



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

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

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Agenda

- Task Force charge
- Overarching goals of USDCI Promotion Model
- Summary of Task Force work
- Promotion Model and Promotion Model Lifecycle (ONC slide)
- Detailed presentation
 - » Proposed Data Element Promotion Criteria
 - » Outline for Data Element Submission Form
 - » Implied responsibilities in the Promotion Model for ONC and submitters
- Issues for further consideration

USCDI Task Force Charge

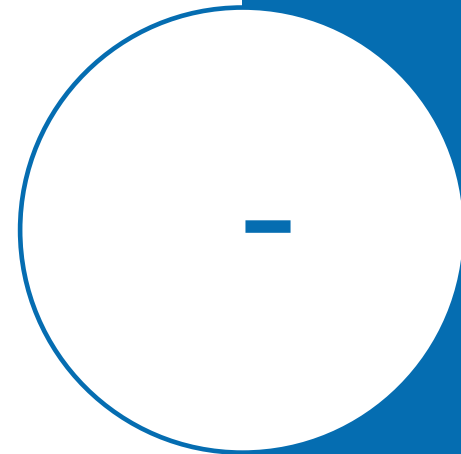
- **Overarching Charge:** Review and provide feedback on the U.S. Core Data for Interoperability (USCDI) Data Element Promotion Model.
- **Specific Charge:** Provide recommendations on the following:
 - » Promotion Model Lifecycle for Submitted Data Elements
 - » Data Element Submission Information
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

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

Overarching Goals of USCDI Promotion Model

- Open, public and transparent submission
- Encourage and enable diverse stakeholders and communities of interest to propose and 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/or communities of interest to plan appropriately
- Establish clear requirements for promotion enabling ONC to appropriately place data elements/classes
- Provide advance notice to industry



Summary of Task Force Work

Reviewed proposed Promotion Model and Promotion Model Lifecycle

- Unanimous agreement without revision
- Proposed model addressed 2018 TF recommendations with a simpler structure

Added details to the advancement process by making recommendations for:

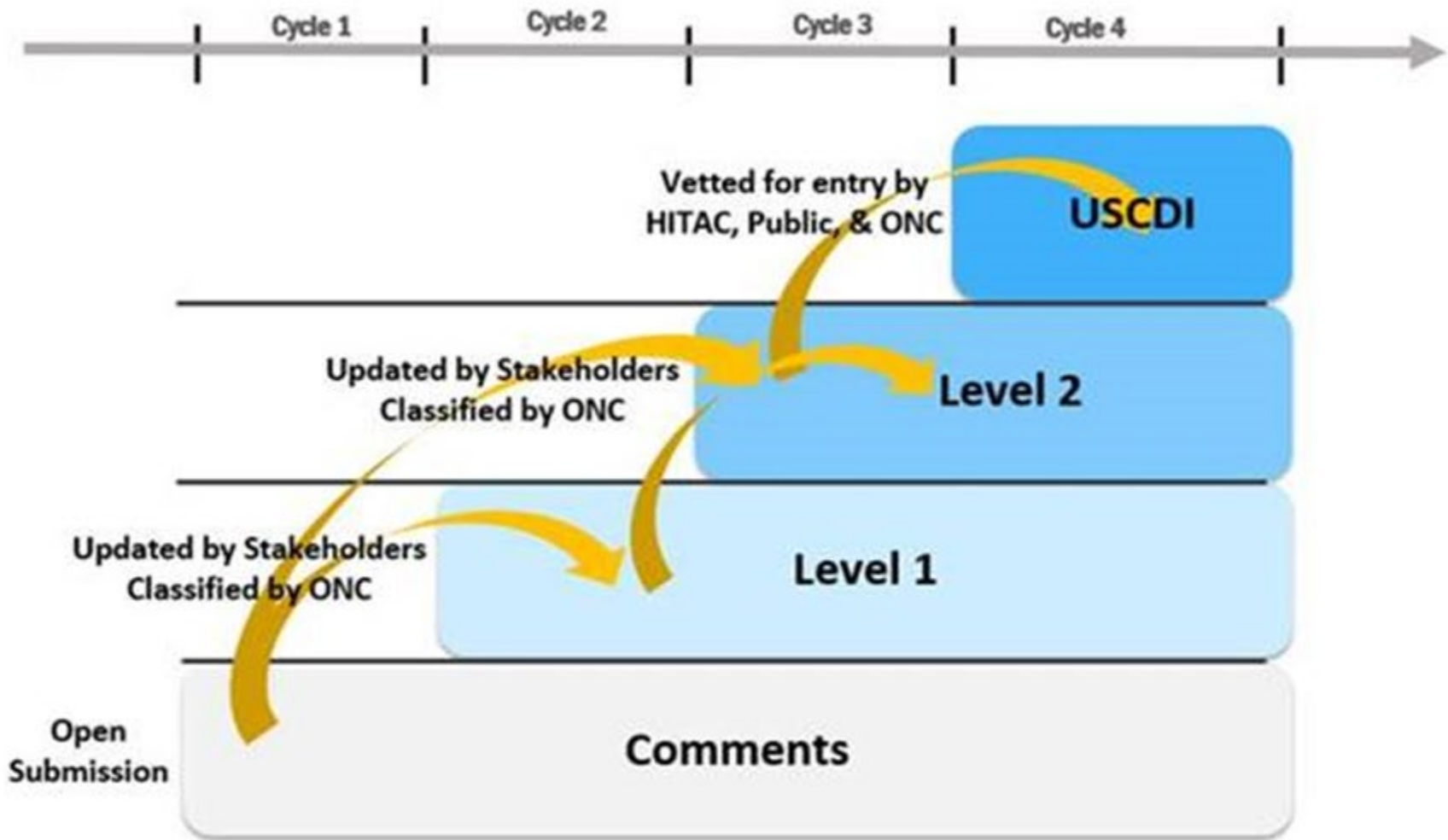
- Specific criteria for advancement between levels
- The application process and submission form
- Creating a “User’s Guide” for those submitting and advancing data elements

Added details for a USCDI Data Element Advisory Process similar to the ISA

- The model by which the ONC will coordinate the identification, assessment, advancement and public awareness of data elements proposed for the USCDI.

Discussed additional issues including:

- Processes to advance strategically important data elements



Detailed Presentation to Advance



Level Advancement

- Criteria to move from Comment to Level 1
- Criteria to move from Level 1 to Level 2
- Criteria to move from Level 2 to USCDI



Criteria to Advance to USCDI

- Role of HITAC
- Role of ONC

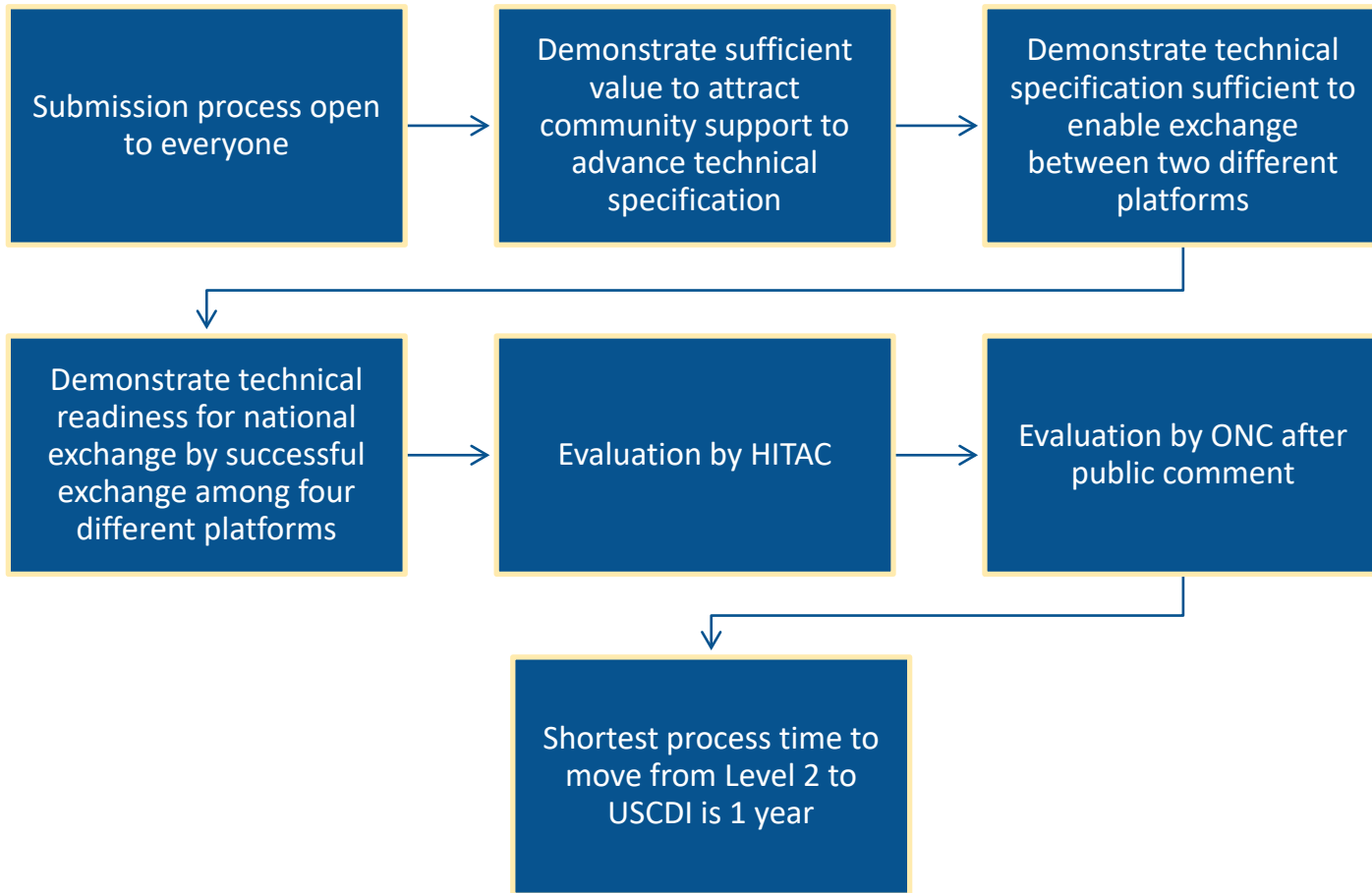


Submission Process / Submission form



User's Guide

Overview of Data Element Advancement Process



USCDI Promotion Criteria: Comment to Level 1 (1 of 3)

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
Justification exists for data element capture and national exchange	Estimate of potential significance	n/a	n/a	Helps determine potential significance of data element
There are applicable Use Cases(s) involving this data element	Clarification	Required for Level 1	Comment	Helps determine potential significance of data element
There are projects currently underway using this data element	Clarification	Required for Level 1	Comment	Helps determine potential significance of data element and potential for promotion

USCDI Promotion Criteria: Comment to Level 1 (2 of 3)

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
This data element is currently captured electronically in one or more electronic systems	Feasibility of capture	Required for Level 1	Comment	Any format is acceptable; demonstrates that someone wants the data electronically
Regarding the systems cited above, how often is the data element collected and how is the data element collected? (free text, coded data element)	Clarification of feasibility	Required for level 1	Comment	Important if these data elements are being collected and in what format

USCDI Promotion Criteria: Comment to Level 1 (3 of 3)

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
A content standard exists for this data element	Technical maturity, feasibility	required for Level 1	Comment	NOTE: This requires only a content standard OR the existence of data element in an implementation guide. Not both. Indicate if the data element is "captured" in discrete field(s), is encoded, or if it is typically in free text.
An implementation guide exists that contains this data element	Technical maturity, feasibility	required for Level 1	Comment	NOTE: As above, only a content standard OR the existence of the data element in an implementation guide is required. Not both.
There have been pilots, "Connect-a-thon"® testing, or production use of this data element	Technical maturity, feasibility	required for Level 1	Comment	Demonstrates that an SDO has initiated work and interest; early stage.

USCDI Promotion Criteria: Level 1 to Level 2

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
The exchange of this data element has been successfully tested at scale between two or more distinct/different EHR platform systems in a production environment	Technical maturity, feasibility	Required for Level 2	Level 1	"unrelated", "different platform", "technically unrelated systems", "distinct EHR platform systems", "commercially separate"; what about registries?

USCDI Promotion Criteria: Level 2 to USCDI

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
The exchange of this data element been successfully tested at scale between four or more distinct/different EHR platform systems in a production environment	Technical maturity	Required for USCDI level	Level 2	We recommend that this item is both about how much the data element has been adopted/scaled and its technical maturity and readiness. (e.g., largest vendors sharing the data vs. smaller specialty systems.)

USCDI Promotion Criteria: HITAC and ONC Review (1 of 2)

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
Evidence exists for the impact of this data element on healthcare costs for individuals or populations	significance, strategic value	Facilitates advancement to USCDI level	Level 2	Submitter to present best argument regarding impact
There is an estimate of the number of providers who would use this data element/class	significance, strategic value	Facilitates advancement to USCDI level	Level 2	Submitter to present best argument regarding impact

USCDI Promotion Criteria: HITAC and ONC Review (2 of 2)

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
The following restrictions potentially limit the standardization of this data element	barriers to deployment	Presence might impede advancement to USCDI level		
The following restrictions potentially limit the use of this data element.	barriers to deployment	Presence might impede advancement to USCDI level		
There is an estimate of the overall burden to implement	barriers to deployment	Presence might impede advancement to USCDI level		Submitter to provide estimates from a variety of viewpoints such as patient, provider, vendors, society, other stakeholders. Give consideration to public comments prior to clearance for USCDI

USCDI Promotion Criteria: Review by HITAC

HITAC will recommend for or against promotion based on a data element achieving technical maturity and weighing the balance between its value to advance the quadruple aim versus the costs and barriers to deployment.

To fulfill this responsibility, the HITAC will:

- Review the evidence for technical maturity
- Review the evidence for the impact of this data element on healthcare costs for individuals or populations
- Review the estimate of the number of stakeholders (providers, patients, researchers, public health, etc.) who would use this data element/class
- Assess the significance of restrictions that might potentially limit the use of this data element.
- Assess the overall burden to implement

USCDI Promotion Criteria: Review by ONC

- Review HITAC recommendations
- Duplicate HITAC review as needed
- Review public comments
- Make final determination on advancement (benefit vs burden)
- Make determination for inclusion in Requirements for Certification and Maintenance of Certification
- Set timeline for industry compliance

Estimated Process Time: Each Cycle = 1 Year

Shortest Cycle Times

- Level 2 to USCDI: 2 cycle
- Level 1 to USCDI: 3 cycles
- Comment to USCDI: 3 cycles

Longest Cycles before Required Resubmission

- Level 2 to USCDI: 4 cycle
- Level 1 to USCDI: 6 cycles
- Comment to USCDI: 6 cycles

Submission Process



Process open to anyone



Submit single elements or entire data classes



Submissions made electronically to an open, searchable, public resource maintained by ONC



Require sufficient information in the application form to enable ONC to easily and accurately place the submission in the proper level



Require the submitter to review the public resource to identify if similar or related elements have been previously submitted



Require the submitter to provide updated information as available to inform ONC's leveling decision



Submission Form includes all items required by ONC for leveling

Submission Form

Five Sections

- I. Identification of Data Element
- II. Justification for Data Element promotion
- III. Extent of use and technical specification
- IV. Potential impact
- V. Potential barriers

Submission Form Details: Sections I & II

Section I: Identification of Data Element

- Name of Proposer
- Contact Information of Proposer
- Data Element Name
- Data Element Description
- Related Data Elements
- Proposed Data Class (Optional)
- Do similar data elements currently exist in the USCDI or Promotion Model system?
 - Y/N/UNK
 - If yes, please explain why this data element should be considered separately

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

Submission Form Details: Section III

Section III: Extent of Use and Technical Specification

- Is this data element currently captured electronically 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 provide a link to the applicable standard
- Does an implementation guide exist that contains this data element?
 - If yes, please provide a link to the IG
- Has there been any “Connect-a-thon”[®] testing, pilots, or production use of the data element?
 - If yes, please provide links to artifacts describing its use
- Has the exchange of this data element been successfully tested between two or more different platforms in a production environment?
 - If yes, please provide links to supporting artifacts
- Has the exchange of this data element been successfully tested at scale between four or more different platforms in a production environment?

Submission Form Details: Sections IV & V

Section IV: Potential Impact

- Is there evidence for the impact of this data element on healthcare costs for individuals or populations?
 - If yes, please provide supporting data
- Please provide an estimate of the potential number of users of this data element and the basis of the estimate.

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

Leveling and Promotion

ONC assumes some key responsibilities

- Assess accuracy of submission
- Identify the need for and request supplemental information
- Display submissions in ways that enable other interested parties to form “communities of interest” and contribute to the promotion of a data element/class. (ISA and “Proving Ground” as potential models)

ONC provides oversight of Promotion Process

- Monitor the progress (or lack thereof) of data elements/classes
- Identify high priority data elements/classes that might need additional resources to advance
- Regularly announce leveling decisions

Summary of Proposed Responsibilities: Submitter and ONC



Submitter: Initiate Process

- Complete Data Element Submission/Application process
- Review data base for similar or related data elements
- Provide updated information to inform levelling decisions



ONC: Create, Revise and Maintain Data Element Promotion Process

- Provide examples of successful applications and review submissions
- Publish data element in searchable, public platform
- Adjudicate leveling/advancement decisions in a timely manner
- Assist/provide guidance to submitters and communities of interest to submit additional submission information as needed
- Provide oversight of data element progress
- Identify data elements with national strategic importance (quadruple aim), identify gaps, develop strategies to add/advance data elements

Issues for Further Consideration

- Should there be a process to identify high priority data elements that are either missing or not advancing?
 - » Does ONC have a role to identify high priority data elements?
 - » Does ONC have a role to propose specific data elements? Or is this best left to the Submission Process?
 - » Does ONC have a role to facilitate the advancement of specific data elements? Or is this best left to the “market”?
- Should there be a process for harmonizing similar or related data elements?
- Would additional tools facilitate this process (e.g. a “sandbox”, “proving ground”, frequent summary updates of data element progress)?
- How does this process apply to "bulk" data classes (e.g.: lab tests, results, medications)? Is there a limit to the number of data elements that can advance at one time?



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Thank you



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