common range (including normal or reference range), common input/display/storage format, common unit(s) & scale of measure, common vocabulary, common codes & value sets 	Have consistent data naming and definition, even/especially if sourced by separate EHR/HIT systems
Known to be sourced as structured (coded) content or not	Show data source as structured content or not
Known, if coded, to include: <ul style="list-style-type: none"> • Coding convention – vocabulary/terminology set or value set – and version 	Show coding convention and version, if applicable
Known as to method and purpose of data capture	Show method and purpose of capture, if applicable
Known as to intended purpose of data use	Show intended purpose of use, if applicable
Known if captured from external sources	Show external data source, if applicable
Known as to how external data is integrated (incorporated) with OR maintained separately from health data/records in local EHR/HIT system	Show data integration or segregation, as applicable

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Immediate Context

It is essential that *immediate context* be bound to and managed alongside each dataset and data element. For example, blood pressure should include the following elements of *immediate context*, including provenance:

Context	Context Element(s)
Who (actor)	Patient or subject of care
	Performer, who measured blood pressure
	Author of health record entry (who may be different than performer)
	Provider: individual practice or organization
What (action taken)	Systolic, diastolic and/or mean measurement
When	Occurred at: date/time/duration
	Recorded at: date/time
Where	Body location, body position, sampling site
	Physical location – e.g., exam room, bedside
	Recorded at: network address and/or device ID
Why	Rationale for, or purpose of, measurement
How	Method – e.g., inflatable cuff with auscultation by stethoscope
Under what circumstance(s) or condition(s)	At rest, pre/post exercise or other condition

To be complete and to establish trust (assurance) and truth (authenticity, accuracy), each element of health information must be carried together and tightly coupled with its *immediate context*.

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Extended Context

Extended context shows key relationships beyond the immediate to measurement at intervals. For example, extending the context of our blood pressure example:

Extended Context	Blood pressure measurement occurring as:	Periodicity
a) Basic vital signs panel	Part of a vital signs panel (e.g., heart rate, respiratory rate, body temperature, pulse oximeter) – as might be captured from the same patient, by the same performer, at the same date/time	Point in time
b) Inpatient vital sign monitoring	Part of a vital signs panel (as detailed in “a” above) – as might be performed hourly in an inpatient setting	Repeated Hourly
c) Outpatient history and physical assessment	Part of a vital signs panel (as detailed in “a” above) – as might be performed in an outpatient clinic, in conjunction with a history and physical assessment	Repeated Periodically - at each visit
d) Weekly monitoring – to rule in/out hypertension	Weekly follow up visits – measuring vital signs (as follow up to “c” above) to determine if patient has hypertension (high blood pressure), performed in an outpatient clinic for four successive weeks	Repeated weekly
e) Weekly monitoring – post hypertension diagnosis	Weekly follow up visits – measuring vital signs to assess effectiveness, dosage levels and possible side effects of medication prescribed after patient was diagnosed with hypertension (as follow up to elevated BP levels detected from monitoring described in “d” above)	Repeated weekly

To be complete and to establish trust (assurance) and truth (authenticity, accuracy), each element of health information must be carried together and tightly coupled with its *extended context*.

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