ONC USCDI V3 Comments submitted on April 29, 2022

The Association of Public Health Laboratories (APHL) is grateful to be able to submit the following comments in support of the curation and advancement of USCDI content:

To address these three questions see attached table labeling existing data elements and identifying new ones.

> #1. Are there any improvements needed in the data classes or elements included in Draft USCDI v3, including:
>
> a. Appropriate and meaningful data class and element names and definitions?
>
> b. Representative examples or value sets used by health IT developers and implementers to fully understand the intent of the data element?
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> #2. Should other data elements classified as Level 2 be added to USCDI v3 instead, or in addition to
>
> those included in Draft USCDI v3? If so, why?
>
> #3. Are there significant barriers to development, implementation, or use of any of the Draft USCDI v3
>
> data elements that would warrant not including them in USCDI v3?
>
> It also includes the specific data elements ONC requested input on and expands upon the elements to be added beyond level 2 in some cases in order to support CLIA required elements for laboratory data exchange (see also comment from 2021-09-29 on Laboratory Report Narrative in V1)."

In general, APHL points out that for ANY identifier listed in the USCDI it is important to record who assigned that identifier, to ensure global uniqueness (two organizations can assign the same identifier without knowing it, and if a third party receives results from both organizations it may inadvertently combine them for the same patient); this element is referred to as "assigning authority".

In addition, APHL has reviewed comments and recommendations from other organizations and adds the following statements:

> #1 APHL supports the recommendations from the Health IT Advisory Committee and its Interoperability Standards Workgroup: https://www.healthit.gov/hitac/events/health-it-advisory-committee-44
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> > Laboratory recommendations (p.11)
> > https://www.healthit.gov/sites/default/files/facas/2022-04-13_IS_WG_Phase_1_Recommendations_Report_revised.pdf

- IS-WG-2022-Phase 1_ Recommendation 23 – Recommend that ONC include in USCDI v3 the following additional Level 2 Laboratory data elements that are already included in CLIA and mapped to existing certification requirements for FHIR, C-CDA and ELR specifications.
    - Unit of Measure
    - Laboratory results: Date and time stamps
    - Laboratory Test Performed Date
    - Specimen Source Site
    - Test Kit Unique Identifier
    - It should be specified that these data elements are required to be sent if present/available and that their inclusion in USCDI does not imply a requirement of collection.

  Laboratory recommendations (p.12)
  https://www.healthit.gov/sites/default/files/facas/2022-04-13_IS_WG_Phase_1_Recommendations_Report_revised.pdf

    - The Interoperability Standards Workgroup requests that ONC charge the Workgroup with further exploration of and development of recommendations regarding the data models necessary to support the interoperability of discrete laboratory test results and include additional applicable data elements in the future.
    - The Interoperability Standards Workgroup encourages ONC to work with stakeholders to advance the Laboratory Reference Range and Interpretation (Level 1) data elements, which are required by CLIA and already referenced by existing Health IT certification criteria so that they can be included in a future version of USCDI.

#2 On any data elements not explicitly listed in the attached spreadsheet, APHL supports CSTE's recommendations to enable better outcomes in surveillance.

#3 APHL has reviewed comments by Quest Diagnostics and supports their recommendations in general. In response to their comment about vocabulary for use with specimen type we like to point out that there is a cross mapping table between values in HL70487 and SNOMED CT specimen hierarchy (http://hl7.org/fhir/conceptmap-example-specimen-type.html). In ELR R1 the value set chosen for SPM-4 = specimen type is a combination of HL70487 and SNOMED CT concepts from the specimen hierarchy available in PHNVADS here (https://phinvads.cdc.gov/vads/ViewValueSet.action?id=1F2170E4-00A6-DF11-9BDD-0015173D1785), though this value set hasn't been updated to the latest underlying SNOMED CT code system version, so may be missing some elements.

Data_class	Data_element	USCDI_level	APHL comment
Patient Demographics	Medical Record Number	Level 2	APHL strongly recommends that medical record number (including the assigning authority) be moved into USCDI v3. Patient identification is a CLIA requirement (§493.1291(c)(1)) and using name and date of birth alone is not always sufficient. In addition this element is critical to include in eCR and ELR and is used heavily for person matching and deduplication as well as when requesting additional clinical information on a case of reportable disease.
Patient Demographics	Gender Identity	V2	APHL supports the approach taken by the HL7 from Gender Harmony project. Of note is that HL7 V2 Management Group has published a short term solution for exchanging this data element in any v2 message (https://confluence.hl7.org/display/V2MG/Short+Term%3A+SOGI+Data+Exchange+Profile) and it points to USCDI v3 for their vocabulary, so alignment with the specific codes proposed by the Gender Harmony project will be critical.
Patient Demographics	Sex (Assigned at Birth)	V2	APHL supports the approach taken by the HL7 from Gender Harmony project, using this data element in the context of Recorded Sex or Gender rather than how it is currently often used as a proxy for Sex for Clinical Use. The latter is critically important to be exchanged for the proper interpretation of laboratory tests and should be added to the USCDI.
Patient Demographics	Sexual Orientation	V2	APHL supports the approach taken by the HL7 from Gender Harmony project. Of note is that HL7 V2 Management Group has published a short term solution for exchanging this data element in any v2 message (https://confluence.hl7.org/display/V2MG/Short+Term%3A+SOGI+Data+Exchange+Profile) and it points to USCDI v3 for their vocabulary, so alignment with the specific codes proposed by the Gender Harmony project will be critical.
Care Team Member(s)	Care team provider NPI	Level 2	APHL requests that Care Team Provider NPI be included in v3. This information is required as part of CLIA (placed by authorized person, §493.1241(a) and §493.1241(c)(1)) as it helps to identify whether or not the person listed as ordering provider is indeed authorized to place the order. In addition for anatomic Pathology CLIA requires that the Principal Interpreter of the result is identified / named (§493.1274 (2) and §493.1274 (3) and §493.1273 (d)); again the NPI is much less ambiguous than a name. It also assists public health departments in identifying who to contact at the healthcare facilities for further information about the patient during case and outbreak investigations (receiving care provider name is often insufficient given common names and missing or erroneous contact information for the provider).
Facility Level Data	Facility Name, Address, Contact Information, Identifier, and Type	Level 2	APHL requests that Facility Information be included in v3. This can be for the facility of the ordering provider (CLIA §493.1241(a) and §493.1241(c)(1) - The address can also be mapped to Care team member location). CLIA also requires identification of the performing laboratory (name and address as on the CLIA certificate, so using the CLIA ID will satisfy this requirement as well; §493.1291(c)(2), §493.1273 (d)). In addition this information is extremely helpful for public health reporting to know which facility the patient was treated in. Facility identifier such as Facility NPI or a laboratories CLIA or CAP number are the best way to transmit the information given common names and sometimes poorly structured facility name and address data. In order of priority APHL recommends Facility Identifier (with assigning authority) > Facility Address > Facility Name > Contact > Type
Laboratory	Laboratory Result Value	Level 2	Result value is a critical field to include in USCDI v3. Many test results for conditions of public health importance cannot be interpreted without a value – these include serologic tests, tests which measure antibiotic susceptibility, Hepatitis C viral RNA, HIV, Hepatitis B viral DNA among many others. Where the result value is qualitative and not free text, it should be encoded using SNOMED CT concepts from the organism or clinical finding hierarchy; for some ordinal results concepts from the qualifier hierarchy should also be allowed. Per previous comment (https://www.healthit.gov/isa/comment/7016) this data element needs to be reconciled with Values/Results available since V1.
Laboratory	Values/Results	V1, V2, V3	Result value is a critical field to include in USCDI v3. Many test results for conditions of public health importance cannot be interpreted without a value – these include serologic tests, tests which measure antibiotic susceptibility, Hepatitis C viral RNA, HIV, Hepatitis B viral DNA among many others. Where the result value is qualitative and not free text, it should be encoded using SNOMED CT concepts from the organism or clinical finding hierarchy; for some ordinal results concepts from the qualifier hierarchy should also be allowed. Per previous comment (https://www.healthit.gov/isa/comment/7016) this data element needs to be reconciled with Values/Results available since V1.
Laboratory	Laboratory results: date and timestamps	Level 2	APHL recommends to further specify the this element as follows: Laboratory Test Performed Date = Date and optionally time the test result was verified and released to be shared, often referred to as Date/time of analysis, or Test date - this is https://www.healthit.gov/isa/taxonomy/term/2436/level-2 Report date/time = Date and optionally time the entire report was released to be shared (either for the first time or as an update); this is a CLIA requirement (§493.1291(c)(3)) - this does NOT YET exist, so maybe this element could be renamed to reflect this aspect. For orders the date and optionally time the test was ordered (entered into the system by an authorized person and available to be sent electronically) -in the current v2 world this date/time is not normally sent in the result messages
Laboratory	Laboratory Test Performed Date	Level 2	This is one of the date/timestamps critical to understanding the result value in the temporal and clinical context.
Laboratory	Specimen collection date/time	Level 2	APHL strongly recommends to include the specimen collection date/time (HIGH PRIORITY) as this provides the temporal context for the lab result value into the patient's clinical state and also for understanding of public health trends. It is also a CLIA requirement (42 CFR 493.1241 (c) (6)) - it is a critical element to properly interpret the result value. This element needs to be reconciled with Test Date=Clinically relevant time).
Laboratory	Accession number	Level 1	APHL urges ONC to include Accession number (with the testing laboratory or its LIS being the assigning authority) to be included in USCDI V3 (HIGH PRIORITY) - this is the main identifier used in the lab for matching purposes of results, so important to know for follow up both on the clinical side as well as for Public Health. In order to be able to link data from EHR-s (reported via eCR) and LIS (reported via ELR) in the surveillance system to support proper public health follow up and case count. This is also a CLIA requirement (§493.1276 (a)); In some labs this may be synonymous with the specimen identifier.
Laboratory	Specimen Identifier	Level 2	APHL urges ONC to include Specimen Identifier (with the testing laboratory or its LIS being the assigning authority) to be included in USCDI V3 (HIGH PRIORITY) - this is the main identifier used in the lab for matching purposes of results, so important to know for follow up both on the clinical side as well as for Public Health. In order to be able to link data from EHR-s (reported via eCR) and LIS (reported via ELR) in the surveillance system to support proper public health follow up and case count. This is also a CLIA requirement (§493.1276 (a)); In some labs this may be synonymous with the Accession number.

Data_class	Data_element	USCDI_level	APHL comment
Laboratory	Specimen type	V3	APHL supports inclusion of specimen type, as not all tests are performed only on one sample type that can be sufficiently encoded in the LOINC of the test. For tests that can be performed on multiple sample types, and where it is not feasible to set these up as different tests with different LOINC mappings (e.g. many tests for infectious agents) this is a CLIA requirement (though CLIA uses the term specimen source (§493.1291(c)(5)), which conflates several aspects about a specimen: its type (what is it), its source site (where is it from), its collection method (how was it obtained) and potentially also any alterations (was something added to it). All of these attributes of a specimen may be of importance for the proper interpretation of the result as well as for the resulting diagnosis. For specimen type we suggest use of SNOMED CT concepts from the specimen hierarchy for now, as it supports the pre-coordination of many of these attributes, when needed and is the closest to CLIA's specimen source. In the long run we hope the specimen cross mapping table being developed by the Laboratory Community of practice can be used to properly represent specimen attributes with their respective SNOMED CT hierarchies. For Public Health Type of specimen is critical for triggering electronic case reports and for making decisions on which cases are invasive (e.g., for S. pneumoniae, MRSA, Group A strep).
Laboratory	Specimen source site	Level 2	APHL supports the inclusion of specimen source site (HIGH PRIORITY), particularly for anatomic pathology samples (for Public Health important for cancer reporting) as one of the attributes conflated into the CLIA requirement to document specimen source (§493.1291(c)(5)). Specimen source site should be coded using SNOMED CT concepts from the body structure for clinical samples. In some instances EHR-s may have to record laboratory test results on non-clinical samples, such as blood products, artificial joints, catheters or the environment, in which cases SNOMED CT concepts from the physical object or substance hierarchy should be used.
Laboratory	Test Interpretation (Abnormal Flag)	Level 1	APHL supports the inclusion of Abnormal flag; sometimes also refereed to as interpretation (HIGH PRIORITY), because it is often used by the clinician to triage which laboratory test results they pay attention to, it is used in decision support for triggering additional tests, reports or specific alerting procedures; this is also a CLIA requirement (§493.1291(c)(6)).
Laboratory	Test Kit Unique Identifier	Level 2	APHL strongly supports the inclusion of test kit identifier for the type of test (the make and model, not the serial number) in USCDI V3 in order to better support those tests, that have not yet been harmonized to an international standard (https://www.harmonization.net/measurands/) - for example during the COVID-19 pandemic it is important for FDA as well as clinical research, clinicians and public health to understand the performance of each test in light of emerging new variants as well as for patient safety to know if a result from an outside lab can be safely included into the patient's flowchart and decision support algorithms; the same LOINC does not guarantee that. the IVD industry has been working on a cross mapping specification that provides the LOINC mapping for each test kit - instrument combination called LIVD; it s an HHS required element during the COVID pandemic. Ideally this would be the UDI (assigned by FDA), but there needs to be support for a different way of identification until ALL test kits have UDIs. Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) is a public-private collaboration of over 70 organizations representing federal agencies, in vitro diagnostics (IVD) organizations, standards development organizations , medical associations, and other professional laboratory organizations with the mission is to “Describe the SAME test the SAME way ANYWHERE in the Healthcare ecosystem” and being able to reference the test kit unique identifier is critical to this effort.
Laboratory	Instrument Unique Identifier	Level 1	APHL supports inclusion of this element, because similar to the Test Kit Unique Identifier the instrument unique identifier is important to preserve to identify performance issues between instruments.
Laboratory	Result Status	V3	Specifically APHL encourages ONC to clarify the definition for Result Status - to ensure it is set to the level of each observation and to add a new element for the report status, which summarizes one or more results including all auxiliary information (patient demographic, clinical information) that contributes to the status. For example a report can be amended, where no result changed, but the results were re-verified after a change in demographics was reported to the laboratory, so the updated report will be re-issued, even if the provider will not update their system with the changes in the demographic data (because their system was the source of truth for these in the first place). CLIA requires a report status (§493.1291(k), §493.1274 (6)) as well as a clear indication what has changed; using a result level status for each observation in addition to the overall report status accomplishes that. For Public Health purposes knowing that a result is preliminary, or final is critical for determining the certainty of the existence of a critical public health condition.
Laboratory	Report status	NEW	To satisfy the CLIA requirement for a report status and in case of correction the basis of correction (§493.1291(k), §493.1274 (6)) this element is needed to highlight a change in the overall report. Used in conjunction with the Result status and a new comment element, when explanations are needed in addition to highlighting the changed result.
Laboratory	Result comment	NEW	To satisfy the CLIA requirement for a report status and in case of correction the basis of correction (§493.1291(k), §493.1274 (6)) this element is needed to highlight a change in the overall report. Used in conjunction with the Result status and a new comment element, when explanations are needed in addition to highlighting the changed result.
Laboratory	Units	NEW	APHL urges ONC to include units (HIGH PRIORITY) for quantitative results as they are critically important to understand the result value and it is a CLIA requirement (§493.1291(c)(6)); it is important to keep value and units together, which is why many systems support the data type of "quantity". So if the Laboratory result value includes descriptions of the different data types being supported, this element may not need to be a separate element, but it MUST be supported in EHR-s and included in all data exchange of the result value (see comment https://www.healthit.gov/isa/comment/7016).
Laboratory	Reference Range	NEW	APHL urges ONC to include reference range (HIGH PRIORITY) because knowing the normal ranges (or other reference points along the abnormality spectrum) is critically important to understand the result value and it is a CLIA requirement (§493.1291(d))