COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #44

Thursday, *February 17, 2022, 12-1 PM ET*

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #44

This week's Diagnostics Evidence Accelerator meeting consisted of 2 presentation:

1. IICC Introduction (Serge Jonnaert, IVD Industry Connectivity Consortium and Ed Heierman, Abbott)
2. Lab Data Interoperability Opportunities (Charles Halfpenny, Consultant, and Eric Crugnale, Sunrise Medical Laboratories)

IICC Introduction (Serge Jonnaert, IVD Industry Connectivity Consortium and Ed Heierman, Abbott)

The slides deck from this presentation can be found on EvidenceAccelerator.org.

The IVD Industry Connectivity Consortium (IICC) began in 2009 with the mission to modernize connectivity between laboratory IT systems and analyzers, to standardize data workflows and make them more secure, but also to reduce the overall cost of deployment and support. The current members of this consortium are volunteers representing leading IVD companies such as Abbott Laboratories, Beckton Dickinson, BioMérieux, Roche Diagnostics, Siemens Healthcare Diagnostics. The goal of the consortium is to create and ensure adoption of an interoperable connectivity paradigm to reduce the complexity and variability of data exchange between IVD testing systems and healthcare informatics systems.

The COVID-19 pandemic exposed major challenges in collecting and aggregating laboratory data and other sources in a uniform way for acute epidemiology reporting and analysis. This challenge was experienced at both the state and national level. Additionally, there were no semantically standardized formats captured at the source (e.g., laboratory, POC, At Home tests), therefore there were a lot of assumptions made. On June 4, 2020, the Department of Health and Human Services (HHS) issued laboratory data reporting guidance for COVID-19 testing to "assure the timely and quality data reporting to state and federal public health agencies". However, many labs were unable to accommodate the requirements into their existing infrastructure.

Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) is a collaboration FDA (CDRH, CDER, CBER), CDC, NIH, ONC, CMS, IICC, LOINC/Regenstrief, SNOMED, EHR Vendors, Laboratories, Standards Developers, and Academia. They worked to unlock electronic health data through the use of real-world data (RWD) and real-world evidence (RWE). IICC's Laboratory Analytical Workflow (LAW) and LOINC for IVD (LIVD) standards supported the main objectives of the SHIELD work. The team recognized that they needed to engage the IVD industry (i.e., IVD Instrument

and test manufacturers and Middleware and LIS suppliers) early to help with applying the new standards and provide LIVD test catalogs. As long-term goals, the IICC would like to enable LIVD FHIR downloadable files; implement LAW/AUTO16; and drive participation in IICC, LOINC, SNOMED, HL7 FHIR, and SHIELD.

IICC is working with IVD companies and laboratories to replace outdated standards with LAW profile. It allows labs to have different layers of data flow and provides the mechanism to send work instruction from the LIS in a standardized format to the instruments. For example, a LIS can have a test order that needs to be sent to an instrument such as an Abbott. If that instrument is unavailable, then the LIS can send the test order to an instrument from a different vendor. This solution is vendor agnostic and will report the data in a standardized format. LIVD will assure that the selection of a test is the right one and the instrument receives the proper instructions and reagent. The data that comes back from this instrument to the LIS will be semantically harmonized and, in a format, where laboratories are able to send the data upstream for further processing.

LIVD is an industry format for publication of LOINC codes for identification of vendor IVD Test Result. This was developed in collaboration with many members from industry. The output is in a human readable format allowing for laboratory personnel to verify the information. Additionally, there is automatic mapping of IVD vendor test result by the LIS. LAW standardizes the data flow of IVD patient and QC Analytical Work Order Steps (AWOS) and test results between instruments, middleware, and LIS systems. This is a standard that is globally published as the IHE LAW Profile and is a public standard that is ready for implementation. This reduces connectivity installation cost and time. This was recast as CLSI AUTO16, replacing LIS01 and LIS02.

The goal of the work that is being conducted is to have a RWD repository that is harmonized and flows from instrument to LIS to electronic health record (EHR). RWD must be complete, consistent, accurate, and contain all critical data elements. LAW and LIVD help IVD Test Results meet these criteria at the very beginning of the journey. Both LAW and LIVD are the first steps to enabling Real World Evidence (RWE) based on IVD test results. LAW supports RWE by the following:

- Improves integrity of patient test result data;
- Requires unique identification of order request at the test/panel level;
- Supports LOINC, JLAC10, and SNOMED CT vocabularies;
- Requires UCUM as the vocabulary for units;
- Requires identification of the instrument performing the test and supports Unique Device Identifier (UDI);
- Provides the ability to capture and send structured, standardized data from the instrument; and
- The LAW content provides Complete, Consistent, Accurate, and Critical Data Elements to use IVD Test Results as RWE.

LIVD supports RWE through the following:

- Supports vendor IVD instruments and manual test kits;
- Requires identification of the equipment performing the test and supports Unique Device Identifier (UDI) for the IVD instrument;
- Establishes the LOINC code for a specific configuration of an IVD Test Performed; and
- The LIVD mapping content provides Consistent, Accurate, and Critical Data Elements to support Real World Evidence workflows requiring Test Performed Identification of IVD Test Results (e.g. comparison of IVD Test Results)

The following FDA activities allowed IICC to conduct the work discussed in the presentation:

- The release of FDA Guidance on LOINC for In Vitro Diagnostic Tests (2018) was released in support of LIVD. The guidance intended to address concerns from IVD Manufacturers.
- The announcement of Medical Device Safety Action Plan (2018) allowed the IICC to improve the ability to synthesize data from different electronic health information sources through NEST (National Evaluation System for health Technology). NEST supports the vision to *"Establish a robust medical device patient safety net in the United States"* (CLSI AUTO16, 2019). Additionally, Medical Device Safety Action Plan advanced medical device cybersecurity through the CLSI AUTO11.

The next steps for IICC to further their work is listed below:

- Enhance the LIVD standard in support of an authoritative Laboratory Information Data Repository (LIDR)
- Launch LIVD evangelization/educational program. Drive IVD manufacturer and national lab groups adoption program
- Further research and develop semantic interoperability standards that are secure, well-structured, and easy to implement and maintain by IVD manufacturers
- Drive adoption by IVD manufacturers through concerted effort of continued evangelization and education
- Expand LIVD and LAW functionality, including Value Set, UDI, LIVD on FIHR, Specimen Mapping, interface improvements, and integration with emerging frameworks (e.g. SOLOR)

Questions and Answers:

- Why do IVD manufacturers want to support IICC?
    - Given the new technology and standards, IVD manufacturers do want to have a cost-effective and time effective solution that will be beneficial for them and their partners. IICC allows for manufacturers to adopt that solution. Additionally, this solution allows for semantic interoperability for all manufacturers. As additional data make its way upstream, there is an opportunity to take advantage of the data for other public health uses.
- In regards to semantic interoperability, was there considerations given to the Library of Medicine's Unified Medical Language System as a unifying reference ontology?
    - This did not come up in the discussion. In 2009, IICC view of semantic interoperability was to understand work flows of laboratories. Since then, they have discovered that the information and data apply to other systems in the IVD manufacturer space.

Lab Data Interoperability Opportunities (Charles Halfpenny, Consultant, and Eric Crugnale, Sunrise Medical Laboratories)

This question and answer session looked at the different lab data interoperability opportunities that are connected to understanding the data flow four essential data elements (i.e., test name, specimen collected date, test result, and test result date). This session was moderated by Susan C. Winckler, the CEO of the FDA Foundation.

Question: Based on your experience, how should the Evidence Accelerator community think about the essential elements? Should we think about the elements as a package or think about the elements individually to achieve data flow into claims and EHR data?

Charles Halfpenny: There are three data elements that will flow to the EHR: collection data, result date, and test result. The challenge is in achieving flow of test name. The name starts of as a code that is local

to the institute that is performing the test. There was a push in industry to have a testing dictionary mapped to LOINC to allow for the flow. However, this did not happen.

Eric Crugnale: With COVID-19, there were many tests that are performed. Therefore, the challenge with test name came up many times. Practical challenges such as laboratories refusing to change the test name to a name that was being used by other laboratories due to their clients not wanting a certain name created barriers. Additionally, there are barriers that clients face in their ability to map LOINC codes to the test names that the different laboratories provided.

Question: What is the primary hurdle to achieve lab data interoperability?

Charles: The primary hurdle is having test name normalization. It is a challenge as larger labs acquire the smaller, independent labs. Some labs will keep the independents labs coding system where as other labs will harmonize the coding system into one standard system. This is similar in health systems where the coding system between hospitals can differ within the different hospitals in the health system. A solution to this is to fix the standardization at the source so that the information can flow from the instrument to the LIS to the EHR. In order to have a solution 'today' for RWE, there will have to be development of initiatives that will have mapping capabilities. This will require a collaboration with LIS vendors and middleware vendors.

Eric: The challenge is with the LIS. The independent and commercial laboratory were not developed for meaningful use. However, when providers started using EHRs, they wanted to have their lab data connect with the EHR. There are many commercial labs that do not have a place to store a SNOMED code or LOINC code to a result code. Therefore, they have to rely on middleware to support this function and there are not many standards to support this. Additionally, incentivizing the labs to support this can be beneficial. This will allow labs to make the necessary updates that are needed.

Charles: Additionally, sharing benchmarking data with the labs could prove to be beneficial as well. The LIS serves a work flow function and getting the information back to the client. The LIS was not built for population health reporting. In prior health reporting, middleware has been used to achieve population health reporting.

Question: Is middleware instead of LIS a better solution as we think about connecting the lab specific data to the real world?

Serge Jonnaert (IICC): Middleware is the solution to the lack of standards. This is something that is IVD industry is working on eliminating because there is a need of one semantic data flow.

Charles: There is a need of additional standards that need to be adopted. When the manufacturers adopt those standards, then the LIS will adopt those standards. For now, we have to work with middleware.

Question: What is one thing that you can do to improve lab interoperability and the sharing of results?

Eric: There a lot of opportunities to update LIS, however, for short term solutions, looking at the middleware can be beneficial. We can apply AI to the middleware layer as a short-term solution to improve lab interoperability.

Charles: For the data that has infectious disease testing, there is opportunity of providing mandates or incentivizing the labs that are providing the data. For example, applying meaningful use requirement for healthcare providers was a driver to bring Medicare cost down. A similar solution can be applied for labs and LIS systems.

Next Steps

- Continue making data connections through the Evidence Accelerator and through www.EvidenceAccelerator.org.

Next Meeting: Thursday, March 17, 2022 12-1 pm ET