COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #35

Thursday, *September 2, 2021, 12-1 PM ET*

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #35

This week's Diagnostics Evidence Accelerator meeting consisted of 3 presentations:

1. Data Interoperability (Gina Valo, FDA)
2. Unique Device Identifiers (Dr. Joseph Drozda, Mercy Health and Terrie Reed, Symmetric Health Solutions, interviewed by Gina Valo, FDA)
3. Ten Things You Need to Know About Working with COVID-19 Diagnostic/Serology Laboratory Data (Susan Winckler and Dr. Carla Rodriguez-Watson, Reagan-Udall Foundation for the FDA)

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in Project One of Diagnostics Evidence Accelerator.

Data Interoperability (Gina Valo, FDA)

Starting in September, the Diagnostics Evidence Accelerator will be focusing on data interoperability. Interoperability is a complex topic that has many parts that need to be analyzed. To illustrate what is meant by data interoperability, an example of talking to a friend in a different country was presented. Questions such as do both friends have the physical ability to speak, type, hear, and read; do the friends speak the same language; do the friends have the same vocabulary; do the friends use compatible communication platforms; and are those platforms configured in a compatible way become important to ensure smooth communication. Data interoperability has similar issues and concerns. To ensure complete interoperability, all data must be using the same language (e.g., HL7 and FHIR), using the same vocabulary (e.g., ICD-10, LONIC, SNOMEDCT), and using compatible platforms (e.g., Cerner, Epic). Additionally, all the platforms that are being used must be configured in a compatible way. Systems that are using the same vocabulary will have semantic interoperability and systems that are using configured and compatible communication platforms will have technical interoperability. Figure 1 below shows components of interoperability. It is very important to have all of the different components of interoperability to work together.

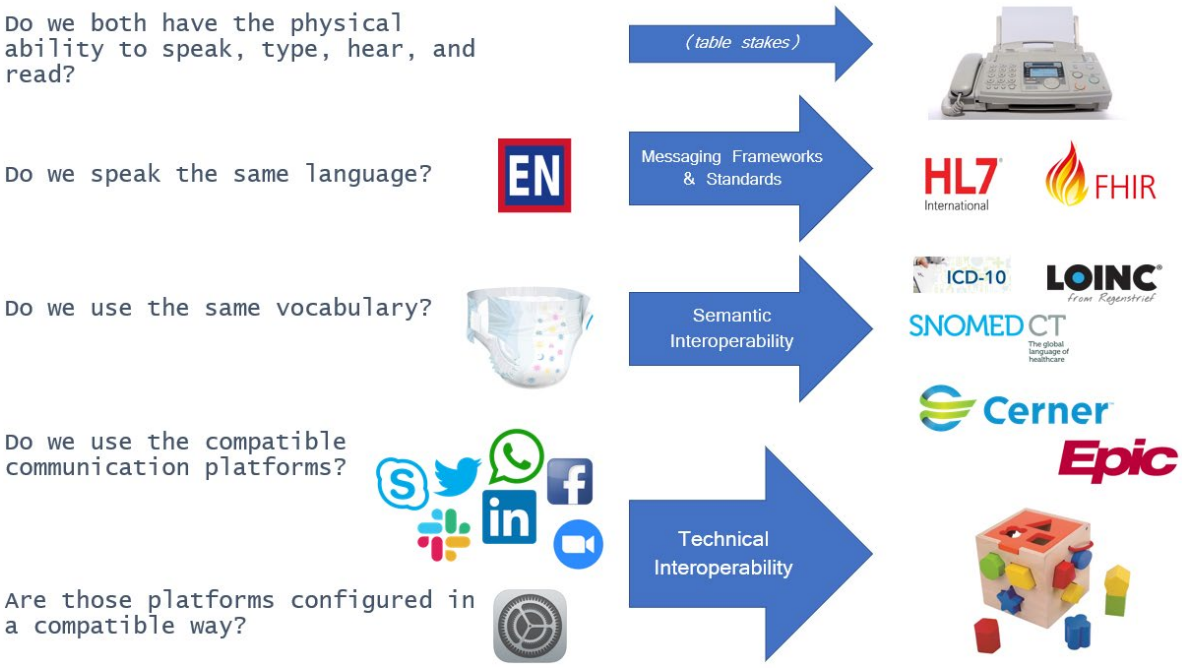

Figure 1: Components of interoperability

<u>Unique Device Identifiers (Discussion with Dr. Joseph Drozda, Mercy Health and Terrie Reed, Symmetric Health Solutions, interviewed by Gina Valo, FDA)</u>

What is an UDI and why is it important?

Terrie: UDI is a set of characters assigned by manufacturers and following a set of formatting rules that are authorized by FDA to meet ISO standards and global uniqueness requirements. Therefore, an UDI, is not an FDA construct, unlike the National Drug Code (NDC) code used to identify medications . UDI is meant to be an identifier that is used globally. 85% of the UDI on labels are created in the GS1 format. Approximately 15% in HIBCC format. UDI can tell us information such as manufacturer name, model type, lot number, serial number, and expiration date.

How does an UDI get generated, stored, and accessed?

Terrie: UDI is generated by a manufacturer and is added to the label of a device to meet FDA regulations. Once the UDI is scanned, there is a database where the information from one part of the UDI is stored, the device identifier of UDI or UDI-DI. The database is public and is managed by the National Library of Medicine. The data is originally populated by the manufacturers into the Global UDI Database (GUDID) at FDA. Each night, FDA transfers the data to NLM's public database - AccessGUDID – Access to the Global UDI Database. The UDI-DI is the key to each record in AccessGUDID and each record is associated with up to 62 attributes about a device like manufacturer, model, brand, whether the device contains latex, is it MRI safe etc.

How is UDI being used in healthcare systems?

Joe: At Mercy Health, UDI is being utilized in a number of different ways. It is scanned for all consumable supplies including implanted medical devices during Cath lab and surgical procedures. This allows

healthcare professionals to pull down the information to which it is linked. At point of care, healthcare professionals will know that the correct device is being implanted and see information such as recalls, expiration date, etc. Additionally, UDI is used by the staff in operating rooms and Cath labs as a way of pulling and managing their inventory and getting trays ready for the operating room. Finally, UDI is being used in research to analyze effectiveness and safety of medical devices and comparing devices that share the same attributes. Therefore, UDI is connected to AccessGUDID enabling capture of a number of associated medical device attributes. Also, some medical devices produced by different manufacturers share attributes such as dimension and the materials with which they're made of, enabling evaluation by common attributes.

Terrie: Symmetric focuses on supply chain and on using UDI and data in AccessGUDID to standardize supply chain data.
Symmetric accomplishes this by matching the current item level data a hospital has to the data in AccessGUDID plus 100s of other data sources. The goal is to fix an antiquated system of relying on manually recording of data off the label of the device vs. scanning the device and auto-populating with data from a master data source like AccessGUDID. In hospitals supply chain is often the source of master data, at least in the device space, so they drive the data that goes into the EHR that drives the data that could potentially go into the charging systems. As more and more registries use EHR data, they too would obtain their data from that supply chain data, originally obtained when scanning the devices received at the hospital receiving dock and warehouse.

Having a unique identifier for a device or diagnostic and getting that from the lab into the EHR and back into the hospital system or healthcare system is a critical element. What are some of the challenges that you faced with UDI and how did you overcome them?

Joe: Implementing UDI capture at the health system or hospital level at the point of care is a key step. If that does not happen, then you really cannot implement different use cases that require connecting an UDI and the device it represents with a patient. Implementing point of care UDI capture at Mercy required a lot of changes to inventory management and internal consulting. The resulting new method of inventory management had significant benefits. Unfortunately, one challenge is that manufacturers can change device identifiers. This causes the team to figure out different ways to group DIs of essentially the same device in order to keep track its performance over time. The supply chain arm of the American Hospital Association has been working with industry and others to address these challenges.
Finally, we need strong international data standards associated with UDI. We need them globally, because we have a global supply chain and I can only hope that we're not building a “Tower of Babel” around something that should be a unified language.

What was the problem that Symmetric was created to solve?

Terrie: Symmetric is a data enablement company that was created to take advantage of the availability of open device-related data sources like AccessGUDID and innovative technology like AI/ML to improve interoperability by automating the capture and transfer of standard device information across health IT systems. Joe mentioned challenges with UDI adoption. Symmetric and other vendors are constantly addressing challenges that arise as hospitals integrate UDI into their systems. For example, Joe mentioned manufacturers changing device identifiers. Symmetric groups those changing identifiers in a way that eliminates that challenge. One thing that Symmetric and other technology companies have a harder time solving is when data about a device is not available in AccessGUDID or when data once

available from AccessGUDID is suddenly removed causing an inability to make matches between hospital data and AccessGUDID. These issues of record availability are often reported to FDA but currently there is no open rigorous process for resolving issues.

What are the core device data elements that require a high level of consistency?

Terrie: There are 62 elements in GUDID, however there are approximately 10 elements that are considered core elements to operate the device ecosystem. Included in these elements are manufacturer name, description of product, size, and device type. I won't list the whole set, but If these elements are standardized, then we can really advance the use of UDI.

Joe: Additionally, there are other clinical attributes that are unique to specific devices, e.g., metal on metal hips, and that play an important role in assessing medical device performance and that are not always available in AccessGUDID as structured data. To achieve the full potential of UDI and various use cases, we need ready access to these clinical attributes also. Also, GUDID needs to evolve over time to stay current with the growing use cases.

Terrie: Private companies are limited in their ability to update a public resource like AccessGUDID. They can only report issues that they discover to manufacturers that own the data and to FDA that provides guidance to manufacturers on how to populate data and enforce data quality issues. The only current process for reporting errors to FDA is through the UDI Help Desk. It would be very helpful to have a more public data quality issue reporting process similar to what is available for FDA adverse event reporting where hospitals can report device adverse events and they can be publicly displayed.

What is your vision to solve some of these problems and what role do you see the different players playing to address this issue and interoperability?

Joe: The solution is to get UDI into all pertinent databases (e.g., EHR, research databases, national registries, claims) that need to be linked. The linkage depends on having adequate data standards that are the same globally. Once this is done, then the solutions for interoperability will come out of the standardization of data.

Terrie: I would like to see FDA work with other Federal Agencies and other jurisdictions around the world to continue to support UDI adoption. FDA worked with ONC in 2014 to include UDI in their certification requirements, so that UDI is now able to be documented when implants are placed in patients. The result of the ONC requirement is that EHRs now contain a field for UDI and six key fields from AccessGUDID. This has incentivized hospitals to adopt UDI. Additionally, UDI Systems are also now rolling out in the EU, Australia and many other jurisdictions. There is a need for the US to meet with these other groups through IMDRF (International Medical Device Regulators Forum) to ensure that the implementations of UDI in each country supports interoperability between countries and could eventually result in being able to scan a device anywhere in the world and have it link to a truly Global UDI database.

Joe: One thing that COVID-19 has taught us is that we have a global supply chain and that sourcing supplies would be greatly facilitated by internationally standardized data.

Gina: UDI could be used to convey the very information that we have struggled to get from a diagnostics perspective, specifically the manufacturer of a COVID-19 test. This would enable the kind of

observational research that we would like to do in terms of safety, effectiveness, and interactions with vaccines, especially for products under EUA. Unfortunately, without this kind of data we have to rely heavily on controlled trials, which require both time and significant resources. We have very few options of knowing which device or which diagnostic test was used for which patient and tying it to patient outcomes.

Ten Things You Need to Know About Working with COVID-19 Diagnostic/Serology Laboratory Data (Susan Winckler and Dr. Carla Rodriguez-Watson, Reagan-Udall Foundation for the FDA)

1. Cycle Threshold is the inverse of Viral Load: When CT is low, VL is high.
2. Laboratory tests and results need to be linked via LOINC and SNOMED codes.
3. LOINC does not differentiate across assays, but only across test types.
4. Instrument data (i.e., manufacturer name, reagent, other meta-data) are not necessarily transmitted to the Laboratory Information System (LIS).
5. Even when listed as a structured field, "result" data is populated not just as the value of the test, but as the specimen, as the test name, and requires work to parse out.
6. Manufacturer field resulted in many different names for the same test.
7. Results were unstructured, took many formats, and took work (Natural Language Processing [NLP]) to decipher even just positive/negative.
8. To do Quality Assurance on test dates, you need to consider the dates that tests were approved or authorized. Useful to have a table that allows you to map the test date in the data with the actual EUA dates to ensure that date of test is correct.
9. Early in the pandemic (~February 2020 to April 2020), folks were discouraged from getting tested.
10. There are many dates for a result: Specimen Collection Date, Accession Date, Test Date, Result Date.

From the Chat Box

- The U.S. needs an interoperable and interconnected network of health informatics systems (HIS) that is capable of promptly responding to unmet critical medical needs, and is based on centrally coordinated data collection and transmission standards that will enable the rapid identification and correction of data errors and faulty decision support systems.
- The resulting problems are an important source of analytical biases and undesirable consequences for patients.
- Earlier this year a patient had a significant stroke and transported to stroke center ED. Even though that facility implanted an MRI-compatible pacemaker and it's documented in their EHR per their MU attestation, they were unable to confirm the pacemaker was MRI-compatible and they canceled the MRI orders. The patient was not diagnosed with stroke until 4 days later when they finally had their MRI, by then missing the critical treatment window. Laymen can look up the UDI via FDA GUDID website to confirm the MRI-compatible device in 10 minutes. How do we fix this sentinel event/patient safety issue with clinicians? The data is there, but it's a usability issue. The patient died a few months later.
- Interoperability needs to start at the data creation level to enable traceability to the source of medical errors.
- It is a real shame that pharmaceuticals do not have global product IDs and lot numbers and a public database of products and APIS marketed throughout the world linking UID to actual product labels would be really helpful.

- With regards to Cycle threshold- due to inconsistent sampling, Ct from one test is not the equivalent of Ct from another. Viral load in the sample may not correspond to viral load in the patient.
- The current status of RWD is that it follows the business panel (i.e. provider or insurer). Nothing follows the patient.
- Symptom onset date and exposure date is hardly captured.

Next Steps

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

Next Meeting: Thursday, September 23, 2021 12-1 pm ET