Lab/Epi CSTE/APHL/CDC Thought Leaders Workgroup Call Meeting Minutes and Action Items

Date:	**Tuesday May 10, 2022**
Start/End Time:	**2:30-3:30p EST**

	Open Call	
1.	Pediatric hepatitis of unknown etiology and adenovirus testing discussions	**Pediatric hepatitis of unknown etiology and adenovirus testing discussions (Kelly Wroblewski, APHL and Caelin Potts, CDC) (***topic continued from 5/3)* • Anticipating another HAN to be released very soon. Posted testing guidance on the webpage (see below). • CDC discussed processes for typing - Each week if positive specimens coming in, send an email to the functional email inboxes. You will receive a response right away with information on processes. CDC will ask you to hold the specimen and ship the following week, for typing specifically. Specimens to arrive early the following week at Wadsworth. TAT for the adenovirus typing is about 2 weeks. • CDC will start regular calls Thurs May 12th at 4-5pm meeting, then regular calls to be scheduled. Sent to POCs for this topic, State Epis, and CLUE list. • CDC is pulling together a small advisory group including academic Peds ID, hepatologist, virologists, pathologists to convene to meet soon and will share that information during discussion on Thursday's call. • STLTs are reported to be having challenges in getting information back from CDC. Not clear if it is related to lab data, pathology reports, or informational? • Feedback provided to CDC re: guidance that went out, some were confused on which items were for clinical versus public health. CSTE collated comments last week on this (clarifying clinical versus public health guidance). Tried separate guidance documents, but was very redundant. CDC wanted to give each state the option of whether they wanted the specimens to go to the SPHLs or not for the diagnostic testing. This is why it was kept together. • If additional concerns or questions, reach out to the CDC functional mailbox. • This call has always been focused on COVID, but wanted to use this forum to outreach on this topic and moving forward to move beyond COVID and use this as a forum for other APHL-CSTE-CDC lab/epi efforts. • Now there is a website posted on the topic: https://www.cdc.gov/ncird/investigation/hepatitis-unknown-cause/hcp.html (testing guidance is located here https://www.cdc.gov/ncird/investigation/hepatitis-unknown-cause/laboratories-testing-typing.html
2.	Project MARS – Mobile Application Reporting through Standards (RADx®MARS)	**Project MARS – Mobile Application Reporting through Standards (RADx®MARS) (Scott Becker (APHL) and Andrew Weitz and Krishna Juluru (NIH))** • Scott Becker facilitated discussion on the NIH Project MARS: https://www.nibib.nih.gov/covid-19/radx-tech-program/mars • Andrew Weitz, NIH, also, presented yesterday's ASE call • Slides to be shared after the call. • Brief overview then questions. • At-home testing supply has far surpassed lab and point-of-care (POC) testing supply, yet most reported test results are from labs and POCs. • Challenges in capturing OTC test results: • Lack of standards for representing and transmitting OTC test results • Incomplete guidance about what test-related metadata to capture and where to send it • Shifting views from states about accepting OTC test results • High per-message costs for services (hubs such as AIMS) that route OTC test results to public health systems • These lessons are relevant to other future diseases with home testing (which will continue to be more common)

		• When invited to report OTC test results through a mobile application, roughly 3 in 4 individuals agree to do so • RADx MARS aims to reduce barriers to OTC test result reporting • Developed HL7 and FHIR specifications for capturing and transmitting OTC test results from mobile and web applications • Piloting in 7 states • Got buy-in from test companies and app developers. • Several leading test manufacturers have already committed. iHealth is the first to go live. Now sending test results in MARS HL7 format to AIMS and is reaching states who are opting to receive the data, and other companies will go live in the next few weeks. All of the other big names for at-home testing companies are on board. • There has been consideration and discussion re: how to release these as a publicly available data in the coming weeks? • Want to explore incentives for reporting. How to coax people to share their results? • Test to treat? If positive, telehealth visit, and get medication shipped to their home. This can encourage reporting. • Will facilitate state access for those that want the data. • About half of the states are accepting it, and NIH would like to know how it is going: challenges, successes, lessons learned. Also, for those who are not accepting it, NIH would like to hear why. • STLTs that opt not to receive these data report that it is partially because of concerns about data quality. • Some STLTs are trying to understand if we need the at-home testing data, as they have augmented case surveillance with wastewater, syndromic, and are streamlining. What are the important uses that will change public health action? • At-home testing will only increase with other diseases and we need to take in all these streams and decide how to evaluate them and how to use them. • Some states have been accepting home self-test reports from individuals. They follow these trends. Looks similar to lab-based reporting. Over time we would work to find a way to use this data. Whether we count these or not would depend on a national picture. • STLTs note that distribution of at-home tests varies by population, for instance, rural populations have decreased availability of lab-based tests, but still can order at-home tests and use these. • STLTs also note that reporting is also important for exposure notification. • How do we incentivize so individuals report positives? • Data is going to HHS protect and if it will be released publicly, these are all important considerations for states in decisions about accepting the data. States could use more information about how this data is being used or planning to be used in the future, which would impact state decisions on whether to use the data • STLTs discuss the importance of understanding the completeness and limitations of the data. What is the utility of one company reporting, if it is only a small proportion of the overall home testing? This would be important for NIH/CDC to discuss with STLTs before being used in CDC CCLs, for example, or before being shared publicly. • STLTs inquired as to how this information was previously shared with STLTs and how decision making occurred regarding the state option to receive data or not. It was shared through the open ELR Thursday calls previously. Now the team will engage in further communication through the State Epis and through CSTE, which is why this meeting was organized. • It might help look at trends in use of at-home tests. Some STLTs are doing regular surveys but this data would help with this as well. • Some STLTs decided not to accept the data because of issues related to person de-duplication. • Question raised re: if the vaccination status was being collected in the process? No, it is not. Vaccine data is not collected because then would need to collect the date of vaccine dose, which vaccine, etc., and it becomes more complicated, building the app becomes more complicated, and as it is more complicated, people may be less likely to fill it out. This was discussed with APHL and several state representatives,

		and several said this was not necessary, it is already collected through other state registries. • Here are the data elements being collected: https://www.nibib.nih.gov/covid-19/radx-tech-program/mars/mobile-app-guidance. • While CDC is eager to see this data and see how it may be used, there is no specific plan from CDC to release this data publicly without a clear explanation of the purpose. • Similar to discussions about COVID-19-associated hospital surveillance, maybe the investigation of these data should not be viewed as nationwide surveillance, but rather to keep up with evolving data trends and understand what these data mean and how they do or don't inform our understanding of disease trends. • In the exposure notification app, people are encouraged to share their positive result, if you are in a state that has enabled self-report, then that information will go through whatever process the state set up for that. DC, California, and some others have done a lot of work on exposure notification (and APHL is the third party server for ENX). Other STLTs don't use the ENX or have had challenges with its utility. • There can be a duplication issue that is being worked out because the data stream is from Hub to state, to HHS protect, while also, in parallel Hub to HHS protect. So, HHS protect might get two of these messages about the same testing event. • At-home tests are not going away. Just as we adapted to CIDTs replacing culture, we will need to evolve to address these tests. • STLTs urged that they should hear about any data releases before they are public to provide input, understand the data limitations, etc. • **Discussion of whether there been any analysis of what data has come in to-date? Re: completeness of name, address, phone number, race, ethnicity? This is important to decide whether or not states want to receive the data.** • **APHL and CSTE will work to get this information.** • FDA is applying pressure, not quite requiring the data, but applying pressure for this approach that the app needs to be available. • **If you are one of the states that are getting the data, RADx MARS would love to work with you to evaluate the completeness of the data, bc the RADx MARS team can only see de-identified data.** • For de-duplication processes, there are some challenges with person de-duplication. Would need to sort out a way to discourage reporting after a first positive. Why we would want to keep this stream separate from ELR at the start. • **We will hear again from the project MARS team with updates.** • **If STLTs would like to ask for the data feed or for further information on the data feed, you can reach out to Brian.garrett@aphl.org**
Tuesday, 5/31/22 at 2:30-3:30 PM ET		

Action Items

[From last meetings, until closed]

#	Activities/Deliverables	Action Item/Responsible	Due Date	Status
1	Project MARS – Mobile Application Reporting through Standards (RADx®MARS)	☐ **If STLTs would like to ask for the data feed or for further information on the data feed, you can reach out to Brian.garrett@aphl.org** ☐ **If you are one a state that is getting the data, RADx MARS would love to collaborate to evaluate the completeness of the data. Email if interested.** ☐ **APHL and CSTE to work with NIH to learn if there has been any analysis of what data has come in to-date? Re: completeness of name, address, phone number, race, ethnicity?** ☐ **Project RADxMARS to return with updates once data is available**	ongoing 5/31/22 5/31/22 ~July	Pending

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