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April 15, 2024

Dear Dr. Tripathi

Oracle Health, a leading supplier of electronic health record, clinical and revenue cycle information systems, is pleased to provide feedback on the draft US Core Data for Interoperability (USCDI) version 5. Oracle Health supports one of the principal purposes of the USCDI to provide scope, guidance, and clarity on the data that HIT can be expected to support when certified to ONC's Certification Program. As the recent HTI-1 final rule states "*This change ensures that Health IT Modules certified to § 170.315(b)(1) are capable of accessing, exchanging, and using USCDI data elements referenced in the standards in § 170.213.*"

We continue to advocate that USCDI, and as appropriate in combination with USCDI+, aims to cover most if not all ePHI plus other data critical to enabling interoperability of ePHI. That goal is not attainable in the short term, but it should and can be a continued aim for USCDI and USCDI+. In that context we generally do not challenge the importance of any ePHI to be included, rather we focus on the readiness of the data in terms of available and sufficiently mature standards with associated implementation guides to enable consistent adoption by all relevant HIT and scaling at a national level without unreasonable risk for re-work when standards and implementation guides have not been widely used in operational settings.

We are providing feedback on the general process how USCDI is managed and maintained that aims to have full alignment of USCDI with the supporting standards and implementation guides as each goes through their update processes, followed by data element specific feedback.

We are happy to provide any additional clarifications on our feedback and continue to be committed to working with ONC and the industry to continue the substantial progress made to date on enabling interoperability without special effort.

Sincerely.

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General Comments

The following comments and suggestions addresses the challenges that USCDI introduces when not does not remain aligned with its supporting standards and implementation guidance, specifically HL7 FHIR US Core, HL7 CDA C-CDA, as well as the ability of ONC's Certification Program to enable more HIT holding EHI to be certified.

USCDI Alignment with Supporting Standards and Implementation Guides

As a result of USCDI starting to include data classes and elements for which the HL7 FHIR US Core and HL7 CDA C-CDA have no guidance at the time of USCDI publication, the actual version of HL7 FHIR US Core and HL7 CDA C-CDA published in support of a specific USCDI version may not fully reflect the scope of that USCDI version. The guides would be in line with the clarifications on intent by ONC representatives during the development of the guides, but to anybody not part of that process there is no transparency that certain reasonable interpretations of USCDI are not covered by the guidance. We note that examples where the variance in interpretation is substantial enough to be of concern goes back to USCDI v3. The following examples and suggestions that are also being expressed by the EHRA are of most concern, i.e., they are in most need for ONC to "amend" the applicable USCDI version to indicate the variance. We do not have a specific suggestion on the format or whether this is stated for each USCDI version for the data class and data element it applies to, or that there is one statement that indicates that the supporting implementation guides supersede any interpretations that one can reasonably derive form USCDI that are not covered in those implementation guides. This can mitigate any confusion where users of certified HIT may inadvertently expect different/more capabilities from certified HIT based on USCDI as published considering the statement in HTI-1 "*This change ensures that Health IT Modules certified to § 170.315(b)(1) are capable of accessing, exchanging, and using USCDI data elements referenced in the standards in § 170.213.*"

The following are examples that also are shared by the EHRA in their response to USCDI v5 and in their letter linked here, which we support.

Procedures

USCDI v3 indicates that any activity performed for or on a patient as part of the provision of care. This implies many different types of activities that are typically not represented as a "procedure" in FHIR and/or C-CDA. We suggest that the scope of procedures is explicitly limited to those activities specifically included through a dedicated data class such as laboratory, immunization, clinical test, diagnostic imaging, and vital signs. And where they are not explicitly called out, we suggest to then include them in the definition of Procedures as done for SDOH interventions. In that context we suggest to include surgical procedures explicitly, even though surgical procedures are typically considered procedures as for many those would typically be the only procedures included under "procedures".

Medication Administration

USCDI v4 includes an example for the Procedures Performance Time data element. This implies the need for recording an administration, particularly considering Immunizations is a specifically recognized data class. We suggest that the medication example is removed as an example.

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Facility Information

USCDI v4 includes Facility Information as a standalone data class without any references to the data classes and context where this is considered relevant. Facility and location information is relevant in many different context, but the intent is to be primarily about where the encounter occurred. In FHIR US Core and C-CDA this is being scoped to the Encounter generally and identifies the data classes that reference Encounter enabling to infer the location through that reference. When the Encounter location is not applicable then they should (not shall) provide the location within the resource itself using the attribute or may use the event-location extension to encourage consistent placement of the location:

US Core DiagnosticReport Profile for Laboratory Results Reporting

US Core Immunization Profile

US Core MedicationDispense Profile

US Core Observation Clinical Result Profile

US Core Procedure Profile

US Core ServiceRequest Profile

We suggest that USCDI is updated to reflect this targeted scope, and adjusts as that is expanded over time.

Workflow Context

USCDI defines data classes very broad allowing for interpretations that it is not only about being able to view/access the data (e.g., presence of an order), but could be interpreted to initiate/manage the workflow, e.g., the placement of an order, the reporting of the result in response to the order, etc. We suggest including a statement of purpose as part of an introduction that the current focus is on enabling access and viewing of the documented data classes and data elements in certified HIT. If there are other use cases for using USCDI that do not involve informing HIT of the scope they are being certified that should then additionally be clarified.

Vocabulary

References to vocabulary are mostly to the overall code system to be used, not to the specific branches that are applicable. While for some, e.g., Clinical Notes, there are references to very specific individual LOINC codes, not having a more targeted middle ground set is causing challenges where they could be very helpful. E.g., what are all Clinical Tests to be considered? What is truly the scope of Procedures? Which SDOH assessment tools are recognized widely enough to be supported (not necessarily documented, but viewable when received). We suggest that vocabulary is more specifically bound in USCDI and accordingly proposed to enable appropriateness of scope.

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Document vs. Note

USCDI v1 started to conflate the concept of a structured document and narrative summary note by using the same LOINC code for either. E.g., the same LOINC code used for the C-CDA Document Type Discharge Summary and for the Discharge Summary narrative note. This is now starting to show the anticipated challenges that had been raised as it is not possible to query for either in their own right where relevant, It also is highlighting that categorization of related/like LOINC codes is relevant as well so that one can get all, e.g., discharge summary related notes and documents. We suggest that ONC work with Regenstrief to identify appropriate categories and specific LOINC codes to distinguish narrative summaries from structured documents and adjust USCDI accordingly.

Patient expressed vs. authored

In USCDI various data classes and elements indicate "patient authored" where "patient expressed" is more encompassing of including those expressed by the patient but authored/documented by a clinician. For example, the various preference data elements. Using "patient authored" implies that the HIT needs to enable in some fashion that it must be able to allow a patient to directly write their information into that HIT. We understand that not to be ONC's intent, but that is a valid interpretation to some. We suggest to both use "patient-expressed" as the reference and clarify that the current scope does not require that the HIT has the ability to support patient authored content in any form (e.g., FHIR writes, portal-based forms, etc.), only that if they happen to support it, it should be accessible as well.

Specimen Condition Applicability

USCDI v4 provides a definition that implies that the focus is on the applicability of a specimen for a particular test based on its condition. During ballot reconciliation of FHIR US Core 7.0.0 it was agreed to that the focus should be on the condition of the specimen that in turn can be used to determine applicability of that specimen for a particular test. Certain conditions would still allow for a test to be valid, or performed with annotations, while other conditions would not be suitable to perform certain tests. We suggest to update USCDI v4 to reflect the clarified intent of the scope and adjust the name accordingly.

Specialty EHR and Other HIT Certification Opportunity

We support that USCDI be used to help scope the progression of standards based interoperability, thus creating a simpler, summary understanding of what data certified HIT can support. However, while ONC's Certification Program references HIT, the approach of requiring support for all USCDI for any HIT wishing to be certified to HL7 FHIR based APIs and HL7 CDA C-CDA based document creates an increasing problem that not all relevant HIT could be certified. Specialty EHRs and non-EHR HIT would have to develop capabilities to support their users that are not relevant to the user of such HIT. The introduction of USCDI+ has to date not demonstrated an opportunity to enable a larger variety of HIT to be certified. While certification is an onerous process, and as such could benefit from streamlining and improvements, HIT that is certified and the source of EHI of interest is more consistently accessible, thus reducing special efforts to connect. We continue to urge ONC

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to enable any HIT that is the source of EHI that should be shared to be certified, thus have predictable, consistent access and sharing methods for the USCDI subset that they actually manage and maintain. Such data would not include any data that is a part of a document that only needs to be displayed/viewed as-is, but the data that is actually entered or ingested into the HIT and managed as individual structured data.

USCDI v5 Proposed Data Classes and Elements

Clinical Notes

We support the inclusion of the two new clinical notes data elements with the following suggested updates:

- Include "Narrative summary" in their descriptions and all other USCDI Clinic Notes data elements, e.g., "Narrative summary of care delivered in an emergency department ". Narrative summary notes are distinct concepts from full documents that can be a mix of narrative notes and individual structured data elements. FHIR US Core expressed Clinical Notes do not have the same meaning as the C-CDA expressed document types that include the narrative summaries as well but are not limited to that.
- Provide flexibility to introduce different LOINC codes for the narrative summary vs. the document. Permitting a clear distinction between USCDI Clinical Notes and C-CDA Document Types, which currently share the same LOINC codes, will enable improved data sharing.

Laboratory – Test Kit Unique Identifier

We do not support the introduction of the Test Kit Unique Identifier as defined. The name and definition imply a requirement for full Unique Device Identifier (UDI) support which is not realistic in the current workflow from instrument to Laboratory Information System (LIS) to Electronic Health Record (EHR), Public Health and beyond. Currently it is hard to even get a free text instrument model or reagent test kit name plus manufacture name. While the information is generally available in the Laboratory, the LIS does not include such information in their results reports. We strongly urge ONC to work with FDA (through SHIELD) and CMS (through CLIA) to focus first on enabling LIS systems to capture and communicate instrument and reagent names plus its manufacturer and then advance both the ability of target HIT such as EHRs and PH systems to receive and forward such information, followed by expanding it to address the full UDI as defined by FDA. We ask that, until there is clear progress on the LIS capabilities, that the EHRs, which are the systems primarily subject to certification to all of USCDI, are not required to receive such identifiers and focus on other, more implementable and usable capabilities.

Observations

With the introduction of an Observation data class it is unclear what data elements apply to any observations, and what data is unique to a particular type of observation. For example, assessments, lab results, vital signs, are all types of observations. We suggest that the Observation data class only contains data elements applicable to an observation, while domain specific data elements are organized within the domain.

As observation data specific to a domain is organized within the applicable domain, we suggest that data is clearly identified to be relevant to the ordering or performance of the service, test, or assessment, i.e.,

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the observation. This, in combination with similar suggestions on the Orders data class will remove ambiguity as to whether the intent is to include in scope the ordering or the performance, or both, while minimizing duplicate data element definitions.

Advanced Directives Observation
We support the inclusion of this data element, but suggest this concept is better addressed as part of a new data class, Advanced Health Directives considering other data elements that will be of interest related to advance health directives, e.g., references to the structured or unstructured document(s) available. This should then include Treatment Intervention Preference and Care Experience Preference to be recategorized into such a new data class as well as all these aspects address the wishes of a patient whether as part of end-of-life decisions, or other preferences, e.g., medication preferences, or religious accommodations influencing the care to be provided.

In that context we suggest renaming this data element to Documentation Status within that data class to better cover the intended scope of availability of documents and consider for future use references to documents available.

Sex Parameter for Clinical Use
We support the inclusion of this data element, but suggest it is relevant to other data classes as well. It not only is relevant to other observations to provide relevant context for interpretation, but also context for the newly proposed Orders data class as it would provide the relevant context in which that the order should be performed, e.g., laboratory orders.

This is an example where it would be helpful to reference the same data element in multiple classes as we suggest in the Orders topic as well.

Orders

Generally we support the introduction of an Orders data class as it can help with the identification of order data that is common across any order. Similar to what we suggest under Observation, order data specific to a domain, e.g., Laboratory, Medication, Nutrition, could then be organized in the domain/data class to which it is specific. The data within such a domain/data class should be defined specific to whether it is relevant to the ordering or performance of that data class, e.g., Laboratory order or test or both. For other data classes this may include other stages of the workflow where certain data is relevant when is to be shared with the patient or other stakeholder, e.g., appointments and referrals.

In the current proposal there are actually not specific data elements defined as just “orders” is too ambiguous and can imply many data elements. We suggest starting with what was ordered (where the code system used depends on the domain/data class in play), who ordered it, when it was ordered, and status. These are elements that most systems would already capture when managing orders.

We note that the examples also include do-not resuscitate orders, which typically implies POLST orders. Such orders require specific documentation and forms to be used to have appropriate legal standing within certain jurisdictions. There are no clear standards as of yet how to capture and represent such orders, unlike laboratory, medications, imaging, and other diagnostic and therapeutic services. We suggest to initially focus on being able to represent these general orders until there is further guidance on how to represent POLST orders.

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Patient Demographics/Information

We note that the Interpreter Needed data element does not indicate the language for which an interpreter is needed. We suggest adding a related data element that indicates the language for which the interpreter is needed.

Provenance

We strongly support the need for further provenance data to enable the receiver of the data to understand relevance based on the source, as well as it can assist with de-duplication and reconciliation efforts upon receipt of data. We are concerned though that the current definition may be interpreted that certified HIT must be capable of supporting patient generated health data with direct writes by the patient to the HIT as patient is indicated to be one of the authors of interest. We urge ONC to clarify that this is not the intent at this stage, while where data is contributed by a patient that should be known. However, that need not mean that the patient is then the "author" as defined by standards supporting USCDI.

Level 2 Data Elements

We recognize the interest and desire to expand USCDI as quickly as possible, thus man will provide suggestions to advance several Level 2 data elements into USCDI v5. We caution ONC adding Level 2 data elements considering the level of effort needed to include many of them in a 1-2 year time window in light of all other efforts and priorities that HIT developers face, such as HTI-1 and client requests for new features that advance their HIT capabilities in support of their operations.

If any Level 2 data elements are still to be considered, we suggest to focus on those that are already widely supported in typical data exchanges. Even then, clarity would still not be sufficient as currently documented in the Level 2 definitions. For examples, laboratory results date time stamps could encompass a variety of date times, not all of which are captured or relevant in all HIT that would be useful to be certified. The clinically relevant data time, for labs the specimen collection data time, would be easy and is already in FHIR US Core / CDA C-CDA, while the analysis date time is not necessarily widely communicated and not as critical depending on context and user.

Consequently, we suggest that ONC holds off on including any Level 2 classes or data elements and proposes a reasonable number for the next USCDI version.