Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

U.S. Core Data for Interoperability Task Force 2021
Report to the Health Information Technology Advisory Committee

PHASE 2 - RECOMMENDATIONS ON THE USCDI EXPANSION PROCESS

JUNE 9, 2021

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Background

Leveraging significant input from the Health IT Advisory Committee and its United States Core Data for Interoperability (USCDI) Task Force, in March 2020, ONC published USCDI version 1, a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The USCDI Task Force further provided recommendations on the expansion process ONC established to develop newer versions of USCDI that could be adopted by health IT developers and provided to their customers to improve interoperable health information exchange and patient access to their data. These recommendations included how to implement the ONC New Data Element and Class (ONDEC) submission system which received over 600 recommendations for new data elements for USCDI Version 2 (v2) in 2020.

On January 12, 2021, ONC published its Draft USCDI version 2 and sought public feedback on data elements included in this version, as well as on data elements that ONC did not include in it. As part of this public feedback process, ONC charged the HITAC to establish a new USCDI Task Force for 2021 to make specific recommendations on the content in the Draft USCDI v2, and to provide feedback on the entire process of expanding the USCDI in future versions.

ONC CHARGES TO THE USCDI TASK FORCE

Overarching Charge

The USCDI Task Force 2021 was charged with reviewing and providing feedback on the Draft USCDI Version 2 content and process.

Detailed Charge

The Task Force's specific charges were to provide recommendations on the following:

1. **(Delivered April 15, 2021)** 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. **(Due September 9, 2021)** 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. **(Due September 9, 2021)** Recommend ONC priorities for USCDI version 3 submission cycle

ADDITIONAL BACKGROUND INFORMATION

The Task Force (TF) includes a robust group of subject matter experts across various stakeholder groups, including direct patient care, patient advocacy, health IT development, standards development organizations, and others. The roster included in the Appendix to this document reflects the TF membership at the time these recommendations were finalized.

The HITAC applauds the work of the ONC in creating the USCDI expansion process which includes:

1. the ONC New Data Element and Class (ONDEC) Submission System to collect and process proposed additional data elements from stakeholders across the nation
2. a process by which ONC evaluates and assigns a level to each submitted data element depending on the overall value, maturity and challenges to implementation
3. the posting of submitted data elements on the USCDI page by level
4. annual prioritization and selection of a subset of items achieving Level 2 by October of each year for inclusion in a draft of the next version of USCDI for comment by the HITAC and the public, and
5. the finalization of the next version of USCDI in July of each year.

We support the majority of the details, processes and published priorities included in this process, and appreciate the consideration given to the recommendations herein. The TF has identified specific recommendations for modifications to the established expansion process with diligence and thoughtfulness.

The TF established a method of collecting and recording individual member's recommendations related to the steps in the existing expansion process as well as the priorities utilized in the 2020-21 submission cycle. Members were able to directly enter their recommendations so they could be discussed during TF meetings.

The TF identified multiple opportunities to improve the expansion process to increase its openness to and inclusion of an even broader range of stakeholders. Specific recommendations focus on methods to increase access for and engagement of members of the public who may not have deep technical expertise but would like to be able to contribute their suggestions and input to the USCDI expansion process.

The TF appreciates the tension between the desire to quickly expand USCDI to meet the many needs of stakeholders, and the need to assure that new data classes and elements have the technical and implementation maturity to be exchanged meaningfully. Therefore, with this in mind, the recommendations advocate a balanced approach whereby high priority and highly impactful data elements/classes could be identified and prioritized for advancement through the ONDEC process and incorporated into USCDI as it is expanded.

Recommendations

INTRODUCTION

The focus of the 2021 USCDI TF in Phase 2 was to address charges 2a, 2b, and 2c, to make specific recommendations on the USCDI new data element submission system (ONDEC), the criteria ONC uses to determine levels of maturity for new submissions, and the criteria ONC uses to select data elements for addition to USCDI.

High level recommendations include:

1. Implement changes to the ONDEC submission system to improve usability and accessibility to a broader set of potential contributors with an emphasis on education and inclusion stakeholders who have not traditionally participated in the standards development process, such as patients, their advocates, and public health professionals.
2. Promote awareness and development of high priority data elements within each level so that they can be matured quickly for inclusion in a future version of USCDI.
3. Make modifications to the Leveling Criteria to support the advancement of data classes/elements that may apply to a narrow stakeholder group when the impact is high.
4. Make additions to the Prioritization Criteria to promote advancement of data elements that address goals of health equity and health data equity, as well as public health and other identified high priority initiatives and use cases, which may change over time.

LIST OF SPECIFIC RECOMMENDATIONS

2a - Evaluate the USCDI expansion process and provide HITAC with recommendations for ONDEC submission system improvements

- **USCDI-TF-2021-Phase 2_Recommendation 01 – Use plain language (https://www.plainlanguage.gov) throughout ONDEC system**

- **USCDI-TF-2021-Phase 2_Recommendation 02 – Add "Unknown" as optional answer to all Yes/No questions in the ONDEC submission form and prep sheet**

- **USCDI-TF-2021-Phase 2_Recommendation 03 – Provide options for submitters to request assistance via chat, email and/or interview with ONC for completion of submission**

- **USCDI-TF-2021-Phase 2_Recommendation 04 – Develop primer and/or additions to ONC HIT Playbook to encourage and support stakeholder engagement in the USCDI process that do not traditionally participate in the process (e.g., patients and their care partners)**

- **USCDI-TF-2021-Phase 2_Recommendation 05 – Consider removing registration requirements (through the Interoperability Standards Advisory process) for submissions or comments in ONDEC**

- **USCDI-TF-2021-Phase 2_Recommendation 06 – Provide tools to promote diverse public engagement or crowdsourcing in the ONDEC submission process**
  - Share via social media app buttons on main page and data class or element pages
  - A Comment button at the top of each page that navigates user to the appropriate Comment field currently found at the bottom of the page
  - Like/Dislike buttons - User registration would be required to post these

- **USCDI-TF-2021-Phase 2_Recommendation 07 – Add submitter stakeholder group drop down list (e.g., patient, care partner / patient advocate, provider, SDO, HIT developer, government, professional group) to submission demographics section**

- **USCDI-TF-2021-Phase 2_Recommendation 08 – Offer special educational materials such as a glossary of terms**

- **USCDI-TF-2021-Phase 2_Recommendation 09 – Allow for a submitter to more easily see if the same or similar elements have already been submitted**
  - This would give the submitter the opportunity to provide comments on an existing data class/element rather than create a duplicative or competing submission.
  - This could be accomplished via an "all submissions/level view" or improved search function including smart/autofill data element name.

- **USCDI-TF-2021-Phase 2_Recommendation 10 – Allow for the submission of user stories in lieu of strict use cases and for specifically describing the benefit(s) of a proposed data class/element and/or harms related to lack of interoperability of the suggested data classes/elements**

- **USCDI-TF-2021-Phase 2_Recommendation 11 – Explicitly state that documented "challenges" related to a submitted data class or element are not used to determine its level, but may be used for prioritization for inclusion in future versions**

Charge 2b - Evaluate the USCDI expansion process and provide HITAC with recommendations for the evaluation criteria and process used to assign levels to submitted data classes and elements

- **USCDI-TF-2021-Phase 2_Recommendation 12 – ONC should support minority use cases where possible. When considering minority use cases, evaluation should include identification of where the use case can be supported by existing/compatible mature data elements/classes and provide direction to stakeholders to support implementation and use (e.g., specifying what note types should be used for exchanging Coroners Reports or Organ transplant harvest reports in the absence of dedicated USCDI note types for these purposes)**
    - This change is meant to support minority use cases within the current constraints of USCDI. Final published versions of USCDI are currently intended to be broadly applicable to all certified HIT applications. If we are going to consider narrower use cases, ONC would need to update certification to accommodate. For example, today a specialty product might only be used in a transplant workflow. It doesn't make sense for every EHR to need to meet the data needs of a specialty transplant module. That would be the consequence of today's certification model. If narrower use case data elements are added to USCDI, ONC should differentiate those use cases in certification.

- **USCDI-TF-2021-Phase 2_Recommendation 13 – Use Case Impact: When determining the level for an item, ONC should consider the item's impact on care and other national priority use cases. For example, data elements of particularly high impact that pertain to a narrower stakeholder group may be advanced from Level 1 or 2.**
    - The current levelling process, as clarified by ONC, excludes data classes and elements that may have a very high impact on a minority of patients or providers. This change provides the flexibility to allow for the advancement of these data when appropriate.

- **USCDI-TF-2021-Phase 2_Recommendation 14 – Periodic Review: ONC should review all items submitted to ONDEC annually, or preferably semi-annually, to validate current level and priority based on the latest information regarding maturity, need, submitted comments, and current criteria.**
    - Periodic review of ONDEC should identify opportunities for advancement of data classes/elements between levels.
    - The date and result of these reviews should be included on the website, and ONC should report to HITAC on review.
    - Periodic review should also identify high priority data classes/elements and provide guidance about the needed development/submission.
    - Recommend that ONC use the USCDI TF as a sounding board for questions or items that do not fall neatly into a particular category.

- **USCDI-TF-2021-Phase 2_Recommendation 15 – Create a dashboard view for USCDI. Items to be included in dashboard could include:**
  - # of submissions within each level
  - Date of / time since last review
  - # of Prioritized items within each level
  - # of submissions at each level by stakeholder categories

- **USCDI-TF-2021-Phase 2_Recommendation 16 – For submissions, include the level assigned for each individual evaluation criterion, as well as the level for the submission overall, and include prioritization criteria applied to all levels, not just Level 2**
  - This granular transparency of the leveling process would help submitters and commenters to provide more specific responses and help to ONC and the public.

Charge 2c - Evaluate the USCDI expansion process and provide HITAC with recommendations for the prioritization process used by ONC to select new data classes and elements for Draft USCDI v2

- **USCDI-TF-2021-Phase 2_Recommendation 17 – When evaluating submitted items ONC should independently assess Technical Maturity (e.g., based on the existence of vocabulary/semantic standards, structural/syntax standards, implementation guides, testing, implementation, and use) and Priority (based on [i] mitigating health and healthcare inequity/disparities, [ii] responding to the needs of underserved stakeholders, and [iii] addressing public health and other priority use cases identified by ONC).**
  - This recommendation specifically identifies several dimensions of priority that the TF feels are important for consideration during the 2021 USCDI submission cycle and beyond. It also supports future flexibility to allow ONC to identify new high priority use cases based on changing circumstances. The TF anticipates that prioritization factors may change over time and should be reviewed as part of each annual cycle of USCDI review.

- **USCDI-TF-2021-Phase 2_Recommendation 18 – Items within each level that are identified as high priority but of insufficient technical maturity for advancement to a higher level or inclusion in USCDI should be clearly identified, communicated to the standards community for expedited work, and to stakeholders to encourage pilot use and iterative deployment.**

- **USCDI-TF-2021-Phase 2_Recommendation 19 – Advancement into a final published version of USCDI should continue to require a minimum degree of technical maturity/readiness. In particular, published implementation guides are highly desirable to support scalable national deployment of a data element/class and should be available for new data classes/elements included in a published version of USCDI.**

- **USCDI-TF-2021-Phase 2_Recommendation 20 – Indicate which Level 2 classes/elements are of high priority but insufficient maturity to be included in the next published version of USCDI. This could encourage industry to strengthen efforts to improve on their maturity.**
  - High priority items with insufficient maturity for advancement should be clearly identified encouraging the community to prioritize and resource efforts to support these data classes/elements.
  - The need to focus on high priority items must be communicated as early as possible. Inclusion in Level 2 enables early signal and focus.
  - While high priority data items that are not sufficiently mature could be included in a draft USCDI published for public comment, this would provide limited time for industry to finalize any necessary standards and/or implementation guides to raise the maturity level. This should only be done when ONC believes the necessary maturity level is imminent, and its inclusion is contingent on the maturity is achieved before finalization of the next version.

- **USCDI-TF-2021-Phase 2_Recommendation 21 – Clarify that the applicability of USCDI extends beyond ONC certification and federal programs, and inclusion in USCDI does not depend upon being required within ONC certification and/or other federal programs.**

- **USCDI-TF-2021-Phase 2_Recommendation 22 – Continue to identify and prioritize for inclusion in USCDI data elements that are already routinely captured or automatically generated within HIT systems.**

Appendix A

Task Force Roster

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