USCDI V5 Comments

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Feedback on ONC General Questions

ONC requested specific feedback and posed some general questions in the Standard Bulletin 2024-01 to seek feedback in the following areas.
(https://www.healthit.gov/sites/default/files/page/2024-01/Standards_Bulletin_2024-1.pdf)

1. Suggestions for improvement in the data classes or elements in Draft USCDI v5, including: a. Data class and element definitions, usage notes, and examples; and b. Examples of code sets used by health IT developers and implementers to communicate data element scope.

   My suggestions are sprinkled throughout. One key strategic suggestion focuses on how to deal with the collective noun problem plaguing the Clinical Notes and other Data Classes. Another strategic suggestion addresses how to limit the size and maximize the effectiveness of the USCDI effort. This suggestion proposes creating a "data element index list" where "more specific" data elements can be listed and categorized using the Data Elements and Data Categories defined in USCDI, thereby minimizing the number of more general Data Elements that need to be defined in USCDI.

2. Should other data elements, already classified as Level 2 on the USCDI web pages, be added to USCDI v5 instead of, or in addition to, those in Draft USCDI v5? If so, why?

   Yes. Many of my suggestions on how to improve USCDI V5 involve changes that impact lower levels of work within the USCDI framework for defining data elements.

3. Are there significant barriers to development, implementation, or use of any of these data elements that warrant a change in definition or removal from Draft USCDI v5?

   I think the most significant barrier is created by not recognizing the notion of "documents". Today, and I would argue for the foreseeable future, the "document paradigm" will continue to be a critical notion in information exchange. A document is a collection of information that has a single context of meaning and single Provenance in terms of who created it, who signed it, who shared it, etc. USCDI needs to resolve the confusion around Consultation Note as a "collection of information" versus Consultation Note as a single narrative note that is written in the context of a consultation. All of the Data Elements in the Clinical Note Data Class have this problem. The Patient Summary and Plan Data Class has this problem. The Advance Healthcare Directive Data Class has this problem. The Clinical Test Result/Report Data Element has this problem. The Diagnostic Imaging Report Data Element has this problem. The Care Plan Data Element has this problem. Not correcting this flaw will be a barrier to development and adoption of USCDI going forward.

   See my specific recommendation on how to address this problem in my USCVI V5 feedback for the Clinical Notes Data Class.

USCDI V5 Feedback on Data Classes and Data Elements

Advance Healthcare Directives – Missing Data Class in USCDI V5

USCDI V5 is Missing a Data Class for Advance Healthcare Directives

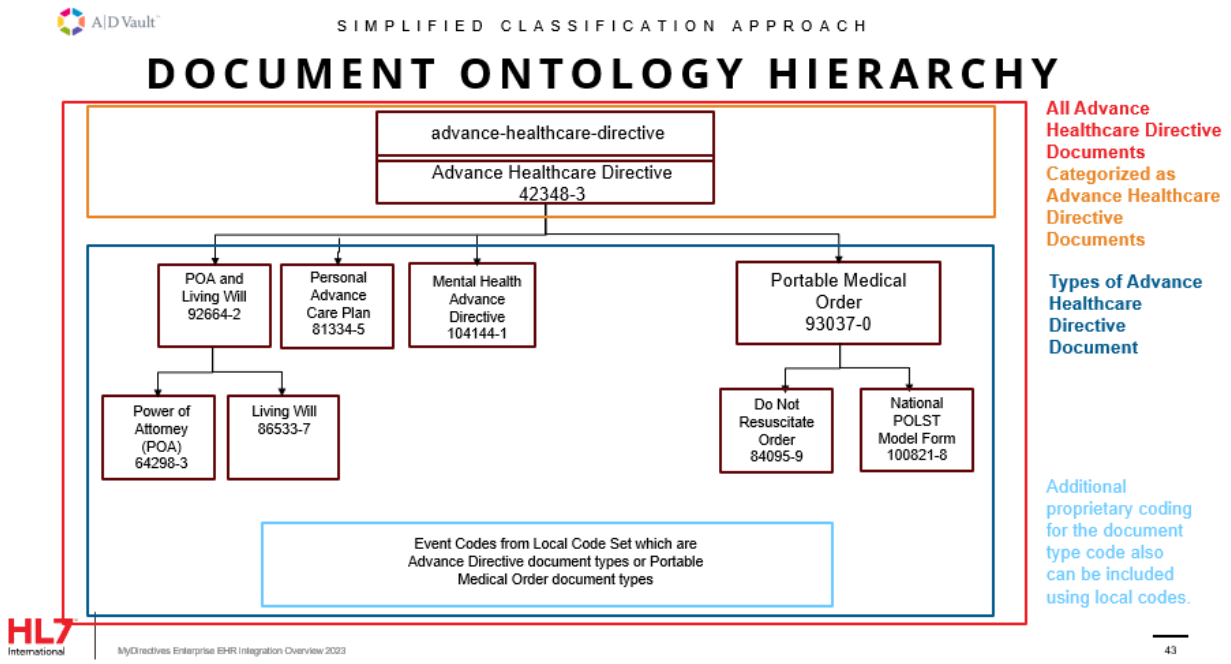
This data class needs to be included in USCDI V5 because of the interdependencies with the other USCDI V5 data elements Care Experience Preference, Treatment Intervention Preference, Patient Goal and Advance Directive Observation. All of these data elements which are in USCDI V5 Draft get exchanged in the context of an Advance Healthcare Directive document. It doesn't make sense to introduce the individual data elements without the "packaging" document data element used to convey the information for exchange. USCDI V5 should move the Advance Healthcare Directives Data Class and Advance Directives data element (Level 2) to USCDI V5.

Note: The data class called "Advance Directives" should be renamed to use the broader concept of "Advance Healthcare Directives". This would allow USCDI to name many "data elements" under this broad class. The data element called "Advance Directives" should be defined in the singular as "Advance Directive" but needs to be more specific such as "Advance Directive Document" or "Advance Directive Observation". When defining a data class, it makes sense to use a plural form of the concept, and individual data elements should be specified as a singular thing.

The applicable vocabulary standards for Advance Healthcare Directive documents include 42348-3 as a general category ranging from Portable Medical Order documents (POLST/MOLST documents) to all sorts of patient authored Advance Directive documents. (See comment below regarding the hierarchy of Advance Healthcare Directive document types.)

Being a document is a very important aspect of this data element's nature because this data element requires "context" to be accurately understood and used and that context is provided by it being a document. Advance Healthcare Directive information also must be human readable for patient safety and risk management. The document paradigm is uniquely positioned to support these key requirements.

Additional more specific types of advance healthcare directive documents are shown in the figure below.



Personal Advance Care Plan, Living Will, and Durable Medical Power of Attorney (Level 1) documents also could be accelerated to be included in USCDI V5 because these data elements simply represent more specific types of advance directive documents. A general Data Element of "Advance Healthcare Directive Document" would suffice to represent all the document types shown in the figure above.

My recommendation would be to pull all these "data elements" into USCDI V5 because they are so tightly wrapped together, but group them as "specific document types" under a Data Element called Advance Healthcare Directive Document. The different types of advance healthcare directive documents are just subsets of various collections of patient goals, care experience preferences, and treatment intervention preferences, along with the needed contextual data elements like witnesses, notary, authenticators, etc., and other administrative information.

One additional data element that isn't yet included but should be considered –even if only to add it at a lower level USCDI notion—is the data element Healthcare Agent. This could be added within the Advance Healthcare Directives Data Class. If cross-referencing among Data Classes becomes possible, Healthcare Agent also could be listed as a Data Element within the Care Team Member Data Class.

Exchange of Advance Healthcare Directive Documents and the associated Advance Directive Observation information includes observations about who a patient has consented to be their healthcare agent(s). Recommend classifying **durable healthcare power of attorney** as a specific type of Advance Healthcare Directive Document (64298-3) and include a Data Element for **healthcare agent** to describe the role a person plays as a surrogate decision-maker when appointed to speak for the patient when the patient can't communicate for themself.

The combined set of recommended changes would clean up the proposed Advance Directives Data Class to look like this:

Advance Healthcare Directives	The Data Class
Advance Directives Document	A collection of advance directive observations with information to support authorization and validation of the content.
Provider-authored Medical Order Form	A collection of provider-authored directives for the delivery of patient care services with information to support authorization and validation of the content.
Advance Directive Observation	A single observation made by a person or provider about an Advance Directive Document or Provider-authored Medical Order form or the care experience preferences, treatment intervention preferences, personal healthcare goals, or orders contained within an Advance Healthcare Directive document/form, or an assertion made by a provider about a patient's advance directive status, such as DNR Status. ***Cross List in Observation Class.***
Provider-authored directive for the delivery of patient care services	A single order made by a provider to direct the patient's course of care, developed to reflect and be consistent with patient's wishes. ***Cross List in Order Data Class.***
Healthcare Agent	The role a person plays as a surrogate decision-maker when appointed by the patient to speak on their behalf when the patient can't communicate for themself. ***Cross List in Care Team Member Data Class.***
Authenticator	A person or organization who manually, electronically, or digitally signs a document or form. ***Cross list in Provenance Data Class.***
Witness	A person who observes or attests to a person completing a document or form (in person or via virtual workflows). ***Cross list in Provenance Data Class.***
Notary	A person who follows defined "notarizing procedures" to complete a notarization process for a document or form.

	Cross list in Provenance Data Class.
DNR Status	Clarifies if CPR should be performed on the patient or if CPR should not be performed. ***Cross list in Health Status Assessment Data Class.***

Orders Data Class

Again, USCDI needs to clarify the difference between a Data Element which is a "document" and a data element which is an individual more specific type of information which may be exchanged within the context of a document or as a clinical statement on its own.

A Portable Medical Order document is a collection of provider-authored directives for the delivery of patient care services. USCDI guidance will continue to confuse the industry (as already has been done by establishing the "clinical note" Data Element without clarifying if this Data Element represents a document which holds a collection of clinical notes expressed as narrative or structured data, or if the clinical note Data Element describes an individual narrative clinical note that would be expressed within the context of a clinical note document.

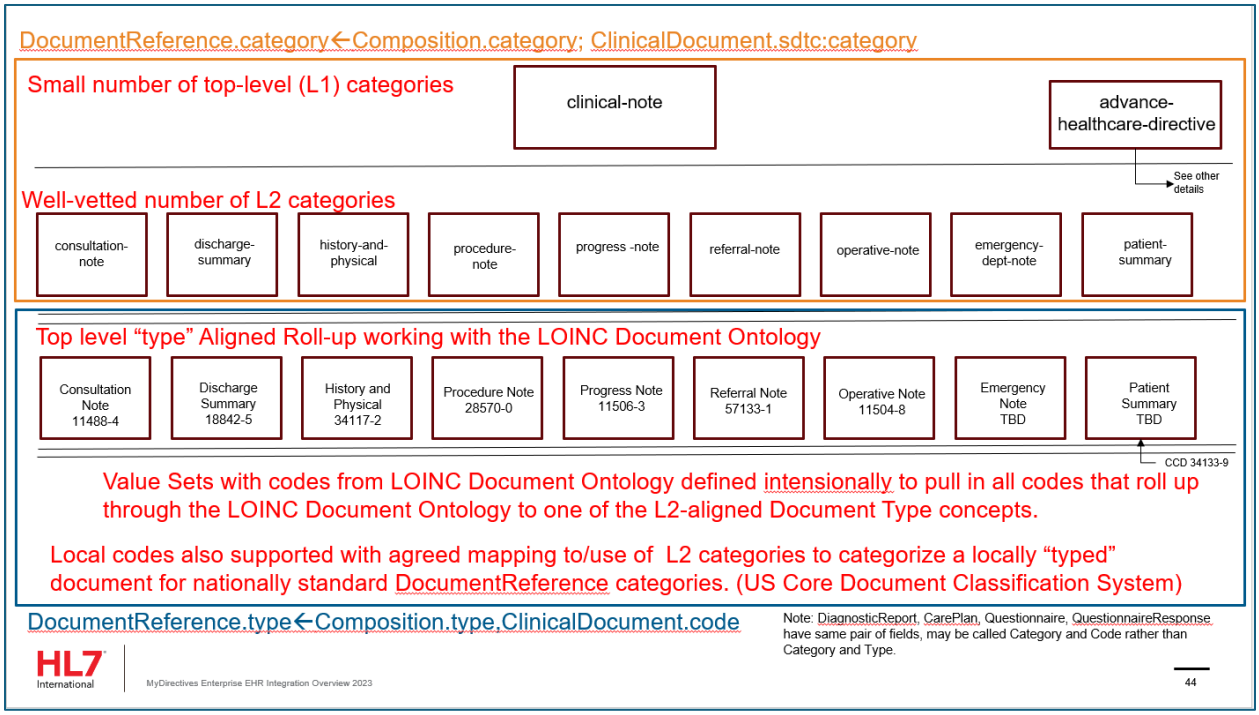
Somewhere within the USCDI efforts, this confusion which I call the "Sheep, Sheep Problem" needs to be addressed. USCDI has a "collective noun" problem which impacts the framework in multiple areas, not just Orders and Clinical Notes. This problem should be addressed sooner rather than later.

Clinical Notes Data Class

USCDI guidance continues to confuse the industry by establishing the "Clinical Notes" Data Class without clarifying that the Data Elements defined within this class may represents a document which holds a collection of clinical notes expressed as narrative or structured data. The clinical note Data Element may describe a collection of data elements, or it may describe an individual narrative clinical note that is expressed within the context of a clinical note document or may be expressed as a single clinical statement that can be understood on its own without the context provided by a document.

This confusion created by the USCDI Clinical Notes Data Class I call the "Sheep, Sheep Problem". USCDI has a "collective noun" problem in the way these Clinical Notes Data Elements are defined. This problem should be addressed sooner rather than later.

One option for addressing this problem is to clarify there are many more specific types of Clinical Documents or Clinical Forms each representing a collection of information with a single context and shared data Provenance information. An opportunity exists to define a hierarchy of Clinical Document and Form types, then the USCDI data elements can focus on just the highest tiers of this hierarchy.



Clinical Notes, Clinical Documents, and Clinical Forms	Broaden the definition of this Data Class to include Documents and Forms
Clinical Document	A collection of narrative and structured data which is created at a point in time to establish a single context for understanding the meaning of the information. The collection of information shares a single Provenance in terms of who created it, signed it, shared it, etc. The collection needs to be human readable, has the potential for authentication, etc. (See the 6 characteristics of a document as established in CDA and FHIR.) The distinction between a Clinical Document and a Clinical Form is nuanced and differentiated by the format used to represent the information.
Consultation Note Document	Wouldn't need to be a separate named Data Element. It is a type of Clinical Document and could be listed as such in the proposed "data element index list".
Discharge Summary Note Document	Same comment as for Consultation Note Document
Emergency Department Note Document	Same comment as for Consultation Note Document

History & Physical Note Document	Same comment as for Consultation Note Document
Operative Note Document	Same comment as for Consultation Note Document
Procedure Note Document	Same comment as for Consultation Note Document
Progress Note Document	Same comment as for Consultation Note Document
Clinical Form	A collection of narrative and structured data which is created at a point in time to establish a single context for understanding the meaning of the information. The collection of information shares a single Provenance in terms of who created it, signed it, shared it, etc. The collection needs to be human readable, has the potential for authentication, etc. (See the 6 characteristics of a document as established in CDA and FHIR.) The distinction between a Clinical Form and a Clinical Document is nuanced and differentiated by the structural format used to represent the information.
Clinical Note	A narrative finding expressed by a clinician in the context of documenting care provided to a patient or observations about a patient for whom care has been provided.
Consultation Note	Wouldn't need to be a separate named Data Element. It is a type of Clinical Note and could be listed as such in the proposed "data element index list".
Discharge Summary Note	Same comment as for Consultation Note
Emergency Department Note	Same comment as for Consultation Note
History & Physical Note	Same comment as for Consultation Note
Operative Note	Same comment as for Consultation Note
Procedure Note	Same comment as for Consultation Note
Progress Note	Same comment as for Consultation Note

Goals and Preferences Data Class

Personal Goals define a desired state to be achieved by a person or a person's elections to guide care.

A Treatment Intervention Preference is a care or treatment activity that the person stating the preference sees as an option that would be considered--or not--for attaining stated goals. A Care experience preference is an aspect of care which the person stating the preference has a

choice about, such as, preferred pharmacy; or other choices which inform providers as they create care plans or deliver care for the patient.

Note: Data elements “Patient Goals” and “SDOH Goals” should be expressed in the singular.

A Patient Goal can be the patient’s goal, or a practitioner’s goal for the patient, or a “shared goal” which is held as a goal by both the patient and the patient’s provider. The definition of the “Patient Goal” data element needs to clarify that it supports the notion of being a “shared goal”, not just held solely by the patient or by the practitioner but held as the goal by both parties.

Observations Data Class

Advance Directive Observation - A single observation made by a person or provider about an Advance Directive Document or Provider-authored Medical Order form or the care experience preferences, treatment intervention preferences, personal healthcare goals, or orders contained within an Advance Healthcare Directive document/form, or an assertion made by a provider about a patient’s advance directive status, such as DNR Status.

The Advance Directive Observation data element is an observation about a person’s available advance healthcare directive information which is expressed in the form of a document. The document is a very important aspect of this data element’s nature because this data element requires “context” to be accurately understood and used. See prior comments about the need to include the Advance Directives data class and advance directive data element in USCDI v5.

Clarify this observation is recording the act of reading/verifying the existence of an advance healthcare directive document or form and identifying the content in the document considered relevant to the course of care for the patient.

Orders Data Class

The “Orders” data element should not be expressed in the plural. Data elements should be expressed in the singular.

The “Portable Medical Orders (level 2)” data element also should be expressed in the singular (Portable Medical Order).

The Portable Medical Order (level 2) data element also should be accelerated to be included in USCDI V5 because this data element represents the type of document/form that is used to represent orders for end-of-life care that can be shared across organizations. Being a document/form is a very important aspect of this data element’s nature because this data element requires “context” to be accurately understood and used and that context is provided by it being a document.

Including the Order data element without the Portable Medical Order data element is less effective than introducing them together. Plus, there is a lot of concern around what order information needs to be represented and exchanged. Often times, orders are a mechanism to drive workflow within an EHR system. Being able to focus the Order data element on order information that needs to be

shared across systems or liberated to exist outside of the context of a system, would help clarify the purpose of the Order data element. This data element should focus on orders that need to be shared outside of the system where the order is created.

Provenance Data Class

The Provenance data class now includes Author as a data element and Author Role as a data element. However, the examples provided for Author Role are actually types of Authors, not Author Roles. An author can be a provider, a patient, a family member, or a device. The examples need to be moved to explain the different types of authors there can be.

Author – Actor that participated in the creation or revision of data. Examples of authors include but are not limited to provider, patient, family member, and device.

Author Role - Category of actor that participated in the creation or revision of data~~. Examples include but are not limited to provider, patient, family member, and device.~~

The Author Role data element describes the role the author plays, and the possible roles differ depending on the type of author.

If the Author is the Patient, then the role they play is "oneself".

2.16.840.1.113883.11.20.12.1	Personal And Legal Relationship Role Type	ONESELF	self	RoleCode

If the Author is a provider, then the role they play is based on the role they are licensed to play within the organization they are working for. Note – this is why the PractitionerRole resource is key to be used in FHIR when referencing a provider. You need to bring together the practitioner, the organization they are working for, and the facility they are working out of. Sometimes you need all that context to understand what role the author is playing. For a Practitioner type of Author, the role is usually expressed using concepts from the NUCC Provider Taxonomy. A great deal of work was done to create curated value sets to use to represent provider roles using NUCC codes was contributed to the Provider Directory IG being developed within HL7. This can be confusing because there is a tight coupling between the type of care a practitioner is licensed to provide and the role that practitioner plays on the care team. For example, a practitioner licensed to practice Cardiology serves the role of a Cardiologist on the care team. There are a few notable exceptions. For example, a practitioner who is a Cardiologist may play the role of the patient's primary care provider. Additionally, HL7 provides a general role designation vocabulary for Practitioners. These value sets are also being used for practitioner roles in the DirectTrust Provider Directory. When conveying the Author's role, a combination of concepts can be needed.

Individual and Group Specialties:
http://hl7.org/fhir/us/ndh/ValueSet/IndividualAndGroupSpecialtiesVS

PractitionerRole Code Value Set: **http://hl7.org/fhir/us/ndh/ValueSet/PractitionerRoleVS**

If the Author is a family member, then the role they play is described as their relationship to the patient, i.e. Mother, Father, Sibling, Child, etc. These family member role terms are typically drawn from the Personal and Legal Relationship Role Type value set.

2.16.840.1.113883.11.20.12.1	Personal And Legal Relationship Role Type

If the author is a device, I'm not sure we have a well established "role type" value set established yet.

Additional roles that are essential for the data provenance requirements in the Advance Healthcare Directives space include: Authenticator, Witness, and Notary.

Authenticator	A person or organization who manually, electronically, or digitally signs a document or form. ***Cross list note: May be relevant in many other Data Classes.***
Witness	A person who observes or attests to a person completing a document or form (in person or via virtual workflows). ***Cross list note: May be relevant in many other Data Classes.***
Notary	A person who follows defined "notarizing procedures" to complete a notarization process for a document or form. ***Cross list note: May be relevant in many other Data Classes.***

Patient Summary and Plan Data Class

This Data Class should include a Patient Summary document which contains a summary of the patient's relevant medical history. This is the type of collection of information carried in a Continuity of Care Document (CCD) or an International Patient Summary (IPS) document. This Data Class needs to include:

Patient Summary Document	A collection of information describing the patient's medical history.
Care Plan Document	A collection of information describing a plan to direct the course of care for the patient.
Screenings and Screening Results	Questions and answers used to gather information from the patient to be used by a provider when assessing the patient, or measuring progress toward a goal.

Assessments	A provider's conclusions about a patient's situation based on gathered information and physical observations of the patient's condition.
Health Concerns	Issues identified by the patient or practitioner as having risen to the level of a "concern" to be tracked and addressed. The issues could be a medical problem identified on the patient's Problem List, or it could any other type of issue that rises to the level of being a concern for the patient's overall health.
Patient Goals	Patients goals, or goals for the patient set by provider or shared goals held by both the patient and provider, established as the desired outcome to guide the course of care.
Interventions or Plan of Treatment	A set of activities to be performed to achieve progress toward a patient goal.
Evaluations	Evaluations are similar to Assessments but for the timing and purpose. Assessments are made to determine diagnoses prior to developing a Plan. Evaluations come after some or all of the interventions in a Plan have been performed and their purpose is to determine progress toward the goals which the plan is intended to meet. Because the diagnostic process is circular, Assessments and Evaluations appear to happen at the same point in the cycle. You have to look at the cycle as a linear process flattened out over time to see they are not the same thing. The work is similar in that there is a human clinician apply their professional judgement to the situation, but the purpose of the work differs. Conclusions regarding progress toward a goal based on qualitative or observable or measurable information gathered by screening instruments, physical assessment, or other types of testing.

Level-2 Feedback

Advance Directives Data Class

Promote the Advance Directives Data Class and the Advance Directive Data Element into USCDI V5 to address other issues described above. The promotion should include naming changes detailed in the feedback on USCDI V5.

Level-1 Feedback

Advance Directives Data Class

Personal Advance Care Plan, Living Will, and Durable Medical Power of Attorney are Advance Directive document types. Again, these are "A collection of advance directive observations with information to support authorization and validation of the content." These don't need to be delayed to Level 1. They are already covered in the Advance Healthcare Directives Data Class.

Quality of Life Priorities are really just a collection of Patient Goals in a "prioritized order". I would recommend for USCDI to expand the title of the Goals and Preferences Data Category to be "Goals, Preferences, and Priorities". Then, simply define the notion of "Priorities" as a collection of goals or preferences in a prioritized order.

This would create a broader and more useful notion, less associated with just end-of-life priorities. In reality there can be relevant priorities to be considered during pregnancy, birth, early childhood development, adolescent maturation, middle-life, and end-of-life. The term "quality of life" seems overly colored with thoughts about the time of life near a pending death, or when managing a debilitated state of existence. Why not create something more general and more generally useful—Priorities?

Level-0 Guidance

Goals and Preferences Data Class

Religious and Spiritual Preferences are currently considered specific types of Care Experience Preferences. Once USCDI defines a generalized Data Element that encompasses may things, it might be nice to just have a list where a specific thing like Religious Preference or Spiritual Preference could be looked up, and the index would show those as types of Care Experience Preferences within the Goals, Preferences, and Priorities Data Class.

This way, it would minimize the number of Data Elements and Data Categories that need to be defined by USCDI, but provide a robust "data element index list" with a "lookup tool" to find very specific types of information which can be classified within the USCDI information ontology. Everything doesn't need to be named individually within USCDI. USCDI should focus on developing a set of top-level notions, then all the "encompassed" smaller, more specific data elements can just get added to a "data element index list". When someone asks to address a new data element

which can't be indexed into the existing USCDI Data Elements, that's when an appropriate higher-level Data Element notion should get proposed in USCDI.

USCDI efforts need to "draw a line" between developing a robust data classification system and promoting a rich pallet of interoperable information.

The Care Experience Preference Data Element already encompasses numerous preferences, including religious and spiritual preferences. See notions in value set Care Experience Preferences at End of Life Grouping.

2.16.840.1.113762.1.4.1115.11	Care Experience Preferences at End of Life Grouping

It is anticipated that other Care Experience Preference value sets will be established to hold additional notions like "preferred pharmacy" over time.

USCDI should remain focused on creating the needed high-level notions that help us expand and accelerate interoperability at the national level and avoid making USCDI so granular as to have the opposite effect. The fact that Care Experience Preference is adopted in USCDI V5 should be sufficient to jumpstart the exchange of all types of Care Experience Preferences. We shouldn't create a situation where people wait to share specific types of information until that exact data element is named in USCDI. There needs to be a way we can agree, as a nation, that Religious Preferences or Spiritual Preferences are types of Care Experience Preferences…and then just add those more specific notions to the "data element index list" with their USCDI categorizations established.

Without a strategy like this to limit the number of needed USCDI data elements, this process will mushroom in size and lose its overall usefulness.