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

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Agenda: 9/27/19

- Overarching goals of USDCI Promotion Model

- Summary of Task Force Work

- Overview of Data Element Advancement Process

- Overview of HITAC meeting

- Additional Concerns/Issues from Industry and HITAC

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 and/or communities of interest to plan appropriately

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

- Provide advance notice to industry

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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

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Overview of Data Element Advancement Process

- Submission process open to everyone
- Demonstrate sufficient value to attract community support to advance technical specification
- Demonstrate technical specification sufficient to enable exchange between two different platforms
- Demonstrate technical readiness for national exchange by successful exchange among four different platforms
- Evaluation by HITAC
- Evaluation by ONC after public comment
- Shortest process time Level 2 to USCDI is 1 year

Topics to Discuss

- Management of Non-advancing Data Elements

- Ambiguous Prioritization of Data Elements

- Rigor of Technical Maturity Assessment

- Unclear Opportunities for Feedback

- Who will do the Upfront Work?

- Timeline from Comment to USCDI is too long

- Ambiguity around Advancing from Level 2

- Harmonization of Data Elements

- "Bulk Data" AKA Large Data Classes

- Others?

Management of Non-Advancing Data Elements

There may be a "build up" of data elements/classes that do not advance from Level 1 or Level 2. This will make it increasingly difficult and burdensome for stakeholders that actively participate in review, assessment, and public comment to provide ongoing feedback on data classes/elements under consideration.

Suggested Updates:

- Clarify removal mechanism.
  - Currently this is time- and –evaluation based (e.g. If the data class has not advanced in technical maturity or standards development within 3 cycles, it will be removed from consideration).
  - Clarify that removal is not permanent.
  - Clarify that removal is stakeholder agnostic. Removal is based on ONC determination of advancement, which is based on submitted information.
  - [Developer experts foresaw a scenario where no individual entity wants to be responsible for recommending a data class/element be removed from consideration due to a negative public perception.]

Ambiguous Prioritization of Data Classes/Elements

Numerous data classes/elements may already have reached a level of maturity that would see them deemed as "ready for the USCDI," but there is not a clear prioritization pathway for addition to the USCDI. This could result in a deluge of new data classes/elements (potentially with limited value) that health IT developers and providers would need to implement in their systems that compete for limited development resources and prioritization against other new features and projects. Suggested Updates:

- Establish a prioritization process for data classes or elements to avoid overwhelming developers and providers.
  - The prioritization assessment should leverage metrics captured in the "Strategic Considerations" section, such as applicability, and include a review of whether clearly defined use cases and workflows are associated with the data class/element.
  - A clear value proposition should be demonstrated prior to adopting a data class/element for use in the USCDI.

Rigor of Technical Maturity Assessment

The considerations included in the draft process may not be adequate to determine whether a data class/element is sufficiently mature for inclusion in the USCDI. Inadequate maturity forces developers and users to use interpretive discretion causing inconsistent implementation across systems and sites.

Suggested Updates:

- Clarify technical maturity documentation requirements beyond being "available."
  - Documentation should be sourced from an accredited SDO and specifications must have passed a consensus-based public balloting process.
- Consider requiring testing in more than 2-4 systems/organizations to better demonstrate the technical maturity of a standard for required deployment across the whole country.
- Real world pilots of a new data class/element needs to be completed using the standard proposed to demonstrate its adequacy.

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Clarify feedback process

It is not clear at which stages stakeholders will have the opportunity to provide feedback on the readiness, applicability, or prioritization of a proposed data class/element.

Suggested Updates:

- Clarify feedback process for each stage (Levels) of the process from industry stakeholders through public comment period.
    - Public input should be sought on the maturity, adequacy, and adoption levels of a standard proposed for a data class/element.
    - Public input should be sought on the maturity and applicability of use cases, workflows, and value proposition more broadly of a particular data class/element.

Who will do the upfront work?

Arien and Ken have separately raised the issue of what's in it for the early promoters? The more efficient business model is to let someone else do the work and adopt the standard when it emerges.

Suggested Updates:

- Discuss who "owns" this process. The Market? The Government as a promoter of public good? Both
- Is there a role for government to support the development of critical standards and data elements?
- Should it be a government funded process that uses private resources?
- New research vehicles or policy vehicles to speed consensus on high priority data elements?

The Timeline from Comment to USCDI is Too Long

The current timeline delineates a minimum of three years to go from comment to USCDI. Synchronization with standards advancement activities contributes to the length as does the process of testing.

Suggested Updates:

- Explore methods to separate Standards Advancement from Data Element Promotion (workflow redesign)
- Consider eliminating "time" as a promotion and use achievement of specific benchmarks
- Shorten the cycle time

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Ambiguity around advancement from Level 2

Although there is high likelihood of advancement to USCDI for data elements that have been promoted to Level 2, there is no certainty of promotion. The lack of certainty will translate into industry reluctance to build Level 2 data elements into new products and thereby extend the duration of the promotion process.

Suggested Updates:

- Develop objective benchmarks to indicate potential for promotion to USCDI
  - Such as: what constitutes a clear estimate of benefit?
  - Burden?
  - Barriers
- Clarify HITAC/ONC Level 2 -> USCDI review process based on these benchmarks

Harmonization of Data Elements

It is unclear how similar data elements will be harmonized during the "Comment" phase

Suggested Updates:

- 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

"Bulk" Data (AKA Large Data Classes)

It is unclear how to assess the burden on industry for moving large data classes into USCDI.

Suggested Updates:

- Determine a reliable and transparent method to determine the impact on vendors of certified HIT of requiring data classes with thousands of data elements
  - Labs results
  - Imaging results
  - Medications
- Explore the need for a parallel USCDI process for large data classes

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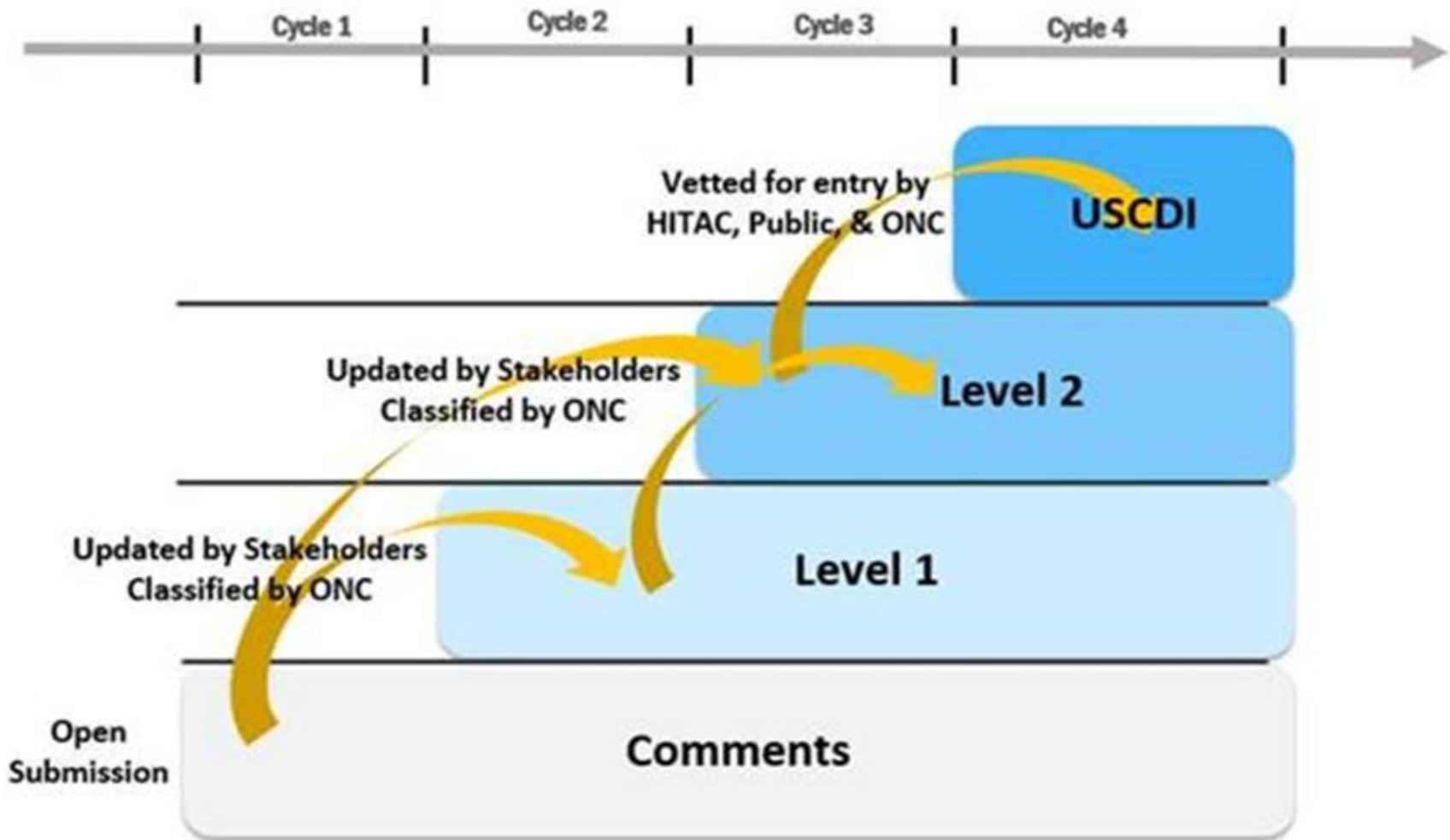Health IT Advisory Committee

Thank you

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Backup Slides

- **Backup Slides**

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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

Detailed Presentation

- 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 move to USCDI

  » Role of HITAC

  » Role of ONC

- Submission process / Submission form

- User's Guide

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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

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 - This demonstrates that someone wants the data electronically
Regarding the systems cited above, how often is the data element colleted 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

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. At an 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 recomment 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

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

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USCDI Promotion Criteria: HITAC and ONC Review cont.

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

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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

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

- Longest before required resubmission
  - Level 2 to USCDI: 3 cycle
  - Level 1 to USCDI: 4 cycles
  - Comment to USCDI: 5 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

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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 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 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

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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 at scale between four or more different platforms in a production environment?

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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 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 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 provides oversight of 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

  - Regularly announcing leveling decisions

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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

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Flagged Issues for Further/Future Discussion

- 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?