

## Quality Management Systems

### National Surveillance System Quality Monitoring

The ultimate value of virologic surveillance data is dependent on the quality of specimens, laboratory procedures and data analysis. CDC and state/local jurisdictions should establish performance metrics and monitor essential components of the national influenza virologic surveillance system to ensure quality and make improvements as needed. Listed in this section are key components that should be routinely assessed, but it should be noted that each quality management system will vary and jurisdictions need not be limited by this list. It is likely that existing data sources can be leveraged to assess the quality of many surveillance components.

### State/Local Quality Management Responsibilities

At the state and local level, quality management systems need to monitor both internal performance and performance in meeting national surveillance requirements including those defined in this document. As discussed previously, influenza virologic surveillance systems are complex and vary across jurisdictions; quality management systems will likewise need to be tailored to each system. Regardless of the assessment mechanism(s), it is recommended that states have some method to evaluate the following elements related to influenza virologic surveillance and make adjustments and improvements as needed.

- Compliance with ELC, PHEP and other cooperative agreement and grant benchmarks for all epidemiology and laboratory components of the surveillance system.

### New Hampshire PHLs Influenza Quality Monitoring, 2013

When it became clear that the 2012-2013 influenza season was ramping up to be the busiest since the 2009 pandemic, staff at the NH PHLs realized they needed to closely monitor influenza submissions in order to ensure resources were appropriately allocated to meet the goals of the surveillance program. This was achieved by building a simple “Daily Flu Data” report in the laboratory LIMS, which effectively extracted all data associated with influenza specimens received from the start of the season in October 2012.

The influenza report was run daily and data was dumped into an Excel spreadsheet. Once populated in the spreadsheet, the data could be manipulated in a number of ways: specimens received by date, specimens received by provider, specimens received by county, etc. This manipulation allowed the team to quickly see if submissions were increasing or decreasing and if the PHL was were obtaining representative samples from across the state. They were able to use this tool to reach out to health care providers and encourage additional submissions from providers in underrepresented areas of the state, while informing others that their submissions had exceeded surveillance needs. By storing the spreadsheet in a shared folder on the network, all staff who needed to use the information were able to access it quickly and conveniently.

- Specimen submissions through the provider networks including consistency, quality and number. Timely electronic transmission of specimen-level data. The PHLIP system is the preferred method of reporting.
- Percentage of influenza test results received by CDC from the PHL within two weeks of the test date.
- Capability to provide year-round molecular testing for the detection, typing and subtyping of seasonal influenza viruses and detection of novel influenza viruses.
- Systematic submission of representative influenza positive clinical materials and/or viral isolates for national virologic in accordance with annual CDC specimen submission guidance.
- Rapid referrals of all unsubtypeable influenza A viruses to CDC.
- Proficiency in PCR methods for influenza virus detection, typing, and subtyping. The laboratory must operate in compliance with the Clinical Laboratory Improvement Amendment (CLIA) 88' Requirements, which include participating in an external/blinded proficiency test for each assay. CDC provides a quality assessment panel to PHLs at least one time per year which helps PHLs fulfill this CLIA requirement. Participation in this CDC assessment also provides data that helps CDC assess and address training needs.
- Usage of IRR-provided reagents, materials and other resources used for national surveillance in comparison to the number of specimens tested and reported to CDC. IRR reagents are provided to PHLs to support testing for national surveillance. Prior authorization from CDC is needed if IRR-provided materials are needed to support special studies.
- Staff expertise to perform each influenza test method used at the PHL. Every PHL should have a competency assurance policy that addresses initial training, assay update training and cross-training to ensure continuity of operations in a surge event such as the 2009 H1N1 pandemic.
- Staff expertise and ability to adopt influenza assay revisions, add additional testing markers or adopt assay interpretation updates. The detection of novel or variant viruses may result in new assay components or modified interpretation guidelines.
- Maintenance of an influenza specimen repository that can be utilized for assay verification and validation and competency testing as needed. Store a subset of positive and negative specimens containing a mix of influenza types and subtypes at -70°C.

**CDC Quality Management Responsibilities:**

- Cross-reference PHL influenza testing data reported to CDC against virologic specimen submissions to CDC and CDC-designated laboratories.

- Monitor national surveillance data for timeliness, adequate testing and specimen submissions numbers and representativeness to ensure the system is able to effectively inform situational awareness and vaccine virus selection efforts. When needed, provide targeted communications to PHLs that are not consistently complying with specimen submission expectations or to request additional specimens as needed. Targeted communications help reduce confusion about specimen requirements and focus attention on key gaps or special needs.
- Monitor IRR reagent ordering history in relation to testing reported to CDC. Targeted follow-up to PHLs can be an effective method for addressing excessive reagent ordering which may be due to oversampling or unrecognized technical problems. When technical problems are identified, CDC and the PHL should collaborate to implement appropriate solutions as needed.

### Considerations for Establishing and Maintaining Quality Management Systems

1. Does your laboratory and surveillance program have mechanisms in place to monitor compliance with grant/cooperative agreement benchmarks and deliverables?
  - Example: Leadership should meet regularly to review grant line items, identify issues and document progress. LIMS and tracking spreadsheets can be used to document and verify deliverables are being met.
2. Does your laboratory and/or surveillance program have processes for monitoring the quality, quantity, consistency, representativeness and timeliness of specimen submissions from specimen providers?
  - Example: Influenza coordinator and PHL may regularly review specimen submission data for quality indicators such as number of specimens rejected for poor quality, number of inconclusive test results, etc.
  - Example: Influenza coordinator and PHL may regularly review number of specimens received compared to number designated by [sample size calculators](#). Sampling may be adjusted as appropriate.
3. Does your laboratory have mechanisms in place to ensure that representative specimens are being submitted to CDC or CDC-designated laboratories in accordance with annual specimen submission guidance and other CDC requests?
  - Example: Use LIMS and tracking spreadsheets to monitor the timeliness of influenza surveillance testing and submissions to CDC or CDC-designated laboratories. Regularly check to ensure specimens submitted to CDC are representative of the influenza activity in your jurisdiction (see examples in Sampling Implementation) and current CDC guidelines. Verify that shipment quantities and frequencies are in compliance with the CDC guidelines.