Implementing HHS reporting requirements of COVID-19 test results and future epidemics: a call to IVD companies for immediate action

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In response to the rapidly evolving COVID-19 crisis, the Department of Health and Human Services (HHS) issued a laboratory data reporting guidance for COVID-19 testing on June 4, 2020 to assure the timely and quality data reporting to state and federal public health agencies of SARS-CoV-2 diagnostic test results, using LOINC and SNOMED-CT in electronic reporting systems. For the purpose of this article, we will focus only on how this requirement affects CLIA certified laboratories, excluding POC CLIA waived tests. While CLIA waived tests were placed under the same mandate, in most cases, there is by default no vehicle for automatic data collection, aggregation, and submission through an LIS or otherwise.

The resulting confusion and frustration was properly chronicled in the November 2020 CAP Today article "Checklist, CLIA line up on COVID reporting" by Anne Paxton. CAP also expressed concerns regarding the call for 18 'required' data elements and more. The intent was right. Unfortunately, the needed infrastructure was not yet in place. While most of the 18 elements could be accommodated through related standards that were already well defined, mature, and published, the device identification to support tracking at the test kit level was not, and neither were the additional questions HHS wanted to get answered for each sample, e.g. Order Entry Question Codes (AOE), calculation input and documenting patient status that could affect result interpretation. These are not the traditional ask at order questions (even though they had to be labeled as such). Neither industry nor clinical laboratories were ready to implement all requirements, thereby avoiding the called for enforcement.

The IVD Industry Connectivity Consortium (IICC) and Regenstrief Institute are two of several organizations that have long touted the benefits of standardized coding of laboratory results and the resolution of related semantic and interoperability issues for the aggregation of big health data for improved real-time epidemiology, comprehensive and geo-specific population health data analysis, and the analysis of non-obvious multi-correlates that can lead to new discoveries. Little did we know that this need would become so acute with the COVID-19 pandemic.

Prior to the COVID-19 crisis, the FDA's CDRH (Center for Devices and Radiological Health) had already launched the SHIELD Workgroup under the leadership of Michael Waters -who sadly enough passed away in September at the height of the pandemic- bringing together representatives of five agencies (FDA, CDC, NLM, ONC, and CMS) and related industry and standards development groups, including the IVD Industry Connectivity Consortium and Regenstrief Institute. Logically, the June 4, 2020 HHS requirement originated from the work already done by SHIELD. But much still needed to be done.

Many testing agencies had never been required to report data to public health agencies. To support the new COVID-19 pandemic reporting requirements, a SARS-CoV-2 LIVD reference file was created and maintained to allow health care facilities to identify the required harmonized codes. This SARS-CoV-2 LIVD file provided healthcare organizations LOINC mappings, SNOMED mappings (specimen and test result description), equipment identifiers, and test kit identifiers for SARS-CoV-2 diagnostic tests approved for Emergency Use Authorization (EUA) by the FDA for use in the United States. For now this excludes laboratory developed test (LDT) although we have to assume that they also used to report data. The file served as an important resource for the creation IVD test results coding that could improve semantic interoperability of test reporting.

Laboratories cannot reasonably be expected to meet the stated requirements without assuring that all upstream systems adopt the same standards and data structures. IVD, middleware and LIS vendors should make this their highest priority. Many of these systems have not been updated to collect and transmit the information required to

support Real World Evidence (RWE) analysis of IVD test results, even though standards such as the LAW (IICC/IHE Laboratory Analytical Workflow published as CLSI AUTO16) and specifications such as LIVD (LOINC for IVD) were created to identify what is required to provide Real World Data (RWD).

Mid 2020, the FDA contracted Deloitte to conduct a pilot with several key laboratory groups in the US, which included an investigation on their adoption and use of LIVD, as stated in the HHS requirement. It became quickly apparent that very few IVD vendors had LIVD catalogs or pre-assigned LOINC codes for tests running on their instruments, let alone where aware of the stated requirement. The IVD Industry Connectivity Consortium tried to assist but many calls to IVD companies remain unanswered to date.

Why IVD Companies Should Act First

The last ten years we have seen an unprecedented collaboration between industry, government, and standards organizations towards the development of well-defined, practical, modularized, and easier to implement interoperability standards; and yet, adoption is still significantly lagging, partially due to the absence of laboratory informatics stakeholder representatives. Most laboratories installing new instruments are forced to revert to specifications that are now more than fifteen years old and no longer meet a laboratory's contemporary data interoperability and security needs.

The IVD instruments is the ultimate source of the clinical test results, so IVD manufacturers must assure that their instruments can capture and properly present the required data in a harmonized semantic format downstream to EHRs, and research and public organizations. This equally extends to middleware and LIS vendors. To assist clinical laboratories to meet the above-mentioned HHS requirement, all systems upstream and downstream must adopt support for the same standardized data elements.

IVD companies should:

- Create LIVD catalogs for their instruments. The LIVD mapping catalogue requires coding for these data elements: LOINC test order, LOINC test result, and Device Identifier and provides fields to describe all allowable specimen as well as detail about expected results and comments that may be helpful to understand the coding. This goes beyond just COVID-19 tests. IVD manufacturers are encouraged to adopt LIVD for all tests running on their instruments, preferably made available to customers electronically using the HL7® FHIR® LIVD definition. LIVD V2.0 may be implemented under a royalty-free public license. Ideally a consensus could be reached to have a central repository hosted by the FDA, IICC, Regenstrief, or other. The LIVD specification can be downloaded here http://ivdconnectivity.org/livd/
- Implement CLSI AUTO16 (analog of IICC/IHE Laboratory Analytical Workflow Profile). It defines plug-n-play connectivity between instruments, middleware, and

laboratory information systems in the clinical laboratory, improving interoperability, reducing connectivity installation cost and time, and improving integrity of patient and QC data. It essentially assures that the required RWD elements for IVD Test Results necessary to support RWE are captured and transmitted downstream, no a vital component in the national response to COVID-19. The specification can be downloaded here https://clsi.org/standards/products/automation-and-informatics/documents/auto16/

- Explore implementing SNOMED-CT where appropriate. The specification* can be viewed here https://www.hl7.org/fhir/snomedct.html
- Actively contribute and participate in standards development and promotion initiatives. Never has the need for industry to collaborate on unified standards been higher. Many areas of the broader healthcare ecosystem (including IVD) still shun the adoption of interoperability standards for fear that it may expose them to competitive pressures. Other industries have proven that standards lead to lowering research and development costs, improve speed to market, and quality and safety of products and services. It also serves the greater good, in this case, allowing the rapid aggregation and analysis of data for epidemiology data and treatment discovery.

COVID-19 exposed our healthcare system's current inability to collect and aggregate quality epidemiology data in a timely manner without significant pains and inefficiencies. Adoption of the called for interoperability standards represent an opportunity that should not be missed. Laboratories should evaluate the tangible benefits that these standards offer their operations, and mandate compliance in all future procurement tenders for any and all health systems. We owe it to the common good to assure that we get better prepared to respond to future pandemics. Industry working closer together on open interoperability can be a big contributor thereto. Stay safe. Stay healthy.

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References

- *Digital Format for Publication of LOINC to Vendor IVD Test Results*0 [online]. San Clemente: IVD Industry Connectivity Consortium, 2021. Available at: https://ivdconnectivity.org/livd/
- *Next-Generation In Vitro Diagnostic Instrument Interface – AUTO16* [online]. Wayne, Pa: Clinical and Laboratory Standards Institute, 2019. Available at: https://clsi.org/about/blog/next-generation-in-vitro-diagnostic-instrument-interface-auto16/
- *Integrating the Healthcare Enterprise Pathology and Laboratory Medicine Technical Framework Supplement: Laboratory Analytical Workflow (LAW).* Rev 1.5. Oak Brook, Ill: Integrating the Healthcare Enterprise, 2016. Available at: https://www.ihe.net/uploadedFiles/Documents/PaLM/IHE_PaLM_Suppl_LAW_Rev1.5_FT_2016-02-24.pdf
- *Devices on FHIR* [online]. Ann Arbor, Mich: Health Level Seven International, 2018. Available at: http://wiki.hl7.org/index.php?title=Devices_on_FHIR
- *Using SNOMED CT with FHIR* [online]. Ann Arbor, Mich: Health Level Seven International, 2018. Available at: https://www.hl7.org/fhir/snomedct.html
- SOLOR and Informatics Architecture [online]. No loc: Healthcare Services Platform Consortium, 2018. Available at: https://healthservices.atlassian.net/wiki/spaces/solor/overview
- *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* [online]. Department of Health and Human Services (HHS), 2021 – Available at: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf
- *Checklist, CLIA line up on COVID reporting* by Anne Paxton [online]. CAP Today, 2020, https://www.captodayonline.com/checklist-clia-line-up-on-covid-reporting/

(*) Standard currently in trial use