FROM SENSING TO MAKING SENSE

Leading Not Bleeding: A Model For Innovation In A Clinical Diagnostic Laboratory Providing Real-time Public Health Surveillance Data

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The COVID-19 pandemic has challenged The Ohio State University in ensuring the safety of over 100,000 faculty, staff, and students in a large urban setting of ~2 million people. In response, we established an innovative CLIA compliant clinical diagnostic laboratory, an integrated contact tracing unit, and an expert internal advisory group. The laboratory was developed in a 60-day rapid sprint and deployed a saliva-based SARS-CoV-2 test (SalivaDirect™). An industrial setup simplified training for a workforce mostly comprised of students and allowed for on-demand scaling from 1,000 to 10,000 tests per day with no automation. This test modality was inexpensive (~$10 each), saving >$100M, and "parallelization" of collection sites and the laboratory provided low turnaround time (~4 hr). In practice this was a highly efficient centralized (i.e., reach-back) laboratory that received multiple streams of samples and processed over 850,000 tests in 18 months. The second innovation was data management. All patient and test data were organized using an Electronic Medical Records (EMR) System that received data directly from laboratory instruments. This provided immediate test results to patients (through the MyChart app), case information to local and state public health officials, and real-time data to our contact tracing unit to inform isolation and quarantine actions. When this system went live, the rapid isolation and quarantine of infected and exposed individuals decreased campus positivity rates from 5% to MixviR, that was adopted by the Ohio Department of Health for decision making. A fourth innovation was the establishment of dust-based epidemiology (DBE). The CLIA lab added another parallel process to analyze sweeper bags obtained from strategic sites on campus. For academic year 21-22 the laboratory delivered a weekly report on abundance (qPCR) and variant type (sequencing) of SARS-CoV-2 across campus. This proved to be highly valuable, removing blind spots and identifying at-risk settings on the campus. Moreover, the laboratory demonstrated that DBE can also identify Norovirus and Influenza A. Lab-based innovations like DBE have enabled routine environmental and viral genomic surveillance to reduce reliance upon individual testing for monitoring trends in transmission, which will be crucial to University policy development and intervention implementations. In summary, with a moderate level of risk, the rigor and standardization of an industrial-modeled CLIA diagnostic lab provided high impact financial savings and tremendous public health benefit while pioneering new methods for environmental surveillance and deciphering and integrating relevant data streams to inform decision making.

Organizational support and staffing from The Ohio State University Infectious Diseases Institute, The Ohio Department of Health, and The Ohio State University Wexner Medical Center. Laboratory support and innovation by Jacob W. Smith, Dakota Sizemore, Haley LeBlanc, Hannah Moulton, Cece Bryant, Amanda Williams, Victoria Barnette, Francesca Savona, Janelle Gabriel, and Jeff Jahnes. Managerial innovation by Rick Shaffer.
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