

Interoperability Standards Workgroup

Phase 2- Recommendations on the ONC Interoperability Standards Advisory

Steven Lane, Workgroup Co-Chair Arien Malec, Workgroup Co-Chair





Workgroup Recommendations and Report

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- Background
- Charges
- Interoperability Standards Advisory (ISA) Overview
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Membership





Interoperability Standards Workgroup 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 C		
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			



Background





HITAC Priority Uses of Health IT

In general, the HITAC shall make recommendations to the National Coordinator for Health Information
Technology on a policy framework for adoption by the Secretary consistent with the strategic plan under
section 3001(c)(3) of the PHSA, as amended for advancing the following target areas:



Use of Technologies that Support Public Health:

The facilitation of bidirectional information sharing between the clinical and public health communities



Privacy and Security:

The promotion and protection of privacy and security of health information in health IT



Interoperability:

Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information



Patient Access:

The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information



Charges





Interoperability Standards Workgroup Charge

Overarching charge: Review and provide recommendations on the Draft USCDI Version 3 and other interoperability standards

Specific charges:

<u>Due</u>

1 Evaluate Draft USCDI v3 and provide HITAC with recommendations for:

April 13, 2022

- 1a New data classes and elements from Draft USCDI v3
- 1b Level 2 data classes and elements not included in Draft USCDI v3
- 2 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.

June 16, 2022



Interoperability Standards Advisory (ISA) Overview





What is the ISA?

- A single, public list of the standards and implementation specifications that can best be used to address specific interoperability needs
- Reflects the results of ongoing dialogue, debate, and consensus among industry stakeholders
- Documents known limitations, preconditions, and dependencies as well as other helpful information
- Serves as an informational resource, is non-binding and does not create or confer any rights or obligations for or on any person or entity
- Available at <u>www.healthit.gov/ISA</u>



How is the ISA used?

- Stakeholders who administer government and non-governmental procurements, testing, certification or grant programs look to the ISA to meet their interoperability needs
- Developers of health IT look to the ISA for available and appropriate standards/implementers specifications to support interoperability efforts
- Implementers and users of health IT products look to the ISA to ensure purchased products include standards that support their specific interoperability needs
- The ISA's informative content regarding limitations, dependencies or preconditions for use is also available to help more fully inform policy and implementation efforts



Ongoing Update Process

- The web-based version of the ISA is updated frequently throughout the year, as new comments from stakeholders come in or as changes occur, with an annual call for review and comments in late Summer timeframe
- ONC Subject Matter Experts review public comments and monitor the standards landscape, making updates to assigned ISA pages
- ONC publishes a static "Reference Edition" of the ISA (PDF) each December that can be referenced in contracts, agreements, or as otherwise needed with certainty that the information will not change
- All prior editions (since 01/2015) available online
- Recent ISA Updates page + RSS feed



High Level ISA Structure

- Vocabulary/Code Set/Terminology Standards
- Content and Structure Standards
- Services/Exchange Standards
- Administrative Standards
 - Under each section, there are Subsections by topic with numerous Interoperability Needs
 - Specific standards and implementation specifications support each Interoperability Need
- Informational Appendices
 - Sources for Security Standards
 - Models and Profiles
 - Educational / Informational Resources
 - State & Local Public Health Readiness for Interoperability
- Specialty Care and Settings pages COVID-19, Opioids, Pediatrics, SDOH



ISA Content

- Characteristics and other helpful information for each standard and implementation specification listed for each interoperability need
 - Standards Process Maturity
 - Implementation Maturity
 - Adoption Level
 - Federally Required
 - Cost
 - Test Tools
 - Limitations, Dependencies, Preconditions and Other Qualifying Information
 - Applicable Value Set(s) and Starter Set(s) and Security Patterns



Additional ISA Resources

- United States Core Data for Interoperability (USCDI)
 - Published standards
 - Expansion process
 - ONC New Data Element & Class (ONDEC) Submission System
- Standards Version Advancement Process (SVAP)
- Public Comment pages
 - ISA
 - USCDI
 - SVAP



ISA Challenges

- Keeping the ISA user friendly and easily digestible as the platform grows
- Satisfying stakeholders with different perspectives
- Ensuring that the ISA remains a valuable resource to different sets of stakeholders





Sample ISA Interoperability Need

Allows a Prescriber to Send a New Prescription to a Pharmacy







Туре	Specification		Implementation Maturity		Federally required		Test Tool Availability
Standard	NCPDP SCRIPT Standard, Implement ation Guide, Version 2017071 ថ	Final	Pilot	•0000	No	\$	Yes
Standard	NCPDP SCRIPT Standard, Implement ation Guide, Version 10.6៤	Final	Production	••••	Yes	\$	Yes ថា
Emerging Standard	HL7 FHIR Medication Request®	In Development	Pilot	Feedback Requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration		
 The following transactions need to be implemented for interoperability purposes: 	Secure Message Router – securely route and enforce policy on inbound and outbound messages without interruption of delivery.		
 SCRIPT 10.6 & SCRIPT 2017071 - NewRx: This transaction is a new prescription sent from the 	Authentication Enforcer – centralized authentication processes.		
prescriber to the pharmacy electronically so that it can be dispensed to a patient	Authorization Enforcer – specifies access control policies.		
 SCRIPT 2017071 - NewRxRequest: This transaction is a request from a pharmacy to a 	 Credential Tokenizer - encapsulate credentials as a security token for reuse (e.g., - SAML, Kerberos). 		
prescriber for a new prescription for a patient NewRxResponseDenied: This transaction is a denied response	 Assertion Builder – define processing logic for identity, authorization and attribute statements. 		
to a previously sent NewRxRequest (If approved, a NewRx wo be sent) • A NewRxResponseDenied response may occur when the NewRxRequest cannot be processed or if information is unavailable	User Role – identifies the role asserted by the individual initiating the transaction.		
	Purpose of Use - Identifies the purpose for the transaction.		
Both the prescriber and the pharmacy must have their systems configured for			
the transaction in order to facilitate successful exchange, including the ability to			



Additional ISA Informational Resources

- About
- Structure
- <u>Timeline and Comment Process</u>
- FAQs



Methods and Approach



Methods and Approach

The workgroup provides recommendations on the following areas:

- Process and structure of the ISA:
 - Ability of stakeholders to discover current standards available/necessary for use cases
 - Coordination and alignment with the USCDI
 - Alignment with federal programs
 - Ties to standards development organizations (SDOs) and "Accelerators"
 - Overall usability and utility for stakeholders
- Expand use cases and track additional standards in the following areas of the ISA:
 - Public Health
 - Health Equity
 - Social Determinants of Health
 - Patient Engagement and Patient Access
 - Care Planning and Care Coordination
 - Provenance
- Expand ISA standards adoption for lab orders and results



Phase 2 Recommendations – ISA Structure and Process





Phase 2 Recommendations – ISA Structure and Process

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

- 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 (see upcoming slides)
- 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 01 – ISA Optimization: Content and Usability Updates (continued)

- ISA Use Cases should include priority use cases identified and voted on by the HITAC on September 9, 2021:
 - 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



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

- 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
 - xviii. All HL7 FHIR Accelerator use cases



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

- 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))
- 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

- 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.

- 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 as well as 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



Phase 2 Recommendations – ISA Content





Phase 2 Recommendations – ISA Content

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

 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

 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



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

 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



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

 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 selfreported race and ethnicity



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

Background

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.

- Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information
- HIPAA Privacy Rule Standard: Right to Amend
- HIPAA Privacy Rule Correction Principle in the Privacy and Security Framework
- The 2011 Health IT Policy Committee recommended to ONC that they establish certification criteria to
 enable the HIPAA request for correction/amendment process and that certified EHR Technology should
 have the ability to transmit amendments, updates or appended information to other providers to whom the
 data in question has been previously transmitted
- 2015 Edition Health IT Certification Criterion [§ 170.315(d)(4) (Amendments)]



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

ISA Recommendation

A. Recommend that ONC include and track "Patient Request for Corrections" as an ISA Use Case for standards development and implementation

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 the designated record set
- C. Recommend that ONC consider Health IT certification criteria requiring certified products to enable the HIPAA request for correction/amendment process via a patient access FHIR 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

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



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

 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

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



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 (elCR 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)
 - 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



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

• 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

*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.



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

- 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— Lab Orders and Results





Additional Recommendations – Lab Orders and Results

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

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



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

- 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
- 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



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

- 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
- 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



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

- A. Recommend that ONC and 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 messages, documents, application programming interfaces (APIs), and/or other future transport mechanisms
- 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
- 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 noted above



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

- 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
- 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
- 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



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

- 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
- 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)



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

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



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

 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 receiving or accessing results



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

 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



Discussion HITAC Voting