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

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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
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).
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
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
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
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
USCDI Promotion Model
Notional Promotion Timeline

- Cycle 1
- Cycle 2
- Cycle 3
- Cycle 4

USCDI

Level 2

Level 1

Comments

Open Submission

Updated by Stakeholders
Classified by ONC

Updated by Stakeholders
Classified by ONC

Vetted for entry by HITAC, Public, & ONC

ONC's USCDI Promotion Model
Annual Promotion/Status Slide
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
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
## Detailed Discussion: USCDI Promotion Criteria

<table>
<thead>
<tr>
<th>Item</th>
<th>Use of Criterion</th>
<th>Criterion Required for Advancement</th>
<th>Level if Criterion is Missing</th>
<th>Comments/Concerns for ONC’s Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justification exists for data element capture and national exchange</td>
<td>Estimate of potential significance</td>
<td>n/a</td>
<td>n/a</td>
<td>Helps determine potential significance of data element</td>
</tr>
<tr>
<td>There are applicable Use Cases(s) citing this data element</td>
<td>Clarification</td>
<td>Required for Level 1</td>
<td>Comment</td>
<td>Helps determine potential significance of data element</td>
</tr>
<tr>
<td>There are projects currently underway using this data element</td>
<td>Clarification</td>
<td>Required for Level 1</td>
<td>Comment</td>
<td>Helps determine potential significance of data element and potential for promotion</td>
</tr>
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<td>-------------------------------------------</td>
</tr>
<tr>
<td>This data element is currently captured electronically in one or more electronic systems</td>
<td>Feasibility of capture</td>
<td>Required for Level 1</td>
<td>Comment</td>
<td></td>
</tr>
<tr>
<td>The following systems capture this data element at the noted level of prevalence using, the following mechanisms</td>
<td>Clarification of feasibility</td>
<td>Required for level 1</td>
<td>Comment</td>
<td>- Need additional language to help w/prioritization (what is ONC’s role?); how is this process realistically open to non-HIT people</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Need ONC group regularly reviewing applications to assess demand/need for health info and if it’s getting collected and how</td>
</tr>
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</tr>
<tr>
<td>A content standard exists for this data element</td>
<td>Technical maturity, feasibility</td>
<td>required for Level 1</td>
<td>Comment</td>
<td>- NOTE: Only a context standard OR the existence of data element in an implementation guide is required. Not both.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- US specific not required</td>
</tr>
<tr>
<td>An implementation guide exists that contains this data element</td>
<td>Technical maturity, feasibility</td>
<td>required for Level 1</td>
<td>Comment</td>
<td>- NOTE: Only a context standard OR the existence of the data element in a implementation guide is required. Not both.</td>
</tr>
<tr>
<td>There have been pilots, connect-a-thon testing, or production use of this data element</td>
<td>Technical maturity, feasibility</td>
<td>required for Level 1</td>
<td>Comment</td>
<td>- This can be early stages. This requirement demonstrates that an SDO has initiated work and interest.</td>
</tr>
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</tr>
<tr>
<td>The exchange of this data element been successfully tested between two or more different platforms in a production environment</td>
<td>Technical maturity, feasibility</td>
<td>Required for Level 2</td>
<td>Level 1</td>
<td>- &quot;unrelated&quot;- different platform, &quot;technically unrelated&quot;; &quot;systems&quot;- &quot;distinct EHR platform systems&quot;; commercially separate?; what about registries; &quot;by at least 2 distinct/different EHR platform systems&quot;</td>
</tr>
</tbody>
</table>
### USCDI Promotion Criteria continued

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<tbody>
<tr>
<td>The exchange of this data element been successfully tested between four or more different platforms in a production environment</td>
<td>Technical maturity</td>
<td>Required for USCDI</td>
<td>Level 2</td>
<td>4 ? Unrelated? See #7</td>
</tr>
<tr>
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</tr>
<tr>
<td>Evidence exists for the impact of this data element on healthcare costs for individuals or populations</td>
<td>significance, strategic value</td>
<td>is this &quot;required&quot; for USCDI or &quot;nice to have&quot;?</td>
<td>?</td>
<td>- copy Nationwide Applicability criteria to earlier in process? (in service of prioritization)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- What kind of evidence? Estimates, expert consensus, published studies?</td>
</tr>
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</tr>
<tr>
<td>There is an estimate of the number of providers who would use this data element/class</td>
<td>significance, strategic value</td>
<td>is this &quot;required&quot; for USCDI or &quot;nice to have&quot;?</td>
<td>?</td>
<td>What kind of evidence? Estimates, expert consensus, published studies?)</td>
</tr>
<tr>
<td>The following restrictions potentially limit the standardization of this data element</td>
<td>barriers to deployment</td>
<td>should the presence of these barriers disqualify a data element from reaching USCDI?</td>
<td>?</td>
<td>any other restrictions?</td>
</tr>
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<td>barriers to deployment</td>
<td>should the presence of these barriers disqualify a data element from reaching USCDI?</td>
<td>?</td>
<td></td>
</tr>
</tbody>
</table>
| 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
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
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
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)?
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
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.
Thank you
Appendix:

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
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?
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