USCDI Task Force 2021 Call #15

Leslie Kelly Hall, Co-Chair
Steven Lane, Co-Chair

May 11, 2021
Meeting Agenda

• Call to Order/Roll Call
• Past Meeting Notes
• ONC Office of Policy Briefing on EHI
• Tasks 2b and 2c
• TF Schedule/Next Meeting
• Public Comment
• Adjourn
# Task Force Roster

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steven Lane (Co-Chair)</td>
<td>Sutter Health</td>
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<tr>
<td>Leslie Kelly Hall (Co-Chair)</td>
<td>Engaging Patient Strategy</td>
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<tr>
<td>Ricky Bloomfield</td>
<td>Apple</td>
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<tr>
<td>Hans Buitendijk</td>
<td>Cerner</td>
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<td>Grace Cordovano</td>
<td>Enlightening Results</td>
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<td>Jim Jirjis</td>
<td>HCA Healthcare</td>
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<tr>
<td>Ken Kawamoto</td>
<td>University of Utah Health</td>
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<tr>
<td>John Kilbourne</td>
<td>VA</td>
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<tr>
<td>Leslie Lenert</td>
<td>Medical University of South Carolina</td>
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<tr>
<td>Clement McDonald</td>
<td>National Library of Medicine</td>
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<tr>
<td>Aaron Miri</td>
<td>The University of Texas at Austin, Dell Medical School and UT Health Austin</td>
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<tr>
<td>Brett Oliver</td>
<td>Baptist Health</td>
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<tr>
<td>Mark Savage</td>
<td>Savage Consulting</td>
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<tr>
<td>Michelle Schreiber</td>
<td>CMS</td>
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<td>Abby Sears</td>
<td>OCHIN</td>
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<td>Sasha TerMaat</td>
<td>Epic</td>
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<tr>
<td>Andrew Truscott</td>
<td>Accenture</td>
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<tr>
<td>Sheryl Turney</td>
<td>Anthem, Inc.</td>
</tr>
<tr>
<td>Daniel Vreeman</td>
<td>RTI International</td>
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<tr>
<td>Denise Webb</td>
<td>Indiana Hemophilia and Thrombosis Center</td>
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ONC Office of Policy Briefing on EHI

Michael L. Lipinski, JD
Director, Regulatory and Policy Affairs Division, ONC
Information Blocking Definition in the Final Rule

(a) Information blocking means a practice that—

(1) Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information; and

(2) If conducted by a health information technology developer, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI; or

(3) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

(b) For the period before October 6, 2022, EHI for purposes of paragraph (a) of this section is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.
Electronic Health Information
What does it mean?

• Electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 to the extent that the ePHI would be included in a designated record set (DRS) as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the actor is a covered entity as defined in 45 CFR 160.103.

Changes and Clarifications from the Proposed Rule

• Focused definition on ePHI included in a DRS.

• This definition does not expressly include or exclude price information. To the extent that ePHI includes price information and is included in a DRS, it would be considered EHI.
Phase 2 Work

1. Evaluate Draft USCDI v2 and provide HITAC with recommendations for:
   1a - Data classes and elements from USCDI v1 including applicable standards version updates
   1b - New data classes and elements from Draft USCDI v2 including applicable standards
   1c - Level 2 data classes and elements not included in Draft USCDI v2

2. Evaluate the USCDI expansion process and provide HITAC with recommendations for:
   2a - ONDEC submission system improvements
   2b* - Evaluation criteria and process used to assign levels to submitted data classes and elements
   2c* - Prioritization process used by ONC to select new data classes and elements for Draft USCDI v2

3. Recommend ONC priorities for USCDI version 3 submission cycle

Due: Complete
Due: September 9, 2021
Due: September 9, 2021

*The Task Force intends to deliver Task 2b and 2c recommendations to the HITAC at its June 9, 2021 meeting
ONDEC Submission System Walk Through

USCDI ONDEC (ONC New Data Element and Class) Submission System

USCDI ONDEC supports ONC’s intent to develop new versions of the USCDI through a predictable, transparent, and collaborative process, allowing health IT stakeholders to submit new data elements and classes. Review the USCDI ONDEC Fact Sheet to learn more.

How It Works

Step 1. Submit new data elements and classes
- **Review Prep Sheet**: See questions and prepare content for your submission - updated to include more information on ONC’s evaluation of submissions
- **Start My Submission**: Registered ISA users only - login or create account here

Step 2. ONC evaluates and assigns a level to each data element depending on the overall value, maturity and challenges to implementation
- Comment • Level 1 • Level 2

Step 3. ONC posts submitted data elements on the USCDI page by level
- Submitters will have an opportunity to add or change information which could change its level determination.
- Other stakeholders can review these submissions and contribute to their development through comments and collaboration with original submitters.

Step 4. Submissions achieving Level 2 by October of each year will be considered for inclusion in the draft of the next version of USCDI. ONC will present the draft to the Health IT Advisory Committee and the public for comment.

Step 5. ONC finalizes the next version of USCDI in July.
USCDI ONC New Data Element and Class (ONDEC) Submission

View Results

Submitter Data Element Use Case

Please note: your name and organization will be visible and associated with your submission. Email

Name of Submitter Required

Email Address of Submitter Required

Secondary Email Address

Organization of Submitter

Save Draft Next
Submit a New Data Class or Select an Existing One **Required**

*New Data Class*

New data class

**Data Element Name** **Required**

**Data Element Description** **Required**

Are there similar or related data elements in USCDI? **Required**

- Yes
- No
- Unknown

Submit an additional data element within this data class

Add additional data element

Save Draft  Back  Next
Briefly describe the main use cases to support adoption of the data element into the USCDI.

Estimate the number of stakeholders who would capture, access, use or exchange this data element or data class.

Link to use case project page.

Attachment(s) describing this use case. (Max: 8MB)

Please add if there are additional use cases for this data element that could affect significant numbers of other stakeholders.

Does this data element support the following aims in healthcare? (check all that apply)

- [ ] Improving patient experience of care (quality and/or satisfaction)
- [ ] Improving the health of populations
- [ ] Reducing the cost of care
- [ ] Improving provider experience of care
- [ ] None of the above
Does a vocabulary, terminology, content, or structural standard exist for this data element? (e.g., SNOMED CT, LOINC, RxNorm)

- Yes
- No
- Unknown

Are there additional technical specifications such as an implementation guide (IG) or profile using this data element? (e.g., HL7® FHIR® US Core Implementation Guide v3.1.0 based on FHIR R4)

- Yes
- No
- Unknown

Which of the following best describes the use of this data element?

- Not currently captured or accessed with an organization
- In limited use in test environments only
- In limited use in production environments
- Extensively used in production environments
- This data element has been used at scale between multiple different production environments to support the majority of anticipated stakeholders

Has this data element been electronically exchanged with external organizations or individuals (including patients)?

- Yes
- No
Describe any restrictions on the standardization of this data element (e.g., proprietary code). Required

Describe any restrictions on the use of this data element (e.g., licensing, user fees). Required

Describe any privacy and security concerns with the use and exchange of this data element. Required

Please provide an estimate of overall burden to implement. Overall estimate of burden to implement, including those not affected by the primary use case(s) (i.e., impact to broader healthcare community for specialty-specific data element submission.) Required

Please provide information on other challenges to implementation
ONDEC Task Force Recommendations for Discussion

- Revise using plain language
- Develop primer or create addition to the HIT Playbook to encourage non-traditional stakeholder participation and understanding of USCDI
- Allow for narrative entries
- Allow for a “not applicable” or “other” for entry to ONDEC to encourage participation
- Remove registration step and continue requests for contact information
- Allow for sharing, tweeting or, other mechanisms to encourage stakeholders to promote and educate others.
- Allow for “like” or “plus one” features for others to demonstrate support for ONDEC recommendations.
# ONDEC Submission Evaluation (Leveling) Criteria – TF Recommendations

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>COMMENT LEVEL</th>
<th>LEVEL 1</th>
<th>LEVEL 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity-Current Standards</td>
<td>May be represented by terminology standard or element of Standards Development Organization (SDO) balloted technical specification</td>
<td>Must be represented using terminology standard or element of SDO-balloted technical specification</td>
<td>Must be represented using terminology standard or element of SDO-balloted technical specification</td>
</tr>
<tr>
<td>Maturity-Current Use</td>
<td>Limited test environments, or pilots</td>
<td>Limited production environments, 1 or 2 different systems</td>
<td>At scale in production environments more than 2 different systems</td>
</tr>
<tr>
<td>Maturity-Current Exchange</td>
<td>Limited exchange with external organizations, on same or different EHR/HIT systems</td>
<td>Exchanged between 2 or 3 organizations with different EHR/HIT systems</td>
<td>Exchanged between 4 or more organizations with different EHR/HIT systems</td>
</tr>
<tr>
<td>Use Cases- # Stakeholders Impacted</td>
<td>Used by few stakeholders, or for narrowly defined conditions or events.</td>
<td>Pertinent to many, but not most patients, providers or events requiring its use or used by few stakeholders or narrowly defined conditions or events if related to underserved patients or public health</td>
<td>Pertains to majority of patients, providers or events requiring its use or used by few stakeholders or narrowly defined conditions or events if related to underserved patients or public health</td>
</tr>
</tbody>
</table>
# Draft Prioritization Criteria for USCDI v3

<table>
<thead>
<tr>
<th>CRITERIA- Prioritization</th>
<th>LEVEL 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address significant gaps in USCDI v1 concepts</td>
<td><strong>MUST</strong> be represented using terminology standard or element of SDO-balloted (or in process) technical specification, AND addresses gaps in care, coordination, or transitions.</td>
</tr>
<tr>
<td>Aligned with existing ONC certification and/or CMS initiatives.</td>
<td>Existing regulatory definitions, vocabulary OR collection methods <strong>MUST</strong> be used or repurposed to meet regulatory needs.</td>
</tr>
<tr>
<td>Modest technical standards development</td>
<td>Technical standards exist and can be repurposed or expanded, efforts are mature AND use case is prevalent. (e.g. operative note)</td>
</tr>
<tr>
<td>Modest aggregate lift for vendor development and implementation</td>
<td>Current data functionality and interoperability exist and can be expanded, efforts are underway, AND use case is prevalent.</td>
</tr>
<tr>
<td>Data addressing Equity/Disparities</td>
<td><strong>MAY</strong> be represented using terminology standard or element of SDO-balloted technical specification AND directly supports national initiative(s) to improve health, healthcare quality, care coordination, or disparities.</td>
</tr>
<tr>
<td>Data supporting underserved stakeholder groups</td>
<td>Pertains to majority of patients, care partners and/or care team members requiring its use, AND addresses needs of the medically underserved, data underserved or populations of underserved.</td>
</tr>
<tr>
<td>Data supporting public health use cases</td>
<td><strong>MAY</strong> be represented using terminology standard or element of SDO-balloted technical specification, AND standards <strong>MUST</strong> be accelerated in response to public health needs</td>
</tr>
<tr>
<td>Meets national imperative. Moderate to High technical and standards uplift.</td>
<td>Timeline driven national imperative within a 2 year horizon, functionally present, standards forming.</td>
</tr>
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USCDI Process, Priority, and Maturity Task Force Recommendations

• For process review of USCDI
  • Semi Annual review by ONC of ONDEC and current leveling for validation/modification. Note date of review within website.
  • Annual or version X review by USCDI task force of ONDEC and current leveling for validation/modification and note validation/changes in recommendations to HITAC.
  • ONC to provide guidance on evolution from USCDI to EHI, the role of USCDI TF in these efforts.
  • ONC to provide guidance for EHI release about standards reuse, repurpose, creation, and the use of free text or narrative approaches to signal the industry as it prepares to meet EHI release.

• Priority and Maturity
  • ONC to adopt two principles in promoting/elevating USCDI in leveling and advancement
    • Maturity: TF recognizes and agrees with ONC maturity levels that quantify and clearly identify standards ready for adoption and adds edits to the existing framework. TF recommends that in addition to maturity standards, consideration must be given to national priorities.
    • Priorities: TF adds priorities that can influence adoption of USCDI, elevation of USCDI level definitions to be used during leveling process and versioning.
Visual Representation Recommendations

• TF recommends that a visual representation depicting both the Maturity and Priority criteria. This depiction would reflect at a glance, where these items “rank”. This may be based upon points, however recognizing that some priorities by nature can be weighted more heavily. In the following example of Advanced Directives, if the check mark is in place, it meets that priority. This is illustrative only and do not reflect current review.
# Visual Representation Example

**Criteria: Maturity**

<table>
<thead>
<tr>
<th>Advanced Directives</th>
<th>Comment Level</th>
<th>Level 1</th>
<th>Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>![Checkmark]</td>
<td></td>
</tr>
<tr>
<td>Current Standards</td>
<td></td>
<td></td>
<td>![Checkmark]</td>
</tr>
<tr>
<td>Current Use</td>
<td></td>
<td></td>
<td>![Checkmark]</td>
</tr>
<tr>
<td>Current Exchange</td>
<td></td>
<td></td>
<td>![Checkmark]</td>
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<td>Use Cases - # Stakeholders Impacted</td>
<td></td>
<td></td>
<td>![Checkmark]</td>
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**Criteria: Priority**

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<th>Address significant gaps in USCDI v1 concepts</th>
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<tr>
<td>![Checkmark]</td>
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<td>![Checkmark]</td>
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**Data supporting public health use cases**

| ![Checkmark] |

**Meets national imperative. May require moderate to High technical and standards uplift.**

| ![Checkmark] |

**Address significant gaps in USCDI v1 concepts**

| ![Checkmark] |
Phase 2 Scheduled Meetings

• May 18, 2021
• May 25, 2021
• June 1, 2021
• June 8, 2021
• June 15, 2021
• June 22, 2021
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 Task Force and made part of the Public Record.
Questions?
Meeting
Adjourned