



The Office of the National Coordinator for
Health Information Technology
Health IT Advisory Committee

U.S. Core Data for Interoperability Task Force

Christina Caraballo, Co-Chair
Terry O'Malley, Co-Chair

June 28, 2019



Agenda

- Call to Order/Roll Call
- Opening Remarks
- Discuss Promotion Model Criteria, Levels and Process
- Public Comment
- Next Steps and Adjourn

USCDI Task Force Charge: Data Element Promotion Model

- **Overarching Charge:** Review and provide feedback on the U.S. Core Data for Interoperability (USCDI) Data Element Promotion Model.
- **Specific Charge:** Provide recommendations on the following:
 - » Promotion Model Lifecycle for Submitted Data Elements
 - » Data Element Submission Information
 - » Data Element Promotion Criteria
- **Supplemental:** Discuss additional defining criteria as needed

Promotion Model Criteria and Levels

- **Task Force Discussion**

To make a comment please call:

Dial: 1-877-407-7192

*(once connected, press “*1” to speak)*

All public comments will be limited to three minutes.

You may enter a comment in the
“Public Comment” field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.



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Meeting Adjourned



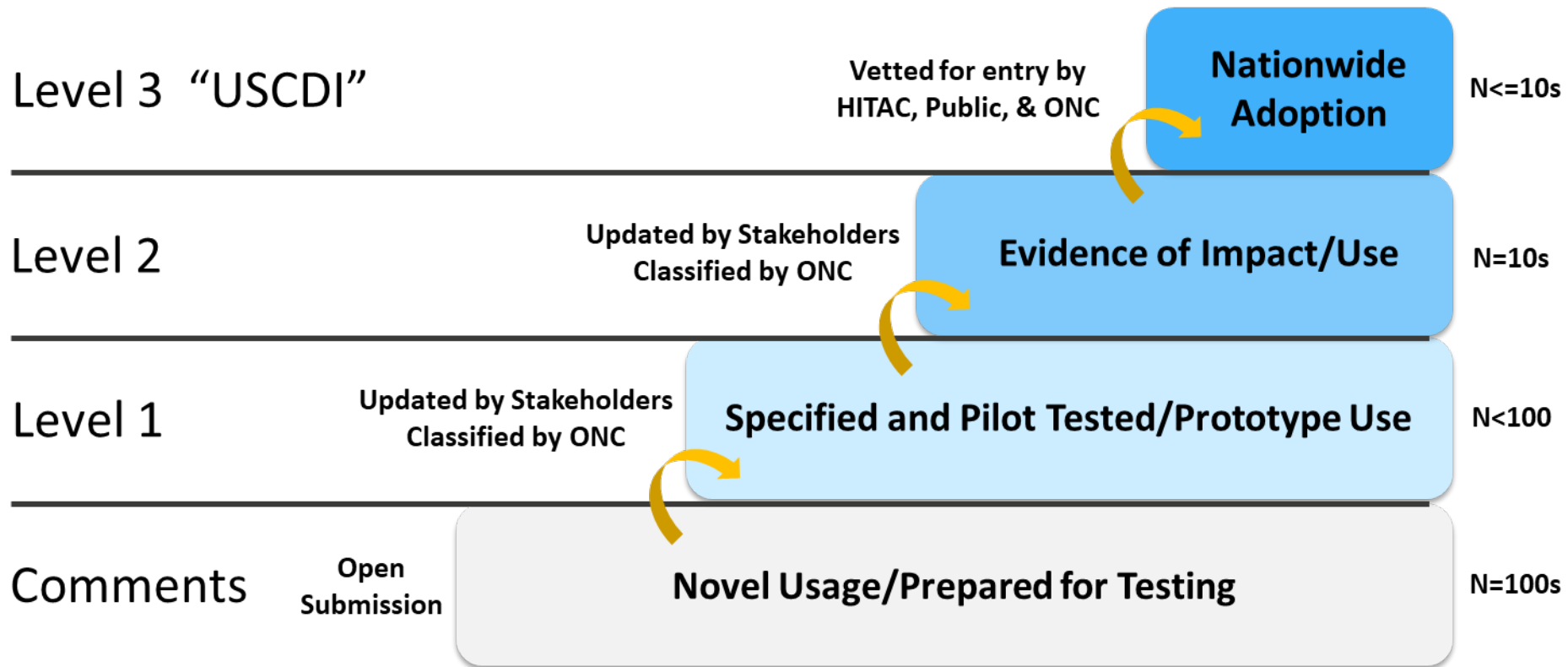
@ONC_HealthIT



@HHSOHC



USCDI Promotion Model – Annual Promotion/Status



Promotion Model Guidelines

- Any individual or entity may submit a Data Element to the USCDI process and contribute to a Data Element's promotion.
- The USCDI Promotion Process guidelines and criteria will be transparent to the public.
- The Data Element information submitted for entry to the USCDI Promotion Process will determine whether the Data Element enters Level 1, Level 2, or requires more development before entering the Process.
- No newly-proposed Data Element can proceed directly into the USCDI.
- Data Elements that do not demonstrate technical development activities will be removed from the promotion process after specified periods of time.

Promotion Model Lifecycle for Submitted Data Elements

- Submitted Data Elements exist as “Comments” and are then classified by ONC.
- Data Elements not classified into Level 1 or Level 2 have three submission cycles from the ONC final decision period before they are removed. Data Element submissions may be updated and resubmitted to be reviewed again.
- Once classified into Level 1 or Level 2, a Data Element has up to three submission cycles to be promoted to its next level (from Level 1 to Level 2, or Level 2 to USCDI).
- When a Data Element is removed from the process due to lack of progress, it is archived in the Comments section.
- After a Data Element’s classification has been published a submitter will have an opportunity to ask for a debrief on the classification decision.

Data Element Promotion Criteria: From “Comment” to Level 1 classification

- A new Data Element submission must include the following information:
 - » Data Element name and description
 - » Why should this Data Element be captured and exchanged nationwide?
 - » Do systems currently capture this Data Element?
 - » Do standards exist to represent and exchange this Data Element?
 - » Please describe any testing, pilots, or production use of the Data Element.
- To be formally entered into the Promotion Process at Level 1, a Data Element must meet the following requirements:
 - » Identify at least one developed use case, including its relevance to nationwide exchange
 - » Identify at least one content standard (or implementation guide) with which it can be used
 - » Demonstrate that it has been tested for exchange

Data Element Promotion Criteria

To move from Level 1 to Level 2 classification

- To be eligible to move to Level 2, a Data Element must demonstrate that it has achieved sufficient technical development to be tested at scale:
 - » Have a definition for the Data Element, including technical representation (structured or unstructured) in at least one content standard (or implementation guide) and, if applicable, vocabulary or value set binding; and
 - » Has been tested successfully in at least two independent systems.

Data Element Promotion Criteria

To move from Level 2 to the USCDI (1/2)

1. Technical Maturity – The Data Element must demonstrate that it:
 - » Has been tested successfully in at least four independent systems.
 - » Has formal, published documentation for its representation and exchange.

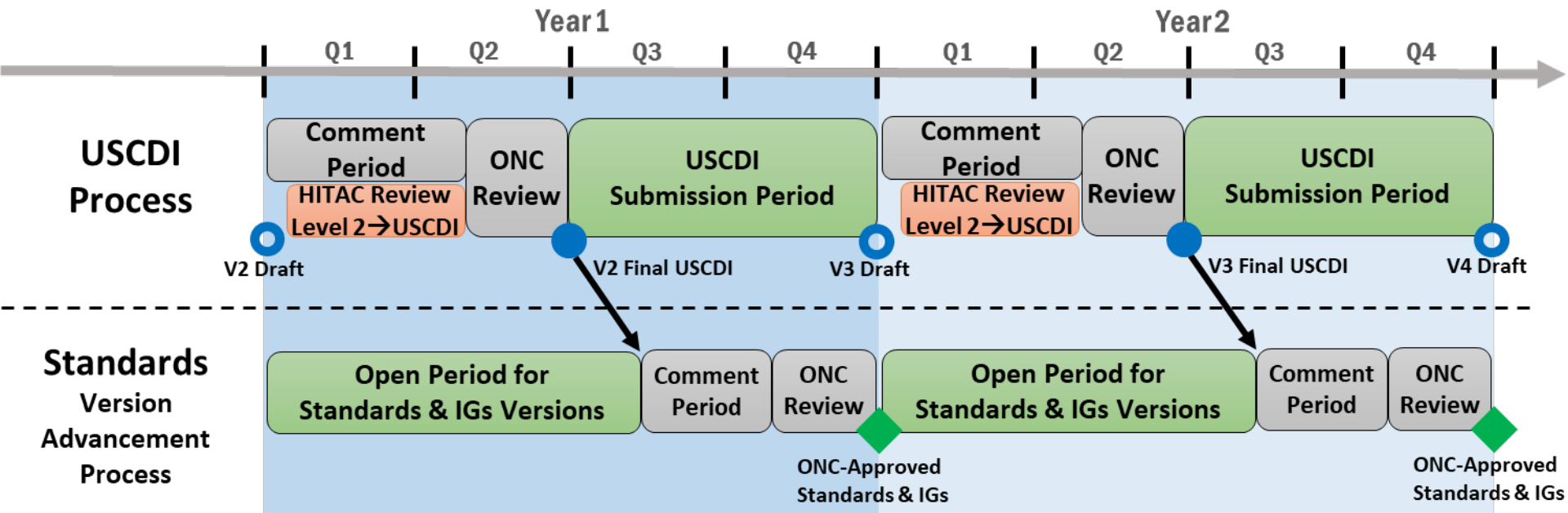
2. Nationwide Applicability – The Data Element submission must include the following information:
 - » How it impacts healthcare costs for individuals and populations
 - » Estimated number of providers who would use this Data Element
 - » Whether there are any restrictions to the Data Element’s standardization
 - » Estimated industry burden to implement the Data Element

Data Element Promotion Criteria

To move from Level 2 to the USCDI (2/2)

- The Health IT Advisory Committee (HITAC) would be charged to review Level 2 Data Elements that seek to move into the USCDI, including
 - » Assess the cumulative impact of USCDI-recommended Data Elements; and
 - » Provide recommendations to the National Coordinator on an annual basis.
- A Data Element would be added to the USCDI when the National Coordinator approves its promotion, weighing feedback from public comment and HITAC recommendations.

USCDI and Standards Versions Advancement Process Annual Relationship (Example Post-Final Rule)



Work Plan – Phase 2

Meeting Date	Potential Discussion Items
May 17, 2019	<ul style="list-style-type: none">• Phase 2 Kickoff• Discuss Promotion Model Guidelines
May 31, 2019	<ul style="list-style-type: none">• Discuss Promotion Model Lifecycle
June 14, 2019	<ul style="list-style-type: none">• Discuss Data Element Submission Criteria
June 28, 2019	<ul style="list-style-type: none">• Discuss Level 1 Classification
July 12, 2019	<ul style="list-style-type: none">• Discuss Level 2 Classification
July 26, 2019	<ul style="list-style-type: none">• Discuss USCDI Classification• Draft recommendations
August 9, 2019	<ul style="list-style-type: none">• Update and refine recommendations
August, 2019	<ul style="list-style-type: none">• Present draft recommendations

Task Force Members

First Name	Last Name	Organization	Organization Type
CO-CHAIRS			
Christina	Caraballo	Audacious Inquiry	Consultant/Patient Advocacy
Terrence	O'Malley	Massachusetts General Hospital	Health & Hospital Organization
MEMBERS			
Tina	Esposito	Advocate Aurora Health	Health & Hospital Organization
Valerie	Grey	New York eHealth Collaborative	Health IT Organization
Kensaku	Kawamoto	University of Utah Health	Health & Hospital Organization
Steven	Lane	Sutter Health	Health & Hospital Organization
Leslie	Lenert	Medical University of South Carolina	Health & Hospital Organization
Clem	McDonald	National Library of Medicine (NLM)	Federal
Brett	Oliver	Baptist Health	Health & Hospital Organization
Steve	Ready	Norton Healthcare	Health & Hospital Organization
Mark	Roche	Centers for Medicare & Medicaid Services (CMS)	Federal
Sasha	TerMaat	Epic	EHR Vendor
Sheryl	Turney	Anthem Blue Cross Blue Shield	Health IT Technology
ONC STAFF			
Al	Taylor	ONC	Federal
Adam	Wong	ONC	Federal

Data Elements in blue are already included in the 2015 Common Clinical Data Set (CCDS).
















Data Elements in pink are those for which ONC seeks recommendations in the Phase 1 charge.

A SET OF DATA CLASSES TO SUPPORT NATIONWIDE INTEROPERABILITY

The USCDI Version 1 (USCDI v1) is proposed as a standard (§ 170.213). It reflects the same data classes referenced by the CCDS definition and includes new required data classes and data elements, noted below.

If adopted, health IT developers will need to update their certified health IT to support the USCDI for all certification criteria affected by this change.

USCDI v1

Assessment and Plan of Treatment 	Laboratory  <ul style="list-style-type: none"> • Tests • Values/Results 	Provenance *NEW  <ul style="list-style-type: none"> • Author • Author Time Stamp • Author Organization
Care Team Members 	Medications  <ul style="list-style-type: none"> • Medications • Medication Allergies 	Smoking Status 
Clinical Notes *NEW  <ul style="list-style-type: none"> • Consultation Note • Discharge Summary Note • History & Physical • Imaging Narrative • Laboratory Report Narrative • Pathology Report Narrative • Procedure Note • Progress Note 	Patient Demographics  <ul style="list-style-type: none"> • First Name • Last Name • Previous Name • Middle Name (including middle initial) • Suffix • Birth Sex • Date of Birth • Race • Ethnicity • Preferred Language 	Unique Device Identifier(s) for a Patient's Implantable Device(s) 
Goals  <ul style="list-style-type: none"> • Patient Goals 	<ul style="list-style-type: none"> • Address *NEW • Phone Number *NEW 	Vital Signs  <ul style="list-style-type: none"> • Diastolic Blood Pressure • Systolic Blood Pressure • Body Height • Body Weight • Heart Rate • Respiratory rate • Body Temperature • Pulse oximetry • Inhaled oxygen concentration
Health Concerns 	Problems 	<ul style="list-style-type: none"> • Pediatric Vital Signs *NEW <ul style="list-style-type: none"> - BMI percentile per age and sex for youth 2-20 - Weight for age per length and sex - Occipital-frontal circumference for children < 3 years old
Immunizations 	Procedures 	

Introduction to Recommendations (April 2018)

- The Task Force recommendations seek to leverage the USCDI process to address the common causes that prevent data from being shared.
 - 1) Data doesn't exist
 - 2) Data exists but is not collected at all or in part
 - 3) Data is collected but there are no semantic standards for normalizing it
 - 4) Data is collected and there are appropriate semantic standards, but they are not being broadly applied
 - 5) Data is collected and semantic standards are applied; however, inconsistent application of semantic and other standards (eg., use of local or custom codes) by organizations inhibits interoperability.
 - 6) Detailed and reliable workflows to share the data outside of the originating organization have not been established.

Summary of Recommendations (April 2018)

- **Recommendation 1:** Establish a six stage maturation process through which data classes would be promoted, each with objective characteristics for promotion
- **Recommendation 2:** Expand the USCDI as each data class completes Stages 1-4 without a predetermined timeline
- **Recommendation 3:** Establish an annual publishing cycle for the USCDI with periodic bulletins as data items/data classes progress from one stage to the next
- **Recommendation 4:** Incorporate public feedback in each stage

Recommendation 1: Stages for the USCDI Process (April 2018)

- Stage 1: Proposed (new)
- Stage 2: In Preparation (new)
- Stage 3: Emerging
- Stage 4: Candidate
- Stage 5: USCDI
- Stage 6: Widespread Deployment (new)

Stage 1: Proposed (April 2018)

- **Purpose of Stage 1:**
Identify data classes and objects of value to any stakeholder
- **How to get in:**
Stakeholder proposes data objects and use cases in shared public resource
- **What happens in Stage 1:**
 - » Stakeholder submissions are sorted
 - » Data objects are aggregated by use and value to many stakeholders to begin the process of creating a data class
 - » Estimate net value and priority level to stakeholders, especially government and patients
- **How to get out:**
 - » Demonstrate high net value to multiple stakeholders
 - » Receive “high” priority rating

Stage 1: Proposed (April 2018)

- **Issues to clarify by testing**
 - » Does this process work?
 - Does it encourage submission by non-traditional stakeholders
 - Does it help identify communities of interest
 - » The cost and resources required to stand-up a public resource
 - » The ease with which stakeholder communities can be identified
 - » A process to identify and specify “value”

Stage 2: In Preparation (April 2018)

- **Purpose of Stage 2:**
Develop tightly defined data class supported by value to multiple stakeholders
- **How to get in:**
 - » Demonstrate high net value to multiple stakeholders
 - » Receive “high” priority rating
- **What happens in Stage 2:**
 - » Develop the Data Class:
 - Identify the data objects that make up the data class
 - Identify and reuse when possible previously specified data objects
 - Harmonization of similar data objects
 - Define the scope of the data class
 - Identify Applicable Standards
 - Identify relevant use cases

Stage 2: Proposed (April 2018)

- **How to get out:**
 - » Data Class and Use Cases sufficiently specified for pilot testing
 - » Two versions of the Data Class are possible
 - One specified to be computable
 - One specified to be sent as minimally structured data sufficient to identify content, patient and receiver
- **Issues to clarify by testing:**
 - » The time and resources required to stand-up a DCWG
 - » Whether this is a process that can work at scale
 - » The degree to which stakeholder communities volunteer to participate
 - » Whether a volunteer DCWG can perform the work assigned to it
 - » Should Stage 3 be where standards are identified and applied
 - » Whether the criteria for moving to Stage 3 are reasonable or whether they create too great a barrier to advancement

Stage 3: Emerging (April 2018)

- **Purpose of stage:**
Test the Data Class in pilot settings, revise and retest
- **How to get in:**
Clearly defined Data Class and Use Cases with applicable standards
- **What happens in Stage 3:**
 - » Testing in Dev Days or Connectathon-type events
 - » Further refinement and specification of data class based on testing in pilot sites
 - » Resolve gaps in applicable standards and identify barriers to data collection
- **How to get out:**
 - » Achieve sufficient technical specificity for testing in production settings

Stage 3: Emerging (April 2018)

- **Issues to clarify by testing:**
 - » The cost and resources required for pilot testing
 - » Whether a DCWG can perform the work assigned to it in this stage
 - » Is the level of testing too little or too much
 - » Whether the criteria for moving to Stage 4 are reasonable or whether they create too great a barrier to advancement.

Stage 4: Candidate (April 2018)

- **Purpose of stage:**
Test data class in production and prepare for deployment at scale
- **How to get in:**
Achieve sufficient technical specificity for testing in production settings
- **What happens in Stage 4:**
 - » Testing and modification to resolve barriers to nationwide implementation
 - » In use in at least one commercial system
- **How to get out:**
 - » Demonstrate that data class is ready to be deployed at scale

Stage 4: Candidate (April 2018)

- Issues to clarify by testing
 - » The cost and resources required for pilot testing
 - » Whether a DCWG can perform the work assigned to it in this stage
 - » Is the level of testing too little or too much
 - » Whether the criteria for moving to Stage 4 are reasonable or whether they create too great a barrier to advancement.

Stage 5: USCDI (April 2018)

- **Purpose of stage:**
Flag the data class as a priority for nationwide deployment and use available resources to drive adoption
- **How to get in:**
Demonstrate that data class is ready to be deployed at scale
- **What happens in Stage 5:**
 - » Policy levers used to promote widespread adoption
 - » QHINs and their participants required to update their technology to support new USCDI data class
- **Widespread adoption = “Stage 6”**