



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

U.S. Core Data for Interoperability Task Force Promotion Model Recommendations

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

October 16, 2019



Agenda

- Task Force Charge
- Task Force Members
- Task Force Meetings and Presentations
- Summary of ONC's Draft Promotion Model
- USCDI Task Force Commentary and Recommendations
- Discussion

USCDI Task Force Charge (Phase 2)

- **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 Charge:** Discuss additional defining criteria as needed
- **Informal Charge:** “The details”
 - » Add details
 - » Think through the process from the “User’s” perspective

USCDI Task Force Members

Name	Organization	Organization Type
Co-Chairs		
Christina Caraballo	Audacious Inquiry	Consultant/Patient Advocacy
Terrence O'Malley	Massachusetts General Hospital	Health & Hospital Organization
Members		
Valerie Grey	New York eHealth Collaborative	Health IT Organization
Ken 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	Federal
Brett Oliver	Baptist Health	Health & Hospital Organization
Tina Esposito	Advocate Aurora Health	Health & Hospital Organization
Sasha TerMaat	Epic	EHR Vendor
Sheryl Turney	Anthem Blue Cross Blue Shield	Health IT Technology
Steve Ready	Norton Healthcare	Health & Hospital Organization
Sasha TerMaat	Epic	EHR Vendor
ONC Staff		
Al Taylor	ONC	Federal
Adam Wong	ONC	Federal

Summary of USCDI Task Force Meeting and Presentations

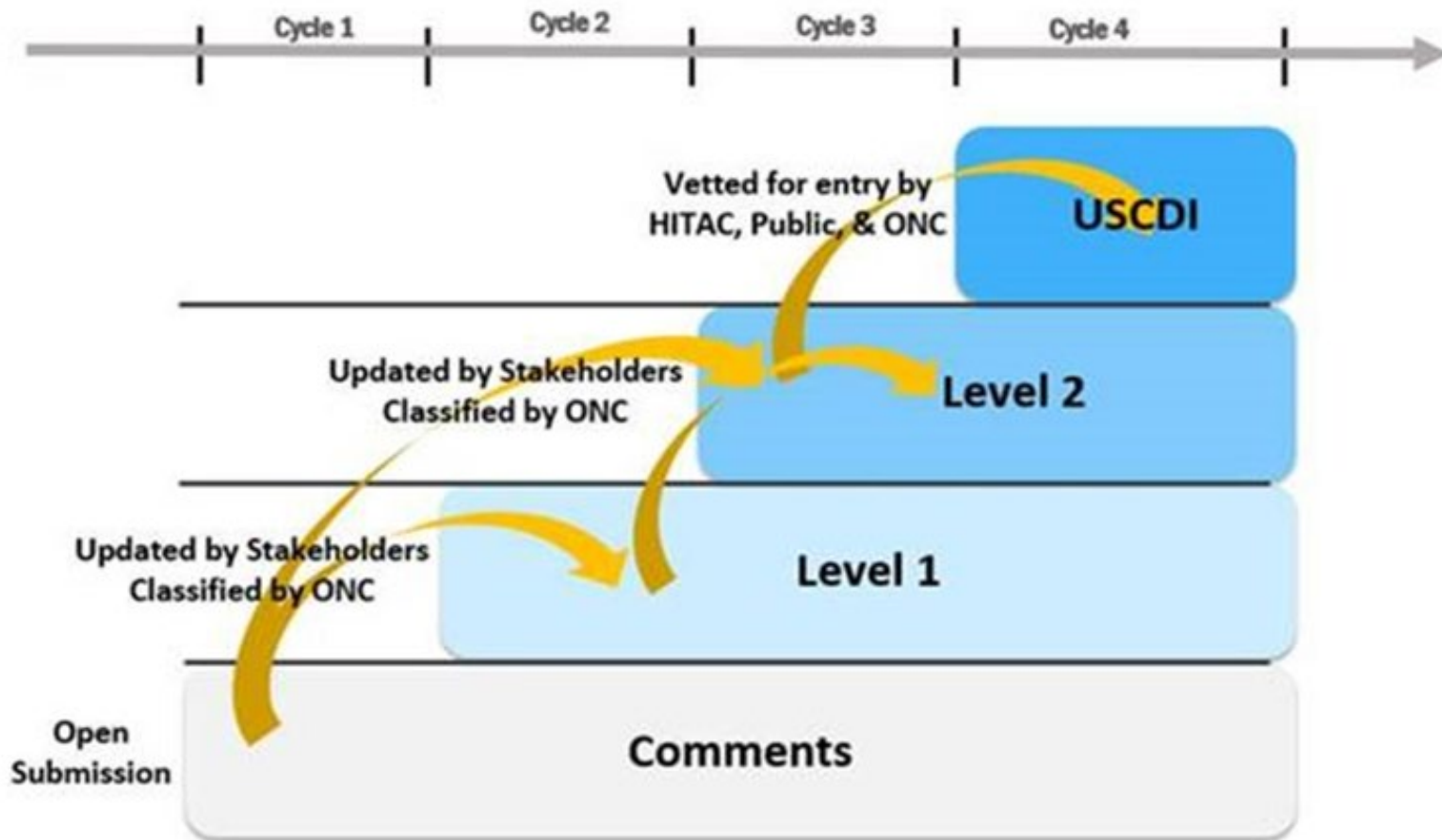
Meeting Date	Potential Discussion Items
May 17, 2019	<ul style="list-style-type: none">• Phase 2 Kickoff• Discuss Promotion Model Guidelines
May 31, 2019	<ul style="list-style-type: none">• Discuss Promotion Model Lifecycle
June 14, 2019	<ul style="list-style-type: none">• Discuss Data Element Submission 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
September 6, 2019	<ul style="list-style-type: none">• Develop Data Element Submission Form
September 17 2019	<ul style="list-style-type: none">• Present draft recommendations to HITAC
September 27, 2019	<ul style="list-style-type: none">• Address HITAC and industry concerns/issues
October 11, 2019	<ul style="list-style-type: none">• Finalize draft recommendations
October 16, 2019	<ul style="list-style-type: none">• Present final recommendations to HITAC

Introduction

The TF overwhelmingly endorses the spirit, direction and emphasis of the ONC draft USCDI Promotion Model. Our comments and recommendations are made in response to issues raised by the HITAC and by TF members and participants.

- The most significant change that we propose is the timeline of the promotion model because the feedback was strongly in favor of a more rapid process.
- Two other substantial recommendations are to institute an annual review of the overall USCDI process and to create a detailed users' guide for data element submission and advancement.
- The remainder of our recommendations focus on the details of the promotion model and concerns raised during our two year deliberation.

ONC Promotion Model



TF Promotion Model

Milestones	Level	Process
Overall burden to implement	USCDI	Review by HITAC and ONC
Known restrictions on use		
Known limits on standardization		
Estimated number of users		
Addresses Quadruple Aim		
Production use for the majority of anticipated users	Level 2	Ongoing addition of supplemental data and ONC review
Production use in several applicable settings	Level 1	
Exchange among several platforms		
Pilots, "Connect-a-thon" [®] testing		
Implementation guide	Comment	
Standard supported by SDO		
Content standard		
Discreet electronic capture		
Identify projects		
Identify use case(s)		
Justify national exchange		

USDCI Task Force Commentary and Recommendations

- Overarching Goals of USDCI Promotion Model
- Key Components of Data Element Promotion Model
- Promotion Process Based on Meeting Milestones
- Data Element Promotion Criteria and Promotion Model Milestones
- Public/Submitter Feedback
- Annual Review of Promotion Process
- Submission and Advancement Users' Guide

Overarching Goals of USCDI Promotion Model

- Open, public, and transparent submission and promotion processes that enables and encourages diverse stakeholders and communities of interest to propose and provide supporting evidence to promote new data elements/classes
- Establish lowest possible barriers for data element submission
- Establish a high bar of technical specification and testing for promotion
- Establish clear requirements for promotion enabling submitters and communities of interest to plan appropriately
- Establish clear requirements for promotion enabling ONC to appropriately place elements/classes into the promotion process for inclusion in USCDI
- Provide opportunities for feedback
- Provide advance notice to industry
- Ensure that newly adopted data elements are ready for implementation, adoption and use

Key Components of Data Element Promotion Model

- Four Data Element Classifications: Comment, Level 1, Level 2, and USCDI
- The process to submit data elements for promotion to USCDI is open to everyone
- Searchable, public-facing work space maintained by ONC to enable and encourage submission of additional information required for data element(s) promotion
- Data element promotion based on meeting specific milestones rather than specific timelines
- Ongoing review by ONC to determine the appropriate level for each data element
- Frequent communication with data element stakeholders regarding level changes and feedback regarding promotion
- Final evaluation by ONC with recommendations from HITAC to assess strategic priority and burden to implement

Recommendation 1 – Promotion Model Based on Meeting Milestones

HITAC members have indicated that the proposed promotion process is too slow. In the ONC proposed model, advancement from one level to the next level requires a minimum of one year. The TF believes that progress through Level 2 should be shortened as much as possible and recommends:

- Promotion occurs solely on the basis of meeting the required milestones without a minimum required promotion cycle time. (See Promotion Process Milestones slides)
- Decouple the promotion process from the Standards Advancement Process
- Publish status of all data elements in the Data Element Promotion Process quarterly in conjunction with a public comment period (See Public/Submitter Feedback slide)

Introduction to Promotion Model Milestones

The TF discussed specific criteria that would need to be met to advance a data element through the promotion process. Once all criteria are met for each “milestone”, the data element advances. The milestones would serve as guidance to data element sponsors. The milestones are discussed in the following sections:

- Administrative requirements
- Promotion from Comment to Level 1
- Promotion from Level 1 to Level 2
- Promotion from Level 2 to USCDI

Recommendation 2 - Promotion Model Milestone: Administrative Requirements

The TF recommends the following administrative expectations for data element sponsors:

- Complete submission form
- Adhere to guidance regarding acceptable standards, code sets and value sets
- Provide sufficient additional information to inform re-leveling
- Respond to ONC feedback regarding submissions required for further promotion

Recommendation 3 - Promotion Model Milestone: Comment to Level 1

The TF recommends the following criteria must be met to move from Comment to Level 1:

- Justification exists for data element capture and national exchange
- There are applicable use cases(s) involving this data element
- There are projects currently underway using this data element
- This data element is currently captured discreetly in one or more electronic systems with preliminary understanding of how often and how the data element is collected (e.g., free text, coded data element)
- A content standard exists for this data element
- This standard is supported by an established SDO that uses a public balloting process
- An implementation guide exists that contains this data element with stability
- There have been pilots, “Connect-a-thon”[®] testing, and/or production use of this data element

Recommendation 4 - Promotion Model Milestone: Level 1 to Level 2

The TF recommends the following criteria must be met to move from Level 1 to Level 2:

- The exchange of the data element(s) has been successfully tested at scale among several distinct/different EHR platforms/systems in a production environment using the previously cited content and transport standards
- Sufficient testing to satisfactorily meet the requirements of the proposed use case(s) in applicable settings
- There has been sufficient testing to satisfactorily meet the requirements of the proposed use case(s) in a “several” applicable settings move to Level 1 to 2

Recommendation 5 - Promotion Model Milestone: Level 2 to USCDI (1 of 2)

The TF recommends the following criteria must be met to move from Level 2 to USCDI:

- **Technical Maturity** - The exchange of the data element(s) has been successfully tested at scale between distinct/different EHR platforms/systems in a production environment sufficient to establish feasibility for the majority of anticipated users
- **National Applicability**
 - » Evidence that the data element(s) supports the quadruple aim
 - » Estimated number of stakeholders who would use this data element/class

(continued)

Recommendation 5 - Promotion Model Milestones- Level 2 to USCDI 2 of 2

- Nationwide Applicability (cont)
 - » All known restrictions potentially limiting the standardization of this data element (e.g. proprietary codes, value sets) have been addressed
 - » All known restrictions potentially limiting the use of this data element (e.g. licensing and fees) have been addressed
 - » There is an estimate of the overall burden to implement (e.g., clinician data capture, patient data submission, health IT upgrade costs)
 - Supporting multiple, complex use cases may present significant challenges to implementers

Recommendation 6 - Final Review of Data Elements Proposed for USCDI

The TF discussed the process for the final review of data elements that have met all of the milestones for advancement into USCDI. The TF recommends:

- Review data elements for:
 - Technical maturity
 - Barriers to implementation, adoption and use
 - Alignment with identified national priorities
 - Industry readiness
- Process:
 - ONC provides the HITAC with a proposed draft of data elements that meet the criteria for promotion into USCDI
 - HITAC provides ONC with recommendations regarding the proposed draft
 - ONC publishes final decisions taking into consideration public comment and HITAC recommendations

Recommendation 7 - Public/Submitter Feedback in Promotion Model

The TF was concerned that there was not an explicit process and timeline for obtaining public and data-element-submitter feedback on the readiness, applicability, or prioritization of a proposed data elements/classes. The TF recommends:

- Solicit public comment quarterly to coincide with updating the status of each data element in the process
- Specifically seek comments on the maturity, adequacy, and adoption levels of a proposed data class/element
- Specifically seek comments on the maturity and applicability of use cases, workflows, and value propositions which may be more broadly applicable for a particular data class/element

Recommendation 8 - Annual Review (1 of 7)

The TF raised the concern that there is still significant uncertainty regarding the model and process, and recommends the following issues for specific attention during an annual review:

- Does the process work?
- Does the process need a “prioritization” function?
- Does the process need a “harmonization” function?
- Does the process need a “stalled data element” function?
- Are the standards development business models adequate to support the required promotion work?
- Is there a role for ONC to identify and promote high priority data elements?

Recommendation 8 a) - Annual Review: Does the Process Work (2 of 7)

- Does the process work as anticipated?
 - Volume of submissions
 - Number of submissions placed directly into Level 1 or Level 2
 - Number of data elements by level
 - Number of advancements by level
 - Number of failures to advance by level
 - Time for advancement to next level
 - Aggregate time from submission to USCDI
 - Are there high priority data elements that are missing?
 - Are there high priority data elements that failed to advance?

Recommendation 8 b) - Annual Review: Prioritization of Data Elements (3 of 7)

The TF was concerned about the potential need for a “data element prioritization” step before promotion to USCDI. The TF makes the following recommendations:

- If in its annual review of the Data Element Promotion Model ONC finds that there are too many data elements eligible for simultaneous promotion to USCDI, ONC should establish a prioritization process to reduce the likelihood of overwhelming both providers and the vendor community with new requirements
- The prioritization process should consider, among other issues, the following:
 - Relevance to meet the Quadruple Aim
 - Extent of applicability
 - Presence of clearly defined use cases and workflows associated with the data class/element
 - Clear value propositions for adopting the data class/element

Recommendation 8 c) - Annual Review: Harmonization of Data Elements (4 of 7)

The TF makes the following recommendations:

- Develop a process for reviewing submitted data elements to identify those that express similar concepts
- Develop a process to determine whether the elements should be merged or remain separate
- Achieve consensus when multiple approaches exist

Recommendation 8 d) - Annual Review: Stalled Data Elements (5 of 7)

The TF concluded that data elements that have neither advanced nor received additional submissions for an extended period of time should be removed from Level 1 and/or Level 2. The TF recommends that ONC institute the following process:

- Provide a warning to submitter(s)/sponsor(s) indicating that data element(s) that have not advanced to the next level AND have not received additional submissions during the expected advancement time are at risk for reassignment to a “stalled” category
- Place data elements that have neither advanced NOR received additional submissions in twice the average advancement time into the “Stalled Data Element” category
- Re-introduce the data element following submission of new information that indicates that the element is more likely to advance

Recommendation 8 e) - Annual Review: Is the upfront work being done? (6 of 7)

TF has raised concerns about the sustainability of the different business models that underpin creation, testing, and maintenance of standards and value sets which underlie the USCDI Data Element Promotion Process.

The TF recommends:

- As part of the Annual Review of the Promotion Process, ONC assess the adequacy of financial support for entities that create, support, test, and maintain important interoperability standards, code sets and value sets.
- If ONC finds gaps that may delay or imperil activities that are essential for nationwide interoperability, it will address these gaps using available remedies

Recommendation 8 f) - Annual Review: Promote High Priority Data Elements (7 of 7)

The TF raised a concern that a promotion process that relies heavily on the private sector to identify and advance data elements of value may not necessarily identify and advance data elements that address national priorities such as the Quadruple Aim.

The Task Force recommends that if, as part of its annual review of the Promotion Process:

- ONC identifies that one or more high priority data elements are missing from the Promotion Process then it will use the tools at its disposal to facilitate the submission of missing priority data elements
- ONC identifies that high priority data elements are not advancing that it will use the tools at its disposal to facilitate promotion

Recommendation 9 - Submission and Advancement Users' Guide (1 Of 5)

The TF discussed the need to provide guidance to submitters and communities of interests to help them adequately provide relevant information to fulfill required criteria and meet milestones to advance through the promotion process.

The TF recommends that ONC create a Submission and Advancement Users' Guide to assist submitters and communities of interest. The TF drafted a Users' Guide as a base for ONC to expand upon. The draft Users' Guide consists of the following key sections:

- Identification of Data Element
- Justification for Data Element promotion
- Extent of use and technical specification
- Potential impact
- Potential barriers

The TF also recommends that as part of the guide ONC provides examples of successful applications and subsequent submissions.

Recommendation 9 - Submission and Advancement Users' Guide (2 of 5)

Section I: Identification of Data Element

- Name of Submitter
- Contact Information of Submitter
- Data Element Name
- Data Element Description
- Related data elements
- Proposed Data Class (Optional)
- Do similar data elements currently reside in the UDA? Y/N/Ukn
 - » If yes, please explain why this data element should be considered separately

Recommendation 9 - Submission and Advancement Users' Guide (3 of 5)

Section II: Justification for Data Element Promotion

- Explain why this data element should be captured and available for national exchange
- Briefly describe a representative use case

Section III: Extent of Use and Technical Specification

- Is this data element currently captured discreetly in any electronic system?
 - » If yes, please cite known systems that capture this data element and briefly describe the format and frequency of capture
- Does a content standard exist for citing this data element?
 - » If yes, please cite the applicable standard

Recommendation 9 - Submission and Advancement Users' Guide (4 of 5)

Section III: Extent of Use and Technical Specification continued

- Does an implementation guide exist that contains this data element?
 - » If yes, please cite the IG
- Has there been any “Connect-a-thon”[®] testing, pilots, or production use of the data element?
 - » If yes, please cite artifacts describing its use
- Has the exchange of this data element been successfully tested between several different platforms in a production environment?
 - » If yes, please cite supporting artifacts
- Has the exchange of this data element been successfully tested at scale between multiple different platforms in a production environment sufficient to establish feasibility for the majority of anticipated users?
 - » If yes, please cite supporting artifacts

Submission and Advancement Users' Guide (5 of 5)

Section IV: Potential Impact

- Is there evidence that the data element(s) supports the quadruple aim?
 - » If yes, please provide supporting data
- Please provide an estimate of number of stakeholders who would use this data element/class

Section V: Potential Barriers

- Are there any restrictions on the standardization of this data element (e.g. proprietary code)?
- Are there any restrictions on the use of this data element (e.g. licensing, user fees)?
- Please provide an overall estimate of burden to implement

Recommendation 10 - Proposed “Pilot” Use Case to Test the USCDI Model

Considering the unknowns regarding the USCDI Data Element Promotion Process, the TF recommends that ONC pilot data elements through the promotion process to identify any issues and create early examples for the Users’ Guide. The TF identified the following data elements for consideration because of their importance, broad stakeholder support and complexity:

- Social Determinants of Health
 - » Data class with data elements at multiple levels of specificity
 - » Identified by the ISP TF as a high priority use case for future consideration



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Thank you



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