AMIA Recommendations to USCDI v5 Draft

Submitted recommendations for each data class and element as summarized below. Under data elements, the data class it is associated with is in parentheses.

Data Class

Clinical Notes:

- Data quality is fundamental to meaningful interpretation of care notes. AMIA recommends the additions of Admission Note and Anesthesia Notes as Data Elements to Clinical Notes.
- Included provenance should disclose when "notes" are generated from pick lists, AI generated, or which have been cut and pasted from elsewhere through a stamp generated by the EHR tool. Consider computer assisted (e.g. voice recognition) and emerging (e.g. generative AI) machine-assisted note composition and the associated provenance needs. This standard assists tracking the clinical notes journey and how they are completed by the care team. Certain electronic health records management systems track the percentage of clinical notes that are copied/pasted.

Diagnostic Imaging:

- AMIA suggests that ONC specify which provider types are referred to as "credentialed professional." Additionally, ONC may wish to include an element to signify the artificial intelligence or algorithmic component of imaging reports, along with a requirement for generation of a report with prioritized results. For software that require FDA approval, the Unique Device Identification number should be included.
- AMIA suggests modifying the title to "Imaging" allowing to encompass all types of imaging in the healthcare setting (including for therapeutic interventions).

Goals and Preferences:

- This data class is defined as "desired state to be achieved by a patient." AMIA encourages ONC to consider renaming this category to "Person Goals and Preferences." Person-centric goals reflect goals over time, not just when the person is a patient. AMIA continues to believe that "goals" should be defined and differentiated (i.e.: person-defined or generated, clinician-captured, obtained through interdisciplinary team members such as care coordinators or social workers, or goals from clinician orders or advanced care planning documents). Identifying the source of the information in this data class is central to interpreting the outputs. For example, the desired goal or outcome stated by the person and captured directly from the person, may or may not have the same perceived value as goals captured from submitted advanced care planning documents or prior clinician orders. There are increasingly structured and validated ways to capture goal setting. The National Committee for Quality Assurance has developed outcome measurements with the patient central to the research.[1] AMIA suggests to align with emerging standards in this

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[1] https://www.ncqa.org/hedis/reports-and-research/pco-measures/

area as we have seen organizations have success – for example – say that having an advanced directive counts for this.

- Patient Goals need to align with Treatment Intervention Preference
- Clarify in each element these are the person's ("patient's") goals & preferences
- Clarify the intent of the first element - Person's desired outcomes of their care - and the third element - wishes when unable to participate in medical decision making for whatever reason
- Separate and distinct from Care Team (including shared decision making) goals, which is captured under the Patient Summary and Plan Data Class.
- Patient Goals should also include Patient Authorized Representative if the patient is unable to communicate their desired outcomes.

Provenance:

- The information contained in this data class is a critical underpinning for all other data classes and elements. Beyond the elements of author time stamp and author organization, the role of the author should be identified. The author may or may not be an identified member of the care team, especially highlighting the possibility of patients and authorized family or caregivers as potential contributors of health data. The author may also be health devices, mobile health applications and remote patient monitoring devices or sensors (e.g., in home, body worn). AMIA recommends potentially creating role buckets, or groupings, such as "patient/caregiver, device, or health system employee/contractor/affiliate" understanding there are not standards to define roles.
- Provenance needs more understanding. There is a care paradigm change and needs to better reflect what is happening in the real world with an emphasis on longitudinal course of care.
- AMIA also recommends Provenance needs identity and role of the actor/author/entity generating the Element is implied but not explicit. Need to tease out other helpful metadata for each USCDI element.

Problems:

- There are limitations on the capture of diagnosis information. ONC's inclusion of SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, March 2022 Release and International Classification of Diseases ICD-10-CM 2022 as vocabulary standards represent an important step, but in reality, the problem or reason for seeking medical attention is often not documented in the health record. In reality, "Actual Date of Diagnosis" and "Date of Resolution" are typically not known or are captured without adequate context to determine accuracy. These elements are included but may not yield any accurate information.
- The elements Date of Diagnosis and Date of Resolution are not useful as such. Consider when (days, weeks, months) first recognized or addressed (Provenance - by whom), and whether resolved or chronic, or the like. Recognize in the context of an interoperable document or data set these represent snapshots in time. Longitudinal observations and trajectories are not well represented in EHRs.

Participation in Clinical Trials:

- AMIA suggests that ONC add "Participation in Clinical Trials" as a data class for inclusion in USCDI v5. It is necessary to capture the unique clinical scenarios of participants enrolled in clinical research studies.

Patient Demographics:

- ONC references applicable vocabulary standards as the CDC Race and Ethnicity Code Set Version 1.2 (2021), and Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised October 30, 1997. The CDC document outlines self-identified race and ethnicity and observer-identified race and ethnicity. **ONC might consider emphasis on self-identification or patient verified race and ethnicity data.** AMIA encourages ONC to ensure that vocabulary standards are updated routinely as standards change and evolve, to avoid stigmatizing language and ensure health equity and respect for all people.

Medical Devices:

- AMIA recommends a more thorough breakdown of the Medical Devices Data Class. For medical devices, there should be a distinguishment between permanent versus temporary data classes. Temporary devices for example PICC line, indwelling foley and suprapubic catheters, and wound vacs. Medical applications should also be included as they are considered medical digital devices, such as digital therapeutics, standard languages, payor exchanges, what is included and excluded in this category.

Data Elements

Assessment and Plan of Treatment (Under Patient Summary and Plan):

- There is a need to recognize that the burden of data collection falls on the end-user clinician. Data should be derivative of the clinical workflow. When conducting a **Social Determinants of Health (SDOH) assessment**, AMIA encourages ONC to ensure that vocabulary standards avoid stigmatizing language and ensure respect for all people. Further, as standards change and evolve, AMIA encourages routine updates and alignment with HL7 FHIR Accelerator, The Gravity Project.

Disability Status (Under Health Status Assessment):

- AMIA suggests that Disability Status, under Health Status/Assessments, be moved to Patient Demographics/Information. The disability community on the whole has argued that questions to assess disability should be addressed to everyone; they should not single out some people for a report as part of health status.

Medication Administration and Medications Dispensed (Under Medications):

- Clarification is needed for the element "Fill Status." Is such information to be generated by the patient, clinician, an exchange, or pharmacy? Medications - medication reconciliation is a notorious problem and documentation of medication adherence is corollary to that problem. Fill history may be available from some pharmacies as a measure of adherence, but whether the patient is actually taking the medication is largely based on patient self-reporting.

Care Team Member Conducting Health Status Assessment (Under Health Status Assessments):

- Health status assessments will vary by care team member. ONC should consider adding an element to identify the care team member conducting the health status assessment, with inclusion of the credential of the care team member. Additionally, it is imperative to consider the sensitivity of the data being collected including the potential misuse of health information and health information technology to investigate and prosecute individuals who can get pregnant, and healthcare professionals trusted with their care

Manufacturer Reference Range (Under Clinical Tests):

- AMIA suggests that ONC include an element to specify the underlying procedure/test with inclusion of the manufacturer's specific reference range for each applicable procedure/test.
- Exclude "manufacturer" suggested reference ranges, interpretations; rather what the generating entity uses for reference, interpretation

Individual Administering Vital Signs (Under Vital Signs):

- ONC should consider adding elements to identify the role of the individual taking the vital signs, differentiating between inputs that might be from a care team member, or patient or family/caregiver, as separate from an automated device or home monitoring system.

Diagnosis (Under Encounter Information):

- With reference to the Primary Encounter diagnosis field, AMIA encourages ONC to replace "diagnosis" with "diagnoses."

Problems (Under Problems):

- Data of Diagnosis and Resolution does not account for the history of the problem/diagnosis/concern. Date of first noted/documented to show historical care would assist in cleaning up the data for reconciliation process.

Lot Number (Under Immunizations):

- AMIA recommends the addition of Lot Number to the Immunizations Data Class. Lot Number will have broad use and impact for immunization safety and effectiveness studies as well as public health surveillance activities. An applicable standard for this data class would be LOINC code: 30959-1 Lot number [Identifier] Vaccine.