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April 14, 2023

Micky Tripathi, Ph.D. M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: United States Core Data for Interoperability (USCDI) Version 4 Draft

Dear Dr. Tripathi,

Oracle Health appreciates the opportunity to submit public comment on the draft USCDI Version 4. As a leading supplier of clinical and management information systems and a market leader in health information interoperability, we believe our experience provides us with valuable insight in this subject area and are grateful for the ability to share that insight.

Oracle Health supports and appreciates the hard work and dedication of you and your staff behind the creation of the USCDI and the ONC New Data Element and Class (ONDEC) submission system and process for ongoing annual expansion of the USCDI. Oracle Health strongly supports ONC's drive for interoperability across healthcare stakeholders and recognizes the valuable role that the USCDI plays in that endeavor.

If you have any questions or if we can provide any additional information, please do not hesitate to contact me at (816) 201-1924.

Sincerely.

Mike Hourigan
Sr. Director, Product Regulatory Strategy
Oracle Health

April 14, 2023

General Comments

USCDI and the HIT Certification Program

As we have expressed in various other public comments related to the USCDI – including on the Cures Act rulemaking and for the draft USCDI v2 and v3 – we continue to be concerned about the rapid expansion of the USCDI given its use as a specification for both HL7® CDA® C-CDA and HL7 FHIR® API based criteria in the HIT Certification Program ("the Program") and the potential for new versions to be adopted as certification requirements in their totality.

While most of the data elements that have been proposed as part of draft USCDI releases have understandable value for particular care venues and/or use-cases, the significance and impact of the inclusion of the whole of a USCDI version as a standard cited in the Program for criteria included in the Base EHR definition (particularly the Transitions of Care and Standardized API criteria at 45 CFR 170.315(b)(1) and (g)(10), respectively) does not appear to be fully appreciated.

We appreciate that the USCDI has important roles to support both federal and stakeholder interests for enabling interoperability. However, based on ONC's stated intent to continually raise the version of USCDI required as part of the Program, any such requirements do in fact become required capabilities of HIT certifying to the above-mentioned certification criteria. This effectively makes USCDI a monolith from a requirements and development standpoint.

Furthermore, while the intent of the USCDI is to serve as a data set for healthcare interoperability independent of specific types of HIT or particular intended use-cases for certification criteria, the USCDI in its present form for the Program must be supported by clinical EHRs utilized in acute and ambulatory care settings to satisfy regulatory requirements. Retaining a whole USCDI version as a certification standard will perpetuate and raise this issue with all future versions of USCDI adopted through both the Standards Version Advancement Process (SVAP) and as a set requirement for any future certification regulation as they raise the minimum version of USCDI cited in Base EHR criteria. At the same time, any other HIT that would benefit from certification, thus advancing the ability to access EHI without special effort, would be stifled.

This is a problem for HIT developers who would be compelled to keep pace with support for new data elements that may be of little applicable value for the healthcare providers they serve or the type of HIT they present for certification. They may support the current scope of the USCDI v1 as it is an appropriate "core" or "common" clinical data set for interoperability, and it does comport well to the current interoperability requirements for a clinical system. However, as new versions of USCDI have been released we have already seen the scope of USCDI expand beyond a core clinical data set by incorporating data classes and elements that are more aligned to administrative, ancillary, and revenue cycle types of applications and purposes of HIT beyond the direct clinical patient care and traditional EHR space.

We support USCDI expansion generally as the data elements have their own merit for the purposes and use cases that define their value. However, we believe it folly to continue to operate under the assumption that all such data must necessarily be supported by a singular type of HIT presented for

certification to the interoperability criteria that currently require the whole of the USCDI. The fact remains that under current ONC and Centers for Medicare and Medicaid Services (CMS) policy, healthcare providers in acute and ambulatory settings would be required to adopt technology supporting new versions of USCDI should the current certification requirements be updated as part of maintaining Certified EHR Technology (CEHRT) compliance. Thus, while the USCDI is intended to be agnostic as to specific care settings or types of HIT, it is effectively regulated in a manner that is. This compels developers serving providers in those venues to invest in support of these capabilities and pass those costs on to the providers, even when those capabilities are not high priorities for them.

There is also the uncertain effect of other payment programs and reimbursement models or state legislators that are beginning to cite USCDI. For example, the Centers for Medicare and Medicaid Innovation's (CMMI's) Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model, which cites USCDI v2 data elements as part of its requirements for participants, legislation from the State of California for their California Data Exchange Framework (DxF), which also cites USCDI v2, and most recently the draft TEF SOPs for Health Care Operations and Risk Adjustments each differently including more or less USCDI v2 data elements. In general, especially at the state level, we are seeing requirements of federal HIT policy elements being inaccurately or incompletely applied. This raises concern that such references to whole versions or part of the USCDI when the policy purpose for its inclusion is more specific creates misalignment with the state's intent, goes beyond where the federal certification floor is, and compels HIT developers to engage in support for a requirement that is outsized to the real purpose of reference to the USCDI. These inconsistencies in the way USCDI is referenced in context of how conformance is currently being certified only add to the concerns on how to effectively advance certified HIT support for the relevant interoperability use cases they need to support in the context of their target users.

If the USCDI were instead treated as a compendium or library of data classes and elements for use by stakeholders to fit their purpose, using standards in combination with properly scoped certification criteria, we believe that states and other policymakers may understand more readily they could use specific data types and classes as their policy purpose, while enabling more HIT to be certified for critical access to EHI.

Accordingly, we strongly recommend ONC shift the policy and structure of USCDI to be treated as a compendium or library of data elements and classes from which interoperability certification requirements could be drawn as befits the purpose of given certification criteria. The same would then be true of other policymakers and legislators able to pick and choose relevant data classes/elements for their specific purposes and needs.

ONC New Data Element and Class System and Level 1 and Level 2 of USCDI

We have also observed with the first few rounds of USCDI expansion that the focus areas seem to be trending towards expansion for purposes not immediately driven by interoperability use cases, rather to introduce into clinical workflow. While the two (interoperability and clinical workflow) are inherently connected, effective data exchange can only happen when there is consistent treatment and understanding of the data as part of clinical workflow and processes at the local system level. Thus, data elements adopted in USCDI should already be well established and aligned concepts in clinical workflow. And more specifically, they should have exchange specifications that are reasonably well adopted in the

industry – not just exchange between at least 4 HIT systems as is the current criteria to be considered a level 2 element for USCDI adoption, which may not cover a large enough community to have sufficiently established how to best share the data and is mature enough to rapidly scale to a national level.

We appreciate that advocates have strong reasons to argue for the support of new data types and elements in the USCDI, and some argue that imposing the near-term development of the underlying support for their interoperability as prerequisite to inclusion only impedes progress. Generally, we do not argue the potential and real value that can be achieved and should be part of USCDI. But including them prematurely considering the way in which USCDI is actually used in the Program ignores the practical reality that it is unworkable to include new data elements and classes without existing and matured standards support. To do otherwise without appropriately scoping them based on practical implementation experience to determine how they should be exchanged downstream just creates unnecessary re-work, missed expectations, or worse, check-the-box capabilities that are not deployed or used by healthcare providers.

Therefore, we ask that ONC think more critically about candidate and recommended data elements for adoption to ensure that there is truly readiness from both an upstream adoption (e.g., in clinical EHR workflow if a clinical concept) and interoperability specification adoption perspective (e.g., existence of well adopted specifications in primary exchange mechanisms, like HL7 FHIR and HL7 CDA C-CDA, that can at least be used as a reliable starting point for profiling in HL7 FHIR US Core and the HL7 CDA C-CDA Companion Guides).

Conflicts in Concept Standards

Finally, we have observed instances in which data elements adopted in new versions of USCDI – or vocabulary standards for those data elements – create a conflict between how that data concept is represented in a particular version of USCDI and how the same concept is represented in existing HIT Certification Program regulations. The most glaring example of this is the Sex data element adopted with USCDI v3. Transitioning from the Birth Sex (or Sex (Assigned at Birth)) concept with the standard at 45 CFR 170.207(n) as vocabulary standard in USCDI v1 and v2 to the nonexclusive Sex concept with SNOMED-CT as the vocabulary standard in v3 created a direct conflict with requirements of the Base EHR Demographics criterion at 45 CFR 170.315(a)(5).

Recognizing that new versions of USCDI are not immediately regulated by the ONC as part of the Program, this still creates a conundrum for HIT developers, healthcare providers, and others seeking to advance to the most recent editions of critical interoperability specifications. Furthermore, this can become a direct issue within the Program as these new versions of USCDI are considered for adoption via the Standards Version Advancement Process (SVAP). Other agencies and regulatory authorities (whether federal, state, local, or otherwise) can also cite new versions of USCDI in their own regulations independent of the Program.

Accordingly, we urge ONC to take care to account for potential conflicts with existing regulations that may be introduced as new data elements and associated vocabulary standards are considered for adoption.

Allergies and Intolerances

Substance (Non-Medication)

Oracle Health supports adoption of the Substance (Non-Medication) data element in USCDI v4 as proposed. Monitoring and exchange of allergies and intolerances for non-medication substances, such

as environmental and food-based allergies, provides clear value to patient care. Furthermore, this is a data point that is already a standard part of medical records and has been appropriately profiled within both HL7 FHIR US Core (US Core AllergyIntolerance Profile – AllergyIntolerance.code) and HL7 CDA C-CDA R2.1 (Allergy - Intolerance Observation (V2) participant/participantRole/playingEntity/code).

We also support the adoption of SNOMED-CT as the vocabulary standard for the data element. SNOMED-CT is the appropriate code system for representing non-medication substances in context of allergies and intolerances as it provides suitable coverage of non-medication substances. It is also already well established as the code system used under the Common substances for allergy and intolerance documentation including refutations value set cited as the binding for the FHIR AllergyIntolerance.code element for non-medication substances, as well as the code system for non-medication substances under the Substance Reactant for Intolerance value set required for representing the substance code in the Allergy – Intolerance Observation (V2) entry template for C-CDA R2.1.

Encounter Information

Encounter Identifier

Oracle Health supports adoption of the Encounter Identifier data element in USCDI v4 as proposed. This data element is already well established as a key data point within health information exchange and has been appropriately profiled within both HL7 FHIR US Core (US Core Encounter Profile – Encounter.identifier) and HL7 CDA C-CDA R2.1 (Encounter Activity (V3) Encounter/id).

Facility Information

Regarding the whole of the proposed Facility Information data, we note that the concepts represented are most valuable as supporting data points for other data classes/elements. For example, in the provision of an encounter or a procedure, the facility information is where an encounter took place or where a procedure was performed. On its own, facility information is unlikely to be useful in a healthcare context. Accordingly, we recommend updating the specific USCDI data classes where facility information is relevant by referencing the Facility Information data class. We specifically suggest to start with Encounter, Procedures, and Laboratory data classes. This will help to appropriately position the new data class within the USCDI as a supporting or referential concept.

Facility Name

Oracle Health supports adoption of the Facility Name data element in USCDI v4 as proposed. This is an essential element to include with the introduction of the data class and is appropriately defined in the draft.

Facility Type

Oracle Health supports adoption of the Facility Type data element in USCDI v4 as proposed. Including the data element without a defined value set or code system as a vocabulary standard is appropriate in its initial phase as part of USCDI v4. However, we note that it is important to consider establishing an appropriate vocabulary standard in future USCDI versions to work towards more consistent representation and exchange. Accordingly, we suggest that ONC work with HL7 to establish a reasonable set of facility types of interest to be adopted as the standard in a future USCDI version.

Facility Identifier

Oracle Health supports adoption of the Facility Identifier data element in USCDI v4 as proposed.

However, we note that it is critical to ensure uniqueness in identifiers relied upon across organizations. Currently, the industry faces challenges with this as many organizations will assign Object Identifiers (OIDs) within their own OID branch to entities (including facilities) outside their organization. Accordingly, we encourage ONC to clarify as part of this data element that only the proper identifiers as assigned by the original owning organization should be relied upon. This will help ensure that facility identifiers are not only unique, but also usable.

Goals

Treatment Intervention Preferences and Care Experience Preferences

Oracle Health currently recommends against the adoption of these data elements within the Goals data class as well as adoption in USCDI v4 due to a lack of appropriate available specifications (particularly in HL7 FHIR) for representing the data. While we understand and appreciate the desire and need for the addition of these data elements to appropriately express patient preferences in data exchange, we believe this is not the proper time or class for these data elements to be added.

While these data elements are proposed for inclusion in the Goals data class, we remain convinced that this is an improper fit given the specialized nature of the data. The preexisting data elements in the Goals data class (Patient Goals and SDoH Goals) are focused on desired future states or outcomes related to a patient's care, whether expressed by the patient themselves, their clinician(s), or other care team members. The newly proposed data elements, on the other hand, express preferences for how their care is delivered and strongly overlap with the approach for portable medical orders as to which interventions (not outcomes) should or should not be performed in certain circumstances. Thus, these data elements are deserving of their own data class (e.g., "Personal Care Preferences") which can suitably represent the scope and intent of the data as important standalone concepts independent of the Goals data class.

Additionally, ONC should consider aligning these with the Level 2 Care Plan and Advanced Directives concepts as patient expressed goals, interventions, care team members, etc. reflecting common concepts. Considering an Advanced Directive to be a type of care plan, which USCDI already covers under the proposed Assessment and Plan of Treatment, from a patient's perspective it can further ensure alignment of concepts used in care plans to appropriately distinguish the goal concepts vis-a-vis the planned and/or preferred interventions/activities from either a patient or clinician's perspective.

As with any data element adopted as part of the USCDI, it is also critical that there are downstream exchange specifications and standards – most specifically, FHIR resources – well aligned to the data concepts. Otherwise, you are left with fundamentally distinct data concepts being inappropriately mixed and hindering the ability of stakeholders to exchange and use the data effectively in the long-term. In this case, there is not currently a resource present in FHIR Release 4 (R4) suitably aligned to the Personal Care Preferences concept to warrant its adoption. We recognize that the PACIO Advance Directive Interoperability Implementation Guide STU 1 has developed initial FHIR profiling of these concepts for ballot utilizing the R4 Goal resource as its base. However, given the distinctions between the data concepts as described above, we do not believe this is the appropriate resource through which to exchange this data in FHIR. Rather, it would be better aligned with the proposed approach for portable medical orders. This points to further maturation of the specification being required.

Advancing USCDI v4 should focus on adding a care plan type that reflects an Advanced Directive enabling a patient's defined care plan to be expressed as narrative, notes, and/or included .pdf-s, and then further define how to structure the content consistently across the variety of care plan types.

Accordingly, while we stress again our recognition of the value these data points provide and agree with the need to eventually include them in USCDI, we strongly recommend deferring their adoption until an appropriate/dedicated FHIR resource becomes available to better support their exchange.

That said, if it is the desire of the ONC to move forward in USCDI v4, we would recommend taking a pragmatic approach with the adoption centered exclusively on the Care Experience Preference data element as represented by the ADI Personal Goal Resource Profile in the aforementioned PACIO IG, and to adopt this data element within its own data class, separate from Goals.

Health Status Assessments

A common theme with the newly proposed elements for the Health Status Assessment data class is a disclaimer within the respective definitions of "but not limited to" in reference to the scope of information covered. While we appreciate the intent to establish flexibility with the data elements, doing so leads to inconsistent definition and treatment of the data elements downstream. Accordingly, we urge ONC to clearly define these data elements with specific scope of the particular components that are desired instead of leaving that open to individual determination. If an element is unable to be clearly defined and scoped, then it is likely not ready for inclusion in the USCDI.

Substance Use

Oracle Health supports adoption of the Substance Use data element in USCDI v4 with some important updates to the current definition. Substance use data is critically important to the holistic view of a patient's care and is important to establish as more central information in EHRs and data exchange.

First, while the information has clear value to clinical care there is not currently a single set of consensus surveys or assessments to coalesce around as a standard set to cite for the element in USCDI. Accordingly, the data element should be adopted as a question and response/observation pair format citing LOINC (for the codified questions) in alignment with the standards cited in the current version of the Interoperability Standards Advisory for representing drug use.[1] If there are particular questions/observations considered as critical components of the element, those should be specifically identified in the definition and reflected in the vocabulary standard. We would recommend the below list as defined in the ISA.

- Drug Abuse Screening Test-10 [DAST-10] (LOINC code 82666-9)
- DAST-10 Total Score LOINC code 82667-7

Second, as a consideration for incorporation of this element into exchange specifications downstream, we note that the frequency of substance use is a critical element to consider as a supporting data point to maximize the value of the data for clinical purposes.

Alcohol Use

Oracle Health supports adoption of the Alcohol Use data element in USCDI v4 with some important updates to the current definition. As with substance use data, alcohol use data is also an important data point to understand the full picture of a patient's health.

[1] https://www.healthit.gov/isa/representing-drug-use

As with other proposed elements in this data class, the definition needs further specificity. In this case, specifically for the particular alcohol use assessments targeted. In the original submission for the data element there were seven specific LOINC codes correlating to various standard alcohol use assessments identified as the applicable standards. Are these the intended scope for the element? Conversely, the current version of the Interoperability Standards Advisory identifies various LOINC codes, particularly those for the Alcohol Use Disorder Identification Test (AUDIT) assessment and abridged Alcohol Use Disorder Identification Test - Consumption [AUDIT-C] assessment for representing alcohol use.[2] Considering the presence of relevant standard assessments that can be coalesced around for this data element, a specific set should be identified as the standard when adopted. We would recommend the below list originating from the submission for the data element, excluding LOINC 5640-8 due to low adoption.

- 69721-9 Do you ever drink alcohol - including beer or wine [Reported.PHQ]
- 74013-4 Alcoholic drinks per day
- 11286-2 Alcohol binge episodes per month - Reported
- 74043-1 Alcohol use disorder
- 64718-0 During this pregnancy, did you receive help with an alcohol or drug problem [PhenX]
- 72109-2 Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]

Additionally, considering that at least some of the possible LOINC codes that could be established as standards for this element represent score calculations from assessments, it is important to note that there should not be an expectation that EHR systems that may exchange the calculated scores are actually responsible for supporting such calculation natively.

Physical Activity

Oracle Health supports adoption of the Physical Activity data element in USCDI v4 with a very specific update to the scope of the element. Based on the stated intent for the element by the original submitters, this data element should be scoped in alignment with the base measure component of the FHIR Physical Activity Implementation Guide (IG).

While the full Physical Activity IG goes well beyond the reasonable scope for this individual data element, focusing on the base measure component represents a reasonable scope aligned with an established specification that can be easily leveraged for further profiling. The base measure component is specifically focused on two physical activity assessment questions represented by LOINC codes 89555-7 and 68516-4. Accordingly, in addition to providing a definition that suitably clarifies the scope of the data element as noted above, these specific LOINC codes should be adopted as the vocabulary standard for the data element.

Laboratory

Result Interpretation

Oracle Health supports adoption of the Result Interpretation data element in USCDI v4 while also recommending a change to adopt a specific value set as the vocabulary standard since one is not proposed for the element. Result interpretations for laboratory test result values as derived against a valid reference range are a standard data point as a required element of a test report under Clinical

[2] https://www.healthit.gov/isa/representing-alcohol-use

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Laboratory Improvement Act (CLIA) regulations.[3] It is critical to include them in laboratory data exchange for understanding clinical impact/significance of a given result value.

Additionally, while not currently profiled as part of the relevant FHIR US Core Laboratory Result Observation Profile, Result Interpretation is already appropriately supported via the Observation.interpretation field in FHIR and via the Result Observation (V3) entry template Observation/interpretationCode field in C-CDA R2.1.

Regarding a vocabulary standard, we strongly recommend adopting the HL7 Observation Interpretation Codes value set for consistent representation and understanding of Result Interpretation codes in exchange. This value set is well established as it is currently used across HL7 v2.x, HL7 v3, and HL7 R1 in addition to FHIR. It also provides complementary value in that it is hierarchical allowing systems to conform at different levels of granularity as appropriate for their particular needs and use-cases.

Result Reference Range
Oracle Health supports adoption of the Result Reference Range data element in USCDI v4 as proposed. As with the Result Interpretation data element, this is a critical data point for understanding clinical impact/significance of laboratory test result values which is well established as a standard element that must be available for laboratory test results per CLIA regulations.[4] It is also a concept that is appropriately supported within FHIR via the Observation.referenceRange field (although not yet profiled in the applicable US Core Laboratory Result Observation Profile) and in C-CDA R2.1 via the Result Observation (V3) entry template Observation/referenceRange field.

We do note that an important consideration for downstream incorporation into interoperability specifications and standards is that numeric reference ranges are not applicable to all laboratory tests, such as tests having codified results. These tests may have a non-numeric reference range while other tests having numeric results may only have a reference range value specified for the upper or lower range. Therefore, when profiled in FHIR US Core, the Result Reference Range data element should be considered a must support element, as opposed to a must have.

Result Unit of Measure
Oracle Health supports adoption of the Results Unit of Measure data element in USCDI v4 as proposed. This is a critical data point in laboratory test result exchange to ensure consistency, and it is well established as a standard element of a test report per CLIA regulations.[5] It is also an appropriately established concept within both FHIR and C-CDA exchange specifications, particularly as part of the FHIR US Core Laboratory Result Observation Profile and C-CDA R2.1 Result Observation (V3) entry template. We also appreciate ONC's specification within the proposed definition for the data element that it applies exclusively to numeric results.

Finally, adopting The Unified Code of Units for Measure (UCUM) as the vocabulary standard is appropriate as a mature standard for representing laboratory result values across the industry. It should be noted that in current practice some laboratories create additional custom values for units of measure, so achieving full alignment of units of measure values to the UCUM in all practices and

[3] 42 CFR 493.1291(c)(6)
[4] 42 CFR 493.1291(d)
[5] 42 CFR 493.1291(c)(6)

exchanges across the industry will be a challenge. However, establishing the standard as part of USCDI is a step in the right direction.

Specimen Condition and Disposition

The Specimen Condition and Disposition concept is well established in the laboratory world as a standard element of a test report per CLIA regulations.[6] However, there a few concerns and limitations with the data element, as proposed.

First, the observation of a specimen's condition and the determination of its disposition or suitability for testing are unique items. The former is a general observation about the specimen itself, whereas the latter is specific to the test(s) that the specimen may be used for. For example, a specimen's condition may be slightly hemolyzed, but it is plausible that it may still be suitable for resulting certain tests, while unsuitable for others. Accordingly, we recommend the proposed data element be split and adopted in USCDI v4 as two distinct data elements for Specimen Condition and Specimen Suitability. The term "suitability" is more appropriately descriptive than "disposition" for the intent of the data element.

Second, for the recommended Specimen Condition data element, we strongly recommend adopting the HL7 VS Specimen Condition value set as vocabulary standard. This is important to establish consistency in exchange and is the value set cited for the Specimen.condition field of the Specimen resource where this data would be exchanged in FHIR. The recommended Specimen Suitability data element, on the other hand, should not have a vocabulary standard adopted as flexibility is needed for this to be a represented as narrative/free-text content to appropriately capture context and detail in various scenarios.

Third, regarding the recommended Specimen Suitability data element, we note that this is especially valuable in scenarios where the specimen was not found to be suitable for testing, yet the test was still performed, and the result recipient must be made aware of that. It may be appropriate in downstream exchange specifications and standards to establish this as a data point that is communicated only in those instances where that was true. Furthermore, how the laboratory communicates this information may vary; some laboratories may use a single word or a short, coded response in the result field while other laboratories may document specimen suitability information in a free-text comment (such as a footnote). The need for communicating that a test was not performed due to the specimen condition, may be relevant, but not as critical to be included in USCDI at this stage as was also discussed during a recent HITAC meeting. We therefore suggest clarifying the specific situation(s) in which the suitability is included in USCDI.

Finally, we note the importance of recognizing that these data elements would not originate from an EHR system. Rather, EHRs would be fully dependent on the source laboratory information system (LIS) to supply the information in the correct format to be capable of sharing it downstream (e.g., via FHIR API responses and C-CDA documents). While this is generally the case for any data element under the Laboratory data class, it is especially pertinent for data like the Specimen Condition and Suitability as they may not be as commonly supplied in a consistent and understandable format by laboratories as other elements.

[6] 42 CFR 493.1291(c)(7)

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Specimen Identifier
Oracle Health supports adoption of the Specimen Identifier data element in USCDI v4 with a recommendation to amend the definition by adding "accession number" as an explicit example of such an identifier. This will help to provide better clarity for stakeholders and follow suit with many other data elements that cite examples in their definition.

Overall, the Specimen Identifier data element is a valuable data point that enables recipients and stakeholders to positively identify the specimen of interest for a given need. And while existing standards adoption may not be extremely high – and appears to be non-existent in the case of C-CDA R2.1 – we believe the presence of the Specimen.Identifier and Specimen.accessionIdentifier fields in the FHIR Specimen resource provides the necessary groundwork of existing specifications to move forward with adoption in USCDI v4.

Specimen Source Site
Oracle Health supports adoption of the Specimen Source Site data element in USCDI v4 with a change to adopt a more specific vocabulary standard. This element is a valuable data point in laboratory data exchange and is well established within the industry. Additionally, while it is not currently profiled in C-CDA R2.1 and not yet profiled in FHIR US Core, it is a concept that is appropriately supported within FHIR via the Specimen.collection.bodySite field in the Specimen resource.

Regarding the vocabulary standard, while the proposed SNOMED-CT code system is appropriate, we recommend adopting the more specific SNOMED CT Body Structures value set. This consists of all SNOMED-CT codes representing an anatomical or acquired body site (body structure) and is already leveraged in the aforementioned Specimen.collection.bodySite field in the FHIR Specimen resource.

We do note that an important consideration for downstream incorporation into interoperability specifications and standards is that the Specimen Source Site may not be relevant or useful for all laboratory tests. For example, the information is critical for Microbiology testing, but may not be relevant for some general laboratory testing. Accordingly, when profiled in FHIR US Core, the data element should be considered a must support element, as opposed to a must have.

Date/Time Data Elements
We have also become aware the Health IT Advisory Committee (HITAC) will likely recommend addition of new date/time observation data elements in USCDI v4 that were not part of the published draft proposals. Specifically, these recommendations would include Laboratory Reporting Date/Time and Specimen Collection Date/Time.

Oracle Health supports adoption of these additional data elements as part of the Laboratory data class in USCDI v4 as they represent well established date/time observations which hold clear value in exchange of laboratory data. However, we do want to ensure that the elements are appropriately defined to avoid confusion or inconsistent use/application downstream.

While the Specimen Collection Date/Time data element is unambiguous, the definition for the Laboratory Reporting Date/Time element should make clear that it is intended to represent the time that the result or report became finalized and available for exchange. Many systems refer to this as the result verification date/time. This would likely be represented in FHIR using the Observation.issued (for results) or DiagnosticReport.issued (for reports) field in combination with an Observation.status or DiagnosticReport.status of Final. If not appropriately defined, this element could easily be confused for

other date/time observations, such as the time the result/report was subsequently printed or exchanged downstream with another system. The time the result or report is printed, output or exchanged may not be a singular event given that a single result can be printed, output or exchanged many times and is not a unique singular event in a result lifecycle. It must be clear in the definition that the Laboratory Reporting Date/Time value represents when the result was *available* for printing, viewing, and sending to another system but that this date does not represent when the print action, the view action, or the interface exchange action occurred.

Medications

Medication Instructions

Oracle Health supports adoption of the Medication Instructions data element in USCDI v4. It is a valuable data point that is well established in the industry, and is also represented in suitably adopted exchange standards, including within the FHIR MedicationRequest resource via the MedicationRequest.dosageInstruction.additionalInstruction and MedicationRequest.dosageInstruction.patientInstruction fields, and the Instruction (V2) entry template in C-CDA R2.1. However, there are some important clarifications needed to ensure it is appropriately and consistently understood and implemented.

First and foremost, it is crucial to better clarify that this data element is intended to be the free text instructions (often labeled as "special instructions") that may be provided to patients by a prescriber or pharmacist which are independent of (and complementary to) other standard dosing details and instruction components which collectively form the full Sig per the National Council for Prescription Drug Programs (NCPDP) Structured and Codified Sig Format standards.[7] For example, the directions may indicate how to consume a medication with food or a full glass of water, or to keep the substance refrigerated. This element could easily be confused with the broader set of details making up a full Sig if not appropriately clarified in the element name and definition. Furthermore, other key components of a medication Sig appear to be sufficiently standardized and adopted across the industry to warrant adoption in USCDI v4.

Accordingly, we make the following recommendations to ONC:

1. Amend the name of the proposed data element to "Patient Instructions" and align the definition to appropriately distinguish the intent and scope of this element as the free text/narrative special instructions providers and pharmacists would provide for consuming medications.
2. Adopt the following additional data elements in the Medications data class to begin progressing towards coverage of the full scope of data points that collectively constitute a medication Sig. While additional data elements, such as Maximum Dose, may also be relevant, these proposed additional elements are an appropriate starting point for a full Sig representation given current state of adoption in the industry.
    - **Administration Site** – this data element would represent the body site where the medication is to be (or was) administered, which is currently supported in FHIR via the MedicationRequest.dosageInstruction.site field on the MedicationRequest resource, as well as the MedicationAdministration.dosage.site field on the MedicationAdministration resource. We note that the MedicationAdministration resource is the most appropriate resource within which to represent this element.

[7] https://standards.ncpdp.org/Access-to-Standards.aspx

- **Administration Route** – this data element would represent how the medication is to be (or was) consumed (e.g., Intravenous or Oral) and is currently supported in FHR via the MedicationRequest.dosageInstruction.route field on the MedicationRequest resource, as well as the MedicationAdministraiton.dosage.route field on the MedicationAdministration resource.
- **Administration Timing** – this data element would represent when the medication is to be administered (e.g., when, how often, and for how long) and is currently supported in FHIR via the MedicationRequest.dosageInstruction.timing field

Second, while it is appropriate for this data element to be expressed as free text/narrative content, it is also important to ensure that it does not become a dumping ground for any free text information related to a medication that may not have a dedicated field or location for exchange. While this is more of a standards implementation point, ONC can help to prevent those mistakes for implementers by providing a more specific name and definition as recommended above.

Finally, we note that an important consideration for downstream incorporation into interoperability specifications is that the Medication Instructions data element is not intended to be aligned with the FHIR Pharmacist eCare Plan Implementation Guide, nor its CDA equivalent, the Pharmacist Care Plan Document, Release 1. These are more detailed and structured guides scoped well beyond a single data element. This seems clear and obvious on the surface but is important to ensure clarity given that these specifications are referenced in the originating submission for this data element.

Medication Adherence

We strongly recommended that the Medication Adherence data element be deferred to a future version of USCDI once more appropriate specifications for exchange are established and adopted to warrant inclusion in the primary data set for nationwide healthcare interoperability.

While the Medication Adherence data element is a valuable data point that is generally well adopted as a concept across the industry, the existing specifications for exchanging this data in a reliable manner are either lacking sufficient level of detail to support the concept (in the case of FHIR) or are non-existent (in the case of C-CDA R2.1).

In the case of FHIR-based exchange, the intent of this data element may already be supported via the MedicationStatement resource (HL7 FHIR R4). However, the intended statuses are not yet clearly represented and require further profiling and possibly extensions to be fit for purpose. Specifically, if a patient is taking only a partial dose of their prescribed medication (e.g., taking a half dose because the medication causes nausea) there is no clearly agreed data element available to appropriately express that scenario. In the case of C-CDA-based exchange, we are not aware of any existing specifications for exchanging this information.

As a final point, it is also worth mentioning that since the patient (or their authorized representatives) will always be the root source of this information, it is sensible to view this as a data point that should be enabled for direct sharing by patients via mechanisms such as patient portals or FHIR write operations using SMART applications. Accordingly, while appropriate guidance does not exist currently for consistent recording and exchange of this data where the patient is the source, ideal implementation of the data element would necessitate even further development of implementation specifications for easily enabling contribution of the data by patients via applications and other consumer-facing means.

April 14, 2023

Procedures

Time of Procedure

Oracle Health supports adoption of the Time of Procedure data element in USCDI v4 as proposed. This data element is already well established as a key data point within health information exchange and has been appropriately profiled within both HL7 FHIR US Core (US Core Procedure Profile – Procedure.performed.performedDateTime) and HL7 CDA C-CDA R2.1 (effectiveTime field on various Procedure Activity (V2) entry templates).

Vital Signs

Average Blood Pressure

Oracle Health supports adoption of the Average Blood Pressure data element in USCDI v4 with some specific clarifications that will be critical to effective implementation and adoption – both initial and long-term.

We agree with the opinions expressed by the American Medical Association (AMA) in their submission for the element regarding its value to clinicians for diagnosing and managing hypertension and other conditions in favor of reliance on numerous individual blood pressure readings. However, this is still a very new concept for EHR systems and other health IT, thus the following points should be taken into consideration with its adoption in USCDI.

First, while we recognize that there is an existing FHIR Average Blood Pressure profile inclusive of certain contextual elements which may be important to meaningfully utilize Average Blood Pressure observations (e.g., the body position, exercise association, measurement setting, and measurement protocol), this profile is not widely adopted and there are still extensive outstanding questions on effective implementation of the concept. Accordingly, we strongly recommend that the initial adoption of Average Blood Pressure in USCDI be isolated to the observation value itself using LOINC 96607-7 (Blood pressure panel mean systolic and mean diastolic), LOINC 96608-5 (Systolic blood pressure mean), and LOINC 96609-3 (Diastolic blood pressure mean) for codification (without particular constraints on how it is calculated) along with the timeframe upon which the average is calculated (e.g., readings across a single day or a multi-day inpatient encounter) and the date/time stamp of when the calculation was produced. This simplified view of the data element will make for a proper starting point for the implementation with room for more specification moving forward.

Second, while adopting the data element in its simplistic form as recommended above is appropriate for initial introduction into USCDI, there is significant guidance needed on how this concept can/should be most effectively incorporated and utilized in EHRs and clinical workflow generally. The following are some examples of areas where such guidance is needed, which we urge ONC to work on in collaboration with the AMA and American Heart Association to provide to stakeholders:

- We understand that the intent is for this concept to be calculated locally within EHRs at the point of care and subsequently exchanged downstream (not calculated at the interoperability layer), but is it intended to be introduced as an independent standalone field that can be recorded by clinicians ad hoc, or as a feature where clinicians can dynamically average out any set of existing blood pressure values they may want in real-time?
- Are there guidelines on the minimum and/or maximum timeframes that should be used to produce average blood pressure observations? For example, averaging across multiple years would seem to provide little value or reliable insights on the surface, but an average for a single day or a single inpatient encounter may be very helpful to downstream care team members.

Similarly, are there guidelines on a minimum or maximum number of individual blood pressure readings that should be included in a single average calculation?

- Are there guidelines on whether different "types" of blood pressure readings (e.g., sitting, standing, supine, etc.) should be mixed together to produce an average blood pressure observation?
- Are there guidelines for utilization of patient-reported blood pressure readings as part of an average blood pressure observation? For example, should these be kept independent of clinically recorded blood pressure readings when producing averages, or mixed?

Head Occipital-frontal Circumference Percentile (Birth-36 months)
After taking a closer look at the preexisting Head Occipital-frontal Circumference Percentile data element, we have identified an update that is needed for the applicable age range. Currently, the element is identified as applicable for children ages birth – 36 months. However, based on existing guidance on the pediatric vital signs data elements, this age range is incorrect.

The ONC's USCDI certification companion guide states that "Pediatric vital signs include both the vital measurements and the percentiles used in the growth charts currently recommended by the Centers for Disease Control and Prevention."[8] Those recommendations are currently to utilize WHO growth standards for children ages 0-2 years, and CDC growth charts for those ages 2 years and older. Based on those recommendations, the WHO's head circumference growth charts for boys and girls ages 0-24 months would be the appropriate charts to center on for the USCDI data element instead of the CDC's head circumference growth charts for boys and girls ages birth-36 months.

Accordingly, the data element should be changed to "Head Occipital-frontal Circumference Percentile (Birth-**24** months)" to align with the established growth chart recommendations and implementation guidelines. This would follow suit with an equivalent change for the Weight-for-length Percentile data element that was adopted with USCDI v3.

Other Level 2 Data Elements

Test Kit Unique Identifier
USCDI Level 2 includes a Test Kit Unique Identifier data element which has gained some support for consideration of inclusion in USCDI v4, particularly the interest in a test kit UDI. We understand the value that this data element would provide in analyzing and understanding context of a patient's lab results (e.g., for a receiving organization to determine whether it is appropriate to trend certain results together, or research and analytics on test performance). However, we are concerned that introducing the data element as proposed would be an overreach of what the industry can legitimately support and implement in the near future.

This is specifically because the element as defined in the Level 2 submission seeks to require the device identifier (DI) information in addition to the basic manufacturer and model information. Although that would not represent a full UDI as some are advocating for, currently, at most a manufacturer name and model/device names is what laboratories are able to provide as part of test results. Thus, adhering to an expectation to share DI information would be particularly difficult to implement for most stakeholders currently.

[8] https://www.healthit.gov/test-method/united-states-core-data-interoperability-uscdi-0

Given the desire for a more robust data element, we recommend postponing inclusion in USCDI entirely and re-visiting as an element for a future draft USCDI version once implementation challenges have been addressed to ensure availability of the data from the source.

Vaccination Event Record Type
USCDI Level 2 includes a Vaccination Event Record Type data element which has gained some support for consideration of inclusion in USCDI v4. This data point is valuable for the purpose of distinguishing between historical vaccinations and new/current administrations as part of a patient's immunization history records. Given that this is a widely supported capability in HIT today that would not impose significant burden for stakeholders, we believe advancing it into USCDI v4 is a reasonable step.

Medication Administration
USCDI Level 2 includes a Medication Administered Code data element which has gained some support for consideration of inclusion in USCDI v4. Inclusion would effectively yield inclusion of a Medication Administration. We are concerned with the ability for many HIT systems to support this data element as the actual administration of a prescribed medication is often not documented unless administered by the health care provider. Additionally, discussions appear to conflate this concept with the ability to create and communicate various medication lists, e.g., discharge medications, active medication prescriptions, and administered medications. Lastly, Level 2 Medications uses "administered" and "administration" without clearly distinguishing that concept, while USCDI v3 is ambiguous as to which medication aspects are actually intended to be included. Accordingly, we recommend that administration/administered related elements be deferred for consideration in a future version of USCDI, while the current USCDI Medication elements (all but the proposed Medication Adherence data element) are clarified to reflect prescribed medications.