Right Size Influenza Virologic Surveillance
Project Charter

Project sponsored by CDC Influenza Division and the Association of Public Health Laboratories
April 2011
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1. **Project Overview**

1.1. **Objectives**

1.1.1. The primary goal of this project is to define the core capabilities and the optimal “right-size” for influenza virologic surveillance to support key state, national and global surveillance requirements to inform policy decisions and disease prevention efforts. Implementation of right-size virologic surveillance guidelines will assist CDC and public health laboratories (PHL’s) maximize available resources, redirect and build new capacity as needed for optimal surveillance.

Appropriate laboratory testing volumes and sampling strategies will be defined for:

- Annual prevalence and strain monitoring for year-round surveillance.
- Assuring detection of unusual cases that may reflect changes in the virus.
- Assuring detection of an emergent strain with pandemic potential or vaccine effectiveness impact
- Monitoring antiviral resistance in circulating viruses
- Informing annual vaccine strain selection
- Guiding public health response and intervention decisions seasonally, in local outbreaks and throughout a pandemic
- Identifying appropriate performance measures to monitor maintenance of needed capacity and timeliness

1.1.2. Pandemic laboratory surge requirements are not the primary focus of the project. However, lessons learned from the testing demands of the 2009 H1N1 pandemic will be captured to inform the development of capability and capacity guidelines that effectively support seasonal surveillance and are rapidly scalable for outbreak and pandemic scenarios.

1.2. **Background**

It is important to maintain a comprehensive system for influenza surveillance for several reasons:

- Influenza viruses are constantly changing which requires ongoing collection and characterization of the strains.
- Influenza strains can rapidly undergo changes leading to pandemics of influenza; surveillance of viruses will detect these changes.
- Vaccines must be administered annually and are updated regularly based on surveillance findings.
- Treatment for influenza is guided by laboratory surveillance for antiviral resistance.
- National responses to emerging pandemic strains are triggered by surveillance data.
- Varying segments of the population are affected by influenza and may require targeted interventions. These groups are determined through influenza surveillance.

The Influenza Division at CDC collects, compiles and analyzes information on influenza activity year round in the United States and produces FluView, a weekly compilation of influenza surveillance information, from October through mid-May ([www.cdc.gov/flu/weekly/](http://www.cdc.gov/flu/weekly/)). The U.S. influenza surveillance system is a collaborative effort between CDC and its many partners in
state, local, and territorial health departments, public health and clinical laboratories, vital statistics offices, healthcare providers, clinics, and emergency departments. The information collected allows state health officials and CDC to monitor when and where influenza activity is occurring, determine the types of influenza viruses circulating and detect changes in the viruses, and track influenza-related illness and measure the impact influenza is having on deaths in the United States. Surveillance data informs state and national policy decisions and disease prevention efforts, and guides clinician patient management decisions. Reliable data can contribute to health care cost savings through reducing use of antibiotics, and reducing disease transmission and hospitalizations. (www.cdc.gov/flu/weekly/overview.htm)

Viral Surveillance — Approximately 80 U.S. World Health Organization (WHO) Collaborating Laboratories and 60 National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories located throughout the United States participate in virologic surveillance for influenza. All state public health laboratories participate as U.S. WHO collaborating laboratories along with some county public health laboratories and some large tertiary care or academic medical centers. Most NREVSS laboratories participating in influenza surveillance are hospital laboratories. All collaborating laboratories report the total number of respiratory specimens tested and the number positive for influenza types A and B each week to CDC. Most of the U.S. WHO collaborating laboratories also report the influenza A subtype (H1 or H3) of the viruses they have isolated and the ages of the persons from whom the specimens were collected. The majority of NREVSS laboratories do not report the influenza A subtype. A subset of the influenza viruses collected by U.S. WHO collaborating laboratories are sent to CDC for further characterization, including gene sequencing, antiviral resistance testing and antigenic characterization. Sequencing of genes encoding for the antigenic portion of Hemagglutinin protein (HA1 domain) and the Neuraminidase is a sensitive method to examine the degree and direction of genetic changes in the viruses. To assure rapid detection of novel influenza A viruses, specimens that contain viruses subtyped as nonhuman in origin and those that are unsubtyitable with standard laboratory methods and reagents are referred to CDC for rapid evaluation.

Public health laboratories serve as the backbone of state and national virologic surveillance programs. Most performed virus culture for many years prior to the introduction of PCR methods. Since late 2008, CDC’s Influenza Division has been providing FDA cleared real time RT-PCR reagent kits to qualified PHL’s to support rapid detection and subtyping of circulating viruses. Currently the ability to reliably detect novel subtypes is located principally in public health laboratories and CDC. Viruses used for annual vaccine development often come from specimens tested in PHL’s. Critical funding that supports in part other components of influenza testing, such as virus culture and personnel is provided by the Influenza Division through CDC’s Epidemiology and Laboratory Capacity Grant program and the CDC Influenza Reagent Resource (IRR). These federal resources are essential to maintaining PHL virologic testing capacity.
Currently the amount of influenza testing performed both at CDC and in PHL’s is largely determined by the capacity of the laboratory. Influenza surveillance coordinators consider geographic diversity when establishing sentinel provider networks that submit specimens to the PHL. Some PHL’s also receive specimens and influenza viruses from clinical laboratories as part of their virologic surveillance program. However, a statistical, systematic approach to determining the amount of testing needed to support disease response and control efforts and policy decisions is lacking. This gap was highlighted during the initial weeks of the 2009 H1N1 response, when PHL’s were inundated with specimens with little or no ability to prioritize testing based on specific surveillance or diagnostic criteria. Post-pandemic, declining federal and state resources to support laboratory surveillance, and the increasing shortages of laboratorians with expertise in classic virologic methods, threaten sustainability of current programs.

Following the 2009 H1N1 pandemic, CDC, APHL and other partners participated in numerous after action reviews where laboratory capacity was identified as a critical surveillance and outbreak response resource. APHL’s Influenza subcommittee identified the need to develop a strategic, scientifically based calculation to right-size all components of virologic surveillance that effectively supports seasonal needs and is rapidly scalable for outbreak and pandemic scenarios. Right-sizing surveillance does not automatically imply downsizing the amount of testing performed; detection of rare changes in influenza viruses may require expanded testing. This project will provide a scientific justification for laboratory resources to reliably support influenza policy decisions. The Influenza Division has provided funding to APHL to support this initiative; this charter describes the project goals and workplan to achieve the right-size objectives.

1.3. Deliverables
1.3.1. Summary report of survey describing current virologic surveillance practices.
1.3.2. Requirements Document: define state and national virologic surveillance needs, and the associated requirements of state and local public health laboratories to meet national surveillance goals (i.e. virologic surveillance business requirements). This document will provide justifications for laboratory surveillance activities and describe best practices to meet surveillance needs. This document will also define core laboratory testing and analysis capabilities for public health laboratories, addressing virus culture, molecular detection, anti-viral resistance testing, antigenic and genetic characterization methods. The concepts, potential benefits and challenges of establishing public health laboratory reference centers to assure sustainable capacity for testing will be described.
1.3.3. Modeling tools to determine effective sample size needed to detect/monitor key virologic surveillance parameters. Models will address right size virologic surveillance for routine/random surveillance as well as geographically targeted or population specific strategies that address specific surveillance questions and challenges.
1.3.4. Guidelines Document: Influenza Virologic Surveillance Implementation Guidance document or toolkit for CDC, state and local health departments and public health laboratories. Guidelines will include principles and functional requirements for an effective virologic
surveillance program, statistical and scientific analysis to support recommendations, templates and modeling solutions to determine right sizing for state based virologic surveillance. Guidelines will be published in MMWR or other appropriate journals.

1.3.5. Performance measures for laboratories at CDC, state and local public health laboratories, and other virologic surveillance partners to monitor maintenance of needed capacity and timeliness of submission of specimens for surveillance and for detection of events of public health importance, notably in concert with International Health Regulations. Measures will be included in surveillance guidance.

1.3.6. Cost estimates to perform routine and enhanced levels of virologic surveillance, including personnel, specimen collection, testing supplies and reagents, and data reporting. Cost estimates to establish and maintain virologic testing reference centers for virus culture, as well as anti-viral resistance testing, and antigenic and genetic characterization methods that are primarily centralized at CDC.

1.3.7. Potential roles for national and regional commercial laboratories in influenza virologic surveillance, including requirements for data collection and transfer to public health agencies will be incorporated into the guidelines and toolkit, and may be developed into a white paper.

1.4. Purpose of Charter

The purpose of the charter is to present the project scope, objectives, roles/responsibilities and work plan (activities, timelines, and deliverables). The charter ensures that all stakeholders understand the project. The charter also serves as the reference to guide the project life cycle, assuring that goals and activities remain within the project scope, and that participants adhere to the work plan and timelines. Revisions to scope, workplan and timelines are permissible as if approved by the project governance body.

2. Project Plan

2.1. Scope

2.1.1. This project will address US domestic virologic (specimen-based) surveillance capacity only. This project will not address sentinel ILI surveillance or other systems to assess hospitalizations and deaths associated with influenza.

2.1.2. Within the scope of virologic influenza surveillance, there are numerous concepts and issues to be considered. A preliminary list of issues already identified by the project sponsors are listed in Table 1. Stakeholder input, as described in the workplan, will assure that all relevant issues are considered in developing the final deliverables.

2.1.3. Although the scope of the project does not include virologic surveillance capacities in laboratories outside the US, the guidelines and recommendations from this project may have international application. Future international application should be considered as tools are developed. Relevant deliverables will be shared with WHO and the North American Pandemic/Avian Plan for Influenza (NAPAPI) for international use as appropriate.
2.1.4. CDC may wish to establish a secondary project to gather expanded clinician input on the types of surveillance data that are useful to inform patient management and control health care costs.

Table 1: Issues to be considered in Right-sizing Virologic Surveillance*

1. Sampling considerations/representativeness of samples
   - Utility of sampling models to define the appropriate testing volumes to support effective surveillance.
   - Population specific surveillance considerations, assuring collection of samples from diverse and specific populations as needed.
   - Sampling considerations for detection of relatively rare events (genetic changes, anti-viral resistance).

2. Governance policies for specimen acceptance and testing,
   - Role of the state and local epidemiologists as gate-keepers for specimen testing demand. Jurisdictional approaches vary.
   - Need for a year-round virologic surveillance system that is also scalable for effective response to outbreaks and pandemics, able to support diagnostic needs and “case counts” in outbreak and pandemic scenarios, and has criteria to determine when to stop using “case counts”.
   - Impact of cost of testing on laboratory capacity.

3. Capabilities and resources in PHLs
   - Impact of overlapping and competing demands on PHL’s: primary role to provide surveillance data to CDC, state/local epidemiologists and policy makers, secondarily providing “diagnostic” support to the health care community/clinicians early in the season, and in the early stages of the outbreak.
   - Potential for technology/testing methods to introduce bias into virologic surveillance, For example, virus culture allows laboratory to detect phenotypic variants, which are not detected by PCR).
   - Impact of changing levels of expertise in PHL’s, including the declining expertise and capacity to perform virus culture, and the varying levels of expertise to perform testing using new technologies (rRT-PCR, pyrosequencing, sequencing).
   - Potential benefits and limitations of establishing public health laboratory reference centers to assure sustainable testing capacity.
   - Role for expanded PHL surveillance for other respiratory diseases to guide public health decisions during influenza season and outbreak settings.

4. Role of private and commercial laboratory sectors
   - Ability to expand surveillance data using results of type and subtype RT-PCR assays for influenza that are now available in many clinical and commercial labs, and influenza sequencing expertise available in some medical and academic centers.
   - Lack of interoperable information systems to capture private sector test results for surveillance purposes.
   - Role of rapid test results in surveillance data.
   - Ability to expand private sector testing for other respiratory diseases into NREVSS data to guide public health decisions during influenza season and ILI outbreaks.
5. Use of alternative electronic data sources
   - Potential use of BioSense and other sentinel/syndromic surveillance systems’ data to inform virologic surveillance requirements; potential addition of virologic surveillance components to these systems.
   - Role of electronic data exchange systems in supporting transfer of virologic surveillance data for analysis and input to disease prevention and response decisions.
6. Role of PHLs in broader health reform initiatives.
   - Potential value of influenza surveillance, especially virologic surveillance information, in controlling/reducing health care costs by improving vaccine uptake and guiding clinician patient management decisions.

2.2. Assumptions
2.2.1. A perfect virologic surveillance system is not achievable.
2.2.2. No single solution will work in every jurisdiction.
2.2.3. Federal funding is critical to support effective virologic surveillance. State funding cannot be relied on to meet national and jurisdictional surveillance goals.
2.2.4. The design and capacity of virologic surveillance systems should be flexible to adapt to changing situations (novel virus detection, outbreaks, pandemic)
2.2.5. Guidelines and recommendations are unlikely to be universally accepted by all state and local programs.
2.2.6. Health care system guidelines for diagnosis and reimbursement for diagnostic testing may limit the number of specimens submitted for influenza testing on a routine basis – impacting access to specimens for surveillance purposes.

2.3. Approach
   The approach proposed for this project is to a) gather and evaluate relevant data to inform the processes and b) engage stakeholders to provide subject matter expertise to inform the development of guidance documents and modeling tools.

2.4. Data gathering activities needed to inform guidelines
2.4.1. Input from CDC, state and local epidemiologists, influenza coordinators, public health laboratory directors and other relevant subject matter experts to review and clarify state, national and international virologic surveillance goals and objectives.
   2.4.1.1. A list of all virologic parameters that need to be detected, and a definition of minimal levels of detections required to effectively inform policy and practice decisions. (Ex: antigenic shift, antiviral resistance markers)
2.4.2. Survey of state and local PHL’s to assess the landscape of current state virologic surveillance systems for influenza and other respiratory pathogens, including how priorities are established and funded, as well as challenges to sustainability. A determination will be made by the lead group with input from the principal advisory group as to whether a survey of a representative subset of laboratories will suffice.
2.4.3. Survey of costs of all components of virologic surveillance

2.4.3.1. Laboratory costs (personnel, supplies, reagents, equipment and data reporting).
These data may be collected as part of above survey.

2.4.3.2. Costs of pre and post-analytical components, including establishing a network of specimen providers, educating providers, specimen collection and transport, and data analysis, will be collected from relevant sources.

2.4.4. Collect details of existing international virologic surveillance strategies used in various WHO regions, especially the European Union system, and strategies developed by PAHO.

2.4.5. Evaluate data from the public health laboratory PCR capacity modeling project (this is a separate APHL-CDC activity performed as adjunct to this project).

2.4.6. Data to develop and pilot sample size models for virologic surveillance, including review of sampling guidelines provided for CSTE IISP project and other systems.

2.4.7. Review of references to laboratory testing and capacity gaps in relevant 2009 H1N1 after action reports (AAR).

2.4.8. Review of relevant literature that addresses sampling methods to support surveillance systems.

2.4.9. List of all state, local and private sector data inputs to national virologic surveillance system. Include relevant inputs to national surveillance criteria and data management requirements from the CDC Influenza Information Management project which is establishing functional requirements for CDC internal influenza information management systems.

2.4.10. Other data needs as identified by stakeholders once the project is underway.

2.5. Work Plan
The project is expected to be completed in approximately two years from the date of Charter approval, with implementation of new guidelines expected beginning in Fall 2013.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Key Participants</th>
<th>Description</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Charter</td>
<td>Lead group members</td>
<td>Draft charter to define project scope, deliverables, workplan, stakeholders, roles and responsibilities</td>
<td>January 2011</td>
</tr>
<tr>
<td>Stakeholder Charter Review</td>
<td>Lead and Principal Advisory Groups</td>
<td>Obtain input (via electronic communication) to charter; finalize scope and deliverables</td>
<td>February – March 2011</td>
</tr>
<tr>
<td>Stakeholder Meeting #1</td>
<td>Select members of lead and principal advisory group</td>
<td>Data gathering 2.4.1.1 Draft a list of all virologic parameters that need to be detected, and a definition of minimal levels of detections needed, to inform policy and practice decisions. Review survey questions (data gathering 2.4.2)</td>
<td>March 2011</td>
</tr>
<tr>
<td>Task Description</td>
<td>Responsible Groups</td>
<td>Timeframes</td>
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<tr>
<td>Charter Sign-off (following approval by APHL BOD)</td>
<td>APHL and CDC ID leaders</td>
<td>Finalized charter signed by governance body, April 2011</td>
<td></td>
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<tr>
<td>Evaluate existing non-US virologic surveillance strategy models</td>
<td>Lead and Principal Advisory groups</td>
<td>Data gathering 2.4.4&lt;br&gt;Collect and review virologic surveillance models used in WHO regions (ex. European sampling model).&lt;br&gt;March–June 2011</td>
<td></td>
</tr>
<tr>
<td>Develop preliminary sample size modeling tools</td>
<td>Lead and Principal Advisory Groups with modeling contractor</td>
<td>Data gathering 2.4.6&lt;br&gt;Preliminary deliverable 1.3.3&lt;br&gt;Develop tools to determine effective sample size needed to detect/monitor key virologic surveillance parameters.&lt;br&gt;May–July 2011</td>
<td></td>
</tr>
<tr>
<td>Introduce project to APHL and CSTE members, and Influenza Surveillance Coordinators</td>
<td>Lead group representatives</td>
<td>Data gathering 2.4.1&lt;br&gt;Project will be introduced through roundtable presentations at APHL and CSTE annual meetings to obtain buy-in and additional inputs.&lt;br&gt;June 2011</td>
<td></td>
</tr>
<tr>
<td>Stakeholder Meeting #2</td>
<td>Lead, Principal and Secondary Advisory groups</td>
<td>Data gathering 2.4.1/2.4.1.1&lt;br&gt;Facilitated brainstorming discussion to capture and define issues impacting virologic surveillance requirements. Review virologic surveillance parameters and proposed modeling tools.&lt;br&gt;July 2011</td>
<td></td>
</tr>
<tr>
<td>Review PHL PCR capacity model data</td>
<td>Lead and Principal Advisory groups</td>
<td>Data gathering 2.4.5&lt;br&gt;Review capacity data obtained from 20 PHL’s through APHL-CDC-BAH rRT-PCR capacity modeling project. Data expected to be available late summer 2011.&lt;br&gt;September - November 2011</td>
<td></td>
</tr>
<tr>
<td>Pilot sampling models</td>
<td>Select 3-4 states</td>
<td>Pilot sampling models in 2011-12 Influenza season. Fall 2011 - April 2012</td>
<td></td>
</tr>
<tr>
<td>Task</td>
<td>Lead Group</td>
<td>Description</td>
<td>Date</td>
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<tr>
<td>Complete data gathering activities</td>
<td>Lead group</td>
<td>Data gathering: 2.4.3 – Additional cost data 2.4.7 – 2009 H1N1 AAR elements 2.4.9 – Data inputs and other requirements from Information Management Project 2.4.10 – Other data needs identified by stakeholders.</td>
<td>March-November 2011</td>
</tr>
<tr>
<td>Draft virologic surveillance requirements document</td>
<td>Lead group</td>
<td>Preliminary deliverable 1.3.1 Draft document, small stakeholder meetings may be required.</td>
<td>Nov 2011 – Feb 2012</td>
</tr>
<tr>
<td>Draft Influenza Virologic Surveillance guidance document</td>
<td>Lead group</td>
<td>Preliminary deliverable 1.3.3 Draft document, small stakeholder meetings may be required.</td>
<td>Nov 2011 – Feb 2012</td>
</tr>
<tr>
<td>Stakeholder Meeting #3</td>
<td>Lead group, Principal and Secondary Advisors</td>
<td>Present draft deliverables to stakeholders</td>
<td>March 2012</td>
</tr>
<tr>
<td>Stakeholder Meeting #4</td>
<td>Lead group, advisors and clinical laboratory representatives</td>
<td>Preliminary deliverable 1.3.7 Obtain input on the potential roles for national and regional commercial laboratories in influenza virologic surveillance.</td>
<td>March 2012</td>
</tr>
<tr>
<td>Develop supplemental modeling tools</td>
<td>Lead group members with modeling contractor</td>
<td>Deliverable 1.3.3 Develop modeling tools to address specific surveillance questions and calculate funding levels for enhanced surveillance.</td>
<td>Jan-May 2012</td>
</tr>
<tr>
<td>Define virologic surveillance costs, develop reference center cost estimates</td>
<td>Lead group (likely with contractor)</td>
<td>Deliverable 1.3.6 Analyze cost survey data to define true surveillance costs. Develop cost estimates to establish and maintain reference centers for select virologic surveillance testing services</td>
<td>Feb-Jun 2012</td>
</tr>
<tr>
<td>Draft white paper on role of private sector testing</td>
<td>Lead group</td>
<td>Preliminary deliverable 1.3.7</td>
<td>Mar-June 2012</td>
</tr>
<tr>
<td>Finalize all sample size modeling tools</td>
<td>Lead group and modeling contractor</td>
<td>Deliverable 1.3.3</td>
<td>June 2012</td>
</tr>
<tr>
<td>Pilot virologic surveillance promising best practices</td>
<td>Select 3-4 states</td>
<td>Pilot practices and models identified through data gathering and stakeholder inputs in select PHL’s during 12-13 Influenza season.</td>
<td>July 2012-April 2013</td>
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<tr>
<td>Stakeholder Meeting #5</td>
<td>All stakeholders</td>
<td>Review draft recommendations, results from pilot projects, and all critical inputs that informed recommendations. Obtain final inputs.</td>
<td>May 2005</td>
</tr>
<tr>
<td>Finalize virologic surveillance requirements document</td>
<td>Lead group and governance body</td>
<td>Deliverable 1.3.2 Incorporate final inputs to document, final review by Lead group and approval by governance body.</td>
<td>May –July 2013</td>
</tr>
<tr>
<td>Finalize Influenza Virologic Surveillance guidance document</td>
<td>Lead group and governance body</td>
<td>Deliverable 1.3.4 Incorporate final inputs to document, final review by Lead group and approval by governance body.</td>
<td>May –July 2013</td>
</tr>
<tr>
<td>Present guidelines and recommendations to APHL and CSTE members</td>
<td>Lead group members</td>
<td>Project deliverables will be presented at APHL and CSTE annual meetings</td>
<td>June 2013</td>
</tr>
<tr>
<td>Implementation begins</td>
<td>Influenza Division, State surveillance coordinators/epidemiologists and PHL’s</td>
<td>Right-size recommendations will be implemented by CDC and state/local jurisdictions. Impact of changes will be monitored and evaluated throughout 13-14 Influenza Season.</td>
<td>August 2013</td>
</tr>
</tbody>
</table>

### 3. Governance

The governance of this project includes a decision making process, definition of stakeholder roles and responsibilities, and assignment of project management and communication responsibilities.

#### 3.1. Decision making process

Reaching decisions on key activities and documents that impact timelines, deliverables and outcomes requires a formalized process. The collaborative decision making process outlined below will ensure that the project goals and objectives are met.
3.2. Roles and Responsibilities (see Appendix A for list of stakeholders)

3.2.1. Governance Body – responsible for overall project management including oversight of planning, managing timelines, approving any project changes, final approval of all deliverables, and evaluation of outcomes. The governance body is comprised of Dr. Nancy Cox, Dr. Dan Jernigan, Dr. Pete Shult, and Rosemary Humes.

3.2.2. Stakeholders

3.2.2.1. Lead group: Collects and analyzes data, drafts documents as defined in deliverables, provides input to modeling tools. Plans and participates in all stakeholders meetings. Provides critical subject matter expertise to overall project.

3.2.2.2. Principal advisory group: Participates in all stakeholder meetings, supports document development, and provides primary document review. Provides unique subject matter expertise as surveillance data consumers and policy decision makers.

3.2.2.3. Secondary advisory group: Participates in relevant stakeholder meetings, provides document review. Provides subject matter expertise as consumers of surveillance data.

3.2.3. Project Management

Overall project management, including fiscal oversight, will be led by Rosemary Humes (APHL) and Dan Jernigan (CDC/ID). Logistics will be managed by APHL staff with assistance from contractor as needed. Logistics includes meeting planning, coordination and communications with stakeholders, document editing and production.

4. Risk Assessment

4.1. The success of the project will be impacted by factors such as:

4.1.1. Scope and duration of project could challenge sustainable commitment of stakeholders.

4.1.2. Unanticipated federal priorities for pandemic preparedness that may disrupt workplan timelines.
4.1.3. Potential failure to reach consensus among the project stakeholders.
4.1.4. Likelihood of acceptance and adoption of guidelines at state and local level.
4.1.5. Availability of federal funding to implement final recommendations.

5. Approvals

Nancy J. Cox, Ph.D.
Director, Influenza Division, NCIRD, CDC

5/18/11
Date

Daniel B. Jernigan, MD MPH
Deputy Director, Influenza Division, NCIRD, CDC

5/18/2011
Date

Peter A. Shult, Ph.D.
Director, Communicable Disease Division and
Emergency Laboratory Response
Wisconsin State Laboratory of Hygiene

5/4
Date

Rosemary Humes MS, MT(ASCP)SM
Senior Advisor, Scientific Affairs, APHL

5-5-11
Date
Appendix A: Stakeholders

A. Lead Work Group

A.1. Association of Public Health Laboratories Influenza Subcommittee
- Peter Shult PhD, Director, Communicable Disease Division and Emergency Laboratory Response, Wisconsin State Laboratory of Hygiene
- Rosemary Humes MS, MT(ASCP)SM, Senior, advisor, Scientific Affairs, APHL
- Sandra Smole PhD, Director, Division of Molecular Diagnostics and Virology, William Hinton State Laboratory Institute, Massachusetts
- Michael Pentella PhD, Associate Director, Iowa State Hygienic Laboratory
- Kirsten St. George PhD, MAppSc, Chief, Laboratory of Viral Diseases, Wadsworth Center, New York State Dept of Health
- Brandon Troy Leader PhD, Microbiology Supervisor, Washington Public Health Laboratories
- Tricia Aden MT(ASCP), Influenza Program Manager, APHL

A.2. Centers for Disease Control and Prevention Influenza Division
- Nancy Cox, PhD, Director, Influenza Division, NCIRD
- Daniel Jernigan MD, Deputy Director, Influenza Division, NCIRD
- Alexander Klimov PhD ScD, Chief, Virus Surveillance and Diagnosis Branch, ID/NCIRD
- Lynette Brammer MPH, Epidemiologist, Epidemiology Branch, ID/NCIRD
- Joseph Miller PhD, Laboratory Preparedness Officer, ID/NCIRD
- Lyn Finelli DrPH, MS, Epidemiologist, ID/NCIRD
- Xiyan Xu MD, Virus Reference Team Lead, Virus Surveillance and Diagnosis Branch, ID/NCIRD
- Julie Villanueva, PhD, Virus Surveillance and Diagnosis Branch.
- Paul Garguillo PhD, Epidemiologist (Statistician), Epidemiology Branch, ID/NCIRD

B. Principal Advisory Group
- Matthew L. Cartter, MD, MPH, State Epidemiologist, Connecticut Department of Public Health (CSTE)
- Lisa McHugh, MPH, Influenza Surveillance Coordinator, New Jersey Department of Health and Senior Services (CSTE)
- Alison Mawle PhD, Associate Director for Laboratory Science, NCIRD
- Joseph Bresee MD, Epidemiology Branch Chief, ID/NCIRD
- CDC Influenza Division subject matter experts
- CDC Influenza Coordination Unit representative
- APHL Infectious Diseases Committee and select members
- Patina Zarcone, Director Informatics and Institutional Research, APHL
C. Secondary Advisors (TBN)

- ASTHO representative TBN
- CDC Health Economist TBN
- HHS: ASPR representative
- CDC: LSPPPO/DPEI/OPHPR representatives
- Ann Moen, Associate Director for Extramural Programs, ID/NCIRD
- APHL Infectious Diseases Committee representatives
- NACCHO representative
- ASM/clinical laboratory representatives
  ACLA/commercial laboratory representatives
- IDSA representative
- AAFP representative
## Appendix B: Project Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>11</th>
<th>12</th>
<th>13</th>
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<tbody>
<tr>
<td>Draft Charter</td>
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<td>Stakeholder Charter Review</td>
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<td>Stakeholder Meeting #1</td>
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<td>Charter Sign-off</td>
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<td>Survey state virologic surveillance practices and costs</td>
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<tr>
<td>Evaluate existing non-US virologic surveillance strategy models</td>
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<td>Stakeholder Meeting #2</td>
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<tr>
<td>Develop preliminary sample size modeling tools</td>
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<td>Introduce project to APHL and CSTE members</td>
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<tr>
<td>Review PHL capacity model data</td>
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<td>Pilot sampling models</td>
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<td>Complete data gathering activities</td>
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<td>Draft virologic surveillance requirements document</td>
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<td>Draft Influenza Virologic Surveillance guidance document</td>
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<td>Stakeholder Meeting #3</td>
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<td>Stakeholder Meeting #4</td>
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<td>Develop supplemental modeling tools</td>
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<td>Define virologic surveillance costs</td>
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<td>Draft white paper on role of private sector testing</td>
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<td>Finalize all sample size modeling tools</td>
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<td>Pilot virologic surveillance promising best practices</td>
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<td>Stakeholder Meeting #5</td>
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<td>Finalize virologic surveillance requirements document</td>
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<td>Finalize Influenza Virologic Surveillance guidance document</td>
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<td>Present guidelines and recommendations to APHL and CSTE members</td>
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<td>Implementation</td>
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Notes:
- Months: J = January, F = February, M = March, A = April, J = May, J = June, A = July, S = August, O = September, D = October, J = November, F = December
- The timeline indicates the progress of the project over the years 2011, 2012, and 2013.