Interoperability Standards Workgroup Report to the Health Information Technology Advisory Committee

PHASE 2 - RECOMMENDATIONS REGARDING THE ONC INTEROPERABILITY STANDARDS ADVISORY

JUNE 16, 2022

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Background

In the 21st Century Cures Act there is a mandate for the National Coordinator (ONC) to convene the Health Information Technology Advisory Committee (HITAC) to identify priority uses of health information technology, identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet those identified priorities, publish a report summarizing the findings of the analysis, and make appropriate recommendations.

ONC CHARGES TO THE INTEROPERABILITY STANDARDS WORKGROUP

Overarching Charge

Review and provide recommendations on the Draft U.S. Core Data for Interoperability (USCDI) Version 3 and other interoperability standards.

Specific Charges

The work group's specific charges were to provide the following:

Phase 1 (Submitted April 13, 2022): Evaluate Draft USCDI v3 and provide HITAC with recommendations for:
1a – New data classes and elements from Draft USCDI v3
1b – Level 2 data classes and elements not included in Draft USCDI v3

Phase 2 (this report, for June 16, 2022): Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications.

In April 2022, HITAC delivered recommendations regarding Phase 1. On April 19, 2022, the HITAC's Interoperability Standards Workgroup (IS WG) started work on Phase 2, delivering this final report to the HITAC on June 16, 2022.

ADDITIONAL BACKGROUND INFORMATION

The IS WG includes an engaged group of subject matter experts representing various stakeholders, including direct patient care, public health, patient advocacy, health IT development, standards development organizations, and others. The roster included in Appendix A to this document reflects the workgroup's membership at the time these recommendations were finalized.

Within the scope of the above charge, the workgroup addressed several specific priorities on which ONC requested input. These priorities include:

- Laboratory Test Orders and Results
- Social Determinants of Health (SDoH) Standards
- Patient Access/Portals/Individual Access Services related standards (including Patient Corrections to the medical record)
- Electronic Case Reporting (eCR)
- Proposed ISA information system enhancements

To assist in the development of these recommendations, the workgroup invited several outside subject matter experts to give testimony regarding their areas of expertise, interest, and work. These included:

On April 19, 2022, Riki Merrick, Association of Public Health Laboratories, and Hans Buitendijk, Cerner and an IS WG Member, presented on and discussed ISA laboratory data.

On April 26, 2022, Evelyn Gallego, EMI Advisors, and Asha Immanuelle, Center for Black Women's Wellness, presented on and discussed the Gravity Project's work on SDoH data.

On May 10, 2022, the workgroup heard several presentations by experts on the topics of eCR and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Patient Right to Request Corrections. These presentations were given by:

1. eCR
    a. Craig Newman, Altarum
    b. John Loonsk, John Hopkins University
2. HIPAA Right to Request Corrections
    a. Grace Cordovano, IS WG Member, Enlightening Results
    b. Dave deBronkart, HL7 Patient Empowerment Workgroup

On May 17, 2022, Andrew Hayden, ONC, presented a historical and structural overview of the ISA.

Note: Links to all presentation materials are available via the IS WG calendar (view meetings tab): https://www.healthit.gov/hitac/committees/interoperability-standards-workgroup

Executive Summary

In this report to the Health Information Technology Advisory Committee, the Interoperability Standards Workgroup prepared and transmits recommendations in the following areas:

- Recommendations on the process and structure of the ISA to improve
    - The ability of stakeholders to discover the current standards available and/or necessary to accomplish use cases, particularly those deemed a national priority,
    - Coordination and alignment with the USCDI,
    - Alignment with federal programs,
    - Ties to standards development organizations (SDOs) and associated "Accelerators," and
    - Overall usability and utility for stakeholders
- Recommendations to improve the standards tracked in the ISA to expand use cases and track additional standards across the following areas in the ISA, including:
    - Public Health,
    - Health Equity,
    - Social Determinants of Health,
    - Patient Engagement and Patient Access,
    - Care Planning and Care Coordination, and
    - Data Provenance

In addition, given the vital importance of orders and results for laboratory data in the health, safety and welfare of the US health care and public health system, we make specific additional recommendations for how to expand maturity and adoption and reduce burden for closed loop order-to-result communication and multi-lateral distribution of results (especially including to Public Health) using standards and comprehensive implementation guidance.

ISA Recommendations

ISA STRUCTURE AND PROCESS

In order to make the ISA a more helpful resource for the healthcare and other stakeholder communities involved with and leveraging health IT, we make the following recommendations to improve the structure and process of the ISA:

IS-WG-2022-Phase 2_Recommendation 01 – ISA Optimization: Content and Usability Updates

The ISA is currently divided into sections for “Vocabulary/Code Sets/Terminology”, “Content/Structure,” “Services/Exchange,” and “Administrative”. While this is a logical division for types of standards, it is currently difficult to cross-assemble all the standards needed to solve a particular problem (use case). There is a current view for “Specialty Care and Settings” which was originally implemented to provide a cross cutting view for Pediatrics then expanded to include Opioid Management, SDoH, and COVID-19. We believe these sorts of cross cutting views are helpful and useful.

In addition, in our review of the ISA, we noted multiple areas where the look and feel and structure of the ISA changed depending on what “path” was used to enter the ISA, leading to some frustration as a particular view of the ISA available from one path requires some work to reach when entering the ISA through other paths, including web search.

Recommendations

A. **Recommend that ONC change "Specialty Care and Settings" to "Use Cases" under the ISA Content section drop-down menu and include "Use Case" in (1) a tab under ISA Content and (2) future Reference Editions.**

B. **Recommend that ONC develop a prioritization/tagging schema to highlight Use Cases that ONC believes warrant particular focus based on national priorities at the then-present time.**

C. **Recommend that ONC expand the Use Case section in ISA to include the following:**
    - ISA Use Cases should include priority use cases identified and voted on by the HITAC on September 9, 2021:
        i. Patient Access
        ii. Value-based care delivery

iii. Cost and efficiency improvements including avoiding duplicative services
iv. Shared care planning
v. Telehealth and remote care
vi. Patient generated health data (PGHD), including patient reported outcomes (PROs) and device data
vii. Patient safety
viii. Disaster preparedness and pandemic response
ix. Population Heath
x. Precision Medicine
xi. Research
xii. Digital Quality Measures
xiii. Registries

- The Workgroup recommends the ISA Use Cases further include:
  xiv. Public Health interoperability
  xv. Achieving Health Equity by Design
  xvi. Patient Request for Correction
  xvii. Price Transparency and Advanced Explanation of Benefits, and
  xviii. All HL7 FHIR Accelerator use cases.

D. **Recommend that ONC review the current ISA format, organization, user interface, and functionality and assess human factors and technology changes that might be warranted to improve the overall usability of the ISA for health technology stakeholders.**

IS-WG-2022-Phase 2_Recommendation 02 - ISA Optimization: USCDI Alignment

As ONC develops new versions of the USCDI, USCDI+, and uses the Systems Version Advancement Process (SVAP) to allow forward compatible version advancement of the USCDI, it becomes increasingly important to align and coordinate the USCDI with the ISA.

Recommendations

A. **Recommend that ONC identify use cases related to data classes and elements submitted via the USCDI submission process and include relevant information fields from the USCDI submission form (e.g., via links to use case project page(s)).**
   - Including and linking this information in the ISA will enable stakeholders to more efficiently and effectively engage in identifying gaps and advancing interoperability needs for high-priority use cases regardless of USCDI level and/or inclusion.

B. **Recommend that ONC add "Challenges" to "Limitations, Dependencies, and Preconditions for Consideration" with guiding text to encourage capturing information that aligns with the USCDI Submission Form (e.g., restriction on standardization and use, privacy and security concerns, implementation burdens, etc.).**

C. **Recommend that ONC include in the ISA the USCDI data element(s) that rely on each standard, where relevant, as well as the USCDI Version or Level where the element currently resides. This is particularly important where a standard or implementation guide is required by a Federal program. Similar treatment may be applied to the USCDI+.**

D. **Recommend that ONC include and track within the ISA all data classes/elements in the USCDI.**

E. **Recommend that ONC create a workflow to incorporate relevant information from all USCDI submissions into the ISA.**

IS-WG-2022-Phase 2_Recommendation 03 - ISA Optimization: Expand ISA Elements

In our review, we noted a number of areas where the ISA could be a more useful tool to stakeholders. As Federal programs tied to standards named in the ISA expand beyond the historical Meaningful Use (MU)/Promoting Interoperability (PI) programs, it is useful to build on the foundation established by the ONC and include data on other, specific programs utilizing standards included in the ISA. It is additionally useful to understand more objectively how maturity and adoption levels in the ISA are assessed.

Recommendations

A. **Recommend that ONC expand the "Federally Required" characteristic beyond "yes/no" to include a list of any relevant Federal program(s) (including agency and program name) which references or requires the ISA item, including the specific certification criterion.**

B. **Recommend that ONC specify in the ISA how the Maturity and Adoption level are determined and provide more transparency and guidance on how specific ISA items are categorized with links to any relevant resources used in the assessment.**

IS-WG-2022-Phase 2_Recommendation 04 - ISA Optimization: Include Most Current Published and Emerging Standards with References to Associated Implementation Guides, Profiles, etc.

Given the rapidly expanding set of “accelerators” associated with Standards Development Organizations (SDOs), we noted areas where the standards included in the ISA had fallen behind the current state of these accelerators and areas where the use cases addressed by accelerators were not included in the ISA at all. A more explicit linkage between SDO accelerator activities and the ISA would address this drift and make the ISA a more useful tool for stakeholders.

Recommendations

A. **Recommend that ONC add an indicator if a use case is being addressed through an "Accelerator" (e.g., through an SDO/profiling organization such as HL7, NCPDP, IHE, etc.).**

B. **Recommend that ONC establish a streamlined process with SDOs and similar bodies (e.g., HL7, NCPDP, X12, DirectTrust, IHE, SNOMED, LOINC, etc.) to ensure that the ISA references the most recent versions of standards and associated IGs and profiles.**

C. **Recommend that ONC coordinate with accelerators and similar projects to create a streamlined process for them to submit to the ISA updates to standards that can be rapidly incorporated, thus creating a more current and timely representation of what is available for use. Access to past iterations of standards should be maintained to support interfaces currently in production that utilize ISA items.**

D. **Recommend that the ISA include and track all the use cases relevant to the HL7 FHIR Accelerators (currently Argonaut, The CARIN Alliance, CodeX, Da Vinci, FAST, Gravity, HELIOS, Vulcan), as well as the PACIO Project, including the relevant implementation guides already published or under development, with associated maturity and adoption information.**

ISA CONTENT

The workgroup makes the following detailed recommendations on standards and use cases listed in the ISA.

IS-WG-2022-Phase 2_Recommendation 05 – Use Case: Referrals Between Providers and Community Based Social Care Providers

Recommendation

- **Recommend that ONC update the use case label in the ISA from the current "Referral to extra-clinical services" to "Referrals between clinicians and community-based organizations and other extra-clinical services".**

IS-WG-2022-Phase 2_Recommendation 06 – Use Case: Achieving Health Equity by Design Including SDOH Data Standards

Recommendation

- **Recommend that ONC include and track in the ISA the use case "Achieving Health Equity by Design" including the relevant standards related to documenting Social Determinants of Health.**

  The recommended structure is:

  Use Cases
  A. Achieving Health Equity by Design
     a. Social Determinants of Health
        i. Vocabulary/Code Set/Terminology, etc.
        ii. Services/Exchange, etc.

Policy Levers

- ONC USCDI
- ONC Health IT certification criteria
- CMS Promoting Interoperability Program
- Executive Order No. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

IS-WG-2022-Phase 2_Recommendation 07 – SDOH Standards: Gravity Project Standards

Recommendation

- **Recommend that ONC update the ISA to integrate the Gravity Project's data elements, domains, assessment tools, value sets, and implementation guides from USCDI v2, as well as the Gravity Project's reference implementation to aid adoption and use by stakeholders:**

A. Vocabulary/Code Set/Terminology
   a. Social, Psychological, and Behavioral Data:

i. Add/Update all Gravity domains
ii. Add/Update with Gravity domain-level assessment tools and Gravity Project value-set authority center (VSAC) value sets for diagnoses, goals, and interventions
iii. Amend Limitations, Dependencies, and Preconditions

B. Services/Exchange
   a. SDOH Clinical Care Implementation Guide
      i. Add SDOH Clinical Care Implementation Guide v1.0.0 STU1
      ii. Add SDOH Clinical Care Implementation Guide v1.1.0 STU2
   b. Add Reference Implementation to improve adoption

Policy Levers

- ONC USCDI
- ONC Health IT HITECH certification criteria
- CMS Promoting Interoperability Program
- Executive Order No. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

IS-WG-2022-Phase 2_Recommendation 08 – SDOH Standards: The Centers for Disease Control and Prevention (CDC) Race/Ethnicity Vocabulary Subsets

Background and Supporting References

Federal standards prioritize self-reported values for one's race and ethnicity:

- "Respect for individual dignity should guide the processes and methods for collecting data on race and ethnicity; ideally, respondent self-identification should be facilitated to the greatest extent possible, recognizing that in some data collection systems observer identification is more practical."
- "Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. In situations where self-reporting is not practicable or feasible, the combined format may be used."

  Federal Register; Vol. 62, No. 210; Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity

Recommendation

- **Recommend that ONC add the "Source and Method of Collecting" race and ethnicity data to the ISA's Race and Ethnicity data elements, consistent with the Federal priority for self-reported race and ethnicity.**

Vocabulary/Code Sets/Terminology

A. Race and Ethnicity
    a. Amend Limitations, Dependencies, and Preconditions to include recommendations for:
        i. Source and method of collecting value for race
        ii. Source and method of collecting value for ethnicity
    - For example, standards for reference in ISA include the FHIR SDOH Clinical Care Implementation Guide STU2 (draft specifications currently in ballot), HL7 C-CDA, and HL7 v2 as available.

Note: this recommendation could have equal merit for other self-reported personal characteristics such as gender identity, sexual orientation, personal pronouns, disability status, pregnancy status, etc.

Policy Levers

- ONC USCDI
- ONC Health IT certification requirements
- CMS Promoting Interoperability Program
- Executive Order No. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government
- White House OMB Standards for the Classification of Federal Data on Race and Ethnicity

IS-WG-2022-Phase 2_Recommendation 09 – Use Case: HIPAA Right to Request Corrections to One's Medical Records

Background and Supporting References

The following serve as essential policy levers and references demonstrating policies and recommendations supporting Patient Request for Medical Record Corrections across the years, yet in 2022, the functionality is still not readily available to allow individuals to exercise their rights provided under HIPAA to request corrections to their health information.

- In its "Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information", ONC adopted the following principle on "Correction" (ONC Correction Principle 2008): "Individuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information (IIHI), and to have erroneous information corrected or to have a dispute documented if their requests are denied."

Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information

- The HIPAA Privacy Rule provides individuals with the right to have their protected health information (PHI) amended in a manner that is fully consistent with the Correction Principle in the Privacy and Security Framework
  HIPAA Privacy Rule – Standard: Right to Amend
- In 2011, the Health IT Policy Committee was tasked to give recommendations that will help build public trust in health information technology and electronic health information exchange (HIE) and enable their appropriate use to improve healthcare quality and efficiency. The Health IT Policy Committee recommended to ONC that they establish certification criteria to enable the HIPAA request for correction/amendment process.
  The 2011 Health IT Policy Committee
- Certified EHR Technology should have the ability by Meaningful Use Stage 3 to transmit amendments, updates, or appended information to other providers to whom the data in question has been previously transmitted.
  The 2011 Health IT Policy Committee
- The 2015 Edition Health IT Certification Criterion [§ 170.315(d)(4) (Amendments)] states: Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.
  2015 Edition Health IT Certification Criterion [§ 170.315(d)(4) (Amendments)]
  - For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.
  - For a denied amendment, at a minimum, append the request and denial of the request in at least one of the following ways: (A) To the affected record. (B) Include a link that indicates this information's location.

ISA Recommendation

A. **Recommend that ONC include and track "Patient Request for Corrections" as an ISA Use Case for standards development and implementation.**
   - Recommend adding "Patient Request for Corrections" to Services/Exchange: "Consumer Access/Exchange of Health Information" and corresponding terminology and exchange standards, where applicable.
   - Recommend adding "Patient Request for Corrections" to Administrative: "Administrative Transactions to Support Clinical Care" and corresponding terminology and exchange standards, where applicable.

Supporting Recommendations

B. **Recommend that ONC clarify in its communications that the HIPAA "right to request corrections to one's medical records" Use Case broadly applies to all PHI in a HIPAA designated record set.**

C. **Recommend that ONC consider Health IT certification criteria requiring certified products to enable a HIPAA-compliant request for correction/amendment process via a patient access FHIR API.**
   - Recommend that such a requirement allow patients, at minimum, to request corrections through the patient access API for all patient data available through the API.

D. **Recommend that ONC collaborate with the HL7 Patient Empowerment Workgroup and other stakeholders to help address gaps in standards, capabilities, and implementation of Patient Request for Medical Record Corrections.**

IS-WG-2022-Phase 2_Recommendation 10 – Use-Case: Enabling Consumers to Download Image Files from Their Health Records

Recommendation

- **Recommend that ONC include and track in the ISA the use case and emerging standards that would enable consumers to use standard APIs to reference, view, share, and/or download both reference and full diagnostic quality (e.g., DICOM and other high-quality images) from their health records maintained by their health care provider or other entity, including referencing images that are maintained in linked Picture Archive Computer Systems (PACS) for use as the consumer chooses including sharing with other entities.**

Supporting Reference

Basic APIs for Imaging Access

IS-WG-2022-Phase 2_Recommendation 11 – Use-Case: Enabling Consumers to Download Their Personal Genomic Variants Data

Recommendation

- **Recommend that ONC include and track the ISA use case and emerging standards that would enable consumers to download their personal genomic variant data via standard APIs from their health care provider or other entity for use as the consumer chooses including sharing with other entities.**

IS-WG-2022-Phase 2_Recommendation 12 – Use Case: Care Plans and Chronic Disease Management

ISA Recommendation

A. **Recommend ONC include and track in the ISA the use case and emerging standards that support dynamic, longitudinal shared care plans, planning and coordination, and link to existing relevant terminology, exchange, and administrative standards already in the ISA that support this use case.**

- A dynamic, longitudinal "care plan" is distinct from an episodic "plan of care" or "plan of treatment." The "plan of treatment" focuses on a particular episode, diagnosis, condition, etc. The longitudinal shared care plan synthesizes the multiple plans for each of the patient's health goals or diseases/conditions into a dynamic, longitudinal shared care plan for the patient across all care teams and settings over time, updated regularly and automatically where appropriate.

Supporting Recommendation

B. **Recommend ONC work with stakeholders such as the AHRQ/NIH eCare Plan, FAST (shared care planning use case), Gravity Project, CMS/CMMI, HL7, and other stakeholders and SMEs to identify and close gaps in existing standards.**

Policy Levers

- ONC USCDI
- ONC Health IT certification criteria, e.g. §170.315(b)(9) Care plan
- CMS Promoting Interoperability Program
- CMMI ACOs and other models
- AHRQ's and NIH's work on a Multiple Chronic Condition eCare Plan using SMART on FHIR
- Executive Order No. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

IS-WG-2022-Phase 2_Recommendation 13 – Electronic Case Reporting (eCR) Standards

ISA Recommendations

A. **Recommend that ONC include in the ISA references to the latest**

- **CDA-based Electronic Initial Case Report (eICR R1.1 in operations, R 3.1 to be published 7/2022),**

- **CDA Reportability Response (RR R1.0 in operations, R1.1 to be published 7/2022), and**
- **FHIR-based eCR suite (R2.0 – eRSD in operations, R2.1 to be published 7/2022).**

B. **Recommend that the ISA separately identify the three transactions specified in the FHIR eCR IG: eRSD, FHIR eICR, and FHIR RR.**

Supporting Recommendation

C. **Recommend that ONC coordinate with Federal partners including CMS, CDC, CLIA; state/local/territorial public health agencies and public health organizations (e.g., APHL, CSTE, ASTHO); SDOs; and other key stakeholders to accelerate maturity and adoption of standardized eCR.**

Policy Levers

- ONC health IT certification requirements
- CMS Promoting Interoperability Program
- CMS IPPS Rule. 2022 Proposed Rule open for comment until 6/17/2022.
- CDC funding of / cooperative agreements with state and local PH agencies (including COVID relief funding) could advance the utilization of specified eCR standards and adoption of technology, e.g., FHIR capabilities.
- CLIA (jointly operated by CMS and CDC) encourage and eventually require clinical labs and healthcare organizations to use LOINC (test name) and SNOMED (result) coded content specific to reportable clinical conditions

Supporting References

Case Reporting to Public Health Agencies

Centers for Medicare and Medicaid Services Fiscal Year 2023 Inpatient Prospective Payment System Proposed Rule Home Page

IS-WG-2022-Phase 2_Recommendation 14 – Coalition for Content Provenance and Authenticity (C2PA) – Standard to certify the source and provenance of online content

Background and Supporting Reference

C2PA addresses the prevalence of misleading information online through the development of technical standards for certifying the source and history (or provenance) of online content. C2PA is a Joint Development Foundation project, formed through an alliance between Adobe, Arm, Intel, Microsoft and Truepic.

C2PA Specifications

Recommendation

- **Recommend that ONC include and track in the ISA the emerging C2PA standard to relevant sections of the ISA that deal with provenance tracking and detection of tampering.**

IS-WG-2022-Phase 2_Recommendation 15 – EHR Clinical Decision Support Rationale

Background

There are some existing standards in the ISA related to CDS Hooks and other clinical decision support standards. Current standards do not address the desirability of making this information available to individuals.

Recommendation

- **Recommend that ONC, include and track in the ISA the use case of documenting, encoding and communicating the decision rationale utilized in generating decision support alerts/recommendations.**
    - This should include the ability to standardize, document, and display the rationale/explanation behind recommendations generated by predictive analytics, machine learning, and artificial/augmented intelligence (AI) tools.

ADDITIONAL RECOMMENDATIONS

Expanding ISA Standards Adoption for Lab Orders, and Results

In addition to our recommendations on the structure and process of the ISA and our recommendations to track additional standards in the ISA, the work group reviewed the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) and LOINC In-Vitro Diagnostic (LIVD) test code work and followed up the ISP TF 2018

recommendations to HITAC on laboratory orders and results[1]. We note that, while the ISA currently tracks standards relevant to orders and results, the current state of adoption on the ground is fragmented and inconsistent, with ad hoc lab and vendor specific implementation guidance. While there is broad adoption of electronic results, this fragmentation leads to underuse of electronic ordering, particularly across systems; to duplicative and error-prone efforts to map code sets across systems; and, as the COVID-19 experience showed clearly, to a failure to consider data use end-to-end. For example, demographic and contact data critical to track disease progress, disparities in cases and treatment, and to conduct case investigation were available in the source ordering systems but missing from the data feeds sent to public health.

Although these recommendations are adjacent to the work group's core charter, we offer these comprehensive recommendations to ONC in consideration of the vital importance they have in the health, safety and welfare of the US health care and public health system.

[1]https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf

IS-WG-2022-Phase 2_Recommendation 16 – Lab Orders/Results: SHIELD/LIVD (Information Model)

Background and Supporting References

Terminology standards are inadequate on their own to meet semantic interoperability needs; standard information and communication models are also needed.

Interoperability Standards Priorities Task Force 2019 Final Report

2022 ISA Reference Edition

Using LOINC with SNOMED CT

Recommendation

- **Recommend that ONC coordinate with HHS partners (FDA, CMS, CDC, among others), SDOs and other stakeholders to further define an interoperable information model based on existing CLIA requirements and the HL7 v2 LOI, HL7 v2 LRI, HL7 FHIR US Core, as well as the emerging HL7 FHIR LIVD implementation guides, and subsequently incorporate this model in ISA and USCDI.**
    - Such an information model should define information standards for interoperable clinically interpretable data, for patient self-management, and for public health.
    - In particular, it should specify that:
        - All laboratory orders be specified with LOINC codes and Healthcare Common Procedure Coding System (HCPCS) administrative procedural codes as needed for purposes of billing
        - All laboratory results should include a code, value, reference range, etc., with associated terminology standards and that such results should use:
            - LOINC for the test,
            - UCUM for numeric results,
            - SNOMED-CT for qualitative results,
            - HL7's HL0078 standard for Test Interpretation codes (High, Low, Normal, Abnormal, etc.),
            - SNOMED-CT for specimen information as appropriate, and
            - UDI data for test kit and other relevant device data.

IS-WG-2022-Phase 2_Recommendation 17 – Lab Orders/Results: SHIELD/LIVD (Orders)

Recommendations

A. **Recommend that ONC, in conjunction with other Federal partners, SDOs, state and local public health, and industry stakeholders create and support a policy framework that encourages, incentivizes, requires or otherwise enables closed loop order-to-result communication and multi-lateral distribution of results (especially including to Public Health) using standards and comprehensive implementation guidance.**

- The HL7 Laboratory Results Interface (LRI) and Laboratory Orders Interface (LOI) specifications and implementation guides are fit for purpose and mapped to suit multiple needs, including Electronic Lab Reporting (ELR) for public health purposes.
- While the associated Meaningful Use/Promoting Interoperability measures regarding incorporation of electronic results by the ordering provider were determined to be "topped out," and therefore removed from the incentive program, we do not have broad deployment of tightly constrained implementation guides that allow full communication of orders and results end-to-end including to public health.
- Note that ELR is still included as a public health reporting measure in PI.

B. **Recommend that ONC, in conjunction with other Federal partners, SDOs, state and local public health, and industry partners create and support an ongoing consensus development process to prioritize and encourage or incentivize the adoption of standardized coding for the most common/important orderable tests and panels of each order type, including conditions that are reportable to public health, and the orders that link to prioritized results.**

- Support the harmonization, advancement, and consensus development of standards-based catalogs of orderable tests, with mappings to associated code systems and codes, and with special emphasis on:
  - Laboratory, Radiology, Cardiopulmonary and other tests using, e.g., LOINC Universal Lab Orders as a standard catalog of orderable lab tests.
  - When using custom panels, non-panel LOINC codes for the individual component tests should be used.
- Standards for order details, such as priority, frequency, timing, and other special instructions should also be prioritized in conjunction with community stakeholders.

- Radiology orders and order details such as imaging modality, anatomic location, laterality, number of views, use of contrast, and priority (which are often pre-coordinated in radiology test names) are available in the LOINC/RSNA/RadLex catalog.

C. **Recommend that ONC, in conjunction with other Federal partners, SDOs and industry partners encourage / incentivize laboratories to submit their self-developed test specifications to LOINC for assignment of standard orderable test codes.**
   - CMS, under the Clinical Laboratory Improvement Amendments (CLIA), regulates Laboratory Developed Tests (LDTs) - tests only performed by a specific lab - while FDA regulates In Vitro Diagnostics (IVDs), including test kits, which are mass produced and performed in many labs).

D. **Recommend that ONC, in conjunction with other Federal partners, SDOs and industry stakeholders support and incentivize the standardization of the multiple existing code sets for orderable tests to LOINC and develop cross maps for administrative purposes.**
   - Currently multiple terminologies such as SNOMED CT, Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) billing codes, Proprietary Laboratory Analyses (PLA) codes, and LOINC codes are used for orderables. These code sets require harmonization amongst one another or, preferably, mapping to LOINC codes to support consistent interoperability.

IS-WG-2022-Phase 2_Recommendation 18 – Lab Orders/Results: SHIELD/LIVD (Results)

Recommendations

A. **Recommend that ONC, other relevant HHS, and other Federal partners create policies sufficient to encourage, incent, require or otherwise enable resulting organizations, (e.g., clinical/pathology labs, imaging centers, providers), to support the resulting information model and associated communication and content standards for orders and results when exchanging this data via electronic messaging, documents, application programming interfaces (APIs), and/or other future transport mechanisms.**

- When result observation values can be coded (as opposed to being quantitative or documented using free text), resulting organizations should use SNOMED CT Concepts (from the clinical finding, organism, or qualifier hierarchies) or, where applicable, LOINC Answer Codes to encode the observation value.
- The International Health Terminology Standards Development Organization (IHTSDO), which is the owner of SNOMED CT, has also published "Using LOINC with SNOMED CT".
- When result observations are quantitative it is critical to include the applicable units of measure, which should be coded using UCUM.
- Some lab tests are performed on different sorts of specimens, which may not be encoded with sufficient granularity within LOINC (e.g., a bacterial culture, which may use the LOINC system 'Specimen' or 'Isolate/Specimen'). In these situations, the submitted sample should be further described with regard to the type and source site (if needed) – these elements should be encoded using the specimen and body site hierarchies in SNOMED CT respectively.
- Many test results can vary depending on the instrumentation on which the testing is performed. Therefore, along with specimen code identifiers as appropriate, information on the instrument, kit, and/or reagents used to generate the results should be included to allow for assessment of comparability of results. UDI information on the instrument and reagent kit would also support post-market surveillance and regulatory decision making.

B. **Recommend that ONC, coordinating with other Federal partners, and with SDOs and industry stakeholders, enable standards, implementation guidance and policy that encourages LOINC and SNOMED encoding as early in the process as possible and maintenance of that coded data throughout the process.**
   - By "as early in the process as possible" we intend to capture encoding in the order, where relevant and at the IVD and IVD/LIS interface. For orders, communication of an order should include the appropriate LOINC code where available. Any Ask at Order Entry (AOE) questions should similarly use LOINC codes, where available, for the question and SNOMED codes, where available, for the AOE answers.

C. **Recommend that ONC, in coordination with other Federal partners and with SDOs and industry stakeholders following the SHIELD project, create sustainable mechanisms that lead to IVD Test devices and LISs to automate mapping and translation sufficient to enable test resulting following the standards described above.**

- As test results are communicated from IVD Test devices to the LIS and on to the EHR, Public Health and/or other systems and organizations, either the IVD test device (if capable and in possession of the relevant context of the test) or the LIS should ensure that the correct codes are included. Guidance on which LOINC and SNOMED are most suitable for the tests performed based on relevant context (e.g., specimen, result, or other considerations) should be made available by IVD test device manufacturers in computable format that laboratories can use to finalize appropriate mapping of IVD test results to results reported back to the ordering provider and beyond.

D. **Recommend that ONC, in coordination with other Federal partners, SDOs and industry stakeholders, assure that there is a well-managed and appropriately resourced process to develop and deliver additional LOINC, SNOMED CT codes when needed for new tests or needed variations of existing tests.**
   - This could take the form of more formal support for the current process to submit, review, and if appropriate approve new LOINC, SNOMED CT and UDI codes.

E. **Recommend that ONC, in coordination with the FDA, SDOs, manufacturers, and industry stakeholders, including SHIELD, enhance the ability for test results to include identification of the device(s) used to perform the test using the device's model, Device Identifier, or preferably the UDI, while streamlining the documentation of such identification as the test is performed and documented.**
   - This should be for any device(s) of interest used to perform the test (e.g., test kits, analyzers, test platforms) while the collection of these identifiers should be as close to the source and automatically communicated with the result or through the use of barcode scanners.

F. **Recommend that ONC, in conjunction with other Federal partners, SDOs and industry stakeholders create policy levers, inclusive of guidance, education, certification criteria and payment programs that lead EHRs, laboratory information systems (LISs) and radiology information systems (RISs) to provide tools and guidance that incentivizes clients/users to map internally generated results and result codes (including observations and values) to standard vocabularies in cases where coding is not done at the source.**

G. **Recommend that ONC, in conjunction with other Federal partners, SDOs and industry stakeholders, create and implement mechanisms to support and ensure proper and consistent LOINC, SNOMED CT encoding across result sources (e.g., laboratories, imaging centers) by resulting organizations.**
   - This could be accomplished using a mapping knowledge base searchable by IVD manufacturer, Device Identifier, or harmonized lab test method (e.g., SHIELD's proposed Laboratory Interoperability Data Repository), auditing, and/or certification by the Clinical Laboratory Improvement Amendments (CLIA) for laboratories.

H. **Recommend that ONC, in coordination with the FDA, SDOs, manufacturers, and industry stakeholders, including SHIELD, provide the ability for testing devices' UDI to be registered in the Global Unique Device Identification Database (GUDID) for additional device information as well as linkage to the mapping knowledge base (e.g., SHIELD's proposed Laboratory Interoperability Data Repository).**
   - This should be for any device(s) of interest used to perform tests (e.g., test kits, analyzers, test platforms) while the documentation of these identifiers should be, where possible, by the device or through the use of barcode scanners.

IS-WG-2022-Phase 2_Recommendation 19 – Lab Orders/Results: Patient-Friendly Names

Recommendation

- **Recommend that ONC, in conjunction with other Federal partners, SDOs and industry stakeholders, encourage the development of and eventually require the use of standard "patient friendly" order and result display names (AKA Consumer Names) for patient consumption, as well as the ability to reference patient-facing explanations in a standardized manner, based on LOINC standards, when sufficiently mature.**

Supporting Reference

Consumer Names

IS-WG-2022-Phase 2_Recommendation 20 – Increasing the Usage and the Accuracy of Standard Codes in Laboratory Test Messages

Recommendation

- **Recommend ONC, in coordination with other Federal partners, SDOs and industry stakeholders, develop and support/incentivize the implementation of a methodology to assess and monitor the actual delivery and accuracy of standard codes in real world laboratory order and result exchanges, including exchanges between ordering providers and laboratories and laboratories and all entities, including public health, receiving or accessing results.**

IS-WG-2022-Phase 2_Recommendation 21 – Lab Orders/Results: SHIELD/LIVD (ELR and eCR alignment)

Recommendation

- **Recommend that ONC, in conjunction with other Federal partners and public health at the state and local level, revisit existing requirements for Electronic Lab Reporting (ELR) given the broad adoption of eCR.**
  - Such a change would allow ELR data flows to more precisely focus on laboratory reporting concerns and enable more robust overall data flows in support of public health.
  - Where eCR is adopted, laboratories should not be encumbered with the collection, storage, and transmission of data not relevant to the processing of test orders, conducting tests, and reporting of the laboratory test orders/results. Such data should be sent by the ordering provider using eCR methodologies combined with any other data that is relevant to PH that the performing Lab would not have or need. Information necessary for accurately matching submissions must be included in all relevant messaging.
  - These recommendations would not apply when eCR is not available (and the result is the only reasonable source of data for public health) or when the laboratory itself is the source of contextual information (e.g., direct to consumer tests or information collected at the specimen collection itself).

Appendix A

Task Force Roster

Name	Organization	Name	Organization
Steven Lane (Co-Chair)	Sutter Health	Kensaku Kawamoto	University of Utah Health
Arien Malec (Co-Chair)	Change Healthcare	John Kilbourne	VA
Kelly Aldrich	Vanderbilt University	Leslie Lenert	Medical University of South Carolina
Hans Buitendijk	ORACLE Cerner	Hung S. Luu	Children's Health
Thomas Cantilina	DOD	David McCallie	Individual
Christina Caraballo	HIMSS	Clem McDonald	National Library of Medicine
Grace Cordovano	Enlightening Results	Mark Savage	Savage & Savage LLC
Steven Eichner	Texas Dept. of State Health Services	Michelle Schreiber	CMS
Adi Gundlapalli	CDC	Abby Sears	OCHIN
Rajesh Godavarthi	MCG Health	Ram Sriram	NIST
Jim Jirjis	HCA Healthcare		