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

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

September 6, 2019

Agenda:

- Call to Order/Roll Call

- Opening Remarks

- Prepare for 9/17/19 HITAC Presentation

  » Task Force charge

  » Promotion Model and Promotion Model Lifecycle (Original ONC slides)

  » Summary of Task Force Work

  » Overarching goals of USDCI Promotion Model

  » Detailed Discussion: ONC Draft Promotion Model and Promotion Criteria, Data Element Submission Form, ONC responsibilities in the Promotion Model

  » Issues for further discussion
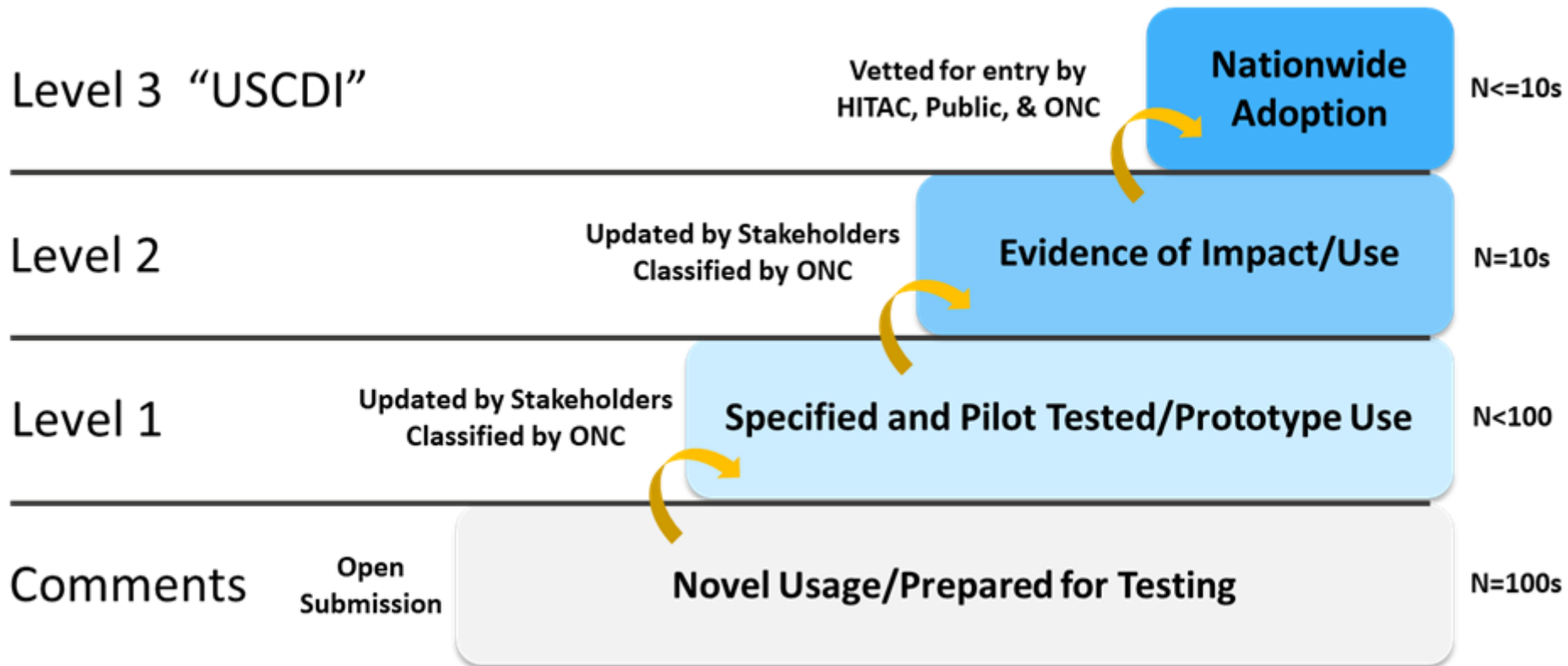
- Public Comment

- Next Steps and Adjourn

The Office of the National Coordinator for
Health Information Technology

Homework prior to 9/6/19 TF Call

1. Please review slide deck for completeness, clarity, sequence. Add "suggested text" in orange if you have any specific text you would like to included. Add a "comment" for everything else.
2. Please review the "Submission Form clean version" tab in the google sheet (see email). Add "suggestions" if you have any specific text you would like to add. Add a "comment" for everything else.

3. Please be prepared to share ideas about the role of the HITAC in the "Review by HITAC" (slide 21).
4. Please review the issues on the slide titled "Flagged Issues for Further/Future Discussion (slide 22).

The Office of the National Coordinator for
Health Information Technology

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:** "Put meat on the bones"

  » Add details

  » Think through the process from the "User's" perspective

The Office of the National Coordinator for
Health Information Technology

ONC's USCDI Promotion Model - Annual Promotion/Status Slide

Level 3 "USCDI" — Vetted for entry by HITAC, Public, & ONC — **Nationwide Adoption** — N<=10s

Level 2 — Updated by Stakeholders Classified by ONC — **Evidence of Impact/Use** — N=10s

Level 1 — Updated by Stakeholders Classified by ONC — **Specified and Pilot Tested/Prototype Use** — N<100

Comments — Open Submission — **Novel Usage/Prepared for Testing** — N=100s

Summary of TF Work

- Reviewed proposed Promotion Model and Promotion Model Lifecycle

  » Unanimous agreement without revision

  » Proposed model addressed all 2018 TF recommendations with a simpler structure

- Added details to the advancement process and made recommendations for:

  » Specific criteria for advancement between levels

  » The application process and submission form

  » Creating a "User's Guide" for those submitting 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

The Office of the National Coordinator for
Health Information Technology
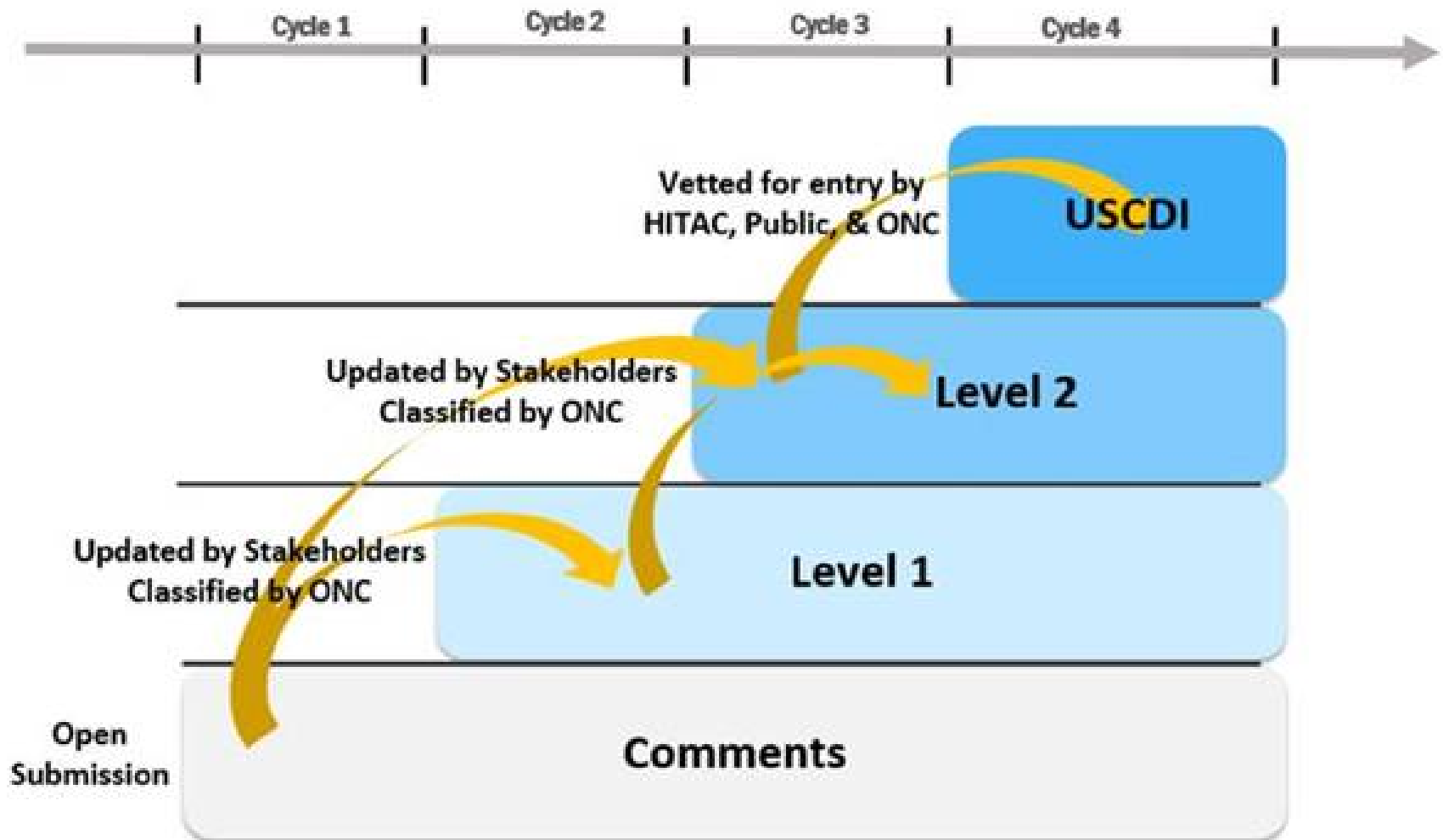
Overarching Goals of USCDI Promotion Model

- Open, public, and transparent submission and promotion processes that enables and encourages diverse stakeholders and communities of interest to propose and 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 to plan appropriately

- Establish clear requirements for promotion enabling ONC to appropriately place elements/classes

- Provide advance notice to industry

The Office of the National Coordinator for
Health Information Technology

2019 Promotion Model Context Slide TBD

- Comment

- Level 1

- Level 2

- USCDI

    » Final advancement to the USCDI determined by HITAC recommendations and ONC decision

- Coordinated with Standards Advancement Cycle

- Submission Process/ISA-like public facing website

- Estimated cycle time = LONG

The Office of the National Coordinator for
Health Information Technology

USCDI Promotion Model
Notional Promotion Timeline

Detailed Discussion

- Submission form

- 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

- Submission process

- User's Guide

The Office of the National Coordinator for
Health Information Technology

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

See Appendix for details

The Office of the National Coordinator for
Health Information Technology

Detailed Discussion: USCDI Promotion Criteria

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) citing 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 continued

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	
The following systems capture this data element at the noted level of prevalence using, the following mechanisms	Clarification of feasibility	Required for level 1	Comment	- Need additional language to help w/prioritization (what is ONC's role?); how is this process realistically open to non-HIT people - Need ONC group regularly reviewing applications to assess demand/need for health info and if it's getting collected and how

USCDI Promotion Criteria continued

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: Only a context standard OR the existence of data element in an implementation guide is required. Not both. - US specific not required
An implementation guide exists that contains this data element	Technical maturity, feasibility	required for Level 1	Comment	- NOTE: Only a context standard OR the existence of the data element in a 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	- This can be early stages. This requirement demonstrates that an SDO has initiated work and interest.

The Office of the National Coordinator for
Health Information Technology

USCDI Promotion Criteria continued

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 between two or more different platforms 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; "by at least 2 distinct/different EHR platform systems"

USCDI Promotion Criteria continued

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 between four or more different platforms in a production environment	Technical maturity	Required for USCDI	Level 2	4 ? Unrelated? See #7

USCDI Promotion Criteria continued

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	is this "required" for USCDI or "nice to have"?	?	- copy Nationwide Applicability criteria to earlier in process? (in service of prioritization) - What kind of evidence? Estimates, expert consensus, published studies?)

The Office of the National Coordinator for
Health Information Technology

USCDI Promotion Criteria continued

Item	Use of Criterion	Criterion Required for Advancement	Level if Criterion is Missing	Comments/Concerns for ONC's Consideration
There is an estimate of the number of providers who would use this data element/class	significance, strategic value	is this "required" for USCDI or "nice to have"?	?	What kind of evidence? Estimates, expert consensus, published studies?)
The following restrictions potentially limit the standardization of this data element	barriers to deployment	should the presence of these barriers disqualify a data element from reaching USCDI?	?	any other restrictions?
The following restrictions potentially limit the use of this data element.	barriers to deployment	should the presence of these barriers disqualify a data element from reaching USCDI?		
There is an estimate of the overall burden to implement	barriers to deployment	should the presence of these barriers disqualify a data element from reaching USCDI?	?	- any specific kind of documentation? - from whose viewpoint is this coming from - quadruple aim; provider burnout; comment/consider from x, y, z, perspectives

Submission Process

- Process open to anyone

- Submit single elements or entire data classes

- Currently labeled as "comment"; recommend changing to "proposed"?

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

  » Strike the balance between sufficient and excessive submission data

  » Require the submitter to identify if similar or related elements have been previously submitted

- SEE "Submission Form clean version" Tab in Google Sheet or Appendix

Leveling and Promotion

- ONC assumes the following 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 oversees the Promotion Process by:

  » Monitoring the progress (or lack thereof) of data elements/classes

  » Identifying high priority data elements/classes that might need additional resources to advance

  » Using its "convening" authority to help assemble resources

The Office of the National Coordinator for
Health Information Technology

Summary of Proposed Role/Relationship of Submitter/Communities of Interest and ONC

- Submitter: Data Element Submission/Application process

- ONC: Review applications

- ONC: Leveling decisions based on applications; acquire additional information as needed

- ONC: Publish data element in "proving ground" type platform to aid public review

- Submitters: establish communities of interest within "proving ground"

- ONC: oversight of data element progress in "proving ground"

- ONC: Assist/provide guidance to individual/communities of interest to submit additional content to be added to the original submission information

- ONC: Identify data elements with national strategic importance (quadruple aim), identify gaps, identify those that are not advancing, develop strategies to add/advance data elements

- ONC: Adjudicate leveling/advancement decisions

- ONC: create, revise and maintain data element promotion process

The Office of the National Coordinator for
Health Information Technology

Review by HITAC

- HITAC will recommend for or against promotion based on whether a data element has achieved technical maturity and whether its value to advance the quadruple aim is greater than 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 providers 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

Flagged Issues for Further/Future Discussion

- Process to identify high priority data elements that are not advancing

  » Implies process to track progress of each data element (who does that? how? How reported?)

- Process to encourage work on high priority data elements

  » ONC convening authority, encouragement, resources, staff

- Need for champions to move a data element through the process, ? role for ONC to convene support, provide resources

- Sandbox which combines "leading" ISA standards with "leading" USCDI data elements as a vehicle for accelerating industry consensus around standards and elements resulting in greater confidence that final standards will emerge

The Office of the National Coordinator for
Health Information Technology

Flagged Issues for Further/Future Discussion continued

- Potential role of Interoperability Proving Ground as a model for how the USCDI Advancement Process could perform. Provide a platform (open, public, searchable) to attract submitters with similar data elements, help create a community of interest.

- What role should ONC take in the process in addition to setting it up and maintaining it?

- Define synergies between ISA, USCDI and Standards Versions Advancement Process and make relationship transparent to the public?

- How do "bulk" data classes (eg lab tests, results) get handled? Is there a numerical limit to the number of data elements that can advance at a time (an old question)?

The Office of the National Coordinator for
Health Information Technology

Flagged Issues for Further/Future Discussion

- How to create data classes by consolidating related data elements
- Should there be a parallel path for "bulk" data classes with a declared date for implementation?

  » Allergies/Adverse Reactions

  » Medications

  » Test/Test Results (all types)

  » Note types

Public Comment

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.

The Office of the National Coordinator for
Health Information Technology

Thank you

Appendix:

Submission Form Detail

Submission Form Detail

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 reside in the UDA? Y/N/Ukn

          If yes, please explain why this data element should be
considered   separately

Submission Form Detail continued

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 electronically in any electronic system?

If yes, please cite known systems that capture this data element and briefly describe the mechanism(s) used and prevalence of capture

Does a content standard exist for citing this data element?

If yes, please provide a link to the applicable standard

The Office of the National Coordinator for
Health Information Technology

Submission Form Detail continued

Section III: Extent of Use and Technical Specification continued

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 between four or more different platforms in a production environment systems?

unrelated
The Office of the National Coordinator for
Health Information Technology

Submission Form Detail continued

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 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)? Y

Please provide an overall estimate of burden to implement