Coronavirus Standards Working Group Meeting Summary

Dear Colleagues -

Thanks so much for a really engaging meeting this morning -- We had a quick update on the Viral RNA Harmonization Study and then Patrick Ayscue led us on a dive into the Genomic Surveillance infrastructure being developed at Chan Zuckerberg Biohub.

Our <u>meeting recording is here</u>, <u>my brief update slides are here</u>, and <u>Patrick's slides are here</u>.

Patrick's presentation and the discussion it sparked illuminated the state-of-the-art in tracking SARS-CoV-2 viral variants, from sample acquisition to sequencing and variant calling to data sharing to cluster analysis of placing genomes in place and time, and ultimately to informed public health action. Beginning with the genomic epidemiology for Ebola in the 2014 outbreak, and following with epidemiology for Zika, a framework was established. The SARS-CoV-2 pandemic presents a problem scale orders of magnitude greater, and the tooling is just being developed, and Patrick presented the <u>Biohub COVID</u> <u>Tracker Project</u>. Patrick reported that this project, developed at Biohub as an answer to a coordinated effort to support the Public Health Labs in California, is being developed to be widely deployed this year.

The group identified key challenges In the discussion that Patrick led, including heterogeneous sequencing of positive samples, inconsistent application of analysis strategies and tools, poor data interoperability and barriers across IT systems (including IT policy limiting Public Health labs from using cloud-hosted systems). The absence of interoperable health records and the US Federal system combine to form Balkanized genomic surveillance capabilities in the US.

There was good discussion by Patrick and the group about the path from samples-to-

surveillance-to-knowledge-to public health action, and Patrick showed a crisp example of an outbreak in a prison population. Metadata annotation of samples and data are key to being able to do this analysis, and the absence of consistency in metadata policy, metadata annotation, and metadata standards were identified as a critical barrier to enterprise-scale success.

Another more subtle consideration is selection of a centralized or distributed sequencing model; the distributed model may enhance turnaround time and responsiveness, but at a cost to big-picture surveillance and without the benefits of highly efficient high-throughput automation and sequencing. Decentralized analysis also begs the question of moving toward more consistent analysis, policy, decision-making, and public health action.

There's lots going on in this space, with US Federal Interagency Working Groups exploring policy options, inconsistent international policy landscapes, and non-profits and NGOs working to get genomic surveillance stood up and functioning globally. The politics of genomic surveillance for public health decision-making and policy setting is an active topic -- examples include county public health authorities objecting to CDC policy on data sharing. Complicated! The confusion is made worse by the differing (sometimes conflicting) goals of local and national surveillance; immediate and local non-pharmaceutical intervention response vs. national surveillance and technical responses.

And... at present the surveillance work is all being done outside of actionable clinical case management, and outside of CLIA-accredited assays. This might indeed evolve.

We will meet again next week!

Key Updates

- The Viral RNA Harmonization Study data are now more than half submitted, and we're going to get the panel to Slovenia with a dry-ice refill intermediate stop in Belgium (thanks Jo!, and thanks Mojca for your patience with us!).
- We're going to meet on Wednesday 14 April at 0900 PDT to discuss the Serology Harmonization Study, with labs and sample providers interested in participating invited to attend. Here's the <u>Zoom link</u> for that call.
- Tim Mercer and I are working on a presubmission inquiry letter for a paper that builds out the draft manuscript from our work last April and May -- we are casting it as a "Roadmap for a Coronavirus Standards Working Group.

Cheers and stay safe!

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