# COVID-19 Evidence Accelerator Collaborative

## Diagnostics Evidence Accelerator #24

Thursday, *February 18, 2021, 12:00-1:00PM ET*

Call Summary

**Introduction to Diagnostics Evidence Accelerator Meeting 24**

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

1. Chicago COVID-19 Health Information Exchange (Bala Hota MD, MPH and Casey Frankenberger, PhD, Rush University Medical Center)
2. A Brief History of Interoperability (Kenneth Mandl MD, MPH, Boston Children's Hospital and Harvard Medical School)

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in this project. As of the week of February 8, 2021 we are on step 4 where Accelerators are refining Aim 2: Positive Percent Agreement & Risk of Seropositivity protocol.

**Chicago COVID-19 Health Information Exchange (Bala Hota MD, MPH and Casey Frankenberger, PhD, Rush University Medical Center)**

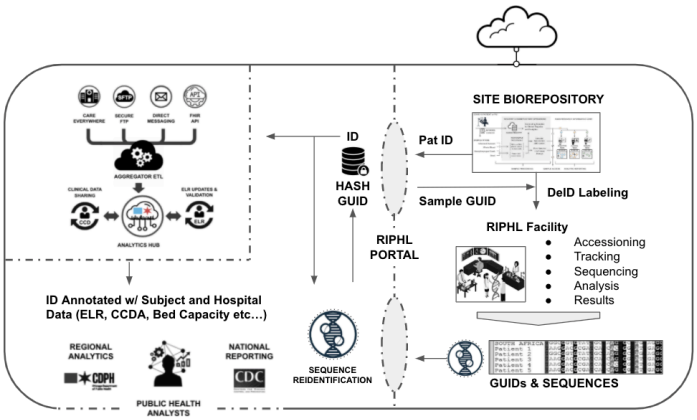
At the beginning of the pandemic, Chicago Department of Public Health (CDPH) realized that there was a large numbers of missing data (e.g. race/ethnicity, hospitalization data, underlying conditions, length of hospital stay). Due to this, there were initial critical needs that were identified by the CDPH. Those needs were timely reporting of essential basic data elements to lead case investigations, efficient mechanism to collect more complete epidemiological and clinical information, including other data sources, and coordinated mechanism for hospital utilization monitoring. This led CDPH to release a public health order that highlighted the role that the health department has in response to the pandemic. One guidance that they released was how to collect and share certain identifiable data variable in a safe manner for public health use.

Through the order, Rush University partnered with the health department to develop the CDPH Data Hub. This hub receives all data variables that are of public health interest. Data from Care Everywhere, Secure FTP, direct messaging, and FHIR API is aggregated and organized in the cloud. The three data points that are collected in the Data Hub are electronic lab reporting (ELR) data, Consolidated Clinical Document Architecture (CCDA) data, and bed capacity. Within the data hub, there is a patient matching algorithm that links the clinic care document data and lab testing. This allows for hospitals to access patient demographic information when a patient is admitted. The linkage between CCDA and ELR provides a COVID 19 registry that can be leveraged for additional analysis. Rush University has partnered with Amazon to create an Amazon based data hub. Their goal is to open source this by the end of

February so the data can be used by other researchers. Rush University is also leveraging Amazon's HealthLake which is a product created to allow the sharing of health records from hospitals on an application on an iPhone.

There were many lessons learned through this research. One lesson learned is a need for capturing data on bed capacity in real time, but during the summer, the cases were significantly reduced, therefore, bed capacity was not an issue. However, COVID-19 long hauler syndrome started becoming a problem. From a public health perspective, understanding, monitoring and addressing long hauler syndrome became important. Also, vaccine scheduling and administration is another area where there is a need to closing the data gap. ZocDoc is a resource that Chicago uses to schedule vaccine appointments, however, integration of the data collected is an issue. Molecular epidemiology of SARS-CoV-2 and gathering real-world evidence (RWE)is important to combat addition strains or future pandemics that may come about.

Their data hub modernized public health infrastructure by being able to capture the data on the cloud. This shorten the time for analysis of data. The cloud also provides a public health repository for different datasets. Dr. Hota provided a privacy protecting record linkage for accelerators to look at. They conducted a validation study between HHS Protect data and the data hubs data which provided alignment in the data. They can link the iCARE (immunization registry) and ZocDoc in their data hub. They plan on creating additional linkages (e.g. FHIR enablement and bed capacity) to the data hub. Rush is working on developing a Regional Innovation Public Health Laboratory (RIPHL Lab) which will service a sequencing lab to sequence the biorepository samples to understand the different variants which will be provided to public health experts. Dr. Frankenberger shared how the deidentified data will follow in the system and will become identifiable once needed. See below for the data flow diagram from the presentation.




Dr. Hota presented the overall lessons learned from their research. The lessons are :

- The agility of cloud based services has compelling value for novel use cases in public health.
- Themes of data integration, patient matching, and ease of reporting have been recurring over the COVID-19 era.
- Ideal scenario is to combine standards, reporting needs, with desire to generate real world evidence.
- Public health is a trusted partner in the data ecosystem and could serve a vital role in data aggregation for local health department.

**A Brief History of Interoperability (Kenneth Mandl MD, MPH, Boston Children's Hospital and Harvard Medical School)**

This presentation focused on the parsimonious approach to interoperability. Dr. Mandl presented a slide that showed the different data variables that we want, however, the EHR presents a wall to accessing all of those variables. Dr. Mandl referenced Heidi, our hypothetical patient, to show the difficulty in the flow of data from EHR, lab, and instrument. Dr. Mandl published an article in which he discussed how EHR can be linked to applications on iPhones. This will allow third party vendors to create applications for easier access that will include data from EHRs onto the patients form.

They leveraged their proposal that was published in the New England Journal of Medicine to create a program that was funded by ONC. The question that they addressed is if EHRs behave like iPhones or Androids in that innovators readily create and widely distribute substitutable apps across thousands of installs, therefore creating an API. They created an application that was able to display data from an EHR. Designers created a cardiac risk app that can be used by doctors, patients, or conversation between doctors and patients. They took 1 SMART app and converted it into 3 SMART systems. They ran the SMART app on an open source and proved that substitutable and reusable apps are important in interoperability.

They created a health apps contest to find a company that is able to create a SMART app that can house all medical records and is user friendly. The winner of the contest application is available in the app store. With SMART apps, they can bring in linkages to external decision support services such as pharmacogenomic rule sets and decision support for doctors. They developed an app gallery for easy access of the various applications that have been developed.

They have seen their work in regulatory policies. CMS, through their Medicaid EHR Incentive Program, requires that patients are able to acquire their medical records through an API. They convened a group called Argonaut which helped all EHR vendors comply with CMS's regulation. Argonaut was successful in getting the SMART onFHIR API in all EHR. Apple used SMART on FHIR API to connect its health app to over 600 health system, therefore patients can receive their health information in a universal format. Apple used on an open source which allowed CommonHealth to create an android version of Apple's health app. This makes the interoperable pieces into building blocks that everyone can use.

This idea was included in the 21st Century Cures Act. The act requires that the API be included in EHR and other forms of health IT. The ONC's Cures Act Final Rule stated that the data interfaces are going to be required and supported across the healthcare ecosystem. There is an analog that was created for the SMART on FHIR API. This will be available next year. This contains population dataset allowing for better analysis of populations. CMS has also created two API: Data at the Point of Care and Beneficiary Claims Data API that can be leveraged. The US Core Data for Interoperability is a standard dataset where we need to lobby to allow for more data to be entered because this data will be the data that will be available for APIs.

They have extended the SMART on FHIR API into a patient generated data framework which allows to wearable devices can be connected to. Dr. Mandl discussed SMART Cards/ Health Wallet which allows patients to get a verifiable credential for vaccines which is in its pilot phase. For the future, Dr. Mandl discussed that they also have SMART Cumulus which get the data out of the API and processes it so it can be used in public health application. CDS HOOKS which triggers decisions support in EHR. Dr. Mandl highlighted core set of EHR data elements and universal approached to interoperability. Those elements

are an app registering and accessing a single patient's EHR data (SMART on FHIR), access to population EHR data in standard format (SMART/HL7 Bulk Data Access), collection of patient generated health data (SMART Markers), verified procedures and results (SMART Health Cards), triggering decision support (CDS Hooks), and processing data from an EHR for learning (Cumulus).

**From the Chat Box**

- An accelerator asked if the CCDA record format standard regardless of the EHR system -- EPIC, Cerner, etc.?
    - As a follow up question, another accelerator asked if this is also standard across all the different implementations of Cerner and Epic?
    - The presenter responded by stating that yes it is standard. The EHR share CCDA records between each other. Care Everywhere creates a database for sharing clinical documents.
- Another accelerator asked if the presenter could talk about how the data hub might be leveraged beyond the pandemic such as being used for regular disease reporting and outbreak investigation. Also, what were the major pain points and how where they overcome?
- A participant stated that the certified EHR systems in the US use Consolidated Clinical Document Architecture (CCDA), part of HHS/ONC EHR certification criteria.
- An accelerator asked the presenter is they are getting patient identifiable info in the data hub.
    - The presenter stated that they are getting identifiable data into the data hub. Because this is reportable data due to the public health order CDPH issued, the city is able to receive these data. The infrastructure is housed in the city's cloud, so it is the owner of the data
- One caller ask the Dr. Hota to describe the time lag for the CCDA data to be transmitted.
- A caller stated that CCDA is a health care delivery tool not intended for clinical research and asked how are you able to make that data use transition.
    - In response to this question, an accelerator stated that it is a data exchange standard, originally part of Meaningful use regulation. It is in use today by EHRs and HIEs.
    - The presenter stated that the CCDA is a data exchange standard - in its original version it is typically used for clinical use. The public health use was a bit novel approach in this use case.
- An accelerator asked how can we decrease the constant data mapping and remapping needed for communicating information.
- An accelerator asked how are you linking mortality data occurring in an out-of-healthcare setting.
    - In response to this question, the presenter stated that they are relying on encounter information in the CCDA records at this point - on our task list is to incorporate vital records data but not implemented yet.
- An accelerator provided a link to all certified health IT systems (most of them using CCDA).
- An accelerator stated that the information that the second presenter is presenting represents a real path forward. The FHIR standard has more strict standards for how to represent data types. We are really enthusiastic about it being the solution, and also want leverage this.
- One accelerator stated that Apple leverages LOINC for their Health Kit.
- A caller asked if this is also being used systematically across EHRs for the new ONC & CMS data blocking.
- An accelerator stated that the FDA BEST IBM project heavily leverages SMART/FHIR/Bulk to support biologic safety and effectiveness surveillance use cases.
    - One caller asked if the FDA MyStudies App use this same interoperable set up.

- One accelerator thanked for the great talk!  RWD has always jumped forward after these types of federal moves; HIPAA and 837/claims, ARRA, PCORI, HITECH. A proactive approach here from research & life science community will be so important.
- Another participants stated that the SMART Health Cards framework is still being refined, but has immense potential for widespread adoption prior to balloting by HL7.

**Next Steps**

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

**Next Meeting: Thursday, March 4, 2021 12-1 pm ET**