The Office of the National Coordinator for
Health Information Technology
Health IT Advisory Committee

Interoperability Standards Priorities Task Force October Update

October Report on ISPTF Activities
Ken Kawamoto, Co-Chair
Steven Lane, Co-Chair
October 17, 2018

Agenda

- ### ISPTF Activities in September

    » Steven Lane & Ken Kawamoto, Task Force Co-Chairs

- ### Orders & Results Draft Priorities & Recommendations Overview

    » Steven Lane & Ken Kawamoto, Task Force Co-Chairs

- ### Discussion of Draft Recommendations

    » Dan Vreeman, Regenstrief Institute/ Logical Observation Identifiers Names and Codes (LOINC)

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ISPTF Activities in September

- The ISPTF held 3 meetings on Orders & Results.

- The TF reviewed the relevant sections of the Interoperability Standards Advisory (ISA) pertaining to Orders & Results.

- The TF received presentations from Ken McCaslin (Accenture), Virginia Sturmfels (Quest Diagnostics), Swapna Abhyankar & Dan Vreeman (Regenstrief Institute/LOINC) on the standards associated with Orders & Results.

- The TF, in subsequent discussion, identified 2 priorities associated with Orders & Results for discussion today.

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Orders & Results Priorities & Draft Recommendations

- Priority 1: Results Ordering

  » Priority 1A: Consistent encoding of Lab & Other test results

  » Priority 1B: Results need to be sent to clinicians in codified format

  » Priority 1C: Results need to be available for patients/proxies to effectively view, receive, and utilize

  » Priority 1D: Orderable tests need to be standardized between systems and with mapping to standard terminologies

- Priority 2: Standardization

  » Priority 2A: Need standard methodology to integrate external decision support for all stakeholders into orders workflow

  » Priority 2B: Need standards to support Prior Authorization workflows

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Priority 1A: Consistent encoding of Lab & Other test results Draft Recommendations

- Standardized Logical Observation Identifiers Names and Codes (LOINC) & Systematized Nomenclature of Medicine - Clinical Terms (SNOMED-CT) coding must be provided by resulting agencies as a Clinical Laboratory Improvement Amendments (CLIA) requirement.

- Identify and prioritize the most common/important results of each order type (including but not limited to lab, imaging, cardiac, pulmonary, neuro-muscular).

- Require and enforce the use of information models and terminology standards for all test orders and results.

- Mapped codes must be included with results as they are maintained in and exchanged between health information technology (HIT) systems.

- Resulting systems, e.g. electronic health records (EHRs) & laboratory information systems (LISs) should provide a mechanism that allows clients to map internal result codes to standard vocabularies.

- Implement mechanisms to support and ensure proper LOINC encoding by resulting agencies, such as auditing or certification by CLIA.

Potential Policy Actions Addressing Priority 1A - ONC

- ONC

  » Use available EHR data sources to assess current compliance with Laboratory Results Interface (LRI) specifications & LOINC and SNOMED encoding to identify areas for additional focus.

  » Work with Health Level 7 (HL7) & industry stakeholders to create a LRI companion guide for HL7 Medical Document Management (MDM) and associated content and terminology standards to allow standards-based exchange of textual reports.

  » Continue work with Center for Medicare & Medicaid Services (CMS), Centers for Disease Control & Prevention (CDC) and associated industry stakeholders, e.g., the American Medical Association (AMA) Integrated Health Model Initiative, to harmonize information models and terminology standards to Electronic Clinical Quality Measures (eCQM) definitions and reportable disease requirements.

  » Continue coordination with Food & Drug Administration (FDA), CLIA and the National Library of Medicine (NLM) to establish mapping between the output of analysis devices and LOINC terms.

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Potential Policy Actions Addressing Priority 1A - FDA & CMS

- FDA

  » Continue to promote use of LOINC in diagnostic device approval and oversight.

- CMS

  » Establish safe harbors or fast lanes for fulfilling CLIA quality obligations through delivery of HHS-endorsed standards-based results (e.g., LRI with LOINC encoding) electronically to certified EHRs.

  » Require certification under CLIA to HHS-endorsed standards-based results (e.g., LRI with LOINC encoding).

  » Work with National Institute of Standards & Technology (NIST) to develop and provide testing program to assure compliance with coding standards.

  » Should above steps be insufficient to promoting standards-based interoperability, require certification as a condition of payment.

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Priority 1B: Results need to be sent to clinicians in codified format Draft Recommendations

- Utilize US Core Data for Interoperability (USCDI) to assure that prioritized results are interoperable via HL7 v2 messages (where applicable), C-CDA, Fast Health Information Resources (FHIR), and future transport standards.

- Prioritize complete and accurate coding at the data source (e.g., LIS, RIS) rather than trying to code or correct externally sourced data downstream.

- Require that resulting agencies provide standardized metadata, (e.g., methodology, units, normal ranges) to ordering and copy to providers as well as patients.

- Standard metadata must be maintained as result data is transmitted between systems (e.g., LISs, Imaging systems, EHRs, PHRs, HIEs, Payers, and Public Health).

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Potential Policy Actions Addressing Priority 1B

- **ONC**

  » Work with HL7 and industry stakeholders to map and harmonize USCDI to LRI, Laboratory Order Interface (LOI) & associated implementation guidance, and Argonaut-profiled FHIR, and support end-to-end stakeholder testing of discrete lab result and report transmission to providers and patients.

- **CMS**

  » Establish guidance promoting use of standards (LRI, LOINC and others) with certified HIT to address laboratory requirements for accurate reporting.

  » Include laboratory and other result transmittal requirements in Advanced Alternative Payment Model (APM) program requirements (e.g., require Medicare Shared Savings Program [MSSP] applicants to specify how provider participants will receive standards-based electronic results).

  » Reconsider "topped out" nature of electronic laboratory receipt in the Merit-based Incentive Payment System (MIPS) program. Previous requirements addressed receipt or entry of electronic laboratory information but not the structure, content and terminology associated with such receipt which should be re-introduced with these additional requirements.

  » Work with NIST to develop and provide testing program to assure compliance.

Other Federal Agencies

  » Require use of standards-based laboratory receipt in VHA, DoD MHS, IHS, and other applicable Federal provider organizations (e.g., DOJ, DHS).

Priority 1C: Results need to be available for patients/proxies to effectively view, receive, and utilize Draft Recommendations

- Require that ordering providers make results available to patients/proxies within a reasonable timeframe, as allowed by state laws, assuring that, where appropriate, providers have an adequate opportunity to review and comment on results to facilitate patient interpretation.

- Make all results in the EHR available to patients via APIs, whether or not results are LOINC/SNOMED-CT encoded.

- Develop and require the use of standardized "patient friendly" result display names to patients based on LOINC and SNOMED-CT standards (in process).

- In the future consider requiring resulting agencies to make results available directly to patients. This could initially be required via CLIA regulations. As necessary, this could be required as a condition of payment for resulting agencies.

- Alignment of state and federal policies to assure consistent and predictable patient data accessibility and interoperability. This should begin with a clear articulation of varying state requirements, followed by specification of national standards to promote maximal sharing of data with patients/proxies in both human and machine-readable formats.

Potential Policy Actions Addressing Priority 1C

- CMS

  » Make patient access to data via APIs a required measure for all relevant programs.

  » Augment program requirements to include receipt of information in other standardized structured formats (e.g., C-CDA) similar to API requirements.

  » Continue to promote patient access and API requirements using certified HIT.

- ONC

  » Facilitate completion and maturation (with relevant stakeholder feedback) of ongoing LOINC work to define patient friendly result display names.

  » Encourage and facilitate use of patient-friendly terms for patient-facing purposes.

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Priority 1D: Orderable tests need to be standardized between systems & with mapping to standard terminologies Draft Recommendations

- Develop and eventually require the use of standards-based catalogs of orderable tests with consistent mapping to associated code sets (e.g., LOINC) for all order types.

- Utilize consensus development process to develop standard orderables for the most common/important tests of each order type, including the orders that link to prioritized results.

- Standardize commonly used order panels, building on the ~2,000 order panels currently cataloged by LOINC.

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- Leverage and advance CDS Hooks standard.

- Develop and support the use of standards to determine and expose net pricing information to relevant stakeholders including providers, payers, and patients.

Priority 2B: Need standards to support Prior Authorization workflows Draft Recommendations

- A number of Prior Authorization standardization efforts are underway, including Da Vinci, NCPDP, and CMS AUC requirements. These efforts should be harmonized into a consistent approach.

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Next Domain Area for ISPTF Review

- Closed Loop Referrals & Care Coordination

  » Meetings scheduled 10/23/18, 11/13/18 and 11/27/18

Discussion of Draft Recommendations

with Dan Vreeman, Regenstrief Institute/ LOINC

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Any Questions?

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