Contents

CHAPTER 2: DOMESTIC SURVEILLANCE

Introduction

Influenza infections remain the most common cause of vaccine-preventable disease morbidity and mortality in the United States. During interpandemic years, influenza is associated with an average of 36,000 deaths and 220,000 hospitalizations annually during wintertime epidemics. Although the highest rates of death and severe disease occur among known high-risk groups, elderly persons, young children, and those with certain underlying diseases, influenza infections are common among all age groups and populations. During influenza pandemics, the disease burden associated with novel virus strains can be much higher in, and the epidemiology of the disease may be different than during seasonal pandemics.

In the United States, the HHS/CDC monitors the disease burden, timing, and strain distribution of influenza through a variety of surveillance systems. These systems include the following: outpatient disease surveillance through a network of sentinel providers; pediatric hospital-based surveillance through the Emerging Infections Program (EIP) and the New Vaccine Surveillance Network (NVSN); mortality surveillance through vital statistics offices in 122 cities, and notification of pediatric influenza-associated deaths by State, local, and tribal health departments; State and territorial epidemiologists' reports of influenza activity; and strain surveillance through a large network of laboratories. The NIH contributes to surveillance activities through its support of diagnostic research by means of grants and contracts with researchers at universities and other institutions. FDA regulates and ensures safety and effectiveness of products (reagents, instrumentation, and systems) intended for use in the collection, preparation, and examination of human specimens that are tested for influenza viruses. The FDA's regulatory process provides valuable scientific input, along with other contributions including guidance on adequate directions for diagnostic test usage.

While U.S. surveillance systems provide regular data on occurrence, strains, and magnitude of annual influenza epidemics, they are not sufficiently comprehensive or timely to address the needs of public health authorities in the event of pandemic influenza. Once sustained person-to-person spread of a pandemic influenza subtype has been documented, domestic surveillance must be able to detect new introductions of infections with the virus. This ability will ensure timely investigation and public health interventions to limit further spread of disease. Once spread has been documented in the United States, surveillance should reliably detect new clusters of illness so that communities can respond appropriately. Surveillance should be able to document disease burden and trends over time.

This chapter describes the key objectives of U.S. influenza surveillance before and during an influenza pandemic, and lists the actions required to develop surveillance systems to

achieve these objectives. The plan focuses initially on continuing to build laboratory and epidemiologic capacity for surveillance and response, and on establishing comprehensive, timely, and sensitive surveillance systems by building on existing systems and by initiating new systems where gaps currently exist.

Surveillance is the cornerstone of pandemic preparedness and response by public health officials, the U.S. health care system, and the broader framework of governmental, economic, and social organizations. Data on trends in disease activity and virus subtype circulation will inform public health decisionmaking during each of the pandemic phases. Surveillance-related activities will vary under different situations. For example, during the pre-pandemic period, enhancing existing systems for surveillance will allow for reliable and rapid detection of the introduction of a pandemic virus subtype or initial cases of illness in the country. The needs during this period will include ensuring that the laboratory systems are in place to detect novel virus subtypes, to enable detection and investigation of suspect cases in a community, and to detect sentinel increases in disease activity. Surveillance data will guide decisions regarding vaccine development, vaccination strategies (including potential revisions to the list of priority groups), use of antiviral medications, and implementation of public health measures to limit the spread of infection. Surveillance also will provide data to assess the effectiveness of public health measures to control pandemic spread and their impact, and to supply important information for public health messages.

Efforts to develop and implement surveillance systems that can effectively meet pandemic preparedness goals and response needs must address several challenges. Public health officials must identify and address programmatic and resource limitations in instituting more comprehensive and timely surveillance systems. Novel data management systems must be designed to ensure appropriately rapid data reporting, analysis, and feedback. The U.S. Government will need to coordinate surveillance activities with international and domestic partners working on other areas of the pandemic response.

Role of HHS in Domestic Surveillance

The role of HHS is to direct and coordinate domestic surveillance efforts. Responsibilities include, but are not limited to:

- Ensure that sensitive and comprehensive laboratory, epidemiologic, and clinical systems are in place to reliably detect and monitor the occurrence of pandemic influenza in each U.S. Response Stage.
- Ensure mechanisms are in place to provide active and passive surveillance during an outbreak, and that these mechanisms have been developed and exercised.
- Reliably detect and investigate initial cases of highly pathogenic avian-influenza (HPAI) disease or disease associated with other influenza virus subtypes with pandemic potential, such as H5N1. These initial cases can result from exposure to

influenza-infected domestic or wild birds, or from travelers who are exposed to avian influenza outside the United States.

- Identify and investigate initial small clusters of human cases associated with pandemic influenza.
- Determine and track trends in the impact of disease in affected areas (including deaths and hospitalizations), in the general population, and among subpopulations where there is increased and sustained transmission of pandemic influenza occurring in the general population.
- Facilitate development and sustainability of sufficient U.S. laboratory capacity and diagnostic reagents in affected domestic regions to provide rapid confirmation of cases in animals or humans.
- Facilitate the development and deployment of rapid diagnostics.
- Ensure maximal sharing of scientific information about influenza viruses among government authorities, scientific entities, and the private sector.
- Guide pandemic responses, including deployment of rapid response team, implementation of pharmaceutical and non-pharmaceutical public health interventions.
- Assess effectiveness of treatment guidelines, vaccines, antivirals, and public health interventions, and use these data to inform prevention and control strategies.

Specific Assumptions and Planning Considerations for HHS Domestic Surveillance

- All persons living in the United States will be susceptible to infection and illness caused by an influenza pandemic. Because of this susceptibility, surveillance should be able to identify cases of disease, collect specimens for virus subtyping, and monitor the disease burden in all parts of the country and in all age groups.
- The clinical attack rate will be 30 percent, and 50 percent of persons who become ill will seek medical care. Surveillance will focus on health care settings because the objectives stated below are best achieved through the detection and monitoring of the most severe cases of disease.
- Risk groups for severe disease and deaths cannot be predicted before the occurrence of a pandemic. Surveillance systems must be sufficiently comprehensive to monitor disease among all ages, and be flexible enough to undergo modifications to focus on specific subgroups if necessary.
- In an affected community, an influenza outbreak will last approximately 6–8 weeks, based on historical information and models. The surveillance needs in each community may well change during the course of a pandemic—from ensuring rapid detection of first cases and collection of clinical samples for characterizing the virus type; to monitoring virus spread and disease burden; and, to recognize the end of the pandemic period.
- The seasonality of a pandemic cannot be predicted. Sensitive, timely surveillance established in advance of the introduction of a pandemic in the United States will be critical to detect introduction. Therefore, pre-pandemic surveillance should be conducted year-round.
- An influenza pandemic occurring in the next few years will most likely be due to influenza A/(H5N1) and will originate outside the United States. Even so, the capacity to detect any unusual and novel subtype of influenza should be established in case the pandemic originates from a different influenza virus or from within the United States.

HHS Actions and Expectations

Pillar One: Preparedness and Communication

The objectives of influenza surveillance will relate specifically to the different stages of a pandemic. However, many of the activities required to build the systems to meet these surveillance goals must be initiated beforehand, during the pandemic alert period.

HHS will support the development and sustainability of sufficient U.S. laboratory capacity and the supply of diagnostic reagents to provide rapid confirmation of U.S. cases in animals or humans.

Rapid diagnostics having greater sensitivity and reproducibility are needed to allow onsite diagnosis of pandemic strains of influenza in animals and humans, and to facilitate early warning, outbreak control, and targeting of antiviral therapy. Novel investment strategies are being explored to advance the development of next-generation influenza diagnostics and countermeasures, including new antiviral medications, vaccines, adjuvant technologies, and countermeasures that provide protection across multiple strains of the influenza virus and several seasons.

Planning for a Pandemic—Development of Diagnostic Tools

A. Action (HSC 6.2.3.2): HHS, in coordination with DHS, DOD, and VA, will compile an inventory of all research and product development work on rapid diagnostic testing for influenza and will reach consensus with these Departments on sets of requirements meeting national needs and a common test methodology to drive further private-sector investment and product development. (Also see chapter 1, Pillar One, Action Y [HSC 4.1.8.4].)

   Timeframe: Within 6 months.

   Measure of Performance: Inventory developed and requirements paper disseminated.

B. Action (HSC 6.2.3.3): HHS, in coordination with DOD, VA, and DHS will encourage and expedite private-sector development of rapid subtype- and strain-specific influenza point-of-care tests.

   Timeframe: Within 12 months of the publication of requirements.

   Measure of Performance: Rapid point-of-care test available in the marketplace within 18 months.

C. Action (HSC 6.1.17.3): HHS, in coordination with DHS, will develop and test new point-of-care and laboratory-based rapid influenza diagnostics for screening and surveillance. (Also see chapter 3, Pillar One, Action AA [HSC 6.1.17.3].)

   Timeframe: Within 18 months.

   Measure of Performance: New grants and contracts awarded to researchers to develop and evaluate new diagnostics.

D. Action (HSC 4.2.3.4): HHS will investigate the development and evaluation of more accurate rapid diagnostics for influenza to enhance the ability of the global health care community to rapidly diagnose influenza. (Also see chapter 1, Pillar Two, Action N [HSC 4.2.3.4].)

   Timeframe: Within 18 months.

Measure of Performance: New grants and contracts issued to researchers to develop and evaluate new diagnostics.

E. Action (HSC 6.2.3.1): HHS, in coordination with DHS and DOD, will work with pharmaceutical and medical device company partners to develop and evaluate rapid diagnostic tests for novel influenza subtypes including H5N1.

Timeframe: Within 18 months.

Measure of Performance: New investment in research to develop influenza diagnostics; new rapid diagnostic tests, if found to be useful, are available for influenza testing, including for novel influenza subtypes.

F. Action (HSC 6.1.17.2): HHS will collaborate with the pharmaceutical, medical device, and diagnostics industries to accelerate development, evaluation (including the evaluation of dose-sparing strategies), clearance/approval/licensure, and U.S.-based production of new diagnostics. Development activities will include design of preclinical and clinical studies to collect safety and efficacy information across multiple strains and seasons of circulating influenza illness, and advance design of protocols to obtain additional updated information to support revisions in product usage during circulation of novel strains and evolution of pandemic spread. Such collaborations will involve early and frequent discussions with the FDA to explore the use of accelerated regulatory pathways toward product approval or licensure. Collaborations concerning diagnostic tests will include CDC to facilitate access to pandemic virus samples for validation testing and ensure that the test is one that can be used to promote and protect the public health during an influenza pandemic. (Also see chapter 6, Pillar One, Action A [HSC 6.7.17.2].)

Timeframe: Ongoing.

Measure of Performance: Initiation of clinical trials of new influenza antiviral drugs and diagnostics.

For Actions A through F, also see Chapter 5, Vaccines [HSC 6.1.15.3, 6.1.17.1, 4.1.5.3, 4.1.6.2, and 6.1.17.1], for a description of effort associated with new influenza vaccines; and Chapter 6, Antivirals [HSC 4.1.6.2, 6.1.15.3, and 6.1.17.2], for a description of effort associated with the development, evaluation, and licensure of new antiviral agents for influenza.

The following steps will be undertaken to address Actions A through F:

Step 1: Establish a cross-agency working group to identify research and product development work on rapid diagnostic testing. Ensure that efforts will comply with the Federal Food, Drug, and Cosmetic Act (FDCA).

Step 2: Compile an inventory of the research and product development work that has been conducted, is underway, and is planned.

Step 3: Convene a meeting to review the research inventory findings; and to discuss and reach consensus on requirements needed for further research and product development efforts.

Step 4: Produce and distribute proceedings of the meeting.

Step 5: Identify funding source and mechanisms to promote research for rapid diagnostic tests.

Step 6: Establish mechanisms for carrying out the evaluations of newly developed diagnostics, beginning with disseminating the performance specifications and obtaining comments through a Federal regulatory or advisory panel, or other open forum.

Step 7: Issue Requests for Proposals and Requests for Applications for research for rapid diagnostic tests that meet the consensus requirements.

Step 8: Make available materials and data needed by researchers to develop rapid diagnostic methods.

Step 9: Coordinate specification of performance and laboratory evaluations with FDA's premarket review requirements for new diagnostics.

Step 10: Establish a cross-agency working group to identify target performance specifications for new diagnostics, standardized specimen types and collection methods, and methods for preparing any contrived samples; to develop and review protocols for evaluating performance and conducting performance testing; to facilitate evaluation by both public health and clinical labs; and, to streamline regulatory pathways.

Step 11: Perform studies to evaluate rapid diagnostic techniques and reagents/test kits currently available; disseminate results.

Step 12: Collaborate with FDA regarding accelerated regulatory pathways, including establishment of criteria used to determine whether improvements to or updating of current diagnostics represent new diagnostic tools requiring new regulatory review and approval (consistent with 21 CFR 807.81, 814.39).

G. Action (HSC 6.1.17.4): HHS will increase access to standardized influenza reagents for use in influenza tests and research. (Also see chapter 5, Pillar One, Action D [HSC 6.1.17.4] regarding the provision of reagents to assist with identifying virus reference strains for vaccine manufacturing.)

Timeframe: Within 6 months.

Measure of Performance: Standardized influenza reagents distributed to domestic and international partners within 3 business days of a request.

Step 1: Develop and test RT-PCR primers and protocols for detection of novel viruses (completed for influenza virus types H5 and H7).

Step 2: Prepare anti-sera and antigens specific for H5N1 viruses for use in laboratory assays.

Step 3: Ensure availability of reference and control reagents in known national repositories and distribute materials to State, local, and tribal health laboratories.

Step 4: Identify and address regulatory pathways to emergency distribution and use of diagnostic tests and reagents during a pandemic state of emergency and at other times when a state of emergency does not exist.

Step 5: Provide updated preparedness information regarding diagnostic tests and reagents to State, local, and tribal public health partners via the Laboratory Reference Network (LRN) and Health Alert Network (HAN).

Step 6: Continue to provide laboratory training workshops for State, local, and tribal health department personnel as needed.

Step 7: Promulgate guidance for testing approaches and specimen referrals from clinical and commercial laboratories.

Planning for a Pandemic—Facilitate Diagnostic Testing

H. Action (HSC 6.2.1.5): HHS will facilitate State, local, and tribal entities preparation to increase diagnostic testing for influenza and increase the frequency of reporting to CDC, in the event of a pandemic.

Timeframe: Ongoing.

Measure of Performance: State, local, and tribal entities are prepared and can increase their diagnostic testing and reporting to CDC when needed during a pandemic.

Step 1: Encourage State, local, and tribal public health laboratory staff to assess current surge capacity in public and clinical laboratories in their jurisdictions and to identify needs to accommodate increased demand during a pandemic.

Step 2: Develop laboratory training curriculum.

Step 3: Provide support to conduct training courses at CDC and at regionally convenient laboratories.

Step 4: Support personnel at Federal and local laboratories to plan and conduct training.

Step 5: Build capacity and framework for timely reporting to and feedback from CDC and State, local, and tribal entities.

I. Action (No HSC Action): HHS will train federal- and state-based epidemiologists and other public health professionals in pandemic influenza response and investigation to provide surge capacity to State, local, and tribal health departments.

Timeframe: Within 12 months.

Measure of Performance: Materials produced and used for training courses.

Step 1: Establish training materials (Web-based, slide sets, written documents) to prepare epidemiologists and other public health professionals in pandemic influenza response and investigation techniques.

Step 2: Identify and train course trainers.

Step 3: Conduct training course during the 2006 Epidemic Intelligence Service (EIS) Introductory Class and during the 2006 Spring EIS conference.

Step 4: Conduct training courses with the World Bank for World Bank missions to assess country needs regarding pandemic preparedness.

Step 5: Work with State, local, and tribal health departments to identify participants for training workshops and investigate mechanisms (financial and logistic) to conduct them.

Step 6: Establish plans to regularly update training materials.

Step 7: Integrate the HHS/U.S. Public Health Services (USPHS) Commissioned Corps (CC)/Office of Force Readiness and Deployment into pandemic preparedness efforts. For example, consider incorporating pandemic influenza modules into CC readiness standards. (Also see chapter 4, Pillar One, Action A [HSC 6.1.2.2], regarding preparations for deployment of Federal personnel.)

Communicating Expectations and Responsibilities

J. Action (HSC 4.1.4.1): HHS will work with DOS, and USAID, and in coordination with other Federal agencies, to help ensure that the top political

leadership of all priority countries understands the need for clear, effective, coordinated, public information strategies before and during an outbreak of avian or pandemic influenza. (Also see chapter 7, Pillar One, Action E [HSC 4.1.4.1].)

Timeframe: Within 12 months.

Measure of Performance: 50 percent of priority countries develop outbreak communication strategies that are consistent with the WHO September 2004 Report detailing best practices for communicating with the public during an outbreak.

Step 1: Further the objectives of the communications chapter of the Security and Prosperity Partnership for North America (SPP) Annex to the HHS Pandemic Flu Plan, which discusses international information-sharing and coordinated communications leading up to and during a pandemic.

K. Action (HSC 6.2.2.10): HHS will promote State, local, and tribal health departments' development of relationships with hospitals and health care systems within their jurisdictions to facilitate collection of real-time or near-real-time clinical surveillance data from domestic acute care settings such as emergency departments, intensive care units, and laboratories.

Timeframe: Ongoing.

Measure of Performance: All states will have initiated discussions with representatives of hospitals and health care systems regarding the collection of real-time or near-real-time clinical surveillance data.

Step 1: Refine current suspect case forms/systems (see **HHS Pandemic Plan**, pp S1-15–S1-19) to reflect current information about H5N1 and incorporate appropriate data standards.

Step 2: Make suspect case forms/systems available to State, local, and tribal health departments and key health care providers through the CDC Web site, CDC Epidemic Information Exchange (Epi-X) postings, HAN, and partner organizations.

Step 3: Develop and pilot test a secure, Web-based data entry system for forms and data reporting/transmission to State, local, and tribal health departments. Case and outbreak investigations will be simplified by using preestablished, easy-to-use data entry forms and computer systems to transmit these data to central nodes (such as State health departments or CDC). For States able to use a Public Health Information Network (PHIN)-compliant State system, provide guidance for submission of standard data from the form. Work with public health and legal officials to identify and address privacy concerns related to the collection,

analysis, and storage of surveillance data in new and enhanced systems. Provide training to State and local health department staff for using the systems.

Step 4: Provide guidance to public health officials and laboratories regarding case definitions, surveillance methods, and diagnostic tests to be used during different stages of a pandemic, such as procedures for conducting confirmatory testing of positive samples and further genetic and antigenic characterization at CDC.

Step 5: Build capacity and framework for timely reporting to and feedback from CDC to State, local, and tribal health departments.

Step 6: Develop systems for data analysis and feedback; incorporate a numbering system that will facilitate linkage with case or cluster investigation forms.

Step 7: Convene a series of discussions among representatives of State, local, and tribal health departments, and hospitals and health care systems to discuss surveillance data needs, reporting procedures, and data analysis and feedback procedures that will facilitate the development of relationships among these entities.

L. Action (HSC 6.2.1.4): HHS will work with Federal, State, local, tribal, and private sector medical facilities to promote the use of standardized protocols for transporting influenza specimens to appropriate reference laboratories are in place. (Also see chapter 8, Pillar Two, Action A [HSC 6.2.1.4].)

Timeframe: Within 3 months.

Measure of Performance: Transportation protocols for laboratory specimens detailed in HHS, DOD, VA, State, territorial, tribal, and local pandemic response plans.

Step 1: Distribute existing protocols and regulations on the proper collection, handling, and shipping of clinical samples and viral isolates.

Step 2: Update health care provider instructions on the collection of clinical and epidemiologic data that should accompany isolates. Incorporate numbering system that will facilitate linkage with case or cluster investigation forms.

Step 3: Develop appropriate laboratory testing algorithms and specimen handling procedures and train local staff to use them. Facilitate incorporating currently used (and available) products into testing algorithms.

Step 4: Advise States on the specific isolate selection criteria that they should use to determine what isolates should be sent to CDC as part of efforts to monitor changes in the antigenicity and antiviral susceptibility of the pandemic virus.

Step 5: Update existing data reporting and feedback systems for timelier sharing of information.

Step 6: In collaboration with USDA, when appropriate, revise laboratory Bio-Safety Level (BSL) standards and inclusion of novel viruses on the select agent list.

M. Action (No HSC Action): Ensure that health care providers and members of the general public are aware of the signs/symptoms and epidemiologic profile of possible clusters. (Also see chapter 7, Pillar One, Actions J and K [HSC 6.1.3.1 and 6.1.3.2] regarding efforts to develop a public engagement and risk communications strategy; and chapter 6, Pillar One, Action R [HSC 6.1.3.1] regarding antiviral drug messaging.)

Timeframe: 12 months.

Measure of Performance: Educational materials are developed and published on http://www.pandemicflu.gov, and are also distributed through health alert network messages and other communication systems.

Step 1: Develop and distribute educational messages targeting public and private health care workers; nursing home personnel; staff in school health facilities, and university infirmaries, large employee health programs, and jail and prison health units; infection control practitioners; pharmacists; day care providers; foreign travelers (e.g., corporate, faith-based, philanthropic); teachers; and, the general public to ensure they are aware of the signs/symptoms and epidemiologic profile of possible clusters. These educational messages must include both case-specific and cluster-associated indicators for reporting, as appropriate for each targeted group. These messages in local languages also will include information on the appropriate reporting mechanisms.

Step 2: Improve the ease of use of methods for reporting suspicious clusters. Continue to work with State, local, and tribal surveillance partners (e.g., Council of State and Territorial Epidemiologists [CSTE]; National Association of County and City Health Officials [NACCHO]; State, local, and tribal health offices) to design logistically feasible reporting mechanisms from health care providers or systems to the public health authorities.

Step 3: Increase awareness of reporting methods when suspicious clusters are identified.

Step 4: Work with State, local, and tribal public health and media to ensure that appropriate materials and processes are developed for and communicated by trade associations that represent targeted providers and systems.

Step 5: Work with the Association for Practitioners in Infection Control and Epidemiology (APIC) and Society for Health care Epidemiology of America (SHEA) on strategies to enhance disease occurrence information across hospitals and other health systems.

Advancing Scientific Knowledge and Accelerating Development

N. Action (HSC 4.1.8.1): HHS will support the Los Alamos H5 Sequence Database and TIGR, for the purpose of sharing avian H5N1 influenza sequences with the scientific community. (Also see chapter 1, Pillar One, Actions N and Y [HSC 4.1.8.1 and 4.1.8.4].)

Timeframe: Within 24 months.

Measure of Performance: Completed H5 sequences entered into both the Los Alamos database and GenBank and annotated.

Step 1: Identify and address barriers and constraints to direct reporting of sequences to Los Alamos H5 and GenBank.

Step 2: Review the databases to identify compatibility with information fields, and data submission and release policies.

Step 3: Establish and convene a workgroup to identify core data that will be included and ways to improve direct reporting and verification of sequences to the Los Alamos H5 database and GenBank.

Step 4: Establish system interoperability so that data can be transferred electronically between the database systems.

Step 5: Establish protocols and procedures for transferring data between the databases.

O. Action (HSC 6.1.15.1): HHS will develop capability, protocols, and procedures to ensure that viral isolates obtained during investigation of human outbreaks of influenza with pandemic potential are sequenced and that sequences are published on GenBank within 1 week of confirmation of diagnosis in index case. (Also see chapter 1, Pillar One, Actions W and Y [HSC 4.1.8.1 and 4.1.8.4].)

Timeframe: Within 6 months.

Measure of Performance: Viral isolate sequences from outbreaks published on GenBank within 1 week of confirmation of diagnosis.

P. Action (HSC 6.1.15.2): HHS will increase and accelerate genomic sequencing of known human and avian-influenza viruses and should rapidly make this sequence

information publicly available. (Also see chapter 1, Pillar One, Actions W and Y [HSC 4.1.8.1 and 4.1.8.4].)

Timeframe: Within 6 months.

Measure of Performance: Increased throughput of genomes sequenced (versus FY 2005 baseline) and decreased time interval between completion of sequencing and publication on GenBank.

The following steps will be undertaken to address Actions O and P:

Step 1: Establish working group of HHS laboratory experts with experience in sequencing of influenza to determine plans for making data available more quickly.

Step 2: Identify laboratories that currently report sequence data and query them to identify barriers and constraints to publishing sequences, including intellectual property issues, concerns of those submitting specimens for sequencing, and mis/over-interpretation of sequence information.

Step 3: Implement protocols and procedures so that sequences can be published within 1 week of confirmation.

Step 4: Evaluate timeframes of sequence postings to GenBank within 1 year and identify remaining or additional barriers and constraints.

Q. Action (HSC 6.1.15.3): HHS shall develop protocols and procedures to ensure timely reporting to Federal agencies and submission for publication of data from HHS-supported influenza diagnostic evaluation studies. (Also see chapter 5, Pillar One, Actions E and L [HSC 6.1.15.3, and 6.1.17.1] regarding vaccine candidate evaluation studies; and chapter 6, Pillar One, Action D [HSC 6.1.15.3] regarding antiviral drug studies.)

Timeframe: Within 6 months.

Measure of Performance: Study data shared with Federal agencies within 1 month of analysis and publication of clinical trial data following completion of studies.

Step 1: Establish a workgroup of representatives from relevant HHS OPDIVs involved with diagnostic evaluation studies.

Step 2: Compile a list of current and planned diagnostic evaluation studies, and their expected timeframe for completion.

Step 3: Develop protocols and procedures regarding sharing of study results among Federal agencies.

Step 4: Implement protocols and procedures to ensure results are shared within 1 month of completion of data analysis.

Step 5: Evaluate timeframes of sharing results within 18 months and identify remaining or additional limitations for sharing results of diagnostic evaluation studies with Federal agencies within 1 month of completion of data analysis.

Pillar Two: Surveillance and Detection

The ability of public health officials to prevent or limit disease associated with pandemic influenza will rely on the rapid, specific identification of initial cases and clusters. Accomplishing this will require sensitive and timely surveillance, widely available laboratory testing capacity, and confirmation and reporting systems that facilitate rapid response by appropriate authorities. These surveillance systems will be linked with those systems for international surveillance, as well as with other public health efforts directed toward response, such as vaccine and antiviral distribution and non-pharmaceutical interventions.

Mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders will be developed and exercised. All levels of government, domestically and globally, will be encouraged to take appropriate and lawful action to contain an outbreak within their communities, provinces, states, or countries. HHS will leverage Federal medical capabilities, both domestic and international, to provide real-time clinical surveillance in domestic acute care settings, such as emergency departments, intensive care units, and laboratories, to provide Federal, State, local, tribal, and public health officials with continuous awareness of the profile and threat of illness in communities.

Guidance and support will be provided to poultry, swine, and related industries on their role in responding to an outbreak of avian influenza, including ensuring the protection of animal workers and initiating or strengthening public education campaigns to minimize the risks of infection from animal products. Rapid-response modeling capability to improve decisionmaking during a pandemic will be developed.

Ensuring Rapid Reporting of Outbreaks

A. Action (HSC 5.2.2.1): HHS, in coordination with DOD, will support DHS deployment of human influenza rapid diagnostic tests with greater sensitivity and specificity at borders and ports of entry to allow real-time health screening. (Also see chapter 3, Pillar Two, Actions B, I and K [HSC 5.2.2.1, 5.2.4.6 and 5.2.4.8]; as well as chapter 8, Pillar One, Action D [HSC 5.1.2.3] regarding travel and border protocols.)

   Timeframe: Within 12 months of development of tests.

Measure of Performance: Diagnostic tests, if found to be useful, are deployed; testing is integrated into screening protocols to improve screening at the 20–30 most critical ports of entry.

B. Action (HSC 6.2.3.4): HHS-, DOD-, and VA-funded hospitals and health facilities will have access to improved rapid diagnostic tests for influenza A, including influenza with pandemic potential.

Timeframe: Within 6 months of when tests become available.

Measure of Performance: Diagnostic tests, if found to be useful, are accessible to federally funded health facilities.

The following steps will be undertaken to address Actions A and B:

Step 1: Convene a working group to establish criteria for the selection of human influenza rapid diagnostic tests that would be deployed to ports of entry and to which Federally-funded facilities should have access; to determine protocols for their use; to identify potential mechanisms for deploying selected tests; and to specify critical ports of entry.

Step 2: Monitor development of more sensitive and specific human influenza rapid diagnostic tests that meet FDCA regulatory requirements or that meet Investigational Device Exemption (IDE) criteria.

Step 3: Identify human influenza rapid diagnostic tests that meet selection criteria.

Step 4: Share information about availability of improved rapid diagnostic tests with medical and laboratory directors of ports of entry and federally funded facilities.

Step 5: Integrate selected diagnostic tests in screening protocols used at the critical ports of entry and federally funded facilities.

Step 6: Use identified mechanisms to deploy and create access to selected rapid diagnostic tests.

C. Action (HSC 6.2.1.1): HHS will provide guidance to public health and clinical laboratories on the different types of diagnostic tests and the case definitions to use for influenza at the time of each pandemic stage.

Timeframe: Guidelines for the current pandemic alert phase will be disseminated within 3 months.

Measure of Performance: Dissemination on http://www.pandemicflu.gov and through other channels of guidance on the use of diagnostic tests for H5N1 and other potential pandemic influenza subtypes.

Step 1: Distribute updated protocols and regulations on the proper collection, handling, and shipping of clinical samples and viral isolates, including updated instructions on the collection of clinical and epidemiologic data that should accompany isolates. Incorporate a numbering system that will facilitate linkage with case or cluster investigation forms.

Step 2: Provide updated preparedness information regarding diagnostic tests, reagents, case definitions, and, specimen selection and handling to State, local, and tribal public health partners via the LRN and the HAN.

D. Action (HSC 6.2.1.2): HHS will ensure that testing (RT-PCR) for H5N1 and other influenza viruses with pandemic potential is available at State public health laboratories, LRN laboratories, and CDC.

Timeframe: Within 3 months.

Measure of Performance: RT-PCR for H5N1 and other potential pandemic influenza subtypes and strains in use at CDC and LRN laboratories.

E. Action (HSC 6.2.1.3): HHS, in coordination with DOD, VA, USDA, DHS, EPA, and other partners, in collaboration with its LRN Reference Laboratories, will be prepared to conduct laboratory analyses to detect pandemic subtypes and strains in referred specimens and conduct confirmatory testing, as requested.

Timeframe: Within 6 months.

Measure of Performance: Initial testing and identification of suspect pandemic influenza specimens completed at LRN Reference and National Laboratories within 24 hours.

The following steps will be undertaken to address Actions D and E:

Step 1: Monitor occurrence of and changes in influenza virus subtypes with significant pandemic potential.

Step 2: Develop and test updated RT-PCR primers and protocols for detection of novel viruses and prepare anti-sera and antigens specific for H5N1 viruses for use in laboratory assays.

Step 3: Ensure availability of reference and control reagents in known national repositories by distributing materials to State, local, and tribal health laboratories that meet FDCA laboratory regulatory requirements or that meet IDE criteria.

Step 4: Identify and address regulatory pathways to emergency distribution and use of diagnostic tests and reagents during a pandemic state of emergency and at other times when a state of emergency does not exist.

Step 5: Provide updated preparedness information regarding diagnostic tests and reagents to State, local, and tribal public health partners via the LRN, Integrated Consortium of Laboratory Networks (ICLN), and HAN.

Step 6: Continue to provide laboratory training workshops for State, local, and tribal health department personnel as needed.

F. Action (HSC 6.2.2.3): HHS, in coordination with DOD and VA, will expand the number of hospitals and cities participating in the BioSense RT program to improve the nation's capabilities for disease detection, monitoring, and situational awareness.

Timeframe: Within 12 months.

Measure of Performance: Number of hospitals (including DOD and VA facilities) participating in the BioSenseRT program increased to 350 hospitals in 42 cities.

Step 1: Analyze BioSense outpatient data to determine if patient visits with the influenza International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code correlate well with existing outpatient influenza-like illness (ILI) data and influenza laboratory data.

Step 2: Review BioSense data to determine if it is possible to identify patients with symptoms comparable to the existing outpatient ILI case definition, and if so, how well these data are correlated.

Step 3: Identify States that are receiving electronic emergency department data on ILI on a daily basis. Collaborate with a small number of State, local, and tribal health departments to pilot use of emergency department (ED)-based systems for near daily reporting of illness and compare the data to existing sentinel provider ILI data.

Step 4: Explore feasibility of harmonizing systems for transmitting such data with BioSense/State infrastructure.

Step 5: Continue to recruit and support implementation of additional emergency departments and hospitals to increase the geographic coverage and enhance numbers of hospitals providing real-time clinical data to BioSense.

Step 6: Collaborate with VA and DOD to gain access to real-time clinical and hospital data (BioSense currently receiving latent coded data only from ambulatory care sites).

Step 7: Implement real-time reporting of clinical laboratory orders and results from three of the largest national laboratory systems.

Step 8: Enhance real-time clinical data sources through the addition of ambulatory care data from the large integrated health care delivery networks and ambulatory care sites associated with the BioSense hospitals.

Step 9: Collaborate with health care information technology vendors to explore mechanisms for implementation of BioSense specifications and standards.

Step 10: Advance the science of real-time bio-surveillance, including usefulness of data, functionality of systems, and utility of BioSense data for response, by supporting rigorous evaluation of analysis and methodologies (through collaboration with key researchers in the field).

G. Action (HSC 6.2.2.4): HHS will reduce the time between reporting of virologic laboratory data from state, local, tribal, and private sector partners and collation, analysis, and reporting to key stakeholders.

Timeframe: Within 6 months.

Measure of Performance: Time delay between receipt of data and collation, analysis, and reporting of results of seven (7) days or less.

Step 1: Identify and assess potential methods for facilitating automated reporting of data from the World Health Organization (WHO) Secretariat and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories to decrease reporting time.

Step 2: Develop and implement methods for collating, analyzing, and reporting data submitted electronically from the WHO Secretariat and NREVSS collaborating laboratories.

Step 3: Revise protocols and procedures for submitting data to reflect new methods.

Step 4: Pilot test the new system prior to the next influenza season.

Step 5: Modify the protocols and procedures based upon the results of the pilot test.

H. Action (HSC 6.2.2.5): HHS will increase the frequency of reporting and the number and geographic location of reporting health care providers from which outpatient surveillance data is collected through the Sentinel Provider Network (SPN), the EIP influenza project, and the New Vaccine Surveillance Network.

Timeframe: Within 6 months.

Measure of Performance: Number of reporting health care providers increased to one or more per 250,000 population.

Step 1: Encourage State health departments to increase the geographic coverage of regularly reporting sentinel providers, including providers serving rural populations.

Step 2: Encourage State health departments to increase the number of providers who report year round.

Step 3: Develop and pilot test protocols (surveillance questionnaires, and specimen collection, handling, analysis, and reporting of results) for suspected, probable, and confirmed pandemic (or potential pandemic) cases and contacts.

Step 4: In collaboration with State and local public health agencies, communicate with providers regarding the importance of timely reporting of influenza-like illness and the definition, testing, and reporting guidelines for suspected, probable, and confirmed cases and their contacts.

I. Action (HSC 6.2.2.6): HHS will improve the speed at which it performs mortality surveillance through the 122 Cities Mortality Reporting System.

Timeframe: Within 3 months.

Measure of Performance: Mortality data collected at CDC within 1 week of decedent's demise increased by 25 percent compared with 2005.

Step 1: Encourage vital statistics offices in 122 U.S. cities to report pneumonia and influenza (P&I)-related deaths on a weekly basis.

J. Action (HSC 6.2.4.2): HHS, in coordination with Sector-Specific Agencies, DOD, DOJ, and VA, and in collaboration with the private sector, will support DHS' lead in preparations to track integrity of critical infrastructure function, including the health care sector, to determine whether ongoing strategies of ensuring workplace safety and operational continuity need to be altered as a

pandemic evolves. (Also see chapter 3, Pillar Two, Action N [HSC 6.2.4.2]; and chapter 8, Pillar Two, Action B [HSC 6.2.2.8].)

Timeframe: Within 6 months.

Measure of Performance: Tracking system in place to monitor integrity of critical infrastructure function and operational continuity in near real time.

Step 1: Convene a working group to identify key indicators of illness and absenteeism, and other measures of the integrity of critical infrastructure and operational continuity.

Step 2: Identify existing or potential mechanisms for compiling data in near real time for the identified indicators.

Step 3: Establish protocols and processes to modify existing approaches or develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to pilot test the system during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

K. Action (HSC 7.1.3.3): HHS, in coordination with USDA, DHS, and the Department of Labor (DOL), will work with the poultry and swine industries to provide information regarding strategies to prevent avian and swine influenza infection among animal workers and producers. (Also see chapter 3, Pillar One, Action S [HSC 7.1.3.3]; and chapter 7, Pillar One, Action P [HSC 7.1.3.3].)

Timeframe: Within 6 months.

Measure of Performance: Guidelines developed and disseminated to poultry and swine industries.

Step 1: Work with State and local health departments, USDA, DOL, and industry/trade organizations to create, update, and implement surveillance protocols (including methods, case definition, questionnaires, data analysis plans, and specimen collection/handling/testing guidelines) among persons exposed to potentially infected birds (domestic/wildlife) to detect animal-to-human transmission.

Step 2: Develop isolation, quarantine, and treatment guidelines.

Step 3: Identify HHS/CDC role, including when HHS/CDC staff will deploy to assist with an outbreak investigation.

Step 4: Update, if necessary, reporting requirements and frequency.

Step 5: Develop guidelines for notification, triage, and clinical management of confirmed or suspected human illnesses identified during surveillance.

L. Action (No HSC Action): HHS, in coordination with other Federal, State, Local, and Tribal partners, will support collaborations across State, Tribal, Military, and international borders to conduct necessary activities in support of cross-jurisdictional planning, coordination, communication, program development, and exercises to enhance pandemic influenza preparedness and response capacity along the borders.

Timeframe: Within 24 months.

Measure of Performance: Cross-border collaborations have fostered the development and exercising of pandemic influenza plans and increased the capacity and capability of state and local public health and medical entities (e.g., primary care, Health Centers, rural health programs, hospitals) for regional and border-wide preparedness and response to an influenza pandemic.

Step 1: Engage federally recognized tribes along the international border in your State in cross-border infectious disease surveillance activities through mutual aid compacts, memoranda of understanding, and/or agreements. Where appropriate, include local bi-national health councils and/or Indian Tribes/Native American organizations in pandemic influenza surveillance activities.

Step 2: In coordination with local public health agencies on both sides of the border, conduct joint, cross-border assessments of information technology and apply information technology to develop or enhance electronic pandemic influenza surveillance, including electronic disease reporting from clinical and public health laboratories and linkage of laboratory results to case report information.

Step 3: Convene and conduct joint pandemic influenza surveillance and epidemiology planning workshops and exercises to discuss, plan, drill, and test cross-border surveillance and/or epidemiology-related activities. Such activities should, where feasible, involve a collaborative and regional approach with neighboring U.S. Border States, appropriate tribal nations as well as Mexico or Canada (as appropriate). These planning workshops and exercises should involve not only border health departments but, where feasible, local hospitals, tribal and Public Health Service health facilities, hospital laboratories, major community

health care institutions, emergency response agencies, and public safety agencies in order to respond in a coordinated manner.

Step 4: Work with representatives from Canada and Mexico to develop a Security and Prosperity Partnership of North America (SPP) annex to each country's pandemic influenza plan.

M. Action (HSC 5.2.4.8): HHS along with DHS, and in coordination with DOT, DOJ, and appropriate state and local health authorities, will develop detection, diagnosis, quarantine, isolation, Emergency Medical Services (EMS) transport, reporting, and enforcement protocols and education materials for travelers, and undocumented aliens apprehended at and between ports of entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza. (Also see chapter 3, Pillar One, Action D [HSC 5.1.1.4]; chapter 3, Pillar Two, Action K [HSC 5.2.4.8]; and chapter 7, Pillar Two, Action C [HSC 5.2.4.8] regarding the development of protocols and educational materials.)

Timeframe: Within 10 months.

Measure of Performance: Protocols developed and distributed to all ports of entry.

N. Action (HSC 5.3.1.5): HHS, in coordination with DHS, DOT, DOS, DOD, USDA, appropriate State and local authorities, air carriers/air space users, airports, cruise lines, and seaports, will implement screening protocols at U.S. ports of entry based on disease characteristics and availability of rapid detection methods and equipment. (Also see chapter 3, Pillar Three, Action E [HSC 5.3.1.5].)

Timeframe: As required.

Measure of Performance: Screening implemented within 48 hours upon notification of an outbreak.

O. Action (HSC 5.3.1.6): HHS, in coordination with DHS, DOT, USDA, DOD, appropriate state, and local authorities, air carriers and airports, will consider implementing response or screening protocols at domestic airports and other transport modes as appropriate, based on disease characteristics and availability of rapid detection methods and equipment. (Also see chapter 3, Pillar Two, Action B [HSC 5.2.2.1] and chapter 3, Pillar Three, Action F [HSC 5.3.1.6].)

Timeframe: As required.

Measure of Performance: Screening protocols in place within 24 hours of directive to do so.

The following steps will be undertaken to address Actions M, N, and O:

Step 1: Establish and implement surveillance and triage protocols (including methods, case definition, questionnaires, data analysis plans, and specimen collection/handling/testing guidelines).

Step 2: Ensure airline and cruise ship personnel are familiar with case finding protocols, and reporting and handling of suspect cases.

Step 3: Develop methods to identify and investigate suspect cases among incoming travelers.

Step 4: Work with immigration officials to update protocols on identification and triage of suspect cases.

Step 5: Develop and implement isolation, quarantine, and treatment guidelines.

Step 6: Update, if necessary, reporting requirements and frequency.

P. Action (No HSC Action): HHS will establish surveillance systems for clusters of illness among health care workers. (Also see chapter 7, Pillar Three, Action D [HSC 6.3.2.6] regarding the implementation of implement infection control campaigns for pandemic influenza.)

Timeframe: Within 6 months.

Measure of Performance: Surveillance systems established and operational.

Step 1: Work with health care providers and infection control societies to investigate current systems that would capture clusters of illnesses among health care workers.

Step 2: Work with health care institutions to develop protocols (including methods, case definition, questionnaires, data analysis plans, and specimen collection/handling/testing guidelines) or amended procedures to existing systems to capture new suspicious clusters.

Step 3: Pilot test new systems in a variety of locations and types of institutions and revise protocols and procedures based on the pilot test results.

Step 4: Develop guidelines for implementing systems.

Q. Action (No HSC Action): HHS will continue existing activities to conduct surveillance of disease among laboratory workers with potential for exposure to avian influenza. (Also see chapter 7, Pillar Three, Action D [HSC 6.3.2.6]

regarding the implementation of implement infection control campaigns for pandemic influenza.)

Timeframe: Ongoing.

Measure of Performance: Surveillance system operational.

Step 1: Review/revise and implement established protocols.

Step 2: Update, if necessary, reporting requirements and frequency.

Step 3: Educate laboratory staff regarding protocols and reporting requirements.

Using Surveillance to Limit Spread

R. Action (HSC 6.2.4.1): HHS, in coordination with DHS, DOD, VA, USDA, and DOS, will be prepared to continuously evaluate surveillance and disease reporting data to determine whether ongoing disease containment and medical countermeasure distribution and allocation strategies need to be altered as a pandemic evolves. (Also see chapter 8, Pillar Two, Action B [HSC 6.2.2.8] Step 4, regarding providing assistance to State, local, and tribal health agencies regarding analysis for their specific jurisdiction.)

Timeframe: Within 12 months.

Measure of Performance: Analyses of surveillance data performed at least weekly during an outbreak with timely adjustment of strategic and tactical goals, as required.

Step 1: Convene a working group to identify key indicators of the impact of pandemic influenza and necessary data for assessing effectiveness of disease containment and countermeasure usage strategies.

Step 2: Identify existing or potential mechanisms for compiling data on a weekly basis for the identified indicators.

Step 3: Establish protocols and processes to modify existing approaches or develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to pilot test the system (including validation of assessment questions/data fields) during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

S. Action (HSC 6.2.2.7): HHS, in collaboration with DHS, DOD, VA, USDA and other Federal departments and agencies with bio-surveillance capabilities and real-time data sources, will enhance National Bio-Surveillance Integration System (NBIS) capabilities to ensure the availability of a comprehensive and all-source bio-surveillance common operating picture throughout the Interagency.

Timeframe: Within 12 months.

Measure of Performance: NBIS provides integrated surveillance data to DHS, HHS, USDA, DOD, VA, and other interested interagency customers.

T. Action (HSC 6.2.5.1): HHS, in coordination with DOD and DHS, will develop and maintain a real-time epidemic analysis and modeling hub that will explore and characterize response options as a support to policy and decision makers.

Timeframe: Within 6 months.

Measure of Performance: Modeling center with real-time epidemic analysis capabilities established.

The following steps will be undertaken to address Actions R, S, and T:

Step 1: Convene a working group to identify data needed by policy and decision makers as they consider and/or implement different response options and to identify where the hub will be located.

Step 2: Identify existing or potential mechanisms for compiling real time data for the identified indicators. Evaluate the use of novel statistical methods to define excess disease occurrences in existing and novel surveillance systems, for example, refine methods for applying the Early Aberration Reporting System (EARS) and other aberration detection algorithms to the outpatient ILI data reported by sentinel providers Apply relevant statistical tools to other existing influenza surveillance systems. Consider platforms such as BioSense that permit visualization and analysis across multiple data sources. Explore other options for statistical methods to aid in timely identification of disease clusters.

Step 3: Establish protocols and processes to modify existing or develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to establish the hub and pilot test the system during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

U. Action (HSC 6.2.2.1): HHS will be prepared to be able to provide ongoing information from the national influenza surveillance system on the pandemic's impact on health and the health care system.

Timeframe: Within 6 months.

Measure of Performance: Surveillance data aggregated and disseminated every 7 days, or as often as the situation warrants, to DHS, Sector-Specific Agencies, and state, territorial, tribal, and local partners.

Step 1: Convene a working group to identify key indicators of the impact of pandemic influenza.

Step 2: Identify existing or potential mechanisms for compiling data on a weekly basis for the identified indicators.

Step 3: Establish protocols and processes to modify existing or to develop new mechanisms for collecting timely data for the identified indicators.

Step 4: Establish protocols and processes for analyzing and reporting the identified parameters.

Step 5: Work with key stakeholders to pilot test the system during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

V. Action (HSC 6.2.2.2): HHS, in coordination with Federal, State, local, tribal and private sector partners, will develop real-time (same-day) tracking capabilities of pneumonia or influenza hospitalizations and influenza deaths to enhance its surveillance capabilities at the onset of and during a pandemic.

Timeframe: Within 12 months.

Measure of Performance: Real-time (same-day) nationwide hospital census and mortality tracking system is operational for use during a pandemic.

Step 1: Identify existing or other potential systems for tracking the number of pneumonia or influenza hospitalizations and deaths during a pandemic, including:

- Feasibility of modifying the Hospital Available Beds for Emergencies and Disasters (HAvBED) System to collect information about the number of emergency- or disaster-related patients that are hospitalized or have died

- Using pandemic influenza as a specific example, including the following:
  - Feasibility of obtaining National Hospital Discharge Survey data in a more timely manner
  - Validity of estimating national mortality based on data from the 122 Cities Mortality Reporting System
  - Feasibility of obtaining timely mortality data from all 50 States through the Electronic Death Registration Project
  - Potential availability and utility of data from the National Association of Health Data Organizations (NAHDO)

Step 2: Modify the existing systems as required.

Step 3: If existing systems are not applicable, establish protocols and processes to develop new systems for collecting timely hospitalization and death information.

Step 4: Establish protocols and processes for analyzing and reporting the hospitalization and death information.

Step 5: Pilot test the system(s) during the next influenza season.

Step 6: Modify the protocols and processes based upon the results of the pilot test.

W. Action (HSC 4.2.5.2): HHS, in coordination with DOS and other Agencies under the SPP will pursue cooperative agreements on pandemic influenza with Canada and Mexico to create and implement a North American early warning surveillance and response system in order to prevent the spread of infectious disease across our borders.

Timeframe: Within 9 months.

Measure of Performance: Implementation of early warning surveillance and response system.

Step 1: Assist DOS in negotiating cooperative agreements with Canada and Mexico to improve pandemic influenza surveillance and preparedness in North America.

Pillar Three: Response and Containment

Surveillance activities will assist with the assessment and monitoring of treatment guidelines, vaccine effectiveness, antiviral effectiveness and resistance, and effectiveness of public health interventions. The surveillance activities carried out by HHS will aid in sustaining U.S. critical infrastructure and essential services, and the U.S. economy. HHS

will encourage the development of coordination mechanisms across American industries to support the above activities during a pandemic.

Containing Outbreaks

A. Action (HSC 5.3.3.1): HHS, in coordination with DHS, DOT, DOS, and DOI, will work with USDA to provide emergency notifications of probable or confirmed cases and/or outbreaks to key international, federal, state, local, and tribal transportation and border stakeholders through existing networks. (Also see chapter 1, Pillar Three, Action L [HSC 5.3.3.1]; chapter 3, Pillar Two, Action A [HSC 5.2.1.1]; and chapter 7, Pillar Three, Action H [HSC 5.3.3.1].)

Timeframe: Ongoing.

Measure of Performance: Emergency notifications occur within 24 hours or less of events of probable or confirmed cases or outbreaks.

Step 1: Convene a cross-agency working group to identify key stakeholders; existing networks available to provide emergency notifications; criteria for providing notifications; and, notification protocols and procedures.

Step 2: Evaluate existing protocols and processes.

Step 3: Develop additional protocols and processes for providing emergency notifications, as appropriate.

Step 4: Pilot test the protocols and processes.

Step 5: Based upon the findings of the pilot test, update the emergency notification protocols and procedures.

Step 6: Maintain regular communication with key partners at Ministries of Health in targeted and at-risk countries, through Health Attaches and other in-country staff. HHS will notify DOS and other partners when news of outbreaks is received and facilitate information exchange with partners. Activities include:

- Remaining in close communication with Ministries of Health and the WHO Secretariat to stay abreast of news of potential or actual outbreaks
- Conducting inter-HHS OPDIV consultations to determine validity of such news
- Communicating the best advice to DOS and other U.S. Government agencies

B. Action (HSC 4.1.5.2): HHS will work with USAID to coordinate and set up emergency stockpiles of personal protective equipment (PPE) and essential

commodities, other than vaccine and antiviral medications, for responding to animal or human outbreaks.

Timeframe: Within 9 months.

Measure of Performance: Essential commodities procured and available for deployment within 24 hours.

Step 1: Coordinate U.S. Government participation in development of the SPP Annex to the HHS Pandemic Flu Plan that will address logistical actions and coordination requirements associated with the movement of medical materiel support across the U.S. border in support of a pandemic influenza response.

C. Action (No HSC Action): Utilize the EIP influenza project, the NVSN, Marshfield Clinic Research Foundation, and/or other sites to conduct epidemiologic studies to assess/monitor treatment guidelines, vaccine effectiveness, antiviral effectiveness and resistance, and effectiveness of public health interventions. (Also see Pillar Three, Action D [HSC 6.1.13.9] below; chapter 4, Pillar Three, Action C [HSC 6.3.4.2] regarding standards of care for medical practice; chapter 5, Pillar One, Action Q [HSC 6.1.14.1] regarding vaccine use and effectiveness; and chapter 6, Pillar Three, Action C [HSC 6.1.13.9] regarding antiviral use and effectiveness.)

Timeframe: Ongoing.

Measure of Performance: Conduct of epidemiologic studies.

Step 1: Develop protocols and processes for active population-based hospitalization surveillance including specimen collection and virologic testing from a subset of hospitalized patients in all age groups in a limited number of sites.

Step 2: Pilot test the protocols and processes.

Step 3: Revise the protocols and processes based on the results of the pilot test.

D. Action (HSC 6.1.13.9): HHS, in coordination with DOD, VA, and in collaboration with state, territorial, tribal, and local partners, will develop/refine mechanisms to: (1) track adverse events following vaccine and antiviral administration: (2) ensure that individuals obtain additional doses of vaccine, if necessary; and (3) define protocols for conducting vaccine- and antiviral-effectiveness studies during a pandemic. (Also see Pillar Three, Action C [No HSC number] above; chapter 5, Pillar One, Action Q and T [HSC 6.1.14.1 and 6.1.13.9]; and chapter 6, Pillar Three, Action C [HSC 6.1.13.9].)

Timeframe: Within 18 months.

Measure of Performance: Mechanism(s) to track vaccine and antiviral medication coverage and adverse events developed; vaccine- and antiviral-effectiveness study protocols developed.

Step 1: Develop protocols and processes for active population-based hospitalization surveillance including specimen collection and virologic testing from a subset of hospitalized patients in all age groups in a limited number of sites.

Step 2: Pilot test the protocols and processes.

Step 3: Revise the protocols and processes based on the results of the pilot test.