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U.S. Department of Health and Human Services
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Dear Dr. Tripathi:

The Association of Public Health Laboratories (APHL) thanks you for the opportunity to provide feedback on draft version 5 of the US Core Data for Interoperability (USCDI).

APHL is a not-for-profit independent organization representing public health laboratories and their needs in public health surveillance and reporting. We have included laboratory related USCDI comments in USCDI ONDEC and below. Some items below are listed here separately for emphasis because of the need to advance their status and their importance to public health reporting and processing of reported data. Data quality and consistency are very important to public health users and USCDI has been very helpful where it has applied.

APHL also includes comments about the electronic case reporting (eCR) program that we help support in cooperation with the Centers for Disease Control and Prevention and the Council of State and Territorial Epidemiologists. The data for the eICR standard, now stipulated in regulation, were identified by public health practitioners through a consensus-based process as being appropriate for a multi-condition, multi-jurisdiction case report.

eCR is in broad implementation nationwide with thousands of reporting health care organizations and has operational needs that are represented below. Unfortunately, the lack of consistency of data from EHRs impacts the quality of the data and their utility for public health purposes. We recognize that all of these data will not be always available from healthcare organizations, but when they are available it is critically important that they be consistently represented and USCDI can be very helpful in this regard. These data are important for USCDI, rather than (or in addition to) USCDI+, because they need regulatory incentives applied to healthcare organizations and EHR companies to present them consistently.

APHL is pleased to provide the following comments on the proposals and considerations outlined for USCDI v5:

Laboratory Related Data Elements

USCDI **Level 2** data elements that need to be promoted to USCDI V5:

- Specimen collection date/time – with the following rationale:
    - Data Rationale (why important to PHA and where currently available):
        - Corresponds to CLIA element in 42 CFR 493.1241 (c) (6) in 42 CFR 493.1241 - Test Request (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=7183fd6176006cf7c40b73d2c39d399a&ty=

HTML&h=L&mc=true&r=PART&n=pt42.5.493#se42.5.493_11241) and called out in CLIA: 42 CFR Part 493 Subpart K - Preanalytic Systems

- This is critical for PH Follow up to determine the temporal context; should already be collected in EHR, if provider collected, is collected in LIS/LIMS and important for result interpretation.
- Specimen collection date/time is so natural to be required that it is not even listed in specimen collection procedures, that enumerate what data must be collected and what needs to be considered – found only one for Turkey; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4622196/
- In looking at specimen reject reasons / acceptability criteria, which are published for each test in the lab's catalog we found most test have one for time delay, which is calculated using the specimen collection date/time to the specimen received date time – here are some examples in the literature (and you can look at pretty much any lab catalog for any test, all of them list acceptability time ranges/cut offs)
    - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6816912/ - time delay element in their study: In Table 1 they indicate time delay as a reason for specimen rejection. Specimen collection time is needed to calculate the time delay. "The request form must document unique study-participant identifiers, specimen collection date and time, study participant demographics, specimen type, and the collector's (phlebotomist's) identity" from this study. For this study, see the relationship between temperature and time. Collection time is crucial to know if the specimen is viable.
- https://a1.mayomedicallaboratories.com/webjc/attachments/142/aecfe40-criteria-for-specimen-rejection.pdf - Mayo on the "general criteria" list
- Use Section 7.2 Report Format for Specimen received date, Test performed date, Report date, Report Update Date and in section 9.2 Specimen Collection Date https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2213906/
- Example from the mayo catalog – see SPECIMEN STABILITY INFORMATION: https://www.mayocliniclabs.com/test-catalog/overview/75759#Specimen
- It is a required data element in the many laboratory data-public health exchange standards:
    - ELR R1 (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98)
    - LOI (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=152)

        - LRI (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
        - NAACR (https://www.naaccr.org/pathology-laboratory-electronic-reporting/)
    - And why NOT to use more generic data elements Performance Time from the procedure class: https://www.healthit.gov/isa/taxonomy/term/1456/draft-uscdi-v5 or Laboratory results: date and timestamps https://www.healthit.gov/isa/taxonomy/term/2426/level-2?
        - This discrete data element is needed until the design of USCDI accommodates a mechanism for each use case to define further constraints of these generic data elements, as otherwise the clinical context and significance of when to collect this element cannot be sufficiently described.
        - This is not a type of procedure date/time, because it is not modeled as a procedure in the EHR-s and LIS and also conceptualizing Laboratory Specimen collection date/time as a procedure time may not be clinically correct as in certain situations, such as during a surgery, the procedure time, i.e., Surgery start time, could be different from the time the specimen is obtained.
- Laboratory Test Performed Date – with the following rationale:
    - This description does not match the name of the data element - as written it describes the "Specimen Collection Date", which is a separately described USCDI+ data element, so the definition needs to be updated to: “Date (and optionally time) when testing was conducted by the testing laboratory.”
    - Data Rationale (why important to PHA and where currently available):
        - This is important for PH Follow up used for laboratory situational awareness and surveillance needs. It is used for very time sensitive tests to determine the validity of the result as compared to the specimen collection date/time. I also supports calculation of turnaround time in the absence of the CLIA required element of report date. It is created by LIS/LIMS and should be available in the EHR-s already
        - It is a requested data element in the many laboratory data-public health exchange standards:
            - ELR R1 (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98)
            - LRI (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
            - NAACR (https://www.naaccr.org/pathology-laboratory-electronic-reporting/)
    - And why NOT to use more generic data elements Performance Time from the procedure class: https://www.healthit.gov/isa/taxonomy/term/1456/draft-

uscdi-v5 or Laboratory results: date and timestamps https://www.healthit.gov/isa/taxonomy/term/2426/level-2?

- This discrete data element is needed until the design of USCDI accommodates a mechanism for each use case to define further constraints of these generic data elements, as otherwise the clinical context and significance of when to collect this element cannot be sufficiently described.

USCDI **Level 1** data elements that need to be promoted to USCDI V5:

- Instrument Unique Identifier – with the following rationale:
  - For laboratory tests that use a test kit and an instrument, both data elements are important to record as both influence the result. So just like its counterpart the Test Kit Unique Identifier it should be include in USCDI V5. The same considerations apply:

    - Proposed update to the definition to align with the test kit identifier: Uniquely identifies the instrument that was used to obtain the Test Result Value. For FDA cleared/approved instruments, a unique device identifier (UDI) should be available. At a minimum instrument model name and manufacturer can be used to identify this element. Also acceptable is the Device Identifier (DI), which is contained within the unique device identifier (UDI) and can be retrieved from GUDID database (https://accessgudid.nlm.nih.gov/). Optimally the full UDI should be used, when available (can be formatted as a barcode and/or human readable text).
    - In addition it would be beneficial to
      - define requirements for storage in the LIS
      - when the instrument identifier is added to the results - options are:
        - provided it via IVD instrument interface as described in IHE LAW = CLSI AUTO-16
        - scan a barcode on the instrument (or at minimum utilized standardized data labels that are standardized to reduce the burden of entering and risk of introducing transcription errors when doing this manually) - this is agnostic to where the scanning happens (can be at LIS or middleware or IVD instrument)
      - assigned to the test during the LIS set up (this would only be at the level of DI) and has a risk of becoming outdated, if not properly maintained
      - The DI can be published in LIVD or looked up in the GUDID database (https://accessgudid.nlm.nih.gov/) based on the manufacturer and model name listed as approved instrument in the test kits package insert (where applicable)

USCDI **Level 0** data elements that need to be promoted to USCDI V5:

- Specimen Collection Method – with the following rationale:
    - PHA needs this element, as specimen collection method is used in laboratory surveillance to identify results from specific collection methods.
    - Similar to specimen type and specimen source site the collection method provides important information to the laboratorian and the epidemiologist as it will indicate if the collection occurred using sterile methods, which is important to know for culture results to rule out contamination.
    - It is a requested data element in the many laboratory data-public health exchange standards:
        - ELR R1 (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98)
        - LRI (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
        - LOI (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=152)
        - US Lab ValueSets (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=413)
        - NAACR (https://www.naaccr.org/pathology-laboratory-electronic-reporting/)
    - And why NOT to use more generic data element https://www.healthit.gov/isa/taxonomy/term/781/draft-uscdi-v5:
        - This discrete data element is needed until the design of USCDI accommodates a mechanism for each use case to define further constraints of these generic data elements, as otherwise the clinical context and significance of when to collect this element cannot be sufficiently described.
        - This is not a type of procedure, because it is not modeled as a procedure in the EHR-s and LIS which is also represented by the fact that in FHIR this is a backbone element in the specimen resource that has many more elements besides a reference to a procedure resource (which it is considered to be part of, not an equivalent to.

Electronic Case Reporting Data Elements

eICR Data Elements in USCDI **Level 2** that need to be promoted to USCDI V5:

- Exposure/Contact Information: Exposure/Contact agent
- Exposure/Contact Information: Exposure/Contact Date
- Exposure/Contact Information: Exposure/Contact Direction
- Exposure/Contact Information: Exposure/Contact Source/Target Participant

- Exposure/Contact Information: Exposure/Contact Type
- Facility Information: Facility Address
- Facility Information: Facility Contact Information
- Facility Information: Facility Managing Organization Identifier
- Health Insurance Information/Medicare Patient Identifier
- Immunizations: Immunization Code
- Immunizations: Immunization Status
- Immunizations: Vaccination Administration Date
- Laboratory: Specimen collection date/time
- Patient Demographics/ Information: Identifier
- Patient Demographics/ Information: Patient Identifier Type
- Problems: Date of Onset
- Social History: Congregate Living
- Travel Information: Travel History Dates
- Travel Information: Travel History Location
- Work Information: Job Employer Address
- Work Information: Job Employer Name
- Work Information: Usual Industry
- Work Information: Usual Occupation

eICR Data Elements in USCDI **Level 1** that need to be promoted to USCDI V5:

- Patient Demographics/ Information: Patient Birth Place
- Work Information: Employment Status

eICR Data Elements in USCDI **Level 0** that need to be promoted to USCDI V5:

- Patient Demographics/
- Patient Demographics/ Information: Tribal Enrollment
    - Note: this data element needs to be promoted in alignment with the Tribal Affiliation data element.
- Pregnancy Information: Estimated Date of Delivery
- Pregnancy Information: Gestational Age
- Pregnancy Information: Last Menstrual Period (LMP)
- Provenance: Unique Identifier
- Social Determinants of Health: Housing Instability and Homelessness

The following new USCDI data elements have been entered into ONDEC with all of the context asked for there, but are listed here as well:

eICR Data Elements in USCDI+ but not in USCDI:

New data elements.

- Clinical Notes: Chief Complaint
- Clinical Notes: History of Present Illness
- Clinical Notes: Past Medical History

- Clinical Notes: Review of Systems
- Health Status Assessments: Pregnancy Status Determination Method
- Health Status Assessments: Pregnancy Status Recorded Date
- Laboratory: Placer Order Number
- Patient Demographics/ Information: Deceased Indicator
- Patient Demographics/ Information: Related Person's Email
- Patient Demographics/ Information: Related Person's Phone
- Pregnancy Information: Estimated Date of Delivery Method
- Pregnancy Information: Gestational Age Determination Date
- Pregnancy Information: Gestational Age Determination Method
- Pregnancy Information: Postpartum Status
- Pregnancy Information: Pregnancy Outcome Date
- Problems: Suspected Diagnosis
- Procedures: Planned Procedure
- Provenance: Report Date
- Provenance: Report Submission Date/Time
- Work Information: Current Employer Phone
- Work Information: Current Job Title
- Work Information: Occupational Exposure/Hazard

eICR Data Elements in neither the current USCDI+ (we have asked for them to be added to USCDI+) nor USCDI:

New data elements.

- Clinical Notes: Reason for Visit
- Exposure/Contact Information: Emergency Outbreak Information
- Patient Demographics/ Information: Related Person’s Address
- Provenance: Author Id
- Provenance: Authoring Device
- Provenance: Custodian
- Provenance: Custodian Organization Address
- Provenance: Custodian Organization Id
- Provenance: Custodian Organization Name
- Provenance: Custodian Organization Telecom
- Provenance: Set Id
- Provenance: Version Number