PROBLEM: The ONC ISA is recommending an interoperability mapping requirement using SNOMED CT® and LOINC® integrated in the National Library of Medicine (NLM) Unified Medical Language System (UMLS) Metathesaurus (consisting of nearly 200 different vocabularies). On the other hand, CMS is requiring a separate coding strategy for reimbursement using ICD-10. By ONC requiring a separate mapping strategy for interoperability from CMS reimbursement terminologies, ONC creates a back and forth mapping that is expensive, cumbersome on the business owner, and adds to semantic ambiguity.

RECOMMEND: ONC resolve the conflicting reimbursement strategies. Reimbursement and interoperability are using conflicting code sets. Clinical point of care terminologies with concept definitions and defined relationships between concepts preserves meanings and concept names and are essential to achieve the ONC goals of a semantically interoperable healthcare ecosystem without “special effort”.

PROBLEM: The ONC recommended with the Health Information Technology for Economic and Clinical Health (HITECH)Act and ‘Meaningful Use’ the federal reimbursement of nursing services based upon Eligible Professional (EP) existing coded strategies that generate revenue. Data collection of the nursing contribution to national healthcare quality was omitted because, in 2020, nursing remains in the room rate and is not revenue generating. The ONC continues to obscure the nursing contribution to healthcare quality by omitting nursing point of care terminology. The nursing point of care terminologies in SNOMED CT® and LOINC® mix multiple terminologies without definitions or linking concept relationship and perpetuate the impression that interoperability is a complete framework for clinical information exchange.

RECOMMEND: ONC recommends to CMS reimbursement for nursing services to promote interoperability. Incorporate and integrate the use of federally-funded, public domain, U.S. Department of Health and Human Services (HHS) approved, NLM Metathesaurus nursing terminology, the Clinical Care Classification (CCC) System https://careclassification.org/ as an alternative to SNOMED CT® and LOINC®. Enhanced nursing data for interoperability to achieve care goals can subsequently be considered for nursing services reimbursement.

PROBLEM: Appears as if the ISA does not recognize the previous recommendations of other federal standards advisory groups (e.g. American Health Information Committee or Healthcare Information Technology Information Standards Panel (HITSP)) who have developed and published standards in these areas. The ISA terminologies referenced have no framework or definitions with which to structure nursing concepts for interoperability. SNOMED CT® and LOINC® specifications proposed for Clinical Nursing Assessments, p. 21; Nursing Interventions, p. 21; and Outcomes for Nursing, p. 22; Patient Problems for Nursing, p. 22. Patient Clinical “Problems”(i.e. conditions), p. 23 do not follow the nursing professional information model or framework for care data.

RECOMMEND: Incorporate and integrate the use of federally-funded, public domain, U.S. Department of Health and Human Services (HHS) approved, NLM Metathesaurus nursing terminology, the Clinical Care Classification (CCC) System https://careclassification.org/ as an alternative to SNOMED CT® and LOINC®. Enhanced nursing data for interoperability to achieve care goals can subsequently be considered for nursing services reimbursement.


There is a current ballot in HL7 to extend the use of diagnosis from within the dental community to the broader medical community and to cross reference SNOMED and SNODENT terms so there is evidence of progress toward dental-medical interoperability (a very positive move) which would lower the adoption level over all but may raise adoption across the community through collaboration and best practice adoption.

Allowing SNOMED CT finding/disorder value sets (and/or CPT value sets) is not advised for recording allergies to substances (whether for foods, environmental substances or medications). The simplest way to document allergic substances is to document using the codes for those substances (i.e. RxNorm codes for medications, SNOMED CT codes for food allergies, environmental allergies, and drug class allergies). Using SNOMED CT findings codes or CPT procedure codes adds a level of indirection and complexity that has the potential to compromise patient safety. SNOMED CT itself will presumably contain links and relationships between the allergy findings and the corresponding allergy substances. But this is not guaranteed to be the case at all times for all substances. Substance codes should be used to record allergies to substances.
Emergency Medical Services  

Interoperability Needs: Allergy and Intolerances—Medications  

Interoperability Need: Representing Dental Encounter Diagnosis.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Allergies and Intolerances (p. 2)  

Interoperability Needs: Allergy and Intolerances—Medications  

Interoperability Need: Representing Dental Encounter Diagnosis. Add the Note Activity template included in the C-CDA Companion Guide Release 2, with elaboration.

Clinical Notes  

Dietary Page 7 substantive  

Dietary and Nutritional Needs—Interoperability Need: Representing Nutrition Assessment, Diagnosis, Interventions and Monitoring/Evaluation: Standard eNCPT

Emergency Medical Services Page 8 substantive

Emergency Medical Services Page 8 substantive

Interoperability Need: Representing Patient Dental Encounter Diagnosis—Standard SNOMED CT

Section I: substantive

Add the Note Activity template included in the C-CDA Companion Guide Release 2, with maturity of “final”

Section I: substantive

Adding “Assessment” to Encounter “Diagnosis” as a data class is appropriate. Adding “Assessment and Plan” to Encounter “Diagnosis” as a data class is not appropriate. The observation/value pair of LOINC/SNOMED CT is appropriate for Assessments and Diagnoses, but the “Plan” portion would likely be more useful if structured differently, possibly with procedure or encounter terminology codes

Section I: substantive

For CDA - recommend referencing the “Provenance - Author Participation” template in the C-CDA Companion Guide Release 2

For FHIR - recommend referencing US FHIR Core 3.1.0 Provenance profile - http://hl7.org/fhir/us/core/STU3.1.1/StructureDefinition-us-core-provenance.html

I believe both of the above should be flagged as “Federally Required” per ONC’s Final Rule in support of the 21st Century Cures Act

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Encounter Diagnosis, Assessment and Plan (p. 9)  

Interoperability Need: Representing Dental Encounter Diagnosis. Add an additional type of just plain SNOMED CT. Recent work has been done through the SNOMED CT Dentistry Clinical Reference Group on diagnosis and dental body structure.

Section I: substantive

Encounter Diagnosis, Assessment and Plan—Representing Dental Encounter Diagnosis. Add an additional type of just plain SNOMED CT.

Can a default phone number and e-mail be designated as patients may have several and using their preferred communications channel (default phone first, default e-mail as a back up etc.)?

I believe as a government employee, when a cost is identified for implementing any standard, a reasonable expectation is to easily and readily identify at least a ballpark estimate of cost, even if it’s a variable range and not just use the $ sign to indicate cost without further elaboration.

As a general comment for all products like NEMSIS, is there a review committee or team that can sample documents in use, or a feedback mechanism to capture usability problems or burdensome processes in use for improving the products as well as a process to review the current state of usefulness of the data collected for decision making, patient care, public health or research?

The electronic Nutrition Care Process Terminology (eNCPT) cannot be evaluated for cost due to technical/administrative issues associated with its website for GFE laptop. I believe as a government employee, when a cost is identified for implementing any standard, a reasonable expectation is to easily and readily identify at least a ballpark estimate of cost, even if it’s a variable range and not just use the $ sign to indicate cost without further elaboration.

Unable to look at UMLS references-account applied for…it appears that this area of healthcare is being taken seriously and progressing

The lack of agreement within the mental, behavioral and social health community is a barrier to information sharing that would improve provider team members (primary care and so on) with a more comprehensive understanding of a patient’s state, treatment successes/failures and a path toward improved outcomes.

I believe both of the above should be flagged as “Federally Required” per ONC’s Final Rule in support of the 21st Century Cures Act

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<tr>
<th>Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Family Health History (p. 11)</th>
<th>page 11</th>
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</thead>
<tbody>
<tr>
<td>1. Under “Applicable Value Set(s) and Starter Set(s)”, the value set for “Problem Type” is mislabeled as “(LOINC code system)”. The Value Set referenced is a SNOMED CT value set.</td>
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<td>2. Under “Applicable Value Set(s) and Starter Set(s)”, two value sets are presented for family relationships and roles. It would seem reasonable also to mention that SNOMED CT can be used to represent family relationships, particularly as in this section, SNOMED CT is listed as a standard for observation values, and depending on the information model used, family relationship may be one of the observation values recorded (in addition to the diagnosis or condition).</td>
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<tr>
<th>Family Health History</th>
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<tr>
<td>For clinical genomics purposes, the Human Phenotype Ontology (HPO) developed by Robinson, et al. and uses information from the Online Mendelian Inheritance in Man to generate its terms. It is popular within the genomics community, and is used by some organizations to describe “phenotypic abnormalities”. What does popular within the genomics community mean? Popular should be replaced with a more specific statistically relevant term. Even the term genomics community is somewhat subjective, in my opinion. If I run a biomarker lab test, am I a member of the genomics community?</td>
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<tr>
<th>Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Health Concerns (p. 15)</th>
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<th>Substantive</th>
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<tbody>
<tr>
<td>1. The “Interoperability need” is phrased as “Representing Patient Health Concerns”. I would suggest it be rephrased as “Representing Patient or Caregiver Health Concerns” to reflect that in many cases (e.g. pediatric care and care of adults with limited cognitive capacity, referral of a patient from another health care provider or facility), someone other than the patient is articulating the concern.</td>
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<td>2. While LOINC is listed as a standard for observation, there does not seem to be a LOINC code that corresponds to health concerns (the closest is a document title LOINC, 75310-8). However, there are LOINCs for “chief complaint” (see above). The current limitation in semantic coverage of LOINC in this area could be mentioned in the “Limitations, Dependencies…” section.</td>
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<td>3. SNOMED CT is appropriate to list as a standard for Observation Values; It may be helpful to identify a value set that limits SNOMED CT to the “clinical finding” and “situation with explicit context” hierarchies to discourage use of other SNOMED CT hierarchies that aren’t semantically aligned with “health concerns” but might be tempting to use for users not familiar with ontologic structures and semantic types. For instance, for a patient presenting to request a sterilization procedure, it would be more appropriate to represent the “health concern” with SNOMED CT 183990000, “sterilization requested”, than SNOMED CT 703145006, “sterilization procedure”.</td>
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<tr>
<th>Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Immunizations (p. 16)</th>
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<tbody>
<tr>
<td>1. Under “Limitations, Dependencies…” the statement “RxNorm is an acceptable alternative code set for local use” is confusing, as it isn’t clear what the ISA is saying its an alternative to; Furthermore, the only two possibilities from the standards listed are CVX and NDC, both of which are noted to be Federally required.</td>
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<td>2. It would be worth referencing the ISA section(s) related to prescribing and/or recording medication administration if they contain information about how to represent route and site of administration, since this often needs to be recorded when documenting immunization administration.</td>
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<tbody>
<tr>
<td>Interoperability Need: Representing Patient Medications-Standard RxNorm-RxNorm is often used for the exchange of information; however, it may not be available for export and import by end users. Reference to endusers should be more specific to categories of users: Physicians, pharmacists, insurance companies, data scientists/researchers, possibly even patients or other categories.</td>
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<tr>
<td>It is unclear how this differs from the preceding section, “Representing Laboratory Tests”. Both sections provide information relevant to representing both the test and result. It might be helpful to combine these into one section.</td>
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<th>Sex at Birth, Sexual Orientation and Gender Identity</th>
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<tbody>
<tr>
<td>My opinion is that this is a highly sensitive area and needs further elaboration in Limitations, Dependencies, and Preconditions for Consideration - with respect to differentiation of birth sex, self-identified sex, and administrative sex.</td>
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<th>Patient identified Sexual Orientation</th>
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<tbody>
<tr>
<td>There is a longstanding contention that the gender designation (and sexual orientation) are administrative roles, within HL7, which is a barrier to capturing reliable information about sexual orientation and in the case of transgender patients, what their original gender was (are they at risk for prostate cancer, uterine cancer etc.) to effectively address their healthcare needs beyond the administrative information that is captured. While solving for a technical requirement, the clinical reality is minimized or ignored and surfacing in the literature, JAMA and AFP, as problematic.</td>
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</table>
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Alcohol Use (p. 32)

1. The hyperlink for text "Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]" is broken (does not reference the AUDIT-C).
2. The bottom two LOINC codes referenced in this section appear to be for the full World Health Organization AUDIT assessment, instead of the screening assessment, the AUDIT-C. Recommend removing these codes or noting that they are for reference only to avoid user confusion.
3. With respect to the use of SNOMED CT to represent AUDIT-C data elements: There is currently one AUDIT-C concept in SNOMED CT to represent the total score, but no concepts to represent the individual question-answer pairs. SNOMED CT would need to create each of the question-answer pairs as pre-coordinated concepts. This might be challenging given that this content may fall outside of SNOMED CT editorial policy (e.g., use of numeric ranges and references to time). Also, SNOMED CT would require intellectual property rights permissions from the AUDIT-C creator(s) to include this content. If SNOMED CT concepts are created, then to support user adoption, it is suggested these concepts be maintained in a NLM VSAC value set.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Depression (p. 32)

1. The hyperlink for text "Patient Health Questionnaire 2 item (PHQ-2)" appears to be broken.
2. Since the recommendation is to use the PHQ-2, it’s not clear why the LOINC code for the PHQ-9 is listed (PHQ-9 panel LOINC code 44249-1). Suggest removing this code or noting that it is for reference to avoid user confusion.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Drug Use (p. 33)

With respect to the use of SNOMED CT to represent DAST-10 data elements, there does not appear to be equivalent SNOMED CT content to represent the DAST-10 data elements. SNOMED CT would need to create each of the question-answer pairs as pre-coordinated concepts. This might be challenging given that this content may fall outside of SNOMED CT editorial policy (e.g., disjunction, complex questions). Also, SNOMED CT would require intellectual property rights permissions from the DAST-10 creator(s) to include this content. If SNOMED CT concepts are created, then to support user adoption, it is suggested these concepts be maintained in a NLM VSAC value set.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Financial Resource Strain (p. 34)

Suggest that the ONC ISA and Gravity Project align on the specifications for representing financial resource strain, food insecurity, and housing insecurity.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Food Insecurity (p. 34)

The hyperlink for text “ Coronary Artery Risk Development in Young Adults (CARDIA) study” is broken.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Housing Insecurity (p. 34)

1. The text for the first LOINC code is correct, but the hyperlink points to the a different (incorrect) LOINC code and should be corrected.
2. It is not clear how the PRAPARE panel should be used (i.e., which specific data elements pertain to food insecurity and which specific LOINC or other standard codes should be used). Suggest removing this reference until clear guidance for its use has been better defined.
3. As CMS supports the Hunger Vital Sign screening tool and LOINC has available codes to support this tool, it is recommended to use the tool and these LOINC codes. It is not clear how SNOMED CT, ICD, CPT, or HCPCS support this data element at this time. Unless specific assessment data elements, standardized vocabulary codes, use cases, etc. are proposed and can be reviewed, suggest removing these standards and focus on LOINC usage to improve adoption and reduce user confusion. Using multiple standards can reduce interoperability if organizations are implementing multiple different standardized vocabularies.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Financial Resource Strain (p. 34)

It is not clear how the PRAPARE panel should be used (i.e., which specific data elements pertain to food insecurity and which specific LOINC or other standard codes should be used). Suggest removing this reference until clear guidance for its use has been better defined.

Financial Resource Strain, Food and Housing Insecurity

pages 34-35 substantive

The gap in SDOH documentation and consideration, while acknowledged, is one that can make a big difference in outcomes so moving toward. On a national allocation of resources note...perhaps, as other countries do, the US could look at how it spends its $3.XT on healthcare and consider shifting that to addres SDOHs to improve outcomes.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Housing Insecurity (p. 35)

It is not clear how SNOMED CT, ICD, CPT, or HCPCS support this data element at this time. Unless specific data elements, standardized vocabulary codes, use cases, etc. are proposed and can be reviewed, suggest removing these standards and focus on LOINC usage to improve adoption and reduce user confusion. Using multiple standards can reduce interoperability if organizations are implementing multiple different standardized vocabularies.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Transportation Insecurity (p. 38)

It is not clear how SNOMED CT or ICD support this data element at this time. Unless specific assessment data elements, standardized vocabulary codes, use cases, etc. are proposed and can be reviewed, suggest removing these standards and focus on LOINC usage to improve adoption and reduce user confusion. Using multiple standards can reduce interoperability if organizations are implementing multiple different standardized vocabularies.

Transportation Insecurity

page 38 substantive

This non-federally required need is mature and widely adopted (no informatino on quality notwithstanding) what makes it so and other required categories not widely adopted...to my point above on understanding the differences for the purpose of moving required categories from nascent/poorly adopted to mature and widely adopted.

Tobacco Use

page 39 substantive

As a leading cause of death, smoke/smokeless tobacco and associated products should be included in US Core and UCDIS categories to reflect type (including emerging types-vaping, marijuana etc., duration and quantity used to effectively address individual patient needs as well as public health and research goals.
Recommend the use of SNOMED CT to represent tobacco use data elements, and specifically second hand tobacco smoke exposure. SNOMED CT has more than sufficient content to represent values for this data element and new concepts can be created as needed.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Tobacco Use (Smoking Status)/Representing Patient Second Hand Tobacco Smoke Exposure (p. 39) page 39 Substantive

1. Recommend the use of SNOMED CT to represent tobacco use data elements, and specifically electronic cigarette use. SNOMED CT has a substantial amount of content to represent the values for this data element and new concepts can be created as needed.

2. Three of the four SNOMED CT codes listed refer to the actual types of electronic cigarettes (“physical object” concepts in SNOMED CT), as opposed to all other recommended concepts in the Tobacco Use section which refer to SNOMED CT “finding” or “situation” concepts. For consistency, suggest removing codes 722498003, 735240008, and 735239006 in this section and replacing with the following codes: 785889008 |Nicotine-filled electronic cigarette user finding| and 786093001 |Non-nicotine-filled electronic cigarette user finding|.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Tobacco Use (Smoking Status)/Representing Patient Tobacco Use (Smoking Status) (p. 39) page 39 Substantive

1. Suggest that all SNOMED CT concepts listed reference the “fully specified name” (the formal, official concept name) rather than a synonym.

2. Some of the SNOMED CT concepts listed have incorrect descriptions: “Former smoker” is no longer an active description for 8517006. "Never smoker" is not a description for 266919005. "Smoker, current status unknown" is not a description for 77176002. "Unknown if ever smoked" is not a description for 266920001.

Vital Signs-Interoperability Need: Representing Patient Vital Signs Page 42 Substantive

In my opinion, a special reference to pacemakers and/or defibrillators and dialysis devices should be identified here since they are highly significant in the scope of chronic and serious medical conditions.

Refferal to a Specialist page 45 substantive

The concept of a closed loop process and messaging that reflects actionable data/documentation, is long overdue as a workflow/process component of healthcare delivery-applications to consults/referrals/prescriptions/lab-rad-diagnostic studies etc.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Documenting and Sharing Care Plans for a Single Clinical Context (p. 47) page 47 Substantive

Recommendation for additional standard: VA Office of Nursing Informatics supports the use of the Clinical Care Classification (CCC) code set for representing Nursing content in care plans.

Interoperability Need: Push Patient-Generated Health Data into Integrated HER Page 126 Substantive

In my opinion, this section doesn’t appear to distinguish PGHD that is auto-generated by devices within the patient’s possession vs PGHD that the patient is self-reporting via a patient portal.

General Comment throughout substantive

Implementation maturity-pilot to production: Many standards in production do not effectively support interoperability as the implementations are divergent so that the intention of interoperability is not met, even though the specified standard is widely distributed in production. Another measure, conformance, would be helpful to assess as it should reflect the proper use of a standard in a uniform manner.

General Comment throughout substantive

Standards Process maturity-the 3 categories: Final, Balloted Draft and In Development reflect the stage of development but nothing about the level of interoperability that the specified standard supports. An analogy would be the state of EHR adoption-do you have one? yes, no, maybe...and what level of interoperability is achieved by the EHR (or in this case, the specified standard)

General Comment throughout substantive

Adoption levels-Feedback requested as this is provided with many of the identified standards/areas of use-is there an active solicitation for feedback from user groups (patients, providers/clinicians, insurers, and so on) and how is it widely known, input collected as provided by users and acted on?

General Comment throughout substantive

Adoption low-high/widespread: there is no qualitative assessment of the nature of adoption-is it just included in a platform? Is it used and to what degree and conformance? What is the quality of the data and documentation/image that is shared and to what level of interoperability does the widespread adoption attain?

General Comment throughout substantive

There are many instances of federally required standards that have low adoption and not required that have high adoption (qualitative assessments aside) That looks like an opportunity to evaluate what the barriers to adoption are for required standards and the widespread adoption of non-required standards.