



# Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

## Meeting Notes | April 19, 2022, 10:30 a.m. – 12:00 p.m. ET

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### Executive Summary

The focus of the Interoperability Standards Workgroup (IS WG) meeting was to work on Charge 2, which is due to the HITAC by June 16, 2022. The WG received a series of presentations on the exchange of lab data and the Interoperability Standards Advisory (ISA). WG members participated in a discussion session following the three presentations. Then, the WG discussed the list of suggested ISA topics, which were recently ranked in order of priority.

There was one public comment submitted verbally, and a robust discussion was held via the chat feature in Zoom Webinar.

### Agenda

10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	Co-Chair Remarks
10:40 a.m.	ISA – Lab Data Presentations
11:20 a.m.	ISA Priority Topic Discussion
11:55 a.m.	Public Comment
12:00 p.m.	Adjourn

### Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:30 a.m. and welcomed members to the meeting of the IS WG.

### Roll Call

#### MEMBERS IN ATTENDANCE

**Steven Lane, Sutter Health, Co-Chair**

**Arien Malec, Change Healthcare, Co-Chair**

Kelly Aldrich, Vanderbilt University School of Nursing

Hans Buitendijk, Cerner

Christina Caraballo, HIMSS

Grace Cordovano, Enlightening Results

Steven (Ike) Eichner, Texas Department of State Health Services

Jeff Ford, Department of Defense (*Attending on behalf of Thomas Cantilina*)

Sanjeev Tandon, Centers of Disease Control and Prevention (*Attending on behalf of Adi Gundlapalli*)

Rajesh Godavarthi, MCG Health, part of the Hearst Health network

Jim Jirjis, HCA Healthcare

Hung S. Luu, Children's Health

David McCallie, Individual

Clem McDonald, National Library of Medicine



Mark Savage, Savage & Savage LLC  
Abby Sears, OCHIN  
Ram Sriram, National Institute of Standards and Technology

## MEMBERS NOT IN ATTENDANCE

Kensaku (Ken) Kawamoto, University of Utah Health  
Leslie (Les) Lenert, Medical University of South Carolina  
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)

## ONC STAFF

Mike Berry, Designated Federal Officer  
Al Taylor, Medical Informatics Officer  
Matthew Rahn, Deputy Director, Standards Division

## Key Specific Points of Discussion

### TOPIC: CO-CHAIR REMARKS

Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven described the plan of work and agenda for the meeting. He explained that the topic of the presentations, the need for discrete exchange of laboratory data in such a way that it can go into workflows and be used appropriately, has been a challenge in health IT that clinicians have faced daily for many years. He described how the process of interoperating between electronic health record systems (EHRs), lab systems, and organizations has changed over the past 20+ years. Steven listed ways in which progress has been made by many different groups but also described systemic challenges and burdens that remain. He stated that a scalable, national solution is needed to work past the current solution, which involves numerous people mapping laboratory data at every organization to maintain flows of data.

Arien added that the last time a previous iteration of the IS WG (the Interoperability Standards Priorities Task Force 2019 – ISP TF 2019) addressed this topic, they concluded that there were zero interoperability barriers to complete transmission of Orders/Results. At the time (before the beginning of the COVID-19 pandemic), there were implementation guides (IG), good work from LOINC on mapping to standards compendia and Ask at Order Entry (AOE) questions, and zero structural barriers to the interoperability of lab data. However, when the pandemic struck, there were massive problems getting the demographic information associated with lab results to public health because the electronic lab orders were often only set up to transmit insurance information electronically. Progress is needed to support the bilateral workflow. He shared recommendations from the ISP TF 2019's final report to the HITAC, which were located at [https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16\\_ISP\\_TF\\_Final\\_Report\\_signed\\_508.pdf](https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf).

### TOPIC: WORKGROUP WORK PLAN

The co-chairs briefly reviewed the charges of the IS WG, which included:

- Overarching charge: Review and provide recommendations on the Draft United States Core Data for Interoperability Version 3 (USCDI v3) and other interoperability standards
- Specific charges:
  - Phase 1: Completed on April 13, 2022, following a presentation to the HITAC and approval by voice vote:
    1. Evaluate draft Version 3 of the USCDI 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: Due June 16, 2022:



1. 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.

## TOPIC: ISA – LAB DATA PRESENTATIONS

The co-chairs welcomed the following presenters:

- Riki Merrick, Lead Specialist, Informatics Terminology, Association of Public Health Laboratories
- Andrew Northrup, Laboratory Data Class Lead, Delivery Branch of the Standards Division, ONC
- Gregory Pappas, originally from the Food and Drug Administration but currently serving as the ONC leader for SHIELD
- Hans Buitendijk, Workgroup Member, Cerner

### Presentation: SHIELD Strategic Plan – Systemic Harmonization and Interoperability Enhancement for Laboratory Data 2021

On behalf of the SHIELD (Systemic Harmonization and Interoperability Enhancement for Laboratory Data) collaborative, Riki presented an ecosystem approach to laboratory interoperability. She shared a disclaimer and agenda for her presentation, which were included in [her presentation slide deck](#).

Riki provided an introduction to the SHIELD public-private collaborative, including its mission, activities to date, stakeholders, and recent challenges. (<https://aspe.hhs.gov/shield-standardization-lab-data-enhance-patient-centered-outcomes-research-value-based-care>) A key takeaway from SHIELD's work to date is that there is no single methodology that can be used to encode all the information needed from the laboratory. She gave an overview of the SHIELD Strategic Plan, which was divided into two stages and includes the pilot stage and the national rollout stage. She illustrated challenges in the current state of data workflows between healthcare providers, labs, public health reporting, secondary uses (e.g., research), health information exchanges (HIEs) and hospital data exchange; this information was detailed in the presentation slides.

Riki described pain points and discussed business needs addressed by SHIELD. She shared business use cases that covered the needs and pain points faced by laboratory and EHR file maintenance, In-Vitro Diagnostic (IVD) manufacturers, information system vendors, and clinicians. She described how the stages and strategies of the SHIELD Strategic Plan address these needs and noted that her presentation would mainly focus on Stage 1 of the strategic plan (Develop Tools and Infrastructure) and related strategies in the feedback loop. She described how SHIELD's strategies in motion would impact and improve existing workflows to share well-curated data with all stakeholders, and these potential workflow/feedback improvements were illustrated in the presentation slides.

Riki detailed action steps for SHIELD's pilot and described related work and connections between the steps, and she emphasized the need to build governance that includes all stakeholders to ensure longevity. She stated that this common meaning around lab data needs to be curated and supported indefinitely. A list of the stakeholders and the next steps for SHIELD were included in the presentation slides.

### Presentation: ISA Lab Pages

First, Gregory clarified that SHIELD is a group of volunteers and champions from many organizations that put together the Strategic Plan, noting that the plan is not binding for the government but that it is a recommended way forward. SHIELD is not an implementing body. But it encourages public and private partnerships to work together to achieve its recommendations.

On behalf of the ONC, Andrew and Gregory presented on coordination ONC has done on ISA lab web pages. Andrew introduced himself and shared a walk-through of the ISA web pages pertaining to laboratory



interoperability. He directed attendees to the ISA main table of contents page at <https://www.healthit.gov/isa/isa-document-table-contents> and explained that laboratory content is located under the following areas:

- Content/Structure tab > Content/Structure Standards and Implementation Specifications > Laboratory: <https://www.healthit.gov/isa/section/laboratory-0>
- Content/Structure tab > Content/Structure Standards and Implementation Specifications > Public Health Reporting > Electronic Transmission of Reportable Laboratory Results to Public Health Agencies: <https://www.healthit.gov/isa/electronic-transmission-reportable-laboratory-results-public-health-agencies>
- Vocabulary/Code Set/Terminology Tab: Vocabulary/Code Set/Terminology Standards and Implementation Specifications > Laboratory: <https://www.healthit.gov/isa/section/laboratory>
- Vocabulary/Code Set/Terminology Tab: Vocabulary/Code Set/Terminology Standards and Implementation Specifications > Public Health Emergency Preparedness and Response > Representing Laboratory Operations (Population Laboratory Surveillance): <https://www.healthit.gov/isa/representing-laboratory-operations-population-laboratory-surveillance>

Andrew displayed each lab-related ISA webpage, defined key terms, and briefly discussed the terminology standards and specifications.

### **Presentation: LIVD Status**

Hans presented on the status of the LOINC/IVD In-Vitro Diagnostic (LIVD) Mapping Implementation Guidance. (<https://ivdconnectivity.org/livd/>) He began by depicting the interplay and workflows between IVD and LIS test/result mapping, including flows between EHRs and public health, which were [depicted in his presentation slides](#). He stated that the encoding and the availability of coding are based on LOINC or LIS test codes, and it is all standardized. He described how IVD Tests are mapped to IVD Result Values and then how this is mapped to LIS Tests and Result Values, noting the same test (depending on context) can map to different LIS Tests/Results values. He explained the process by which LIS Test Results are mapped to LOINC and LIS Results Values are mapped to either LOINC or SNOMED, depending on what is appropriate. Hans emphasized that the current process requires human intervention and individual interpretation to complete the mapping. A future scenario would have the LIVD create a mapping catalog that identifies the most likely and appropriate mapping for the workflow. He noted that different LOINC codes could be generated from one test, depending on a variety of contexts.

Hans discussed the status of LIVD, and he described its history and goals by highlighting which items have already been published, which are currently in use, and which are in progress. He briefly explained the balloting and publication process. He explained that the information is guidance and not authoritative and included weblinks within his presentation slides.

The co-chairs thanked the presenters and invited all attendees to share comments and questions with the presenters.

### **DISCUSSION:**

- In response to a request from Arien, Riki explained that the acronym LIDR refers to the Laboratory Inventory Data Repository. She stated that SHIELD wants to have information that is available in LIVD and any other metadata about the lab tests to be available for inquiry.



- In response to comments made in the public chat in Zoom during the ONC presentation on lab-related ISA webpages, Arien described the steps in the ISA Standards Maturity Process. Also, he described how previous public-private partnerships developed the LIR and the LOI specifications and certifications. He stated that because lab results were routinely performed and delivered electronically, they have not gotten to the point where lab results are standardized, nor have they not gotten to the next step of lab orders. Because that work was not completed when they were impacted by COVID, the infrastructure was not set up by which both Laboratory Orders Interface (LOI) and Laboratory Results Interface (LRI) would have provided a direct flow into electronic lab reporting (ELR) and then be the infrastructure for SHIELD and LIVD. (<https://oncprojectracking.healthit.gov/wiki/pages/viewpage.action?pageId=30834747> ) He encouraged WG members to re-read previously completed reports to the HITAC and ONC.
- At the conclusion of the presentations, Arien described the current state of interoperability of lab data and noted that “interoperable,” in this context, means that the information is available in a structure with terminology that is clinically interpretable which would allow decision support tools to be provided for the patient to enable appropriate clinical and patient self-management. He stated that to achieve this, elements of lab data must be coded with LOINC as the test, the numeric result with a UCUM units of measure, or SNOMED-CT for a non-numeric, qualitative result. He discussed where data originates, how encoded data moves in workflows, and he described tools and different terminologies that are used by labs in mapping. He described how smaller hospitals in particular may use proprietary terminologies to do this mapping manually and the resulting challenges. He stated that the future state envisions a world without all of the manual mapping and lack of standardization in which information that flows from the IVD is pre-normalized to the appropriate LOINC code and then to the LIS, with the results also supported by pre-normalized mappings. Full end-to-end mapping would exist in a future state between the order and the orderable and through workflows, including public health reporting and other data streams.
  - Hung commented on how even very high levels of precision of mapping are not adequate to for all the variations of the future use of lab data (i.e., the use of real-world evidence and patient-generated data for regulatory decision making is difficult without knowledge of the platform from which it was generated). An ecosystem approach is necessary because no single ontology is sufficient to support all the robust interoperability uses. The plan is for a series of standardized codes to serve as a “fingerprint” for the lab results so they retain all information and current/potential use cases as they flow through the healthcare ecosystem.
- Clem submitted several comments:
  - He supports the use of LIVD to solve problems.
  - Lab tests usually go to the laboratory system first and not directly to the medical record, so laboratory stakeholders must be involved.
  - Some tests are already very standardized using international standards, so be cautious about making the standards for the process too difficult to achieve.
- Hans stated that mapping lab data to the device is a challenge and suggested ways in which the mapping could be done. He asked the WG members to consider what solutions are most realistic. If the intent is to map to the device using the proper LOINC and SNOMED-CT codes, it will be difficult to achieve, and he suggested that the focus should be on mapping in the LIS and how to make this process easier using automation.
  - Arien clarified that the orderables should be delivered to the LIS in a standardized way so the LIS can drive the underlying lab workflow in a more automated way, with the understanding that there will be some mapping.
  - Ike commented that there are other data being provided to public health through the laboratory information management system (LIMS) and asked if there are other ways of routing data to avoid the need to have the LIMS be modified continuously to support workflows. Arien explained that this information is collected using ask on order entry (AOE) fields in the workflow, which are being standardized; this work is being encoded in the LOI



and companion information.

- Arien commented that before the IS WG makes recommendations, they should review the ISP TF recommendations made previously to the HITAC and ONC. Steven supported this suggestion and invited Riki and Hung to join the co-chairs in putting together a draft of a revised and updated set of recommendations based on those that were made previously. Arien noted that the previous recommendations assumed that all the regulatory levers were available to drive broad scale lab interoperability. Recent work from SHIELD and LIVD can be applied. The link to the previous recommendations was included in the public chat in Zoom.
- Clem discussed the partitioning of lab tests and shared statistics on the mapping and coding of lab tests. He stated that the majority have the specimen type built into the test name and code and suggested that by parting these lab tests off, achievements could be maximized. He added that the policy levers have not been applied, so the WG should recommend this activity as a key point of activity. WG members discussed whether they could ask for ONC's position, and Arien suggested that Gregory could share ONC's policy view and shared policy goals between ONC, FDA, and HHS, rather than discuss regulatory levers.
  - Hung shared his concerns about using regulatory levers now and described the challenges labs face around the accuracy of coding lab data. He cited research that found that there is only around an 80% accuracy rate around the LOINC coding for common lab tests, and none of the laboratories did coding correctly for highly standardized tests. Labs are trying, so putting additional pressure on them when they have already demonstrated that they are struggling may be a mistake. SHIELD's approach to move efforts upstream to the IVD manufacturers would ensure that the information provided to labs is pre-curated and empowers them.
  - Arien discussed pain points or potential points of failure around mapping and emphasized that the mapping problem must be prioritized.



- Mark highlighted the need for patients to have equal access to lab results and asked for clarification as to whether this is in scope for the WG's ISA work. Should standards be identified for patients in the Fast Healthcare Interoperability Resources (FHIR) APIs?
  - Arien referenced previous task force recommendations that emphasized the need to make information available to patients via FHIR-based APIs so that data can flow electronically. Mark responded that he would review and sharpen older recommendations. Grace commented that the older recommendations document is robust, and there is an opportunity to have continuity between that document and the current WG's recommendations.
  - Hans suggested reviewing the recent IS WG 2022 recommendations on the USCDI v3 and comparing them with the previous task force recommendations to see what kinds of data are being exchanged. Arien commented that the WG just made recommendations for the USCDI to include interpretation codes and other missing elements. The WG will now need to add in learnings from the pandemic and to focus on public health.
- Jeff asked WG members to comment on interoperability standards for the dental community (including small and large clinics, the VA and DoD, and others). Can they be merged into the healthcare delivery model?
  - Steven responded that there has been a broad gap between dental and other medical/health information. Though the focus of ONC has been on healthcare, dental use cases could and should be considered.
  - Jeff responded that dental care delivery is healthcare delivery and described how more specialized dental care has more in-depth uses, like IV sedations, checks on pregnancy status, or surgery for periodontal disease or cranial abnormalities. He suggested that closing the gap in standards could be useful.
  - Clem commented that all of the standards that exist in FHIR are fit for delivering dental information and that standards for dental codes exist in LOINC. Dental providers must embrace options.
- Hung commented that there are harmonization measures that could be taken, including a harmonization indicator discrete data element to alert downstream users that the test has already been harmonized at the vendor level. There is an opportunity to raise the profile of harmonization efforts that have already been performed. (<https://www.harmonization.net/>)
- Clem commented that there is a spectrum of differences amongst instruments and how they map to tests. Newer instruments are "smarter." The WG will have to push for the use of LIVD.

## TOPIC: ISA TOPIC PRIORITIZATION DISCUSSION

IS WG members reviewed the specific Phase 2 charge (listed above), and, previously, WG members were asked to prioritize the ISA topics by ranking them in order of importance. Arien explained how these rankings were collected and tabulated, and he shared the prioritization framework via a working Google spreadsheet in which WG members already began to compile information on each of the priority topics, including observations, recommendations, policy levers, use cases, specifications, and more. He stated that just because a use case is lower in the WG's prioritized ranking, it does not mean that the WG will not make recommendations. He encouraged members to look for areas where the ISA is not tracking a known use case or standard and to share thoughts about connections between the ISA and the USCDI in the working document.

The list included:

- High Priority:
  - Lab Orders/Results: Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD)/LOINC In-Vitro Diagnostic (LIVD) test code mapping tool
  - Social Determinants of Health (SDOH) Standards: Centers for Disease Control and Prevention (CDC) Race/Ethnicity vocabulary subsets



- Lab Orders/Results: laboratory information system (LIS) to electronic health record (EHR)/public health (PH) systems
- SDOH Standards: Gravity Project Standards
- Medium Priority:
  - CDC: Electronic Case Reporting (eCR) Standards
  - Care Plans/Chronic Dx Management
- Additional Priorities:
  - HIPAA right to request corrections to one's medical records
  - CDC: PH Data Systems Certification
  - Portal Data Aggregation Across Multiple Portals
  - Data Exchange Formats for Price Transparency
  - Data Sharing Between Federal & Commercial Entities
  - Occupation and Location of Work

#### DISCUSSION:

- Hans asked for clarification on the intent of the working documents and whether suggestions for policy levers and adoption tools should be shared.
  - Arién confirmed that this was the intent and explained in-scope ways in which the WG can make recommendations related to the ISA. If the WG wants to make recommendations that are deeper (beyond tracking), it will have to use the prioritization framework to determine which use cases should be considered first.
  - Mark suggested framing use cases in the ISA and stated that this would be useful for the SDOH and Gravity Standards.

## Action Items and Next Steps

Homework for this April 26, 2022, IS WG meeting includes:

- Document observations and recommend additional ISA topics in Google Sheet.
- Hans, Hung, and Riki Merrick have reviewed the lab-related recommendations pulled from the 2018/2019 ISP Task Force reports and provided redline comments in a Google doc. Please review and add your comments as well.
- WG members who have not yet ranked the ISA topic priorities should do so in the ISA Priorities Google Sheet

## Public Comment

### QUESTIONS AND COMMENTS RECEIVED VERBALLY

There was one public comment received verbally:

Adam Davis, MD Sutter Health: This is Adam Davis from Sutter Health, and I'm also the co-chair for the Care Everywhere Governing Council for Epic and the co-chair of the Data Usability Workgroup for the Sequoia Project. I wanted to comment that lab interoperability is important to clinicians, as we all know. I think the final solution of getting back to the instrument level and having perfection of the mapping is a great goal, and I think there is a real vision for that. Seeing some of that vision laid out today was really inspiring. I do wonder if there is an opportunity for a parallel path for lower-hanging fruit. As Dr. Lane talked about at the beginning of the meeting, there are efforts at some health systems to map certain labs but the process is quite laborious, which has led health systems to the abandon that for trending and clinical decision support and quality measures. I wonder if there is a pathway to doing some parallel work to allow already standardized or harmonized labs, such as sodium or creatinine, to be more easily mapped between health institutions while we wait for that instrument-level mapping. I think there is a big split between what clinicians care about in





terms of those labs and what lab directors do. We, at the clinician level, actually don't really care what the reference range for that sodium is because I have a general idea is a 140 is a 140 is a 140. I know that is not true for all labs, but I wonder for some of the labs we could work towards that, while waiting for this more permanent solution. Thank you.

#### WG MEMBER RESPONSES AND DISCUSSION:

- Riki: One of the things that SHIELD is working on is prioritizing which labs to identify, and we do know that there is a list of harmonized tests that are harmonized to an international standard. Those are definitely on the docket to be included. Part of SHIELD is a parking lot/next step where we will look at the harmonization aspect of other lab tests that are not yet harmonized to an international standard, so that is something that comes up on our calls regularly. It is definitely on top of mind, as well, but that requires different expertise than the data side of things.
- Steven: The key point that Dr. Davis is raising is can we make a plan that produces an early result for those harmonized labs that could be put into practice, say next year, in addition to this longer process, which clearly is needed and is on the right track, but which will take time.
- Arien: It sounds like the WG recommends that ONC work with other federal stakeholders to accelerate interoperability for the class of lab results that account for 90/10 power-law dynamics for the number of lab tests that account for the vast majority of lab results.

#### QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Michael Berry: Welcome to the Interoperability Standards Workgroup. We will be starting soon. Please remember to change chat to "Everyone" if you would like everyone to see your message. Thanks.

Jim Jirjis: Jim Jirjis Joined

Arien Malec: I want to point the work group back to our recommendations from 2018, revised 2019, on Orders/Results (and other topics)

Arien Malec: [https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16\\_ISP\\_TF\\_Final\\_Report\\_signed\\_508.pdf](https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf)

Mark Savage: Is or should the patient's right of access to lab results be a part of this ecosystem and discussion? Perhaps another great use of the patient-facing FHIR API. Appears that patients are not part of the stakeholders involved?

Arien Malec: If we go back to the recommendations we made in 2018/19, we firmly address patient use cases.

Arien Malec: But all these uses \*assume\* that interoperable data is generated at source.

Steven Lane: There will be a clear need for policy levers to require labs to participate and comply with this system/solution. Is there a way to work on this need now, in parallel with piloting the LIDR solution, so that we can enjoy the benefits of this functionality ASAP once it is available and proven?

Arien Malec: I keep going back to our report and thinking - yeah, do that.

Arien Malec: Use CLIA, FDA regulatory oversight, establish certification criteria for LIS, EHRs, public health systems.

David McCallie: What kind of data is in LIDR? Is it actual results, or just metadata about tests?

Arien Malec: Tie programs to bilateral standards-based exchange aligned with SHIELD.



Arien Malec: IVD to LOINC mapping, I believe... — metadata about tests.

Steven Lane: Who pays for all this?

Arien Malec: We do? Taxpayers mostly?

Steven Lane: Members of the public - Please consider updating your display name to include the organization that you are representing.

David McCallie: who would implement LIDR?

Riki Merrick: That is why we have business cases described in the plan - for example IVD vendors have an interest in having the IVD data hub as well as support for IHE LAW implementation

Steven Lane: We welcome public comment, here in the meeting chat, which becomes part of the public record for this meeting and can be referenced in the future. We also reserve time at the end of the meeting for verbal public comment. If there is apparent interest in taking advantage of this opportunity we can dedicate additional time to public comment. Feel free to express your interest in this opportunity here so that we can go to public comment early if needed.

Arien Malec: If you go back to the recommendations we made in 2018, this would get populated on approval (PMA, 510k) using FDA regulatory authority, and via LISs using CLIA regulatory authority, & we need to work out the funding model for the central infrastructure. *[sic]*

Riki Merrick: there may be others in the healthcare ecosystem that will pay for support rather than keeping funds for data mapping

Grace Cordovano: Can someone explain what “balloted” means with respect to Standards Process Maturity?

Riki Merrick: CLSI-AUTO-16 = IHE LAW

Arien Malec: Balloted means that it went through a formal voting and review process at a standards organization (HL7 in this case).

Grace Cordovano: Once balloted, does that make the standard “draft” or “Final”

Mark Savage: “Balloted Draft” – when this designation is assigned, the standard or implementation specification is considered to be a Draft Standard for Trial Use (DSTU), Standard for Trial Use (STU), or in a “trial implementation” status by the organization that maintains it and has been voted on or approved by its membership as such. This designation does not include standards and implementation guides that are unofficial drafts and early “works in progress”.

Arien Malec: There’s a separate step to get to “Standard”

Riki Merrick: The FHIR Lab catalog is eDOS on FHIR

Mark Savage: <https://www.healthit.gov/isa/isa-structure>

Arien Malec: As Mark noted, we go from DSTU to STU to Standard in HL7.

Steven Lane: The costs of standing up and maintaining mapping have become s limiting barrier for organizations attempting to interoperate discrete lab data. For organizations which have started doing this work, the value proposition of this will be clear. For others, who have not yet begun mapping, it will be more challenging to contemplate additional costs related to transmitting/accessing lab results.



Arien Malec: @Steven, sadly many community hospital labs have historically used proprietary terminology and haven't incurred the cost of mapping.

Riki Merrick: many implementation guides go through Standard for Trial Use (STU) stage in order to test what works and what doesn't rather than making it normative right away - the difference is just that it is a bit easier to adjust in STU vs normative

Gregory Pappas: SHIELD will publicly release the Strategic Plan in coming weeks.

Riki Merrick: Note that LOI and LRI R3 are actually published - we are in the process of publishing the next release

Riki Merrick: DSTU got renamed to STU - it's the same

Steven Lane: Are LOINC and SNOMED competing in this space, or have they carved up the work, each doing their own subset? At the very least we should hope that we can identify a single international standard to avoid the confusion of having to maintain mapping between standards.

Riki Merrick: From the LIVD perspective LOINC encodes the performed test, SNOMED CT encodes qualitative result values, specimen information

Riki Merrick: and we also support UCUM for units of measures

Hans Buitendijk: Note that in latest LRI version(s) ELR is fully incorporated as a profile.

Steven Lane: Thanks Riki. Reassuring. This differentiation should be made crystal clear in the ISA itself.

Riki Merrick: LRI R3 has the PH component - that is essentially the newer version of ELR, but ELR R1 is what most PHAS have implemented, so might take a bit to migrate them

Arien Malec: Thanks you — sorry for the confusion on DSTU/STU.

Riki Merrick: @David - We still need to find a home for LIDR - it needs to be supported by folks that are knowledgeable in mapping to LOINC and SNOMED CT and should be accessible by ALL lab data users - both human readable and via computer systems

Arien Malec: And IVD stands for In-Vitro Device, AKA "lab analyte machine"

Arien Malec: <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation#:~:text=Definition%3A%20In%20vitro%20diagnostic%20products,prevent%20disease%20or%20its%20sequelae.>

Arien Malec: "In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae."

Steven Lane: (Another acronym within an acronym...)

Riki Merrick: currently we distribute the LIVD for SARS-COV-2 as a spreadsheet through a CDC webpage, since the use case is for reporting to Public health - this was the fastest, easiest way to share the information, but there are for sure better ways to do this

Steven Lane: The key question for our Workgroup is what shall we recommend that ONC do to support this work?



Arien Malec: I'd like go back to our 2018/19 recommendations and get sharper here with more reference to SHIELD/LIVD....

Grace Cordovano: Arien, I like that idea. The recommendations document looks very robust and updating them with 2022 recommendations would be useful and provide continuity.

Riki Merrick: we also want specimen information encoded in SNOMED CT

Steven Lane: We also want the lab orders to be interoperable so that patients can choose where to go to have their testing done with the assurance that the result will reliably get back to the ordering and any CCed providers as well as the patient themselves (and be available for future access via query).

Mark Savage: To @Steven question, can, or how can, ISA as a catalog of available standards and suggestion of use cases connecting dots help build business models and policy incentives?

Hans Buitendijk: The ISA is a library of most current, known standards/implementation guides. Other programs (certification, etc.) would consider those for inclusion. So in itself, the ISA does not really move the needle.

Hung S. Luu: Platform information (instrument and kit UDI) are essential for decision support, comparability and real world evidence use.

Riki Merrick: HUNG+1

David McCallie: Seems like the first step is to get standards at the source - the IVD device, and then ensure that info flows downhill thru the rest of the system

Adam Davis: It seems like there is a lot of work to do and allow interoperable labs all the way from the instrument to the end user. I support that goal, but in the meantime as we work towards that goal is there a parallel pathway that could be taken to allow the currently "harmonized" or "standardized" labs to be more easily exchanged without laborious mapping efforts? I mean clinicians don't care about the details of the machine or even the reference range for the sodium they measured on a patient. For the common labs which have been lower variance at the lab level we need tools now to automate the mapping so creatinines [*sic*] and hgba1c's can be trended while awaiting for the more global solution.

Riki Merrick: yes - that is the idea!

Hans Buitendijk: At source (IVD Test) the challenge is to have the context that would determine correct LOINC/SNOMED map. That means they would need information from the LIS to do it there.

Steven Lane: We will go to raised hands next

David McCallie: @hans - no, that mapping has to get added later. The machine only knows about itself. But that info makes all the downstream mappings easier?

Riki Merrick: Yes - IVD needs to provide ALL POSSIBLE LOINCS for their test (they may pick the one that best describes what comes off their machine, but clinical context may need to be added by the LIS for a specific patient result - they do that when they set up the instrument in their LIS.

Riki Merrick: Yes Clem - IVD - to LIS - to EHR-s

Arien Malec: @clem — my statement is that the end of a lab workflow is for the record to be available to the EHR or the patient or the public health system at the end, and to get there we need to go to the LIS and lab workflow with IVDs.



Adam Davis: @clem, here here!

Steven Lane: Members of the public should review Recommendation 23 that our WG presented last week to HITAC and which have been formally transmitted to the ONC.

[https://www.healthit.gov/sites/default/files/facas/2022-04-13\\_IS\\_WG\\_Phase\\_1\\_Recommendations\\_Report\\_revised.pdf](https://www.healthit.gov/sites/default/files/facas/2022-04-13_IS_WG_Phase_1_Recommendations_Report_revised.pdf)

Steven Lane: Also Recommendation E on Page 12.

Arien Malec: That LIMS information is reflex/AOE and collected in EHRs.

Riki Merrick: Ike - I agree - that's the discussion to use the eCR dataflow for data that Labs don't need to make result determinations

Hans Buitendijk: AOE's can be asked for, or pre-populated where already available.

Riki Merrick: we should get away from moving PH data that labs don't need through that flow and support better implementation of eCR = data flow out of the EHR-s to PH

John Loonsk: +1 Riki

Arien Malec: Yes, lab + eCR should be the standard workflow we work towards...

Hans Buitendijk: +1 Riki

Hans Buitendijk: That means we need to look at a mix of LRI/ELR and eCR to address Public Health and research needs.

Riki Merrick: Can you share the link to the 2018 recommendation in the chat

Hung S. Luu: Happy to help

Riki Merrick: Happy to help

Arien Malec: [https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16\\_ISP\\_TF\\_Final\\_Report\\_signed\\_508.pdf](https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf)

Riki Merrick: Thank you!

David McCallie: funny that clinicians know what those tests mean, even if the codes are not consistent. But I agree we ought to fix this.

Steven Lane: In the 2019 Taskforce recommendations the relevant Laboratory-related recommendations begin on Page 7 with recommendations regarding patient access to lab results on Page 17.

Steven Lane: Wit additional lab-related recommendations going on from there.

Grace Cordovano: From the 2018/2019 recommendations "Patient Access to Data Observations: Patients' access to their own data is important for patient-centered, patient-engaged care. A detailed discussion with recommendations is provided in the Orders & Results section below, but this issue affects more than orders & results.

Recommendations:

- Support patients' access to their data, in realms beyond orders & results (e.g., clinical notes, goals, care plans, histories, and vital signs). "



Arien Malec: Our glaring omission from that report was, uh, public health.

Grace Cordovano: [https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16\\_ISP\\_TF\\_Final\\_Report\\_signed\\_508.pdf](https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf)

Arien Malec: And research.

David McCallie: @hans +1 - the missing data elements!

Riki Merrick: +1 Hans

Grace Cordovano: Arien/Steven, could you clarify by what you are more specifically looking for in the Observations column?

Steven Lane: Observations = What we see in the ecosystem today, what needs exist, what potential solutions, etc.

Riki Merrick: If we have the list of harmonized lab tests we could populate the MVP of LIDR with those codes to make them accessible

Arien Malec: In my previous work, a very very small number of tests accounted for the vast majority of results — getting these results right should be an early priority....

Steven Lane: Does anyone have a link to the list of harmonized labs?

Arien Malec: Random Googling got me here: <https://www.harmonization.net/measurands/>

Arien Malec: Not sure if that's the right resource.

Carmela Couderc: <http://build.fhir.org/ig/HL7/dental-data-exchange/>

Hans Buitendijk: Agreed that where devices can receive order information, and have that LOINC encoded, the device can do it.

Hans Buitendijk: But that appears to still be a minority.

## QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

## Resources

[IS WG Webpage](#)

[IS WG – April 19, 2022 Meeting Webpage](#)

[IS WG – April 19, 2022 Meeting Agenda](#)

[IS WG – April 19, 2022 Meeting Slides](#)

[HITAC Calendar Webpage](#)

## Meeting Schedule and Adjournment

Steven and Arien thanked everyone for their participation, summarized key achievements from the current meeting, and shared a list of upcoming IS WG meetings. Steven explained that the WG would have another chance to provide detailed commentary and rankings and to share questions on topics.

The next meeting of the IS WG will be held on April 26, 2022.

The meeting was adjourned at 12:02 p.m. E.T.