PACIO Project Comments on ONC’s USCDI

September 28, 2022

The PACIO Project workgroup offers the following comments on the USCDI v.4:

Provenance

- The PACIO (Post-Acute Care Interoperability) Project, established February 2019, is a collaborative effort between industry, government, and other stakeholders, with the goal of establishing a framework for the development of FHIR implementation guides to facilitate health information exchange.

- The PACIO Community recommends Elements that are currently at other levels should be upgraded.
  - **Author (currently on level 2)** - Author time and organization is not going to have a lot of meaning without the author particularly in non-institutional data sources. As we move to more patient centered care, there will be other contributors of data including patients and non-clinician Caregivers.
  - **Signature (Currently Comment)** – Some documents and other information, such as end of life, like POLST, orders need to be signed in order to trusted and used. Without a signature there is no way to validate the veracity of data that may not be coming from a direct trusted source.
  - **Author Role(s) (Currently Comment)** – The role in which data is captured is important to more fully understand data. It is important to know not only what organization or author created the data but the capacity in which they were operating under in order to properly understand the data.
  - **Purpose of Capture (Currently Comment)** – Information is gathered from numerous sources for their own specific purposes. The level of detail, completeness, and quality of the information is going to be highly dependent on the interests of those capturing the information. This is important to understand more about the data and how it can be further used for things such as population and public health.

Candidate and Emerging Data Classes and Elements Under Consideration: Advance Directives

- The PACIO (Post-Acute Care Interoperability) Project, established February 2019, is a collaborative effort between industry, government, and other stakeholders, with the goal of establishing a framework for the
development of FHIR implementation guides to facilitate health information exchange.

- The PACIO Community wishes to update the ONC/USCDI with current efforts relating to the concept of Advance Directives and portable medical orders authored by practitioners in that domain. The PACIO Community continues to test FHIR interoperability of Advance Directive Information (ADI) during HL7 and CMS Connectathons (September 2021, May 2022, and July 2022) and resolve HL7 balloting comments in preparation for publication in upcoming months of a FHIR based Advance Directive Information Implementation Guide (IG) as Standard for Trial Use-1 (STU1). As part of the work, PACIO completed an environmental scan across states and other jurisdictions to inform a design that could work on a national level while allowing for jurisdictional differences. PACIO’s focus has been on “model of meaning” of ADI concepts as opposed to “model of use” where only specific narrative or forms are used, as part of enabling semantic interoperability of these concepts. A benefit of exchanging semantic meaning recognizes the current reality of diverse state and local jurisdictional processes present as the nation moves towards standards-based data exchange. The PACIO ADI Community has been working with external national organizations on the concept of practitioner-authored information which spans all types of advance directive concepts, including during emergency situations, end of life situations, and whenever an individual is unable to express for themselves their treatment wishes and desires.

- Over the last year the Post-Acute Care Interoperability (PACIO) project has been developing a FHIR (Fast Health Interoperability Resources) Implementation Guide (IG) to support advance directive interoperability. The PACIO Advance Directives Interoperability (in FHIR) Project Scope Statement was approved by HL7 in December of 2020. Under this charter, PACIO has been actively engaging both the provider and data standards communities in weekly meetings and enabling participation in testing events (HL7 Connectathons) to validate consensus guidance for representing advance directive information using FHIR. The FHIR IG resulting from this work was balloted in January of 2022. Through this process, previously established HL7 CDA and C-CDA IG’s for advance directive information have been leveraged to support the development of the new FHIR IG. Testing activities and experience has validated the use of existing data templates and increased community involvement has expanded understanding of the advance directive data class. This maturation process also has advanced the clarity and specificity of the terms used to describe the data elements associated with this important class of data.

- One of the most important aspects to appreciate about advance directives is the complexity of the information due to authorship by different stakeholders. Data provenance is critical for advance directive
The inclusion of patient-authored information is critical to enabling systems to represent those aspects of content that are created by patients themselves and those aspects of content that are created by clinicians or care team members. To address this complexity, the PACIO Community has defined three categories of advance directive information. One of the categories describes information authored by patients themselves and the other two categories address information authored by clinicians and practitioners.

For the two categories of clinician or practitioner-authored information, one category addresses patient preferences for medical interventions related to the current episode of care, such as a (Do Not Resuscitate) DNR or (Do Not Allow Resuscitation) DNAR orders. The other category addresses orders for life sustaining treatments should a future medical event require those decisions need to be made, based on a patient’s confirmed wishes. There are multiple forms that are in use across the U.S. to represent this type of content such as POLST, MOLST, POST, MOST, and the like. Below is a description of the three categories of advance directive information needed for interoperable data exchange that facilitates care and care planning.

- **Type I: Patient-Authored Advance Directive Information**
  - Patient-authored Information
  - Used as a tool for sharing an individual’s (patient’s) medical treatment and intervention goals, preferences, and priorities (GPP)
  - Provides guidance that a patient would want known as part of ensuring their care or treatment plan is informed by this guidance during a potential future medical emergency, in the case where the patient is unable to communicate for himself or herself

- **Type II: Practitioner or Clinician-Authored Encounter-Centric Advance Directive Information**
  - Practitioner-authored
  - Physician documentation in the form of an order or chart note, created directly from the patient’s stated goals, preferences, and priorities
  - Instructions are relevant ONLY to the current episode of care
  - The patient, or healthcare agent, has provided direct input that practitioners take into consideration when creating instructions about treatments that shall or shall not be utilized during a medical emergency occurring within the current episode of care.
• **Type III: Orders for Life-Sustaining Treatments**
  - Practitioner-authored
  - A set of medical orders intended to travel with a patient and be available across the continuum of care, to include episodes of care outside of the one where the portable medical order was authored
  - The patient, or healthcare agent, provides direct input in the creation of the instructions. These orders document a provider’s directions, created in collaboration with the patient or their designee, regarding treatments that shall or shall not be performed during a future medical emergency. The orders are based on a patient’s wishes for or against the treatments under specific circumstances.

  - Over the past year, the work and testing within HL7 and the PACIO Community has brought about greater community consensus, drawn more implementers of the standard, and provided increased learning and experience with data exchange of standards-based advance directive information. These learnings have enabled greater clarity about the Advance Directive Data Class and Data Elements previously proposed in 2020, including how the previously proposed Advance Directive Data Elements included concepts represented at different levels of organization. While some were specific data elements, others were collections that represented a bundle of data elements rather than a single data element.

    The feedback provided below explains recommended updates based on the considerable implementation experience with standards-based advance directive interoperability gained during the past twelve months. Based on the ongoing maturation in this area, there are recommendations for updates to the previously proposed Data Elements in the Advance Directives and Orders Data Class. These modifications provide clarification of data elements and bundling of data elements. This complete write-up is being submitted to provide an overview of the full set of recommendations for advancement of this Data Class and the included Data Elements.

  - Update “**Advance Directive**” Data Class to USCDI Level 2: Although the new PACIO Advance Directives Interoperability FHIR IG won’t publish until late 2022, considerable progress has been made on implementer consensus about how to represent and exchange advance directive information. The additional maturity should be recognized in an upgrade from Level 1 to Level 2. Following ballot reconciliation and publication of the FHIR IG, The Advance Directive Data Class should be added to USCDI ONDEC submission for V4 in 2022.
• Modify “Durable Medical Power of Attorney” to “Healthcare Agent” and Advance to USCDI Level 2. The notion of “Healthcare Agent” is better described as a collection of data elements which may establish one or more “Durable Medical Powers of Attorney” but is part of a set of data elements that may include additional details about the specific powers or limitations associated with that established role. With this context in mind, the data element “Healthcare Agent” is a broader term to encompass the content that could be exchanged, a subset of which might be the designation of a “Durable Medical Power of Attorney”. Over the past year multiple organizations have used both CDA and FHIR standards to share this important patient-generated information. In addition, the CDA guidance has been balloted twice within HL7, the FHIR IG currently is resolving dispositions to comments from the January 2022 ballot.

• There are LOINC Codes that represent this data element and it is part of both CDA and FHIR IGs. (81335-2 Patient Healthcare agent)

• There is a well-established value set for representing a primary, secondary, or tertiary healthcare agent when multiple agents are established. (Healthcare Agent or Proxy Choices, urn:oid: 2.16.840.1.113762.1.4.1046.35)

• The PACIO Community strongly recommends the Healthcare Agent data element be advanced to USCDI Level 2.

• Modify “Living Will” to “Priorities Under Certain Health Conditions” and “Priorities Upon Death”: While the concept of “Living Will” remains important to be included in the USCDI, further community discussion led to modifying the data element from “Living Will” to “Priorities Under Certain Health Conditions” and “Priorities Upon Death”. The notion of “Living Will” is better described as a bundle of data elements which identify a person’s “Priorities Under Certain Health Conditions” or “Priorities Upon Death”. Over the past year multiple organizations have used both CDA and FHIR standards to share this important patient generated information. In addition, the CDA guidance has been balloted twice within HL7, the FHIR IG is preparing to be balloted in January 2022.

• There are LOINC Codes that represents these data elements (81336-0 Patient Goals, preferences, and priorities under certain health conditions and 81337-8 Patient Goals, preferences, and priorities upon death) and instructions for using both are included in the CDA and FHIR IGs.
• Value sets for common treatments a patient may prefer to receive or not receive under certain conditions as well as priorities upon death are defined and available for use in the NLM VSAC. (Intervention Preferences at End of Life, urn:oid:2.16.840.1.113762.1.4.1115.9 and Health Goals at End of Life Grouping, urn:oid:2.16.840.1.113762.1.4.1115.7)

• The PACIO Community recommends modifying “Living Will” to “Priorities Under Certain Health Conditions” and “Priorities Upon Death” and advancing both of these data elements to USCDI Level 2.

• Remove “Personal Advance Care Plan” as a data element: While the concept of “Personal Advance Care Plan” remains important to be included in the USCDI, further community discussion led to clarification of the request of this item. The “Personal Advance Care Plan” concept is better described as a bundle of information which includes the data elements of “Healthcare Agent”, “Priorities Under Certain Health Conditions”, “Priorities Upon Death”, “Quality of Life Priorities” and “Care Experience Preferences”. The recommendation to advance the data elements that are part of the bundled Personal Advance Care Plan items are identified and justified in each specified data element.

• Advance “Quality of Life Priorities” to USCDI Level 2: The “Quality of Life Priorities” data element provides details on a person’s quality of life priorities based on their unique, personalized views for what is important to them in order to have a good quality of life. The need and maturity of this data element has been validated by the PACIO Community. In addition, the CDA guidance has been balloted twice within HL7, the FHIR IG currently is resolving dispositions to comments from the January 2022 ballot. There is a LOINC Code that represents this data element, and goes so far as to enable an individual to state what is most important to them, next most important to them, and so on to enable ranking of the person’s value-based priorities for what makes a good life to them personally which is useful when formulating treatment protocols(81340-2 Goals And/Or preferences in order of priority [Reported]) and it is part of both CDA and FHIR IGs.

• There is a well-established value set for representing priorities. (Health Goals at End of Life Grouping, urn:oid:2.16.840.1.113762.1.4.1115.7)

• The PACIO Community strongly recommends the “Quality of Life Priorities” data element be advanced to USCDI Level 2.

• Advance “Care Experience Preference” to USCDI Level 2: The current data element of “Care Experience Preference” provides details
on a person’s preferences for their care experience based on cultural, religious or spiritual, and personal preferences. The need and maturity of this data element has been validated by the PACIO Community. Over the past year multiple organizations have used both of these CDA and FHIR standards to share this important patient generated information. In addition, the CDA guidance has been balloted twice within HL7, the FHIR IG currently is resolving dispositions to comments from the January 2022 ballot.

- There is a LOINC Code that represents this data element (81338-6 Patient Goals, preferences, and priorities for care experience) and it is included in both CDA and FHIR IGs defining standardized exchange of advance directive information.

- There is a well-established value set for representing care experience preferences. (Care Experience Preferences at End of Life Grouping, urn:oid:2.16.840.1.113762.1.4.1115.11)

- The PACIO Community strongly recommends this data element be advanced to USCDI Level 2.

- Update “Advance Directive Observation” Data Element to USCDI Level 2: The current clinician-authored data element of “Advance Directive Observation” is critical to ensuring clinicians can record and share information about available patient-documented goals, preferences and priorities for treatments and interventions regarding future medical care that should be considered. This data element is routinely captured in the context of a Patient Summary or Encounter Summary authored by a clinician or assembled by clinician’s EMR system. This observation is recorded when a clinician verifies the presence of a patient’s advance directive information or confirms the patient has medical orders for life-sustaining treatments and documents reviewing this information.

- The PACIO Community strongly recommends the “Advance Directive Observation” data element be advanced to USCDI Level 2.

- Advance the “Orders for End of Life Care” data element under the Order data class to USCDI v4. It is recognized that the previous concept of “Portable Medical Orders for Life-Sustaining Treatments” was too narrowly focused and additional practitioner-authored orders related to goals of care and specific medical treatments or interventions should be included. These orders for end of life care are established by a practitioner regarding treatments that restore, sustain, or prolong a patient’s life. These types of medical orders are intended to be consistent with the patient’s instructions and wishes.
• The PACIO Community strongly recommends this data element be promoted to USCDI V4.

• The recommendations provided for consideration continue to mature through thoughtful discussion and testing in the open community of PACIO. The result of the proposed changes will incorporate the involvement of patient, provider, and data standards community. We strongly encouraged the Health Information Technology Advisory Committee to move the data elements contained in this document as recommended.