March 28, 2024

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200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:  
https://uscdiplus.healthit.gov

Re: United States Core Data for Interoperability Plus (USCDI+) Use Cases: Case Reporting and Laboratory Data Exchange

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC’s United States Core Data for Interoperability Plus (USCDI+) Use Cases: Case Reporting and Laboratory Data Exchange. HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries.

We appreciate ONC’s on-going effort to drive innovation through USCDI and USCDI+. HL7’s specific feedback regarding the USCDI+ Public Health (PH) Domain Laboratory Data Exchange Use Case and related issues is detailed below. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Orders and Observations and Public Health. Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

Charles Jaffe, MD, PhD  
Chief Executive Officer  
HL7 International

Julia Skapik, MD, MPH  
Board of Directors, Chair  
HL7 International

Sincerely,

Charles Jaffe  
Julia Skapik

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Chief Executive Officer  
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Julia Skapik, MD, MPH  
Board of Directors, Chair  
HL7 International
HL7 Responses to ONC’s USCDI+ Use Cases: Case Reporting and Laboratory Data Exchange

Related to the USCDI+ Public Health Domain Laboratory Data Exchange Use Case

HL7 General Comments:

• HL7 encourages ONC to utilize formal data classes, value sets and data element definition codes for all USCDI+ content and to allow users to filter by category and data class. HL7 recommends a USCDI+ section in which core components in USCDI are pointed to by the domain sets.

• HL7 seeks clarification around the relationship between USCDI and USCDI+, in particular whether only USCDI data of interest should be referenced in the USCDI+ PH Laboratory Data Exchange or electronic Case Reporting (eCR) use cases only, or whether it is assumed that USCDI applies to all USCDI+ PH use cases.

• HL7 notes that the USCDI+ PH Laboratory Data Exchange use case does not include any patient demographic data, thus making it difficult to understand which data from USCDI would be of interest. HL7 suggests that USCDI+ use cases always include the specific data elements of USCDI, avoiding any ambiguity.

• HL7 also seeks to clarify whether the fact that USCDI+ PH indicates discrete fields means that conformance to USCDI+ PH would require access/exchange as discrete data and therefore that inclusion of the data elements only in narrative text is not allowed. Or conversely in this scenario, is that level of specificity articulated in the supporting interoperability implementation guides that could be used for conformance testing if not certification.

HL7 Laboratory Data Exchange Comments:

HL7 notes that the USCDI+ Laboratory Data Exchange use case description below includes a wide range of laboratory data of interest, including data relevant for ordering as well as reporting:

"The exchange of reportable laboratory order and result data necessary for the investigation and treatment of reportable diseases. Includes electronic ordering and reporting of suspect cases, reporting point of care and at-home testing results to public health, and other more traditional lab data exchange with immunization & vital records systems."

HL7 highlights that it is ambiguous whether any of the following would be included: genomic data, North American Association of Central Cancer Registreries (NAACR) reporting, anatomic pathology, hematology and Healthcare-Associated Infections (HAI) reporting. NAACR reporting in particular, would have overlap with the USCDI+ Cancer topic. As it pertains to USCDI+, it is not clear whether NAACR data requirements would be listed in both Laboratory Data Exchange and Cancer use cases, Cancer use case only, or Laboratory Data Exchange use case only. HL7 recommends including further explanatory language covering how use cases across domains would relate and whether laboratory data exchange is meant to be inclusive of genomics data.

HL7 observes that --given that the USCDI+ Public Health Domain Laboratory Data Exchange Use Case can cover many data elements --it is uncertain if all data is relevant to all sub-use cases. For example, data relevant for ordering may not be relevant for reporting. Or data that would be inappropriate for the
ordering and initial reporting would be critical to be available for follow-up queries in support of an investigation.

In addition to the data elements already included, HL7 recommends the following data relative to laboratory reporting that is included in the Electronic Laboratory Reporting (ELR) implementation guide used in certification:

- Reason for Study (See HL7 v2 OBR-31 definition)
- Observation Method (See HL7 v2 OBX-17 definition)
- Date/Time of Analysis (See HL7 v2 OBX-19 definition)
- Performing Organization Information (See HL7 v2 OBX-23/24/25 definitions)

For patient demographic data in particular HL7 recommends to minimally include:

- Patient Identifier
- Patient Name
- Patient Date of Birth (DOB)
- Patient Address

Regarding the context of a laboratory order, HL7 highlights the following data is of importance to include:

- Ordering Provider (See HL7 v2 OBR-16/17/24 definitions) and/or Ordering Organization (See HL7 v2 ORC-21/22/23 definitions)
- Ask at Order Entry (AOEs) data specified by the laboratory as needed to properly interpret the test

HL7 notes that including demographic and AOE data that was of specific interest during the COVID-19 pandemic caused challenges, particularly when including this data in the order and onwards with the laboratory report. Including demographic and AOE data that was of specific interest during COVID-19 was not necessary for the operational performance of the test and interpretation, but solely used for public health analytics in support of specific impact and policy analysis. HL7 also recommends ONC clarify that USCD+ PH does not imply data elements identified for each use case be present on the order or in the result report or both.

Therefore, HL7 recommends that any data beyond the performance and interpretation of a test is clearly identified for investigation and/or emergency declarations. HL7 also recommends ONC clarify that USCD+ PH does not imply data elements identified for each use case be present on the order or in the result report or both. Rather, relevant supporting interoperability implementation guides should be used to indicate when and what data is to be communicated and how. Thus, while today an existing Health Level Seven Version 2 (HL7 v2) data stream may be seen as the best vehicle for communication, a more optimum flow taking advantage of case reporting and/or immediately triggered follow-up queries--using HL7 FHIR-based Application Programing Interfaces (APIs) such as those being pursued by the
HL7 HELIOS Accelerator—may be more effective and reduce burden on providers and laboratories alike.

HL7 notes the inclusion of specimen condition acceptability and test kit unique identifier in the USCDI+ Public Health Domain Laboratory Data Exchange Use Case. These are currently being proposed to USCDI v5 where HL7 will provide more feedback on the definition and practicality for current inclusion. The following are initial considerations:

- The specimen condition acceptability should not be considered a characteristic of the specimen, rather of the test/observation that could not be performed due to the condition of the specimen. A specimen may be in a condition that could be acceptable for one test, but not another. Within the interoperability standards there would be at least two fields: one on the specimen to reflect the actual condition of the specimen, and one or more fields to list the reason(s) the test could not be performed and/or if results must be considered in context of a sub-optimum condition of the specimen.

- The test kit unique identifier implies introduction of the robust U.S. Food and Drug Administration (FDA) UDI (Unique Device Identifier) concept. HL7 notes that in reality the laboratory has typically no access to the UDI as defined by the FDA, rather at most the reagent, instrument, and manufacturer names, perhaps a model number. HL7 recommends that USCDI+ PH Lab focuses on the elements of the UDI that are practically able to be provided by a laboratory and included in the results report and -- as the ability to capture a more complete or full UDI advances within the laboratory environment -- to expand USCDI+ PH Lab accordingly.