IVD Industry Connectivity Consortium

IVD LOINC Vocabulary Update

June 7th, 2018
What is the IVD Industry Connectivity Consortium?

- **Mission**
  - Modernize connectivity between laboratory IT systems and analyzers
  - Enable clinical laboratories to achieve more and spend less

- **Members:** Abbott Laboratories, A&T, Beckman Coulter, Beckton Dickinson, bioMérieux, Data Innovations, Hitachi, IZASA SA, Orchard Software, Ortho Clinical Diagnostics, Roche Diagnostics, Samsung, Siemens Healthcare Diagnostics, Sunquest Information Systems, and Systelab Technologies SA.

Mission: "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"
LAW Laboratory Analytical Workflow

- Standardizes the data flow of IVD patient and QC analytical work order steps (AWOS) and test results between instruments, middleware, and LIS systems
- Is a global standard published as the IHE LAW Profile
- Is commercially available and ready for implementation
- Will be published as CLSI AUTO16, replacing LIS01 and LIS02
- Substantially reduces connectivity installation cost and time
LIVD LOINC for IVD

- Industry format for publication of LOINC codes for identification of vendor IVD Test Results
- Human readable format for use by laboratory personnel
- Enables automatic mapping of IVD vendor test result by the LIS
- Developed in collaboration with
Using IVD Test Result Data in Real World Evidence Workflows

- An IVD Test Result’s journey to an electronic repository of Real World Data (RWD) begins at the IVD Instrument
- Real World Data must be Complete, Consistent, Accurate, and Contain all Critical Data Elements
- LAW and LIVD help IVD Test Results meet this criteria at the very beginning of the journey
- LAW and LIVD are the first steps to enabling Real World Evidence (RWE) based on IVD Test Results
Using IVD Test Result Data in Real World Evidence Workflows

- CLIAC (Clinical Laboratory Improvement Advisory Committee) Meeting in April, 2018
  - Laboratory Interoperability was on the committee agenda
  - LAW and LIVD were discussed
  - The committee response was very positive
  - The committee drafted a recommendation for the use of LAW and LIVD by the industry
How LAW Supports Real World Evidence

- **Improves integrity** of patient test result data
- Requires **unique identification of each order request** at the test or test panel level
- Supports **LOINC**, JLAC10, and **SNOMED CT** vocabularies
  - **LOINC** is recommended as a standard vocabulary for Observation Identification
  - Provides guidance on populating CE data type when **LOINC** is used for Observation Identification
  - However, many manufacturers use vendor-specific 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
- The LAW content provides Complete, Consistent, Accurate, and Critical Data Elements to use IVD Test Results as Real World Evidence
How LIVD Supports Real World Evidence

- 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 Result
- The LIVD mapping content provides Consistent, Accurate, and Critical Data Elements to support Real World Evidence workflows requiring Test Result Identification of IVD Test Results (e.g. comparison of IVD Test Results)
Next Steps

- Publish LAW as the CLSI AUTO16 standard
- Formalize the LIVD HL7 FHIR definition with the HL7 Orders and Observations Working Group
  - September Working Group meetings for a ballot
  - Evaluate testing during FHIR Connectathon at a HL7 Working Meeting
  - First step in automating the use of LIVD content
- Explore IVD Value Set Mapping as part of the SHIELD (Systemic Harmonization and Interoperability Enhancement for Lab Data) initiative
IVD Value Set Mapping

- Instruments are reporting qualitative result values today
  - Ordinal
  - Nominal
  - Semi-quantitative
- In general, manufacturers use vendor-defined “answer strings”
- A common vocabulary would support Real World Evidence workflows (e.g. comparing qualitative answers for equivalent IVD Test Results)
Define the Scope

- What is the code set for the mapping?
  - LOINC Answer List
  - LOINC Answer
  - SNOMED

- Consider publishing manufacturer mappings in a common location?
  - Intentionally out of scope during development of LIVD
  - Manufacturers maintain and own the content
  - A third-party maintains mappings that can be accessed through a FHIR API
  - Value Set Authority Center (VSAC) from NLM may be an option
Mapping Approach

- Support the same technologies as LIVD
  - Spreadsheet table
  - JSON based on a FHIR definition

- Assume mapping is taking place outside of the instrument
  - Mapping activity is separate from the reporting activity that provides a specific result
  - Mapping content is limited to data required to perform the mapping
Mapping Approach

- Create separate mappings for the value sets
  - Simplifies content with two mapping data sources
  - Incorporating into LIVD complicates the mapping content with duplicate information

- Create a mapping for each instrument/assay to reduce ambiguity because
  - It is an answer to a specific question
  - The concept may be different across tests
Mapping Approach

- Maintain alignment with LAW and LIVD Data Content
  - LAB-29, OUL\(^R22\) from LAW
  - OBX-3 Observation Identifier
    - OBX-3.1 Vendor Transmission Code
    - OBX-3.2 Vendor Analyte Name
  - OBX-5 Observation Value
    - Coded Value
    - String
  - OBX-18 Equipment Instance Identifier
    - Equipment Manufacturer
    - Equipment Model
General Comments

- The IVD Test Identification mapping was better understood than the Value Set mapping
- Licensing costs for SNOMED are being addressed
- Final mapping content should be simpler
  - 1:1 rather than one to many
  - Possibly easier for manufacturers to use long term within the instrument
- Will be an international approach, but manufacturers will decide what languages they support
General Comments

- IICC will focus on the mapping (technical) aspect of the problem
  - The following are out-of-scope for IICC
    - Adoption by manufacturers
    - Education for laboratories
    - How content is obtained (e.g. from a common location)
    - Addressing regulatory obstacles
  - Other organizations must address these areas
    - SHIELD (industry collaboration)
    - MDIC (Medical Device Innovation Consortium)
    - AdvaMedDx (Advanced Medical Technology Association)
Thank You!

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