Surge Capacity for Influenza Surveillance, Novel Event Investigation and Outbreak Events

The virologic surveillance system should be flexible and scalable for rapid, effective response to support initial diagnostic needs and case counts in rare/novel influenza event investigations and enhanced surveillance in outbreak and pandemic scenarios. Pre-event and during an event, communication and coordination between epidemiology and laboratory leadership will be essential to develop, refine and change the strategy for virologic surge sampling and testing.

Pre-event:

- Ensure that PHL representatives are included in state preparedness and pandemic planning activities. Address the role and resource needs of the PHL in state/jurisdictional pandemic plans. Pandemic Planning Information can be found at: www.cdc.gov/phpr/coopagreement.htm, www.cdc.gov/flu/pandemic-resources/tools/index.htm.

- Utilize the APHL Infectious Disease Planning and Response Framework Checklist to identify key partners and preparedness activities, including validation of new testing methodologies, biosafety, regulatory requirements, training, information dissemination, specimen collection and transport guidance.

- Develop and maintain a laboratory pandemic surge plan that is integrated into a laboratory wide Continuity of Operations Plans (COOP). The surge plan should address:
  - Communication/coordination with epidemiologists for specimen triage,
  - Algorithm changes to improve efficiency and throughput or to meet specific surveillance needs,
  - Resources (e.g., staff, cross-training, equipment, space, reagents and consumable supplies),
  - Biosafety considerations for working with novel viruses,
  - Options to mitigate the capacity gaps and bottlenecks identified in the APHL-CDC Influenza Laboratory Resource and Process Modeling Project report provided to participating states by APHL/CDC.

- Establish mechanisms to determine and implement a sampling strategy for investigation following detection of a rare/novel influenza event. Consider the potential scenarios that may define sampling approaches, such as the need to identify additional cases and detect person-to-person transmission. Consider targeted surveillance options including clinical severity criteria, exposure risk, number of hospitalized cases/deaths and other event specific needs.

- Establish criteria for specimen triage and decision points for performing diagnostic testing and/
or expanding virologic surveillance testing. Draft scenario specific scale up and ramp down criteria that can be quickly applied when a rare/novel influenza event or outbreak occurs.

- Define laboratory testing algorithms that may be implemented to accommodate the influx of surveillance and diagnostic specimens.

- Periodically assess laboratory contingency and crisis surge capacity, as defined in Surge Requirements Intent section. Laboratory capacity modeling has been conducted in over 35 PHLs using a model developed by APHL and CDC. These models estimated baseline capacity, identified likely sources of bottlenecks in a surge event and evaluated the impact of various changes on overall throughput. Utilizing a surge algorithm with surge resources (staff, equipment, etc.) that are expected to be available to the laboratory during emergency periods of high testing demand provided a capacity increase of 127% compared to the Influenza A/B Typing Assay with reflex Influenza A Subtyping algorithm and baseline resources. The implementation of a super surge process strategy, which included changing from the Influenza A/B Typing with full Influenza A Subtyping Panel baseline to an Influenza A/B Typing only testing algorithm, along with the addition of staff and equipment, could increase national aggregate PHL daily capacity from approximately 5,000 specimens to approximately 14,250 specimens – an estimated change of 185%.

- Utilize sample size calculators to estimate the number of samples to be collected and tested for various rare/novel influenza event investigation scenarios. Compare laboratory surge capacity to likely sample size expectations so that both epidemiology and laboratory leaders understand capacity gaps, if any. Collaboratively explore strategies to reduce sample size or increase capacity.

- Identify and address expectations to support diagnostic testing needs, including potential support to assist clinical laboratories validate tests for the new virus.

**Event:**

- Use sample size calculators to determine the appropriate sample size for the investigation, based on the scenario, acceptable confidence level and error rate. Sustaining testing to provide daily case counts will not be possible and states should consider use of sample size calculators to adjust testing volumes as necessary to answer key surveillance objectives as the event evolves.

- Develop, refine and change state/local and/or CDC guidance based on the latest information as needed dependent on the specific event:
  - Defined surveillance/investigation objectives,
  - Targeted sampling approaches,
  - Initial virus detection reporting criteria (laboratory to epidemiology),
  - Ramp up/ Ramp down criteria.

- Revise testing algorithms to improve efficiency and throughput or meet specific surveillance needs.
• Communicate closely with health department leadership; participate in state health department emergency operations.

• Provide timely specimen collection, testing and biosafety guidance to clinical laboratories and clinicians.

Detailed guidance on pandemic response is beyond the scope of this document. During a large scale event, CDC, CSTE and APHL will coordinate to provide timely direction and support. It is important that information disseminated by CDC, state health officials, and APHL to PHL directors is disseminated to the laboratory staff. Management and technical staff should participate in CDC/APHL conference calls to obtain pertinent recommendations.