

Kentucky Pandemic Influenza Preparedness Plan

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Division of Epidemiology and Health Planning

Kentucky
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| Kentucky Pandemic Influenza Preparedness Plan TABLE OF CONTENTS | | |
|--|--|-------------|
| EXECUTIVE SUMMARY | | 1-3 |
| BASE PLAN | | 1-13 |
| | I. INTRODUCTION | 1 |
| | II. COMMAND AND MANAGEMENT | 6 |
| | III. APPENDICES | 12 |
| LABORATORY AND SURVEILLANCE SUPPLEMENT I | | 1-4 |
| | I. RATIONALE / OVERVIEW | 1 |
| | II. GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 2 |
| | III. GUIDELINES FOR THE PANDEMIC PERIOD | 3 |
| | IV. APPENDICES | |
| HEALTHCARE PLANNING SUPPLEMENT II | | 1-6 |
| | I. RATIONALE/OVERVIEW | 1 |
| | II. GUIDELINES FOR HEALTHCARE SYSTEMS RESPONSE (Interpandemic and Pandemic Alert Periods) | 1 |
| | III. GUIDELINES FOR HEALTHCARE SYSTEMS RESPONSE (Pandemic Period) | 4 |
| | IV. GUIDELINES FOR HEALTHCARE SYSTEM RESPONSE (Subsided Period) | 5 |
| INFECTION CONTROL SUPPLEMENT III | | 1-18 |
| | I. RATIONALE | 1 |
| | II. OVERVIEW | 1 |
| | III. RECOMMENDATIONS FOR INFECTION CONTROL IN HEALTHCARE SETTINGS | 2 |
| | IV. RECOMMENDATIONS FOR INFECTION CONTROL IN SCHOOLS AND WORKPLACES | 18 |
| | V. RECOMMENDATIONS FOR INFECTION CONTROL IN COMMUNITY SETTINGS | 18 |

| Kentucky Pandemic Influenza Preparedness Plan TABLE OF CONTENTS CONTINUED | | |
|--|---|-------------------|
| CLINICAL GUIDELINES SUPPLEMENT IV | | 1-42 |
| | SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR CLINICAL GUIDELINES | 1 |
| | I. RATIONALE | 3 |
| | II. OVERVIEW | 3 |
| | III. CLINICAL GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 4 |
| | IV. CLINICAL GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 10 |
| | V. APPENDICES | 25- 42 |
| VACCINE SUPPLEMENT V | | 1-11 |
| | SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE | 1 |
| | I. RATIONALE | 2 |
| | II. OVERVIEW | 2 |
| | III. GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 2 |
| | IV. PREPAREDNESS PLANNING FOR VACCINATION AGAINST A PANDEMIC INFLUENZA STRAIN | 4 |
| | V. VACCINE DISTRIBUTION | 4 |
| | VI. RECOMMENDATIONS FOR THE PANDEMIC PERIOD | 9 |
| | VI. APPENDICES | 11 |
| ANTIVIRAL SUPPLEMENT VI | | 1-11 |
| | SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE | 1 |
| | I. RATIONALE | 2 |
| | II. OVERVIEW | 2 |
| | III. GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 2 |
| | IV. PREPAREDNESS PLANNING FOR USE OF ANTIVIRALS DURING PANDEMIC | 4 |
| | V. RECOMMENDATIONS FOR THE PANDEMIC PERIOD | 8 |
| | VI. APPENDICES | 11 |

| Kentucky Pandemic Influenza Preparedness Plan TABLE OF CONTENTS CONTINUED | | |
|--|--|-------------|
| COMMUNITY CONTAINMENT SUPPLEMENT VII | | 1-10 |
| | I. RATIONALE/OVERVIEW | 1 |
| | II. GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT AND PREVENTION INTERPANDEMIC AND PANDEMIC ALERT PERIODS: | 1 |
| | III. GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT AND PREVENTION PANDEMIC PERIOD: | 3 |
| | IV. MANAGING TRAVEL-RELATED RISK OF DISEASE TRANSMISSION INTERPANDEMIC AND PANDEMIC ALERT PERIODS: | 5 |
| | V. LEGAL AUTHORITY FOR PUBLIC HEALTH EMERGENCIES: | 6 |
| | VI. APPENDICES | 8 |
| PUBLIC HEALTH COMMUNICATIONS SUPPLEMENT VIII | | 1-9 |
| | I. RATIONALE/OVERVIEW | 1 |
| | II. GUIDELINES FOR INTERPANDEMIC PERIOD | 1 |
| | III. GUIDELINES FOR THE PANDEMIC PERIOD | 5 |
| | IV. GUIDELINES FOR THE POST PANDEMIC PERIOD | 8 |
| PSYCHOSOCIAL CONSIDERATIONS SUPPLEMENT IX | | 1-6 |
| | I. RATIONALE/OVERVIEW | 1 |
| | II. SCOPE OF OPERATIONS | 1 |
| | III. SITUATION AND ASSUMPTIONS | 1 |
| | IV. CONCEPT OF OPERATIONS | 2 |
| | V. GUIDELINES FOR RESPONSE PHASES | 4 |

EXECUTIVE SUMMARY

It is not a question of if but when another influenza pandemic will occur. Kentucky must be prepared for this and other types of public health emergencies. To lessen the impact of an influenza pandemic, the Kentucky Department for Public Health has created the Kentucky Pandemic Influenza Preparedness Plan to promote an effective response throughout the pandemic. The plan was originally drafted in 2002 but is being updated through a coordinated effort of the Kentucky Department for Public Health (KDPH), Kentucky Division of Emergency Management (KYEM), Kentucky Office of Homeland Security (KOHS), Kentucky Department of Education (KDE), Kentucky Department of Agriculture (KDA), Kentucky Department of Criminal Justice Training (DOCJT), Kentucky State Police (KSP), Chamber of Commerce, universities, local health departments and other partners and stakeholders. The plan is considered a “living document” and will be updated with changes as needed.

Some of the most diverse areas within the United States are in Kentucky. The state ranges from the Eastern Coal Fields, a rugged mountainous region to the gently rolling central part of the state, the Bluegrass Region, to the Western Coal Fields. Kentucky’s health and medical community has been divided among the 14 Health Resource Service Administration (HRSA) planning regions. Each region has its unique planning considerations, culture and players. Even though Kentucky has over four million residents and is geographically and culturally diverse, it is a tightly knit state. Public health has built strong relationships with preparedness partners and stakeholders and knows this will go far in response to nature’s “pop quizzes”. Understanding and appropriately addressing these facets will allow Kentucky to be as prepared as possible for a public health emergency such as an influenza pandemic.

While a successful pandemic response is dependent on public health response, many agencies, organizations, and private institutions will need to work in a coordinated and collaborative manner to ensure an effective overall response in Kentucky. Some key players and planning activities include:

- KDPH as the lead agency for preparedness and response to an influenza pandemic in Kentucky.
- Local health departments are critical to planning and response as all disasters and emergencies are local.
- Emergency Management and Homeland Security will be important for ensuring overall coordination of government resources.
- First responder agencies have important manpower and logistical resources that will be necessary for ensuring the safety of individuals and communities.
- Hospitals and healthcare institutions will be the frontline of a pandemic and are essential planning partners at the local and state level.
- Volunteer agencies serving as important partners in emergency response activities.
- Businesses and schools will need to collaborate and coordinate with public health to help limit the spread of disease.

These entities have been critical to the development of the plan, and are encouraged to develop their own influenza pandemic response plans that coordinate with the Kentucky Pandemic Influenza Preparedness Plan. Kentucky Pandemic Influenza Preparedness Plan will become an integral part of the Kentucky Emergency Operations Plan.

The United States Department of Health and Human Services (HHS) has incorporated the World Health Organization's (WHO) Pandemic Planning Periods and Phases into its influenza pandemic response plan. In keeping with the national model, the Kentucky Pandemic Influenza Preparedness Plan identifies responsible parties and prescribes necessary actions, based on the WHO/HHS pandemic periods.

The heart of the Kentucky Pandemic Influenza Preparedness Plan is the Response Activity Supplements section, which addresses the concepts listed below. These supplements are subject-area specific and provide very detailed planning and response activities for both state and local health departments. The supplements include:

- *Laboratory and Surveillance* - The capability of identifying pandemic influenza viruses depends not only on rapid detection and characterization, but also on strong partnerships between clinical and public health laboratories. This supplement provides guidance to stakeholders such as health care providers that serve as sentinel sites for reporting, local health department surveillance contacts and health care providers who voluntarily submit specimens to the state laboratory.
- *Healthcare Coordination and Planning* - The healthcare system in Kentucky will experience significant strains on its resources during a pandemic. Preparedness for this area includes surge capacity, mortuary issues, data collection, and mental health concerns. This supplement provides detailed guidance to healthcare agencies on pandemic influenza coordination and planning.
- *Infection Control* - Because a vaccine may not yet be widely available and the supply of antiviral drugs may be limited, infection control will be an important strategy. The Infection Control Supplement provides guidance to healthcare and public health partners on basic principles of infection control for limiting the spread of pandemic influenza.
- *Clinical Guidelines* - Early identification and appropriate medical intervention are essential for patients who present with suspect pandemic influenza symptoms. The Clinical Guidelines supplement provides recommendations on the initial screening, assessment and management of patients who present from the community with fever and/or respiratory symptoms during the pandemic phases.
- *Vaccine and Antiviral Distribution and Use* – During a pandemic, antiviral drugs may or not be effective or available for all. Vaccine is unlikely to be available, especially early in a pandemic. The Antiviral Supplement provides

recommendations to state and local partners on the distribution and use of antiviral drugs for treatment and prophylaxis during and influenza pandemic.

- *Transmission of Disease* - Public health interventions, such as quarantine and social distancing, will be necessary during a pandemic to slow the transmission of disease in the community.
- *Public Health Communications and Training* - Providing accurate and timely coordinated messages during a pandemic will be critical to successful control and response. This supplement provides guidance on internal communications, communication with stakeholders and partners, and risk communication for the public.
- *Psychosocial Considerations* - Response agencies and organizations need to ensure the safety and well being of response personnel to ensure sustained and effective response. This supplement addresses the all-hazards approach that the Kentucky Community Crisis Response Board (KCCRB) will take in response to situations as they relate to the psychological and behavioral health.

The Kentucky Pandemic Influenza Preparedness Plan serves as a guide for the state during the various pandemic phases. The goal of this plan is to prevent illness and death and preserve critical community infrastructures. The potential impact of a pandemic could be both medical and economic. It is important to respect the potential impact a pandemic poses to all parts of society. Because Mother Nature does not aim, all citizens of the Commonwealth are at risk during a pandemic. The Kentucky Department for Public Health serves as the lead in this type of event, but it will require coordination and collaboration with many state and community partners to effectively manage a pandemic. In order to adequately prepare, the Kentucky Department for Public Health encourages all sectors to participate in planning, exercising, and responding to pandemic influenza.

**KENTUCKY PANDEMIC INFLUENZA PREPAREDNESS PLAN
BASE PLAN**

| TABLE OF CONTENTS | | |
|--------------------------|---|-------------|
| | | PAGE |
| I. | Introduction | 1 |
| | A. Purpose | 1 |
| | B. Influenza Virus | 2 |
| | C. Background | 2 |
| | D. Planning Assumptions | 3 |
| | E. Basis of Estimates | 5 |
| | | |
| II. | Command and Management | 6 |
| | A. Major Roles of HHS | 6 |
| | B. Major Roles of KDPH | 6 |
| | C. Major Roles of LHD | 7 |
| | D. KDPH Command and Control | 7 |
| | 1. Interpandemic Period and Pandemic Alert Periods | 7 |
| | 2. Pandemic Period | 8 |
| | | |
| III. | APPENDICES | |
| | Appendix 1. Organizational Chart | 11 |
| | Appendix 2. Glossary | 12 |
| | | |
| | | |
| | | |

I. INTRODUCTION

Experts say it is not a question of if, but when the next pandemic will occur. The economic costs associated with pandemic influenza are expected to be in the billions of dollars. Estimates of morbidity and mortality will place a tremendous burden on the Commonwealth's health and medical systems. Health and medical personnel, as well as infrastructure workers, (i.e., law enforcement, fire and public works), will not be immune to the threat of an influenza pandemic. The potential threat of a pandemic can not be taken casually. To prepare for the next pandemic, the Kentucky Department for Public Health (KKDPH), Division of Epidemiology and Health Planning (DEHP), in cooperation with many state and local organizations and partners, have developed this Kentucky Pandemic Influenza Preparedness Plan which provides strategies to reduce pandemic influenza-related morbidity, mortality, and social disruption in the state.

A. Purpose

The purpose of this plan is to provide a guide for state and local agencies on detecting and responding to an influenza pandemic. The major goals of the plan are to prevent illness and death and preserve critical community infrastructures. The plan describes a command structure and provides guidelines to the state and local health departments on the following issues:

- Laboratory and Surveillance: Supplement I
- Healthcare Planning: Supplement II
- Infection Control: Supplement III
- Clinical Guidelines: Supplement IV
- Vaccine: Supplement V
- Antiviral: Supplement VI
- Transmission of Disease: Supplement VII
- Public Health Communications: Supplement VIII
- Psychosocial Considerations: Supplement IX

If confronted with pandemic influenza, the priorities of KDPH will be to assure the continuation and delivery of essential public health services, while providing assistance to meet emergency needs of the affected population. This plan establishes the framework and guidelines for ensuring that an effective system of health and medically related emergency response is in place to contain adverse outcomes of influenza pandemic.

In the face of a pandemic threat or ongoing nationwide influenza pandemic, the need to vaccinate millions of persons as rapidly and safely as possible will pose a potentially overwhelming burden on the usual sites for annual influenza vaccination. As knowledge and infrastructure change, the plan should be revised accordingly. In addition, in the event of a pandemic, the judgments of leadership, based on the epidemiology of the virus and the extent of population infection, may alter or override anticipated action plans.

The Kentucky Pandemic Influenza Preparedness Plan must be considered a "living document" that will be updated when new information and guidelines from the WHO or CDC are available. At any time during the stages, the activities may be changed or cancelled by KDPH.

B. Influenza Virus

Influenza is a highly contagious illness and can be spread easily from person to person. It is spread through droplet contact from the nose and throat of an infected person during coughing and sneezing. Rapid onset of high fever, chills, sore throat, runny nose, severe headache, nonproductive cough, and intense body aches - followed by extreme fatigue - are signs and symptoms of influenza. The incubation period is from one to five days. Annual seasonal epidemics typically occur from December to April in the continental United States, including Kentucky.

Influenza A and B are the two types of influenza viruses that cause epidemic human disease. Influenza A viruses are further categorized into subtypes on the basis of two surface antigens: hemagglutinin and neuraminidase. Influenza B viruses are not categorized into subtypes. Influenza A viruses are unique because they can infect both humans and animals and are usually associated with more severe illness than type B influenza viruses.

Antigenic drift and *shift* are the terms used to describe how influenza viruses mutate. *Antigenic drift* is a minor change caused by mutation that results in the emergence of a new strain within a subtype. Antigenic drift has been responsible for heavier-than-normal influenza seasons in the past, like the outbreak of influenza A Fujian (H3N2) in the 2003 – 2004 influenza season. Drifts can occur in both type A and B influenza viruses. *Antigenic shift* is associated with influenza pandemics. It is a major change caused by genetic recombination that results in the emergence of a novel virus strain that has not previously infected humans. Only in influenza type A viruses does antigenic shift occur. As an example, H3N2 and H5N1 can form H5N2

C. Background

The devastation that could accompany an influenza pandemic is not reflected in the public's perception of the annual flu season, despite the fact that influenza causes significant morbidity and mortality each year. In 1918, the public shared today's casual view of the virus. Influenza was, as recorded by A.W. Crosby in Influenza 1918, The American Experience, "a homey, familiar kind of illness, two or three days in bed, a week of feeling shaky, and then back to normal." Thus, the rapid and gruesome deaths that occurred during the 1918 pandemic were shocking to both physicians and the public.

A local historian from a small town in southern Ohio put the potential impact of a major shift in viral sub-types into perspective when he recalled the influence of the 1918 pandemic on his community. The town was located near a military encampment. The historian recalled how the young soldiers would arrive at the camp in the morning healthy and well and, within twenty-four hours, be dead. The dead were so numerous, the community's funeral parlors were overcome and makeshift morgues were located throughout the community. The infamous "Spanish Flu" of 1918 was responsible for more than an estimated 20 million deaths worldwide and at least a 500,000 deaths in the United States.

The mortality rates from the pandemics of 1957 and 1968 were lower due in part to less virulent viruses, antibiotic treatment of secondary infections and improved supportive care. Significant

societal changes have occurred since 1968, making it difficult to predict the level of illness and disruption that an influenza pandemic could cause today. Increased international travel, a larger cohort of persons over 65 years of age, and a larger number of persons with immunosuppressive conditions contribute to the predicted difficulty.

The following estimates of the impact of a pandemic on Kentucky’s population and health resources have been made using the CDC FluAid software application. The software permits the planner to alter variables to reflect on different, possible scenarios. The jurisdiction’s population and health status characteristics are two variables that may be manipulated.

D. Planning Assumptions

In order to perform preparedness planning for a pandemic, certain assumptions need to be made regarding the evolution and impacts of a pandemic. Determining the potential impact of a pandemic is difficult, but studying pandemics in the past can be useful to help with future predictions. In the 20th century, all pandemics had similar characteristics. For example, each one had about 30% of the U.S. population develop the illness, with about half of those seeking medical care. The highest rates of illness have been in children. School-age children, however, have not had the highest rates of death and severe disease. Virtually all communities experienced outbreaks and rapid geographical spread in each pandemic. The following are national pandemic planning assumptions:

- Susceptibility to the pandemic influenza subtype will be universal.
- The clinical disease attack rate will be 30% in the overall population. Illness rates will be highest among school-aged children (about 40%) and decline with age. Among working adults, an average of 20% will become ill during a community outbreak.
- Of those who become ill with influenza, 50% will seek outpatient medical care.
- The number of hospitalizations and deaths will depend on the virulence of the pandemic virus. Estimates differ about 10-fold between more and less severe scenarios. Because the virulence of the influenza virus that causes the next pandemic cannot be predicted, two scenarios are presented based on extrapolation of past pandemic experience (Table 1).

Table 1. Number of Episodes of Illness, Healthcare Utilization, and Death Associated with Moderate and Severe Pandemic Influenza Scenarios in the United States*

| Characteristic | Moderate (1958/68-like) | Severe (1918-like) |
|-------------------------|--------------------------------|--------------------|
| Illness | 90 million (30%) of population | 90 million (30%) |
| Outpatient medical care | 45 million (50%) of those ill | 45 million (50%) |
| Hospitalization | 865,000 | 9,900,000 |
| ICU care | 128,750 | 1,485,000 |

| | | |
|------------------------|---------|-----------|
| Mechanical ventilation | 64,875 | 742,500 |
| Deaths | 209,000 | 1,903,000 |

* Estimates based on extrapolation from past pandemics in the United States. Note that these estimates do not include the potential impact of interventions not available during the 20th century pandemics.

- Risk groups for severe and fatal infections cannot be predicted with certainty. During annual fall and winter influenza season, infants and the elderly, persons with chronic illnesses and pregnant women are usually at higher risk of complications from influenza infections. In contrast, in the 1918 pandemic, most deaths occurred among young, previously healthy adults.
- The typical incubation period (the time between acquiring the infection until becoming ill), for influenza averages 2 days. We assume this would be the same for a novel strain that is transmitted between people by respiratory secretions.
- Persons who become ill may shed virus and can transmit infection for one-half to one day before the onset of illness. Viral shedding and the risk for transmission will be greatest during the first 2 days of illness. Children will shed the greatest amount of virus and, therefore, are likely to pose the greatest risk for transmission.
- On average about 2 secondary infections will occur as a result of transmission from someone who is ill. Some estimates from past pandemics have been higher, with up to about 3 secondary infections per primary case.
- In an affected community, a pandemic outbreak will last about 6 to 8 weeks. At least two pandemic disease waves are likely and may occur over different influenza seasons. Following the pandemic, the new viral subtype is likely to continue circulating and to contribute to seasonal influenza.
- The seasonality of a pandemic cannot be predicted with certainty. The largest waves in the U.S. during 20th century pandemics occurred in the fall and winter. Experience from the 1957 pandemic may be instructive in that the first U.S. cases occurred in June, but no community outbreaks occurred until August. The first wave of illness peaked in October.

Other planning assumptions include:

- A pandemic is inevitable and will impact all states and regions.
- Vaccine safety is important, but also important is speed and efficiency in administering vaccine.
- The general public will be involved, concerned and desirous to receive information. Those responsible must clearly communicate the facts, risks and necessary protection steps to the public.
- It is difficult to perceive any aspect of society that will not be affected by a pandemic of even minor severity.

- Volunteers, especially health and medical volunteers, will be available and able to be utilized.
- Antiviral agents are likely to only be available for limited distribution.
- Vaccine may not be available for some time.

A summary of pandemic influenza morbidity and mortality data for Kentucky (as created by Flu Aid) is as follows:

E. Basis of Estimates:

- Gross Attack Rates – 15%, 25% and 35%
- High risk percentages by age category:
 - 0-18 years of age; 6.4% of the population
 - 19-64 years of age; 17.0% of the population
 - 65+ years of age; 47.0% of the population
- Hospitalization rates are equal to the software’s default percentages for high risk and non-high risk populations.
- Inter-pandemic deaths attributed to influenza and pneumonia are 1,030 persons (taken from state surveillance data for the calendar year 2003).

Deaths: (Most Likely)

| | | | |
|------------------------------------|------|------|------|
| Attack rate | 15% | 25% | 35% |
| Gross number deaths | 1842 | 3069 | 4296 |
| Inter-pandemic “base” | 834 | 834 | 834 |
| Incremental deaths due to pandemic | 1008 | 2235 | 3462 |

Deaths: (Maximum)

| | | | |
|------------------------------------|------|------|------|
| Attack rate | 15% | 25% | 35% |
| Gross number deaths | 3103 | 5172 | 7241 |
| Inter-pandemic “base” | 834 | 834 | 834 |
| Incremental deaths due to pandemic | 2269 | 4338 | 6407 |

Hospitalizations: (Most Likely)

| | | | |
|--|---------|---------|---------|
| Attack rate | 15% | 25% | 35% |
| Number of hospitalizations | 7233 | 12055 | 16878 |
| Average length of stay per hospitalization | 6 days | 6 days | 6 days |
| Total patient days | 43398 | 72330 | 101268 |
| Pandemic period | 8 weeks | 8 weeks | 8 weeks |
| Average daily census | 775 | 1292 | 1808 |

Hospitalizations: (Maximum)

| | | | |
|--|---------|---------|---------|
| Attack rate | 15% | 25% | 35% |
| Number of hospitalizations | 9483 | 15807 | 22130 |
| Average length of stay per hospitalization | 6 days | 6 days | 6 days |
| Total patient days | 58698 | 94842 | 132780 |
| Pandemic period | 8 weeks | 8 weeks | 8 weeks |
| Average daily census | 1048 | 1694 | 2371 |

II. COMMAND AND MANAGEMENT

The HHS Pandemic Influenza Plan clearly states the roles and responsibilities of HHS agencies and offices and gives HHS Actions for Pandemic Influenza Preparedness and Response. KDPH will lead the state response to pandemic influenza. It is imperative that both state and local health departments know their role in response to pandemic influenza. This section lays out major roles of federal, state and local health during the Interpandemic, Pandemic Alert and Pandemic Periods.

A. Major Roles of HHS

Interpandemic and Pandemic Alert Period:

- Expand the supply of antiviral drugs by stimulating increased U.S.-based production capacity
- Expand U.S.-based production capacity for pandemic vaccine and work with manufacturers to ensure that pandemic vaccine is produced at full capacity

Pandemic Period:

- Provide ongoing information from the national influenza surveillance system on impact of the pandemic on health and healthcare system
- Assist in conducting outbreak investigations, as requested by state
- Conduct epidemiological and laboratory-based studies (“special studies”), as requested
- Distribute public stocks of vaccines, when they become available
- Provide guidance on community containment strategies, including travel restrictions, school closings, and quarantine and isolation
- Communicate with the public via the news media
- Monitor the response
- Distribute public stocks of antiviral drugs and other medical supplies from the Strategic National Stockpile (SNS) to the states

B. Major Roles of the KDPH

Interpandemic and Pandemic Alert Period

- The KDPH will have responsibility for implementation of the Kentucky Pandemic Influenza Preparedness Plan.
- Enhance disease surveillance to ensure early detection of the first cases in the state
- Coordinate storage and distribution of antivirals

- Coordinate with local health departments for local pandemic influenza planning
- Coordinate with partners agencies on pandemic planning through activities such as Pandemic Influenza Summit and exercises
- Enhance laboratory capacity

Pandemic Period

- The Commissioner of Public Health (State Health Officer) will have primary authority for implementation of the pandemic response plan
- Provide guidance on clinical management and infection control
- Provide guidance on disease transmission using a range of containment strategies
- Provide ongoing communication with the public
- Coordinate with partners to provide psychological and social support services to emergency field workers and other responders
- Coordinate antiviral and vaccine distribution

C. Major Roles of Local Health Departments

Interpandemic and Pandemic Alert Periods

- Identify administrative and medical decision makers during the pandemic
- Coordinate with community partners and stakeholders on pandemic planning through activities such as Pandemic Influenza Summit and exercises.
- Develop a local pandemic influenza preparedness plan that correlates with existing emergency plans
- Meet with local stakeholders and review major elements of the local pandemic influenza plan
- Decide when the pandemic plan is implemented and assure local emergency plans are implemented during the influenza pandemic
- Develop and implement a local mass vaccination and/or distribution plan
- Develop a plan to close businesses and other public events, if necessary
- Collaborate with the local school board for closing and re-opening of school.
- Develop a plan to educate the public prior to the onset of the pandemic. Identify administrative and medical decision makers during the pandemic Pandemic Alert Period

Pandemic Period

- Enhance disease surveillance to ensure early detection of the first cases of pandemic influenza in the county or district
- Distribute antiviral drugs and vaccines and communicate with HRSA planning partners on clinical management and infection control
- Prevent local disease transmission using a range of containment strategies
- Provide ongoing communication with the public
- Coordinate with psychological and social support services to provide assistance to field workers.
- Communicate on a timely basis the status of county to KDPH.
-

D. KDPH Command and Control

1. Interpandemic Period and Pandemic Alert Period

Phases 1-2

Phases 3-5

- The ESF 8 DOC Manager will convene a Pandemic Influenza Planning and Management Team to develop a Pandemic Influenza Preparedness Plan for Kentucky. (Note: This document is a product of this activity).
- The members of the Pandemic Influenza Planning and Management Team will assist on issues related to their specific areas of expertise for implementation of the state's public health response to pandemic influenza. Members of the Pandemic Influenza Planning and Management Team include:

From CHFS:

**Director of Division of Epidemiology and Health Planning
Preparedness Branch (9)
Vital Statistics (2)
Communicable Disease Branch (5)
Division of Communications
CDC Field Epidemiologist
Response
State Public Health Veterinarian
Immunization Branch (3)
Local Health Department Operations
Division of Laboratory Services (3)
Office of Information Technology
Public Health Protection and Safety
CHFS General Counsel
Office of Information Technology
Office of Aging**

Other Agencies:

**KY Dept. of Education
KYEM (2)
KOHS
US Army (Fort Campbell)
University of Kentucky
University of Louisville
Lexington Metropolitan Medical System (MMRS)
Louisville MMRS
Northern KY MMRS
Local Health Department (3)
DOCJT
Justice Cabinet
State Representative
KCCRB
Chamber of Commerce
Coroner's Association**

- Responsibilities of the Pandemic Influenza Planning and Management Team include:
 - Developing the CHFS response to pandemic influenza
 - Providing guidance and support to local health departments to prepare for an influenza pandemic
 - Assisting with KDPH response by serving in the incident command structure
- The Pandemic Influenza Planning and Management Team will review the Kentucky Pandemic Influenza Plan at least annually and update the document as needed. The Planning Coordinator from the Public Health Preparedness Branch will be responsible for reviewing and updating the document.
- The Planning and Management Team is working during Interpandemic to:
 - Help promote county and/or regional planning
 - Help promote planning within HRSA regions
 - Identify state and local law enforcement personnel who will assist in maintaining public order and enforcing control measures during a pandemic

- Make planning decisions on acquisition and distribution of antiviral drugs and vaccines
- Conduct state-level table top exercises
- Encourage local jurisdictions to conduct exercises and drills

2. Pandemic Period

Phase 6

Executive Level

- In the event of the occurrence or threatened or impending occurrence of any of the situations or events contemplated by KRS 39A.010, the Governor may declare, in writing, that a state of emergency exists. Conditions enumerated in KRS 39A.010 include “threats to public safety and health.”
- The Cabinet Secretary will advise the Governor on pandemic influenza issues.
- In consultation with Kentucky Emergency Management (KYEM), the State Health Officer will help determine the need for activation and, if activated, when closure of the state Emergency Operations Center (EOC) is appropriate. Full or partial activation of the State EOC will be discussed.
- The State Health Officer will determine when to advise the CHFS Secretary to recommend the Governor declare a "State of Emergency in Kentucky" in response to the influenza pandemic
- The State Health Officer or designee will act as an advisor and will collaborate with Emergency Management set the incident objectives, strategies, and priorities and has overall responsibility of the operations.
- The State Health Officer will ensure continuity of critical operations (COOP) for public health.

Command Staff

- General Counsel will be responsible to provide legal advice to Cabinet Secretary and State Health Officer
- The Public Information Officer (PIO) is responsible to disseminate information to the public in a timely manner and participate in the Joint Information System (JIS). It may be necessary to send an additional PIO to serve at the Joint Information Center (JIC).
- The State Epidemiologist reports to the State Health Officer regarding the state’s public health response to pandemic influenza and will make recommendations based on epidemiology and communicate up and down the chain of command. The State Epidemiologist will oversee the operations level and communicate directly with the ESF 8 DOC Manager.
- The Cabinet Liaison will work with other agencies and will likely serve as the state Emergency Operations Center.

Operations Level

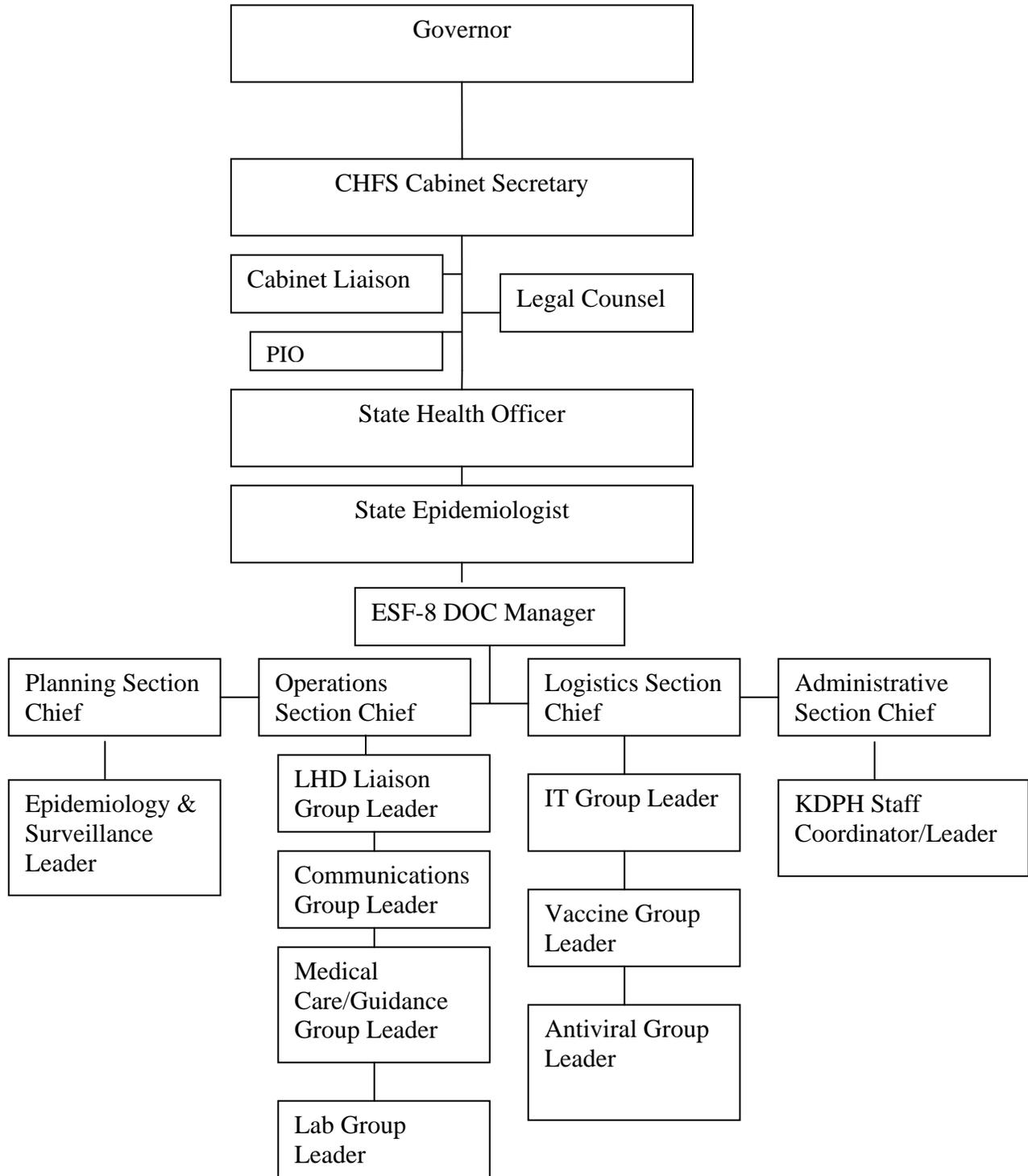
- The ESF-8 DOC Manager will meet with response team members as often as needed to guide the implementation of Kentucky's pandemic influenza response. The ESF 8 DOC Manager will oversee all section chiefs. Responsibilities of the ESF 8 DOC Manager include:
 - Update the State Epidemiologist and oversee operations, planning, logistics and administration.
 - Conduct briefings on a regular basis with CHFS leadership and staff

- Oversee the Operations Section and monitor the state's daily response to situation
- Oversee the Planning Section
- Oversee Logistics Section
- Oversee the Finance/Administration Section
- The following section chiefs will be assigned to coordinate activities:
 - Planning Section Chief – Major responsibilities include:
 - Gather, analyze and disseminate intelligence and information
 - Managing the planning process
 - Decide on the benefit using of alternate facilities during the influenza pandemic will and arrange for additional facilities to use for the pandemic response
 - Compile the Incident Action Plan and recommending objectives
 - Develop a written Action Plan/Situation Status, if necessary.
 - Track daily activities for KDPH
 - Track and receiving updates from the Regional Epidemiologists, Planners, Regional HRSA Coordinators and keeping the ESF 8 DOC Manager informed of the pandemic response
 - Communicate with other Divisions within the KDPH as needed regarding the status of the influenza pandemic and the KDPH response
 - Work closely with the ESF 8 DOC Manager, so that information is shared effectively and results in an efficient planning process.
 - Operations Section Chief – Major responsibilities include:
 - Develop and implement strategies and tactics to carry out the incident objectives
 - Organize, assign and supervise resources for operations
 - Work closely with the ESF 8 DOC Manager and PIO to be sure that information is shared effectively and results in an efficient process
 - With guidance from the ESF 8 DOC Manager, ensure that public messages are communicated
 - Coordinate KDPH response activities with those of the local health department
 - Responsible for communicating need for reassigned KDPH employees to Admin/Finance Section Chief
 - Logistics Section Chief – Major responsibilities include:
 - Provide support, resources and all other services needed to meet the operational objectives
 - Obtain, maintain, and account for essential personnel, equipment, and supplies
 - Track supply, storage and movement of antivirals and vaccines
 - Work closely with the ESF 8 DOC Manager to be sure that information is shared effectively and results in an efficient process.
 - Administrative/Finance Section Chief - Major responsibilities include:
 - Monitor the assigned responsibilities of staff
 - Serve as liaison with the State Health Officer, the Secretary of the CHFS and the Director of Public Affairs, CHFS
 - Provide administrative support during the pandemic response
 - Coordinate program support during the pandemic response
 - Assess the availability of KDPH personnel available to assist in the pandemic response, upon recommendation from Operations Section Chief

- Contact other Divisions within the KDPH for assistance, as necessary
- All Divisions within the KDPH may assume a supportive role, working within the ESF-8 DOC in ways appropriate to their program authority and responsibilities.

APPENDIX 1

Organizational Chart for the Cabinet for Health and Family Services



APPENDIX 2 GLOSSARY

| | |
|---|---|
| Continuity of Operations (COOP) | Ensures that essential services are prioritized and continue to operate. |
| Epidemic | The occurrence of a disease in a community or region clearly in excess of normal expectations |
| Health Alert Network (HAN) | A program used to communicate health and emergency messages |
| Influenza-like illness (ILI) | The presence of fever $\geq 100^{\circ}$ F, with a cough or sore throat |
| Joint Information Center (JIC) | A central location for involved agencies to coordinate public information activities and a forum for news media representatives to receive disaster or emergency information |
| Joint Information System (JIS) | The overall system for public information. |
| Novel virus | A virus rarely, or not previously known to infect humans |
| Pandemic | The occurrence of a disease in excess of normal expectations in extensive regions, countries and continents |
| Strategic National Stockpile (SNS) | A federal cache of medical supplies and equipment to be used in emergency and disaster situations |
| Subtype | Identification of influenza A viruses according to the hemagglutinin (H) and neuraminidase (N) components of the virus, such as H1N1 or H3N2 |
| Surveillance | The collection, analysis and dissemination of data |
| Syndromic | Based on clinical signs and symptoms |

**KENTUCKY PANDEMIC INFLUENZA PREPAREDNESS PLAN
LABORATORY AND SURVEILLANCE SUPPLEMENT**

| TABLE OF CONTENTS | | |
|--------------------------|---|------------|
| I. | RATIONALE / OVERVIEW | 1 |
| II. | GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 2 |
| | A. Epidemiological and Laboratory Surveillance for Human Infection | 3 |
| | B. Laboratory/ Epidemiological Support for Seasonal/Interpandemic Influenza Surveillance | 8 |
| | C. Laboratory/Epidemiological Support for Novel Influenza Subtypes | 8 |
| | D. Laboratory Planning to Support the Response to a Pandemic | 9 |
| III. | GUIDELINES FOR THE PANDEMIC PERIOD | 10 |
| | A. Epidemiological and Laboratory Surveillance for Human Infection | 10 |
| | B. Laboratory Support for Disease Surveillance | 12 |
| | C. Laboratory Support for Clinicians | 12 |
| | D. Biocontainment Procedures | 12 |
| | E. Occupational Health Issues for Laboratory Workers | 12 |
| IV. | APPENDICES | |
| | Appendix 1. Influenza Sentinel Surveillance System | 1-3 |
| | Appendix 2. Guidelines for Submitting Influenza Virus Isolates | 1-3 |
| | Appendix 3. Human Influenza A (H5) Screening Form | 1-5 |
| | Appendix 4. Influenza A (H5) Screening Form Instructions | 1-4 |
| | Appendix 5. Guidelines for Reporting A (H5) | 1-7 |
| | Appendix 6. Specimen Collection Guidelines | 1 |

LABORATORY AND SURVEILLANCE SUPPLEMENT

This supplement provides guidance on surveillance and laboratory activities during the various phases of pandemic.

I. RATIONALE/OVERVIEW

Surveillance for pandemic influenza centers around four major issues that will vary in importance depending on the pandemic phase: (1) to respond to every individual case to limit the spread of disease; (2) to respond to clusters or upward trends or outbreaks; (3) to provide information to plan prevention programs and (4) to provide information to evaluate prevention and control programs. In order to evaluate and tailor disease control interventions of a novel virus, it will be crucial to collect and analyze detailed real-time data on its clinical and epidemiological characteristics.

An effective statewide pandemic influenza surveillance system requires a well-functioning, interpandemic influenza surveillance system. Surveillance needs will expand and change as an influenza pandemic evolves from the initial stages (i.e., when a novel influenza virus is first identified in one or more persons), to a pandemic (i.e., with efficient human-to-human transmission). Surveillance needs will differ depending on where the disease has been identified, whether there is coexisting disease among livestock or other animals, how efficiently transmission occurs between people, and whether disease outbreaks have occurred in the United States or other countries.

Disease surveillance data will be critical to guide the implementation of control measures (i.e., restricting travel, closing schools, canceling public gatherings, initiating antiviral and vaccine administration to target groups, etc.), assessing the impact of a pandemic on the healthcare system, and assessing the social and economic impact on society.

The goals of disease surveillance are to:

- Serve as an early warning system to detect increases in ILI in the community.
- Monitor the pandemic's impact on health (e.g., by tracking outpatient visits, hospitalizations, and deaths).
- Track trends in influenza disease activity and identify populations that are severely affected.

Diagnostic testing for pandemic influenza virus may involve a range of laboratory assays, including rapid antigen tests, reverse-transcription polymerase chain reaction (RT-PCR), virus isolation, and immunofluorescence antibody (IFA) assays. During the earliest stages of a pandemic, public health, hospital, and clinical laboratories might receive a large and potentially overwhelming volume of clinical specimens. Pre-pandemic planning is therefore essential to ensuring the timeliness of diagnostic testing and the availability

of diagnostic supplies and reagents, addressing staffing issues, and disseminating protocols for safe handling and shipping of specimens. Once a pandemic is underway, the need for laboratory confirmation of clinical diagnoses may decrease as the virus becomes widespread.

The goals of diagnostic testing during a pandemic are to:

- Identify the earliest Kentucky cases of pandemic influenza (whether the pandemic begins in the United States or elsewhere).
- Support disease surveillance to monitor the pandemic's geographic spread and impact of interventions.
- Facilitate clinical treatment by distinguishing patients with influenza from those with other respiratory illnesses.
- Monitor circulating viruses for antiviral resistance and antigenic drift or antigenic shift.

In conjunction with recommendations from other public health partners, such as the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), the Division of Epidemiology and Health Planning (DEHP) will provide updated guidance to medical providers and local health departments on an ongoing basis. Surveillance activities outlined below will be contingent on local, national and international influenza activity at the time.

II. GUIDELINES FOR INTERPANDEMIC AND PANDEMIC ALERT PERIODS

The objectives of surveillance for pandemic influenza will vary based on the phase of the pandemic.

Interpandemic Surveillance Objectives

During the interpandemic phase, sentinel surveillance throughout the state is used to assess the seasonal burden of influenza. Surveillance data is primarily used to enhance the influenza vaccination program and to identify the predominant circulating strains of influenza. Surveillance serves not only to detect local outbreaks of seasonal influenza, but also unusual clusters of illness that may be due to a new influenza virus. Influenza is not a reportable disease, however, outbreaks or clusters of any disease, including influenza, are reportable by Commonwealth of Kentucky regulation.

Interpandemic and Pandemic Alert Novel Influenza Virus Surveillance Activities

- Ensure early detection of cases and clusters of respiratory infections that might signal the presence of a novel influenza virus.
- Ensure laboratory resources are available to rapidly detect the introduction of a novel virus.

- If a novel strain of influenza is confirmed, ensure prompt and complete identification and reporting of potential cases to facilitate control and management of local outbreaks.

A. Epidemiological and Laboratory Surveillance for Human Infection

During WHO Pandemic Phases 1 and 2 (Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals), DEHP will:

- Continue all interpandemic influenza surveillance activities as described in Appendix 1.
- Encourage influenza sentinel providers and health departments to perform year-round reporting of ILI activity.
- In conjunction with local health departments and the Kentucky Hospital Association (KHA), work closely with healthcare organizations and healthcare providers to implement active surveillance in emergency departments, inpatient wards, and intensive care units and explore developing an enhanced surveillance system for pneumonia and influenza-associated hospitalizations.
- Continue the planned implementation of WebEOC in the DPH, Local Health Departments, and hospitals throughout Kentucky. WebEOC will permit exchange of information regarding influenza and pneumonia-related hospitalizations and deaths.
- In conjunction with local health departments and hospitals, work with state and local medical examiners to establish lines of communication and explore developing an enhanced surveillance system for influenza and pneumonia-related deaths. Register all medical examiners on KY Health Alert Network (HAN) and create a medical examiner listserv.
- Continue working with the FEMA Region IV Planning Coalition to establish mass fatality teams (SMORT).
- Continue working to establish an electronic death registry.
- Encourage the use of influenza and rapid diagnostic tests, IFA assays, and PCR to detect the first cases of novel virus infection in Kentucky, and target containment strategies, such as isolation and quarantine, contact tracing, and use of limited vaccine and antivirals in the populations at risk during the interpandemic period and early stages of a pandemic, before community transmission is established.

- Request local health departments to report any suspect avian influenza cases and forward clinical specimens to the Division of Laboratory Services (DLS) for concurrent testing.
- Expand the capacity for novel virus testing among local laboratories, including providing training, technical assistance, and reference or validation testing. Request laboratories to report testing for any suspect avian influenza cases and to forward clinical specimens to the DLS for testing.
- Coordinate with the Kentucky Department for Agriculture, Kentucky Poultry Federation, and Kentucky Fish and Wildlife Resources for enhanced surveillance and reporting of novel influenza virus in poultry workers, commercial and private poultry flocks, and wild birds to identify disease activity in animal populations and to characterize the human health threat.
- Share influenza surveillance data and epidemiological information in a timely manner with local health departments, regional epidemiologists, and the CDC.
- Develop and implement criteria and protocols for epidemiologic investigation of influenza outbreaks, influenza case clusters with unusual clinical presentations, and clusters of unexplained pneumonia.
- Enhance and expand capacity at the local levels to conduct case investigations and epidemiologic investigations. These activities will include conducting an inventory of current capacity, determining current skill levels, conducting drills and exercises in case investigations, developing forecasts of future capacity needs under different pandemic scenarios, identifying gaps in capacity, and building ERRTs (Epi Rapid Response Teams) and Epi Strike Teams throughout the state.
- In conjunction with local health departments, evaluate and implement an outbreak management system to assist with case management, case ascertainment, case reporting, surveillance, and data analysis.
- Develop protocols that clearly designate who will conduct epidemiologic studies of novel influenza strains and coordinate between local, state, and federal investigations.
- Identify funding and training strategies to ensure that epidemiologic capacity at the state and local levels is consistent with current and future needs.

During WHO Pandemic Phases 3 and 4 (Pandemic Alert Period: Human infection with no or very limited human-to-human transmission), DEHP will:

- Upon lab confirmation of the first case of novel influenza virus in Kentucky, develop and distribute guidance to local health departments on surveillance, case detection, contact tracing, and infection control. DEHP will coordinate disease control activities and provide technical assistance to local health departments with any confirmed cases of novel influenza virus infection.

- Actively monitor and implement as necessary, any changes in recommendations and guidelines for surveillance and diagnostic testing from CDC (e.g., revision to the case definition, screening criteria, case report forms, or diagnostic testing algorithms), and post a case screening form and a case report form for laboratory confirmed cases on the DPH Influenza website at:
<http://chfs.ky.gov/dph/epi/Influenza.htm>

- Disseminate case definitions, clinical criteria, and epidemiological criteria for the evaluation of patients with possible novel influenza to all Health Departments for distribution to their local medical community. The current criteria is as follows:
 - During the Pandemic Alert Period, human infections with novel influenza A viruses will be uncommon. Therefore, **both clinical and epidemiologic criteria should be met**. The criteria will be updated as needed and posted at www.cdc.gov/flu.

 - **Clinical criteria**
 Any suspected cases of human infection with a novel influenza virus must meet the criteria for ILI: **temperature of >100.4°F (>38°C) plus one of the following: sore throat, cough, or dyspnea.**
 - Because of the large number of ILI cases during a typical influenza season, during the Interpandemic and Pandemic Alert Periods laboratory evaluation for novel influenza A viruses is recommended **only** for:
 - a) Hospitalized patients with severe ILI, including pneumonia, who meet the epidemiologic criteria (see below), or
 - b) Non-hospitalized patients with ILI and with strong epidemiologic suspicion of novel influenza virus exposure (e.g., direct contact with ill poultry in an affected area, or close contact with a known or suspected human case of novel influenza within 10 days prior to onset of symptoms.).

 - See the Clinical Guidelines Supplement of this plan for more detailed recommendations for the evaluation of patients with respiratory illnesses.

 - **Epidemiologic criteria**

Epidemiologic criteria for evaluation of patients with possible novel influenza focus on the **risk of exposure** to a novel influenza virus with pandemic potential. Although the incubation period for seasonal influenza ranges from 1 to 4 days, the incubation periods for novel types of influenza are currently unknown and might be longer. Therefore, the maximum interval between potential exposure and symptom onset is set conservatively at 10 days.

- **Exposure risks** — Exposure risks fall into two categories: a) travel and b) occupational.

a) Travel risks: Persons have a travel risk if they have, within 10 days prior to onset of symptoms:

- 1) recently visited or lived in an area affected by highly pathogenic avian influenza A outbreaks in domestic poultry or where a human case of novel influenza has been confirmed, **and**
- 2) either had direct contact with poultry, **or**
- 3) had close contact with a person with confirmed or suspected novel influenza. Updated listings of areas affected by avian influenza A (H5N1) and other current/recent novel strains are provided on the websites of the OIE (http://www.oie.int/eng/en_index.htm), WHO (www.who.int/en/), and CDC (www.cdc.gov/flu/).

Direct contact with poultry is defined as: 1) touching birds (well-appearing, sick, or dead), or 2) touching poultry feces or surfaces contaminated with feces, or 3) consuming uncooked poultry products (including blood) in an affected area. Close contact with a person from an infected area with confirmed or suspected novel influenza is defined as being within 3 feet (1 meter) of that person during their illness. Because specific testing for human infection with avian influenza A (H5N1) might not be locally available in an affected area, persons reporting close contact in an affected area with a person suffering from a severe, yet unexplained, respiratory illness should also be evaluated.

Human influenza viruses circulate worldwide and year-round, including in countries with outbreaks of avian influenza A (H5N1) among poultry. Therefore, during the Interpandemic and Pandemic Alert Periods, human influenza virus infection can be a cause of ILI among returned travelers at any time of the year, including during the summer in the United States. This includes travelers returning from areas affected by poultry outbreaks of highly pathogenic avian influenza A (H5N1) in Asia. As of May 2006, such persons are currently more likely to have infection with human influenza viruses than with avian influenza A (H5N1) viruses.

b) Occupational risks

Persons at occupational risk for infection with a novel strain of influenza include:

- 1) persons who work on farms or live poultry markets
- 2) persons who process or handle poultry infected with known or suspected avian influenza viruses
- 3) workers in laboratories that contain live animal or novel influenza viruses
- 4) healthcare workers in direct contact with a suspected or confirmed novel influenza case.

Information on limiting occupational risk is provided on the Occupational Health and Safety Administration (OSHA) website at:
www.osha.gov/dsg/guidance/avian-flu.html.

During the Interpandemic and Pandemic Alert Periods, when there is no sustained human-to-human transmission of any novel influenza viruses, **direct contact** with animals such as poultry in an affected area or close contact with a case of suspected or confirmed human novel influenza is **required** for further evaluation.

During the Pandemic Alert Period, Phases 3 and 4, the majority of human cases of novel influenza will result from avian-to-human transmission (see Box 1). Therefore, a history of direct contact with poultry (well-appearing, sick, or dead), consumption of uncooked poultry or poultry products, or direct exposure to environmental contamination with poultry feces in an affected area will be important to ascertain.

During the Pandemic Alert Period, Phase 5, a history of close contact with an ill person suspected or confirmed to have novel influenza in an affected area will be even more important.

Other avian influenza A viruses

Although the epidemiologic criteria for novel influenza are based on recent human cases of avian influenza A (H5N1), they are intended for use in the evaluation of suspected cases of infection with any novel influenza A virus strain.

Other avian influenza A viruses that have caused human disease include the highly pathogenic viruses H7N7 and H7N3 and the low pathogenic viruses H9N2 and H7N2. Some of these human cases have occurred in Europe (Netherlands) and North America (Canada and the United States). Therefore, the same high-risk exposures defined above for avian influenza A (H5N1) also apply to other avian influenza A viruses.

A strong epidemiologic link to an avian influenza outbreak in poultry, even in areas that have not experienced poultry outbreaks of avian influenza A (H5N1), may raise the index of suspicion for human infection with avian influenza A viruses.

In the future, other animal hosts (in addition to poultry) or novel influenza A virus subtypes (in addition to H5N1) might become significantly associated with human disease. If such events occur, this guidance will be updated.

- Communicate with local health departments, regional epidemiologists and infection control practitioners via the Infection Control Listserv, email, WebEOC (if necessary) DPH Influenza website <http://chfs.ky.gov/dph/epi/Influenza.htm>, HAN, *Kentucky Epidemiologic Notes and Reports*, and conference calls to share information on surveillance criteria, case management, specimen collection, appropriate testing, and community containment.
- In conjunction with local health departments and the Kentucky Hospital Association (KHA), continue working with healthcare organizations and healthcare providers to implement active surveillance in emergency departments, inpatient wards, and intensive care units. Develop an enhanced surveillance system for influenza and pneumonia-related hospitalizations.
- In conjunction with local health departments and hospitals, continue working with state and local medical examiners to develop an enhanced surveillance system for influenza and pneumonia-related deaths. Ensure that all medical examiners are registered in HAN and the medical examiner listserv is current.
- Continue working to establish mass fatality teams and an electronic death registry.
- Issue guidance for managing suspect novel influenza cases; including infection control guidelines, guidelines for collecting and shipping specimens for influenza A diagnostics, and laboratory biosafety guidelines for handling and processing of specimens of novel influenza A. Laboratory biosafety guidelines will be posted on the DLS website along with specimen submittal forms at: <http://chfs.ky.gov/dph/info/lab/>
- Work with health departments to detect and monitor persons who have recently traveled to areas where the novel virus has been identified and who present with clinical illness consistent with influenza. Provide technical assistance and guidance to assess and report suspect cases of novel virus infection.
- Encourage all influenza sentinel providers to report data year-round and educate sentinel providers of enhanced surveillance activities, including submission of

specimens to DLS, and of the need to report suspect cases to their local health department for further evaluation and testing.

- Recruit additional sentinel physicians to report ILI activity, collect respiratory specimens, and submit them for testing.
- Encourage reporting of all suspect human cases of the novel influenza virus cases of clinical illness consistent with a novel influenza virus through an electronic case reporting system.
- Generate weekly reports of statewide influenza activity and distribute surveillance data to local health departments, regional epidemiologists, participating agencies, CDC, DPH public information officers, and KY Emergency Management (KYEM).
- Review plans to further enhance influenza surveillance if efficient person-to-person transmission of the novel virus is confirmed, including training additional personnel on surveillance, case detection, contact tracing, and infection control issues.
- Work with the KY Department of Agriculture (KDA), KY Poultry Federation (KPF), and KY Department of Fish and Wildlife Resources (KDFWR) on enhanced surveillance and reporting of novel influenza virus detection in poultry workers, commercial and private poultry flocks, and in wild birds to identify disease activity in animal populations and to characterize the human threat.
- Collaborate with commercial laboratory stakeholders who are offering novel virus testing to report any preliminary positive results for novel virus infection to either the local health department or the DLS.
- Encourage submission of clinical specimens from ILI cases from all sources (public and private clinics, sentinel providers, and hospitals) and facilitate subtyping of influenza A viruses.
- In coordination with the CDC, develop, distribute and implement case management protocols to ensure that suspect human cases are promptly identified and isolated and that the source(s) of exposure (animal vs. human) are determined. Ensure protocols are distributed to local health departments and settings where cases and their contacts might be diagnosed.
- In collaboration with the CDC and local health departments, conduct, direct, coordinate, or provide guidance on epidemiologic investigations of human cases to identify the populations at risk, the current clinical characteristics of the disease, and the risk that infected persons or their environment may pose to others, including an assessment of likely human-to-human transmission.

- In conjunction with local health departments, develop a database or registry for case investigations, case management, case ascertainment, case reporting, surveillance, and data analysis.
- Coordinate with CDC and other partners on studies of viral shedding and determine the infectious and incubation periods for use in defining the duration of isolation and quarantine.
- Summarize and distribute study results to local health departments, and utilize the *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Non-pharmaceutical Interventions* to assess recommendations regarding the application and utility of non-pharmaceutical containment measures.

During WHO Pandemic Phase 5 (Pandemic Alert Period: Substantial pandemic risk with larger clusters of disease, but still limited human-to-human transmission; sustained community transmission possible), DEHP will:

- Communicate with the CDC to monitor any changes in recommendations and guidelines for surveillance and diagnostic testing, including guidance on triaging specimens for testing and choosing which isolates to send the CDC and immediately inform local health departments and sentinel sites of new recommendations.
- Recommend which subset of suspect cases of ILI meet the criteria for influenza testing at either the institutional, local, or the state level and post recommendations on HAN and the DPH Influenza website: <http://chfs.ky.gov/dph/epi/Influenza.htm>.
- Work closely with local health departments to manage new suspect cases, provide confirmatory testing, and implement containment strategies to prevent or limit local spread.
- Provide technical assistance to guide expanded testing on specific cases that represent a risk of spread of the novel virus infection in the community, including those who have an epidemiologic link to infected cases or who are hospitalized. Communicate with CDC concerning management, reference laboratory testing, and containment strategies in these cases.
- Continue working with the KDA, KPF, and KDFWR on enhanced surveillance and reporting of novel influenza virus detection in poultry workers, commercial and private poultry flocks, and in wild birds to identify disease activity in animal populations and to characterize the human threat.

- Communicate current surveillance criteria for cases of human novel virus infection, and the need to report data year-round and submit clinical specimens on ILI cases to sentinel providers and local health departments.
- Utilize WebEOC and EMSystems in conjunction with local health departments and hospitals to monitor bed counts and influenza and pneumonia-related hospitalizations and deaths.
- Generate weekly reports of statewide influenza activity and make current surveillance data available to all participating agencies as well as the CDC, local health departments, regional epidemiologists, DPH Public Information Officers, and KY EM.
- Maintain expanded critical laboratory testing capacity, including novel virus testing based on availability of reagents and laboratory supplies from manufacturers.
- Communicate via e-mail, Infection Control Listserv, HAN, WebEOC, *Kentucky Epidemiologic Notes and Reports*, and conference calls with stakeholders regarding the detection and circulation of novel virus worldwide and in the United States and provide detailed guidance on updated case definitions, diagnostic algorithms, laboratory infection control issues, surveillance criteria, case management, specimen collection, and appropriate testing.. As the pandemic progresses and guidelines and testing algorithms are revised, DPH will communicate the changes and post the information on the DPH Influenza website at: <http://chfs.ky.gov/dph/epi/Influenza.htm>
- In coordination with the CDC, review and revise case management protocols to reflect current recommendations and epidemiologic data.
- Continue pandemic influenza-specific epidemiologic investigations and other special clinical studies.

B. Laboratory/ Epi Support for Seasonal Influenza Surveillance

- The DLS will ensure all participating sites will have a constant stock of test kits for rapid diagnosis based on the availability of reagents and supplies from manufacturers. The DLS monitors and replaces inventory weekly to ensure an abundant amount of supplies. During times of surge, inventory is monitored daily.
- The DEHP influenza coordinator will send guidelines to Local Health Department and Health Care Provider sentinel sites, and Local Health Department Surveillance Contacts, as well as health care providers who voluntarily submit specimens to the state laboratory, detailing routine surveillance guidelines recommended by the CDC and the WHO for

submitting influenza isolates (i.e. numbers of samples, when to send samples etc.) See Appendix 1, 2, and 5.

- DEHP will also send a reminder to those sites which request kits that the only portion of the kits which expire is the transport media. Staff at the sentinel site can order only this portion of a kit, if applicable.
- The DLS has implemented a plan for surveillance of ILI among laboratory personnel.

C. Laboratory/Epi Support for Novel Influenza Subtypes

- The DLS will ensure all participating sites will have a constant stock of test kits for rapid diagnosis, based on availability from manufacturers. The DLS monitors and replaces inventory weekly to ensure an abundant amount of supplies. During times of surge, inventory is monitored daily.
- The DEHP influenza coordinator will distribute the CDC guidelines for suspect avian flu cases (see Appendix 3, 4, and 5) to hospital Infection Control Professionals, Local Health Department Surveillance Contacts, Local Health Departments and Health Care Provider sentinel sites. In addition, “DPH Guidelines for Reporting Suspected Cases of Avian Influenza” and instructions for submitting specimens will be posted on the DPH Influenza Website, HAN, and published in the *Kentucky Epidemiologic Notes and Reports* publication.
- If ILI is suspected, a nasopharyngeal/throat specimen should be collected on viral media for transport. (Instructions for collection of these specimens are provided with the collection kits sent out by the DLS.) Concurrently, a rapid antigen test should be performed if ILI is suspected.

SEE APPENDIX 7 for DO’S and DONT’S of specimen collection.

- If a specimen has been reported to contain influenza A virus (positive rapid antigen test) and the individual’s condition meets the screening criteria (see Appendix 5) please contact DEHP immediately to obtain a Screening Form. Epidemiology will then determine if the CDC Director’s Emergency Operations center should be contacted and fax the screening form if necessary.
- In the event of a pandemic, submission of influenza samples may be restricted as determined by guidelines from CDC and the DEHP.
- The DEHP will develop extended addendum forms to the influenza screening form for tracking activities of suspected novel influenza cases (travel agenda,

flight numbers, contacts...) similar to those used for SARS histories. (See Appendix 4.)

D. Laboratory Planning to Support the Response to a Pandemic

- For detection and characterization of novel influenza strains, PCR will be performed on any suspect avian or novel influenza strains. If needed, culture of these viruses will be performed only in the DLS BSL-3 Laboratory.
- The DLS has instituted PCR typing for influenza type A, B, H1, H3, and H5 strains. This allows the capability to detect avian influenza as well as a novel strain during routine surveillance.
- The DLS has switched culture methods from traditional cell lines to R-mix shell vials. This has allowed for an overall decrease for identification and typing of influenza from approximately 6 days to 2 days.
- Laboratory reporting will be included in the testing algorithm and should be similar to the current standard.
 - Lab results can be reported electronically to local health departments.
 - Lab results can be reported via fax and de-identified results can be sent electronically via email.
 - Once the PHIN compliant Laboratory Information System (LIMS) is implemented, laboratory results can be sent electronically to other entities as well as local health departments.
- Diagnostic reagents and kits will be distributed based upon their availability from manufacturers.
- Distribution of diagnostic reagents and test information for nursing homes to confirm influenza will be coordinated through the local health departments and the local health center nurses, and the DEHP influenza coordinator and the DLS.
- Distribution of diagnostic reagents and test information for sentinel sites will be coordinated through local health departments or sentinel labs, the DEHP influenza coordinator, and the DLS.
- Laboratory Surge Capacity Planning
 - Continue cross-training of BT personnel in viral culture and PCR.
 - Communicate and coordinate with DEHP to limit the number of samples submitted by any one site. This would also apply to the distribution of collection kits.
 - Continue annual training, workshops, and monthly newsletters for the 65 sentinel laboratories throughout Kentucky. Each sentinel lab is

registered in the KY HAN. Notification via HAN is exercised regularly.

- Continue development of the packaging and shipping certification training module for TRAIN.
- Continue working with the designated local health department laboratory for training and proficiency testing of technologists.
- Continue planning and coordination with the 41st Civil Support Team of the National Guard for laboratory capacity building.

- Partnerships

- Healthcare providers and clinical labs
- Packaging and shipping training provided by DLS.

III. GUIDELINES FOR PANDEMIC PERIOD

Pandemic Surveillance Objectives

Case-based surveillance and control strategies should be maintained if it serves clear objectives, such as to support planning of the use of scarce resources, evaluate control measures or monitor changes in the influenza virus. The data collection process in this phase will be modified based on available resources.

At Phase 6 onset, case-based detection will be in place. During the peak of pandemic influenza activity, case-based detection methods will no longer be practical and surveillance data collection will be geared toward estimating community impact. Case-based detection will again become important as elimination of the pandemic influenza strain becomes feasible due to vaccine availability or an immune population.

Pandemic Influenza Virus Surveillance Activities (after case-based detection methods are no longer applicable)

Once a pandemic has been confirmed, monitor:

- Change in circulating virus, including development of anti-viral resistance, and shifts in the affected populations.
- Impact on human health, by conducting ongoing assessment of the morbidity and mortality.
- Evaluation of community- and population-based control measures, as applicable.

A. Epidemiological and Laboratory Surveillance for Human Infection

During WHO Pandemic Phase 6 (Pandemic Period: Increased and sustained transmission in the general population), DEHP will:

- Monitor the epidemiology and impact of the pandemic on Kentucky.
- Communicate via e-mail, Infection Control Listserv, HAN, WebEOC, *Kentucky Epidemiologic Notes and Reports*, and conference calls with stakeholders regarding the detection and circulation of novel virus worldwide and in the United States and provide detailed guidance on updated case definitions, diagnostic algorithms, laboratory infection control issues, surveillance criteria, case management, specimen collection, and appropriate testing.. As the pandemic progresses and guidelines and testing algorithms are revised, DPH will communicate the changes and post the information on the DPH Influenza website at: <http://chfs.ky.gov/dph/epi/Influenza.htm>
- Sustain the capacity to perform laboratory-based surveillance as long as possible because influenza viruses may undergo antigenic drift or develop resistance to antiviral drugs.
- Support local health departments, public and private medical providers, hospitals, and other stakeholders to maintain surveillance efforts for cases of novel virus infection. As the pandemic progresses and laboratory services become overwhelmed, public and private medical providers and hospitals may be asked to selectively submit clinical specimens as directed by the CDC. If laboratory supplies and reagents are exhausted, surveillance for novel virus infection will rely on a presumptive clinical diagnosis made by clinicians.
- Recommend discontinuing individual case reporting and request regular status reports from local health departments on cumulative statewide counts associated with novel virus infection, morbidity, and mortality. Such reports might include the number of:
 - Clinically suspected cases
 - Laboratory confirmed cases
 - Persons hospitalized with a novel virus infection
 - Deaths attributed to novel virus infection
- In collaboration with the CDC and local health departments, and as resources are available, conduct investigations to:
 - Describe unusual clinical syndromes
 - Describe unusual pathologic features associated with fatal cases

- Determine efficacy of vaccination, if vaccine is available, or antiviral prophylaxis
 - Assess antiviral effectiveness in circulating strains to help refine antiviral recommendations and target high risk groups
 - Assess the effectiveness of non-pharmaceutical containment measures such as school and business closures
- Determine which populations are at greatest risk and, in conjunction with the CDC, refine and revise priority groups for vaccination as vaccine availability increases.
 - Utilize the electronic death reporting system to track influenza and pneumonia-related deaths.
 - Generate weekly reports of statewide influenza activity and make current surveillance data available to all participating agencies as well as the CDC, local health departments, regional epidemiologists, DPH Public Information Officers, and KYEM.
 - As resources permit, and depending on guidance from the CDC, continue to conduct laboratory testing for influenza.
 - As resources permit and as indicated by the CDC, characterize the strain of incoming specimens and isolates to detect antigenic drift variants and reassortant viruses that could limit the efficacy of vaccines produced against the original pandemic strain.
 - As resources permit, continue to perform laboratory testing critical to ongoing surveillance.
 - Continue situation-specific pandemic influenza epidemiologic investigations and other special clinical studies, as necessary.

B. Laboratory Support for Disease Surveillance

- Support will remain the same as with routine surveillance. DLS will heighten communication with the DEHP.
- DLS will rely upon the CDC for recommendations in submission of samples, testing protocols and acquisition of reagents.

C. Laboratory Support for Clinicians

- The DEHP influenza coordinator will provide consultation to the local health department sentinel sites regarding when rapid detection kits should be used. DLS will provide rapid detection kit with instructions for collecting the specimens and performing the test as well as safe handling practices.

D. Biocontainment Procedures

- PCR may be performed in BSL-2. Viral culture must be performed in BSL-3.

E. Occupational Health Issues for Laboratory Workers

- If staffing becomes critically low due to illness or time off to care for family members, the DLS surge capacity plans of cross training will go into effect.
- DLS will provide all laboratory technicians education concerning the appropriate PPE, biosafety level techniques and preventive exposure precautions during the processing and testing of influenza as well as symptoms associated with ILI, and seasonal influenza vaccine for lab staff.

See HHS plan for appendix – guidelines for shipping as well as diagnostic assays.

Appendix 1

Influenza Sentinel Surveillance System (ISSS)

A. Sources of Information for the ISSS

Influenza like illness (ILI) is reported by sentinel Local Health Department (LHD) sites. All sites surveil absenteeism in a school district, or schools representative of grades K-12, for one day each week. Every site is requested to also surveil a nursing home for ILI. Some LHD sites also surveil health care providers and hospitals.

Sentinel Health Care Provider (HCP) sites report ILI to the Centers for Disease Control and Prevention (CDC), and obtain specimens for laboratory culture confirmation.

Mandatory reporting of culture confirmed cases within one week is required of laboratories.

Long-term care facilities are required by law to report immediately to the LHD, two or more ILI within a one-week period of time.

B. Description of Data Collected

Beginning October through May, LHD sentinel sites send an email, fax, or phone in weekly reports of ILI counts received from medical practices, nursing homes, and hospitals; absenteeism for schools is collected on Tuesdays. Numbers and types of influenza virus isolates from clinical laboratories are maintained in a database and reported to CDC. HCP sentinel sites send information about ILI by age group to the CDC through an automated touch-tone system, fax or phone. The state influenza coordinator has access to the computer data. Laboratory confirmed cases, ILI reports from sentinel LHD sites and HCP sentinel sites are considered in determining the state's activity code for each week. The state's activity code is reported to the CDC. The information is also compared to previous weeks of the current season and to previous influenza seasons.

ILI and absentees for six weeks in the fall are used to determine outbreak baseline numbers for LHD sentinel site participants. HCPs and hospital outbreak baseline numbers are three ILI. The nursing home outbreak baseline number is two. School absentees for six weeks are added together, divided by six and multiplied by two to obtain an outbreak baseline number for each participating school district. Outbreak baseline numbers are used to compare the levels of ILI. The State Influenza Coordinator uses all the information to make a subjective determination regarding the influenza activity rating for the State Epidemiologist's report each week. Activity levels and definitions are:

- **No activity** – Overall clinical activity remains low and there are no lab confirmed cases

- **Sporadic** – Isolated cases of lab confirmed influenza in the state and ILI activity is not increased, or lab confirmed outbreak in a single institution in the state and ILI activity is not increased.
- **Local outbreak** – Increased ILI within a single region and recent (within the past three weeks) laboratory evidence of influenza in that region. ILI activity in other regions is not increased, or two or more institutional outbreaks (ILI or lab confirmed) within a single region and recent lab confirmed influenza in that region. Other regions do not have increased ILI and virus activity is no greater than sporadic in those regions.
- **Regional** – Increased ILI in greater than or equal to two but less than half of the regions and recent lab confirmed influenza in the affected regions, or institutional outbreaks (ILI or lab confirmed) in greater than or equal to two and less than half of the regions and recent lab confirmed influenza in the affected regions.
- **Widespread** – Increased ILI and/or institutional outbreaks (ILI or lab confirmed) in at least half of the regions and recent lab confirmed influenza in the affected regions and recent lab confirmed influenza in the state.
 - Lab confirmed case = case confirmed by rapid diagnostic test, antigen detection, culture, or PCR. (At the beginning of the season, the State Epidemiologist may report “No Activity” until there is evidence of culture confirmed cases in the state regardless of rapid antigen reports.)
 - Institution includes nursing home, hospital, prison, school, etc. ILI activity can be assessed using a variety of data sources including sentinel providers, school/workplace absenteeism, and other syndromic surveillance systems that monitor ILI.
 - Region-Geographical subdivision of a state defined by the Department for Public Health (DPH). In KY, the 15 Area Development Districts (ADDs) are used. The identity of specific isolates from Kentucky and other nearby states, and information on the age of the person tested and date of collection of the isolate, are used to interpret whether outbreaks of ILI in the state actually represent influenza, and if so, what type and whether the strain is thought to be a close match to the content of the currently available vaccine.

C. Data Publications

Data publications include *Kentucky Epidemiologic Notes and Reports* seasonal summary, weekly influenza laboratory confirmed cases charts on the website, *Yearly Reportable Disease Summary*, and the *Five-year Summary for Reportable Diseases*.

D. Data Limitations

The system relies on the accuracy of reporting by the sentinel sites.

E. Uses of Information

The activity information can be used to promote influenza immunization, let clinicians know whether the circulating strain is a match for the current vaccine; and whether it is one which will respond to antiviral chemoprophylaxis and therapy. In addition, laboratory information can be used to prepare for the possibility of

responding to an influenza pandemic. The public can be informed about what influenza strain is circulating, how influenza activity compares with other years, and what populations are affected. The state influenza coordinator sends a weekly activity report to the Cabinet's Communications Office and the CHR Infection Control listserv for release to the media.

F. System Evaluation

The system is informally evaluated at the end of each influenza season. Summary information is evaluated by the State Influenza Coordinator, and the coordinator determines how well the system provided answers to the frequently asked questions during the season. The system has not been formally evaluated.

Appendix 2

GUIDELINES FOR SUBMITTING INFLUENZA VIRUS ISOLATES TO THE WHO COLLABORATING CENTER FOR INFLUENZA, CDC 2005-06 SEASON

The use of rapid antigen detection methods for influenza is increasing and provides valuable information for clinicians. However, we would like to stress the importance of continuing virus isolation. The antigenic analysis of circulating strains of influenza, which is dependent upon the isolation of influenza virus, is necessary for the successful selection of each year's influenza vaccine strains. We appreciate your contributions in this critical public health effort by submitting influenza isolates for antigenic analysis. Influenza isolates of particular importance for antigenic analysis are listed below.

1. **Pre-season isolates** from persons whose influenza illness appears related to overseas travel and the first isolates of the season. These isolates can provide important information regarding the match between vaccine and circulating strains for the current year and provide information necessary for vaccine formulation for the next year. Imported cases of influenza A that cannot be subtyped may also be indicative of an imported avian influenza human infection.
2. **Isolates collected during the beginning of increased influenza activity** (usually during December and early January) and during peak activity (usually mid-January to early February). Five isolates from each time period are requested.
3. **Late season isolates**, after major outbreak activity is over. These isolates may be the harbingers of new variants that are just beginning to circulate.
4. **Isolates of a type or subtype present as a minor component** (10% or less) of the year's epidemic.
5. **Isolates that cannot be subtyped by HI testing with kit reagents.** Please telephone (404) 639-3591. Isolates of influenza A that cannot be subtyped could be indicative of avian influenza. It is important to contact the state health office and send the specimen or isolate to the CDC Influenza Laboratory.
6. **Isolates from persons receiving an antiviral agent or from their contacts who become ill.** The increased use of antiviral agents for treatment and prophylaxis of influenza has created the potential for the emergence and spread of antiviral resistant viruses.
7. **Isolates from persons who are immunized against influenza**, for example, in nursing homes where residents were immunized with the current vaccine.
8. **Isolates from cases of suspected animal-to-human transmission** of influenza virus. These are needed to monitor the characteristics of the viruses and to examine the potential for spread.

- B. See attachment- Human influenza A (H5) domestic case screening form and instructions.
- C. See attachment -Reporting suspected avian flu cases and collection guidelines.
- C. Laboratory Algorithm for flu testing and reporting

Influenza Testing Algorithm

Tube Culture Influenza Isolation & Identification

Specimen Collection

- Step 1 Isolation swabs collection kits are provided by the DLS to sentinel Influenza sites, Health Depts, Hospitals, Health Care Clinics, and Doctor's Offices. These kits contain all the materials and Instructions for collecting and submitting flu samples to the DLS.
- Step 2 The preferred submissions are Nasal or Throat swabs that are collected and shipped overnight in the M4RT transport media provided in the kit.
- Step 3 Prepaid mailing labels are provided with the isolation kits to facilitate their shipment.

Day One at the DLS

- Step 1 Specimen Receipt
- Step 2 Log In
- Step 3 Swab Preparation
Inoculation - Tube Culture
- Step 4 Lines

Note* - Any specimen received that meets the case definition or is highly suspected of being a possible novel (example A-H5N1) flu strain is immediately pulled for PCR flu testing to facilitate faster identification of its strain type.

Day Two - Day Nine

Daily Tube

Readings

- Step 1 The tube lines are read using a light microscope for signs of CPE. (Cytopathic effect)
- Step 2 If positive CPE is observed then the specimen tubes are pulled for Resp IFA testing.
- Step 3 If the Resp IFA shows Pos for Flu A or B then a culture tube of primary Monkey or Canine Kidney is pulled for the Hemagglutination test (HA).
- Step 4 At various days of Incubation (usually 3 to 6 days) primary Monkey or Canine Kidney tubes are pulled for the HA test and performed, regardless of the presence of Positive CPE.
- Step 5 Any specimen testing positive for the HA test is considered tittered for the Hemagglutination Inhibition test (HI) to obtain flu strain typing. A positive HA test is necessary before an HI can be performed.
- Step 6 A HI test is performed on all positive HA specimens and will be identified as a flu strain type (A H3N2, A H1N1, or a B type).

- Step 7 Any specimen testing IFA pos for FLU A or HA positive that is not identified by the HI test is considered an aberrant sample and immediately sent to CDC for strain typing confirmation.
- Step 8 Any specimen deemed aberrant is then tested by the PCR flu test to identify any possible Flu A H5N1 activity.
- Step 9 Samples testing positive and identified by HI and/or PCR are resulted immediately to submitter and epidemiology.
- Step 10 At the end of Nine days of observation any specimen that shows no signs of CPE, has tested Neg by Resp IFA, and is HA negative is resulted as "NO VIRUS ISOLATED".

Epidemiologic Risk Factors

CDC Case ID:

| 5. Travel/Exposures | | | | | |
|--|--------------|----------------|---|--------------|----------------|
| A. In the 10 days prior to illness onset, did the patient travel to any of the countries listed in the table below? If yes*, please fill in arrival and departure dates for all countries that apply. | | | | | |
| <input type="checkbox"/> Yes* <input type="checkbox"/> No** <input type="checkbox"/> Unknown **if patient did not travel outside U.S., skip to question 6. | | | | | |
| Country | Arrival Date | Departure Date | Country | Arrival Date | Departure Date |
| <input type="checkbox"/> Afghanistan | | | <input type="checkbox"/> Myanmar (Burma) | | |
| <input type="checkbox"/> Bangladesh | | | <input type="checkbox"/> Nepal | | |
| <input type="checkbox"/> Brunei | | | <input type="checkbox"/> North Korea | | |
| <input type="checkbox"/> Cambodia | | | <input type="checkbox"/> Oman | | |
| <input type="checkbox"/> China | | | <input type="checkbox"/> Pakistan | | |
| <input type="checkbox"/> Hong Kong | | | <input type="checkbox"/> Papua New Guinea | | |
| <input type="checkbox"/> India | | | <input type="checkbox"/> Philippines | | |
| <input type="checkbox"/> Indonesia | | | <input type="checkbox"/> Saudi Arabia | | |
| <input type="checkbox"/> Iran | | | <input type="checkbox"/> Singapore | | |
| <input type="checkbox"/> Iraq | | | <input type="checkbox"/> South Korea | | |
| <input type="checkbox"/> Israel | | | <input type="checkbox"/> Syria | | |
| <input type="checkbox"/> Japan | | | <input type="checkbox"/> Taiwan | | |
| <input type="checkbox"/> Jordan | | | <input type="checkbox"/> Thailand | | |
| <input type="checkbox"/> Laos | | | <input type="checkbox"/> Turkey | | |
| <input type="checkbox"/> Lebanon | | | <input type="checkbox"/> Viet Nam | | |
| <input type="checkbox"/> Macao | | | <input type="checkbox"/> Yemen | | |
| <input type="checkbox"/> Malaysia | | | | | |
| For the questions 5B to 5E, In the 10 days prior to illness onset, while in the countries listed above | | | | | |
| B. Did the patient come within 1 meter (3 feet) of any live poultry or domesticated birds (e.g. visited a poultry farm, a household raising poultry, or a bird market)? | | | | | |
| <input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | | | |
| If Yes* | | | | | |
| C. Did patient touch any recently butchered poultry? | | | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | | | |
| D. Did the patient visit or stay in the same household with anyone with pneumonia or severe flu-like illness? | | | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | | | |
| E. Did the patient visit or stay in the same household with a suspected human influenza A(H5) case?* | | | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | | | |
| F. Did the patient visit or stay in the same household with a known human influenza A(H5) case?* | | | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | | | |
| * SEE Influenza A (H5): Interim U.S. Case Definitions | | | | | |

CDC ID:

| 6. Exposure for Non Travelers | |
|--|--|
| For patients whom did not travel outside the U.S., in the 10 days prior to illness onset , did the patient visit or stay in the same household with a traveler returning from one of the countries listed above who developed pneumonia or severe flu-like illness? | <input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| If yes*, was the contact a confirmed or suspected H5 case patient? | <input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| If yes*: CDC ID: _____ STATE ID: _____ | |

Laboratory Evaluation

| 7. State and local level influenza test results | |
|---|---|
| Specimen 1 | |
| <input type="checkbox"/> NP swab <input type="checkbox"/> Bronchoalveolar lavage specimen (BAL) <input type="checkbox"/> NP aspirate <input type="checkbox"/> OP swab <input type="checkbox"/> Other _____ | Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Test Type: <input type="checkbox"/> RT-PCR <input type="checkbox"/> Direct fluorescent antibody (DFA) <input type="checkbox"/> Viral Culture <input type="checkbox"/> Rapid Antigen Test* | Result: <input type="checkbox"/> Influenza A <input type="checkbox"/> Influenza B <input type="checkbox"/> Influenza (type unk) <input type="checkbox"/> Negative <input type="checkbox"/> Pending |
| *Name of Rapid Test: _____ | |
| Specimen 2 | |
| <input type="checkbox"/> NP swab <input type="checkbox"/> Bronchoalveolar lavage specimen (BAL) <input type="checkbox"/> NP aspirate <input type="checkbox"/> OP swab <input type="checkbox"/> Other _____ | Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Test Type: <input type="checkbox"/> RT-PCR <input type="checkbox"/> Direct fluorescent antibody (DFA) <input type="checkbox"/> Viral Culture <input type="checkbox"/> Rapid Antigen Test* | Result: <input type="checkbox"/> Influenza A <input type="checkbox"/> Influenza B <input type="checkbox"/> Influenza (type unk) <input type="checkbox"/> Negative <input type="checkbox"/> Pending |
| *Name of Rapid Test: _____ | |
| Specimen 3 | |
| <input type="checkbox"/> NP swab <input type="checkbox"/> Bronchoalveolar lavage specimen (BAL) <input type="checkbox"/> NP aspirate <input type="checkbox"/> OP swab <input type="checkbox"/> Other _____ | Date Collected: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Test Type: <input type="checkbox"/> RT-PCR <input type="checkbox"/> Direct fluorescent antibody (DFA) <input type="checkbox"/> Viral Culture <input type="checkbox"/> Rapid Antigen Test* | Result: <input type="checkbox"/> Influenza A <input type="checkbox"/> Influenza B <input type="checkbox"/> Influenza (type unk) <input type="checkbox"/> Negative <input type="checkbox"/> Pending |
| *Name of Rapid Test: _____ | |

CDC ID:

| 8. List specimens sent to the CDC | | | | | |
|---|--|-------------------|--|--|---|
| Select a SOURCE* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate, bronchoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue | | | | | |
| Specimen 1: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Source*: -----</td> <td style="border: none;">Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> <tr> <td style="border: none;"></td> <td style="border: none;">Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> </table> | Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| Specimen 2: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Source*: -----</td> <td style="border: none;">Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> <tr> <td style="border: none;"></td> <td style="border: none;">Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> </table> | Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| Specimen 3: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Source*: -----</td> <td style="border: none;">Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> <tr> <td style="border: none;"></td> <td style="border: none;">Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> </table> | Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| Specimen 4: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Source*: -----</td> <td style="border: none;">Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> <tr> <td style="border: none;"></td> <td style="border: none;">Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> </table> | Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| Specimen 5: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Source*: -----</td> <td style="border: none;">Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> <tr> <td style="border: none;"></td> <td style="border: none;">Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y</td> </tr> </table> | Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y |
| Source*: ----- | Collected : __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| | Date Sent: __ __ / __ __ / __ __ __ __ m m d d y y y y | | | | |
| Carrier: | Tracking #: | | | | |
| 9. Case Notes: | | | | | |
| | | | | | |

Influenza A (H5) Domestic Case Screening Form Instructions

Q1. Reported By

Date reported to state or local health department: Date case was first reported to the state or local health department.

State/local Case ID: Case number used by local jurisdiction to identify case.

Last name, First name, State, Affiliation, Email, Phone 1, Phone 2, Fax: Information on how to contact the state or local official responsible for following case.

Q2. Patient Information

HIPPA Note: Please note that CDC is conducting these activities in its capacity as a public health authority, as defined by the Health Insurance Portability and Accountability Act (HIPAA). Health care providers and health departments **may therefore disclose protected health information to CDC** without individual authorization. The information being requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR §164.514(d) of the Privacy Rule, and protected health information will not be disseminated. Nevertheless, individual local and state health department privacy policies may vary, and should be followed accordingly.

Age at onset: If patient less than one month old, round age up to one month.

Race: Please choose only one race. For multiracial patients indicate race they most closely identify with.

Ethnicity: Please answer this question **in addition** to the Race question above.

Q3. Optional Patient Information

Last name, First name: Please see HIPAA note above. The patient's initials should be listed if state or local policies preclude release of the patient's name.

Q4. Signs and Symptoms – Self-explanatory

Q5. Travel/Exposure

Q5A: The list of affected countries may change. CDC will notify state and local health officials if the list of affected countries changes. In addition, a current list of affected Asian countries can be found at the World Organization for Animal Health website (http://www.oie.int/download/AVIAN_INFLUENZA/A_AI-Asia.htm).

Transit through an airport (i.e., patient did not leave the airport) within an affected country **does not** count as exposure in that country. If patient **did not** travel to any countries affected by

avian influenza outbreaks within 10 days prior to illness onset, skip to Question 6 on Exposure for Non-Travelers.

Q5E: Clinical and epidemiologic criteria for a suspect case in an affected country:

Any person with radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness (regardless of poultry exposure)

OR

Any person with **all** of the following:

- 1) documented temperature of >100.4°F (>38°C), **and**;
- 2) cough, sore throat, or shortness of breath; **and**;
- 3) history of contact with
 - a. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) **or**
 - b. Anyone hospitalized or died of a flu-like illness.

Q6. Exposure for Non-Travelers: See clinical and epidemiologic criteria for influenza A(H5) above

Q7. State and local level influenza testing section – Check off type of specimen, date of specimen collection, type of testing and results for tests conducted at the state and/or local level.

Q8. List Specimens sent to the CDC – Check type(s) of specimen being sent (i.e, clinical material, extracted RNA, or viral isolate).

List specimen source (i.e., Serum (acute), serum (convalescent), nasopharyngeal (NP) swab or aspirate, bronchoalveolar lavage specimen (BAL), oropharyngeal (OP) swab, tracheal aspirate, or tissue (specify source)), and dates collected and sent.

Note: Please list acute and convalescent sera as separate specimens.

Q9. Case Notes: Please include in notes section any pertinent information not covered in the questionnaire.

CDC Contact Information Section – For CDC use only

CDC Case ID: CDC case ID number will be automatically generated when initiating new data entry form. The number system for cases identified in the United States will start with USH5 and the two-digit year, followed by a dash and the two letter state code for the state where the case was identified and a 4 digit sequential number starting with 0501 (e.g., the first surveillance case identified in 2005 in Alabama would have CDC case ID USH505-AL0501).

Clinical case: Indicates the patient meets the influenza A(H5) surveillance clinical criteria (see box below). Include date patient met clinical case definition

Influenza A positive case: Indicates the patient meets the influenza A(H5) surveillance criteria (see box below) and has a positive influenza A test at the state or local level. Include date of positive influenza A test.

Confirmed Case: Indicates the patient meets the influenza A(H5) surveillance criteria and has a positive influenza A(H5) test confirmed by the CDC Influenza Lab (see box below). Include date of positive influenza A(H5) test.

Ruled out/Non-case: Indicates that the patient had a negative PCR or culture for influenza A, had known non-H5 human influenza (i.e., influenza A(H1), influenza A(H3), or influenza B), had an alternative diagnosis other than human influenza, or did not meet influenza A(H5) clinical or epidemiologic criteria for a suspect case. (see box below).

Date Entered by CDC: Date data is entered into CDC database

CDC Contact: Name of CDC personnel responsible for following case

Contact Date: Date case was first reported to the CDC

Influenza A (H5) Surveillance Criteria

1. Patient is hospitalized and has:
 - a. radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established **and**;
 - b. a history of travel within 10 days of symptom onset to a country with documented H5N1 avian influenza infections in poultry or humans. Ongoing listings of Asian countries affected by avian influenza are available from the World Organization for Animal Health (http://www.oie.int/download/AVIAN_INFLUENZA/A_AI-Asia.htm).

OR

2. Patient is hospitalized or ambulatory and has:
 - a. documented temperature of $>100.4^{\circ}\text{F}$ ($>38^{\circ}\text{C}$), **and**;
 - b. cough, sore throat, or shortness of breath; **and either**;
 - c. history of contact within 10 days prior to onset of symptoms with:
 - i. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an affected country **or**
 - ii. a patient with known or suspected influenza A(H5) infection.

OR

- d. traveled to an affected country within 10 days prior to onset of symptoms and tests positive for influenza A

Confirmed influenza A(H5) case

Patient is suspect case of influenza A(H5N1) and is laboratory confirmed by CDC as influenza A(H5) positive by:

- a. PCR, or
- b. viral culture, or
- c. influenza A(H5) specific serology

Guidelines for reporting domestic suspect and confirmed human cases of avian influenza A(H5) to CDC and the collection and shipping of specimens for influenza A(H5) testing

Since February 3, 2004, CDC has issued several Health Alert updates requesting that local and state health departments enhance surveillance for human avian influenza A (H5) illnesses. The following document contains more detailed information on reporting and on the collection, shipping and testing of clinical specimens. A case report form and instructions are also attached.

In collaboration with state and local health departments, CDC is collecting information on suspect and confirmed human influenza A(H5) cases in the United States. This effort is intended to enhance current influenza surveillance for early identification of patients with influenza A(H5) infection. CDC requests that state and local health departments obtain specimens for influenza virus testing on patients meeting the influenza A (H5) surveillance criteria below.

Influenza A (H5) Surveillance Criteria

1. Patient is hospitalized and has:
 - a. radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established **and**;
 - b. a history of travel within 10 days of symptom onset to a country with documented H5N1 avian influenza infections in poultry or humans. Ongoing listings of Asian countries affected by avian influenza are available from the World Organization for Animal Health (http://www.oie.int/download/AVIAN_INFLUENZA/A_AI-Asia.htm).

OR

2. Patient is hospitalized or ambulatory and has:
 - a. documented temperature of >100.4°F (>38°C), **and**;
 - b. cough, sore throat, or shortness of breath; **and either**;
 - c. history of contact within 10 days prior to onset of symptoms with:
 - i. poultry or domestic birds (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an affected country **or**
 - ii. a patient with known or suspected influenza A(H5) infection.

Patients meeting the influenza A (H5) surveillance criteria may be tested at the state/local level for influenza A or influenza A(H5) if laboratory capacity is available. **See Laboratory Testing Procedures section below for precautions on working with clinical specimens that potentially contain influenza A(H5).**

Specimens from persons meeting the influenza A (H5) surveillance criteria should be sent to the CDC if:

1. specific influenza A(H5) testing done at the state /local laboratory is positive (**this should be done only if the laboratory is able to test for influenza A(H5) by PCR or if they have a BSL 3 with enhancements facility for influenza A(H5) viral culture**),

OR

2. testing for influenza A is positive by PRC or rapid antigen detection* and the referring jurisdiction is not equipped to test for influenza A(H5),

OR

3. the referring jurisdiction is not equipped to test for influenza A by PCR and is requesting testing at CDC.

State and local health departments **should not** report patients who meet the clinical and epidemiologic criteria but who have an alternative laboratory confirmed diagnosis (e.g. influenza A(H3), influenza A(H1), influenza B, or a non-influenza etiology) or who have tested negative for influenza A by PCR.

*Because the sensitivity of commercially available rapid diagnostic tests for influenza may not always be optimal, CDC also will accept specimens from persons meeting the above clinical criteria even if they test negative by influenza rapid diagnostic testing if PCR assays are not available at the state laboratory.

A **confirmed human influenza A(H5) case** is a case meeting surveillance criteria above that is laboratory confirmed by CDC as influenza A(H5) positive by:

- a. PCR, or
- b. viral culture, or
- c. influenza A(H5) specific serology

HIPAA

CDC is conducting these activities in its capacity as a public health authority, as defined by the Health Insurance Portability and Accountability Act (HIPAA). Health care providers and health departments **may therefore disclose protected health information to CDC** without individual authorization. The information being requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR §164.514(d) of the Privacy Rule, and protected health

information will not be disseminated. Nevertheless, individual local and state health department privacy policies may vary, and should be followed accordingly.

Reporting Suspect Cases of Human Influenza A(H5)

A. Initial Report: Prior to submitting a case report form, health department officials should first contact the CDC Director's Emergency Operations Center (DEOC) at 770-488-7100. This number is available 24 hours a day, 7 days a week. DEOC staff will notify a member of the human influenza A(H5) surveillance team who will contact the health department and provide a unique CDC case ID number for each case which meets the surveillance criteria.

B. Written Materials

1. **Case Report Form:** Following the initial telephone report, health department officials should submit a completed CDC case report form. This form is available through Epi-X, or by contacting CDC DEOC at 770-488-7100.
2. **Sending case report form to CDC:** Materials should be faxed to CDC at 888-232-1322. Please include the CDC case ID number, contact information, and a cover sheet with the header "ATTN: Influenza A(H5N1) case reporting." Rapid return of information is of high priority; complete as much of the case report form as possible and transmit to CDC within 3 to 5 business days of first contact. The remaining information can be sent as soon as it is available. CDC staff will assist local and state health departments in completing the case report forms as needed.

C. Laboratory Procedures, Specimen Collection and Shipment

1. **Laboratory precautions for influenza A (H5) testing:** Highly pathogenic avian influenza A(H5N1) is classified as a select agent and **must be** worked with under Biosafety Level (BSL) 3+ laboratory conditions.
 - a. **Culture only at BSL 3 with enhancements level facilities.** This includes controlled access double door entry with change room and shower, use of respirators, decontamination of all wastes, and showering out of all personnel. Laboratories working on these viruses must be certified by the U.S. Department of Agriculture. CDC does **not recommend** that virus isolation studies on respiratory specimens from patients who meet the above criteria be conducted unless stringent BSL 3 with enhancements conditions can be met and work is separate from other human influenza A (i.e., H1 or H3) virus work. Therefore, respiratory virus cultures should not be performed in most clinical laboratories and cultures should not be ordered for patients suspected of having influenza A (H5N1) infection.

- b. PCR and rapid antigen detection:** Clinical specimens from suspect influenza A(H5) cases may be tested at the state/local public health laboratory by PCR assays using standard BSL 2 work practices in a Class II biological safety cabinet. In addition, commercial rapid antigen detection testing can be conducted under BSL 2 levels to test for influenza.
- 2.** To assist public health laboratories respiratory illness diagnostic efforts, CDC has developed real-time PCR protocols for a number of respiratory pathogens, including influenza A and B viruses, adenovirus, metapneumovirus, Legionella, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*. **These protocols are currently available only to public health laboratories and have been posted at the APHL Members Only (password required) Web site www.aphl.org/Members_Only/index.cfm,** under SARS. These protocols are not available in all public health laboratories, and physicians should consult with their local public health laboratory when ordering these tests.

3. Sample Collection and Shipping instructions

- a. Respiratory specimens:** Aliquots of extracted RNA (for PCR positives) and/or clinical specimen (i.e., nasopharyngeal and oropharyngeal swabs, nasal washings, tracheal aspirates) should be sent through established channels (e.g., via the state laboratory) or directly to CDC for viral characterization.

Specimens should be frozen at -70° C and shipped on **dry ice** directly to CDC **overnight** to the address in Section 4d.

- b. Serum specimens:** A serum sample (5-10 cc) should be collected in a serum separator tube, centrifuged, and stored locally at -20° F. A convalescent serum sample should be drawn 2-4 weeks later and both acute and convalescent sera should be sent to the CDC for serologic testing.
 - c. Autopsy Specimens:** CDC can perform immunohistochemical (IHC) staining for influenza A(H5) viruses on autopsy specimens. Viral antigens may be focal and sparsely distributed in patients with influenza, and are most frequently detected in respiratory epithelium of large airways. Larger airways (*particularly primary and segmental bronchi*) have the highest yield for detection of influenza viruses by IHC staining. Collection of the appropriate tissues ensures the best chance of detecting the virus by (IHC) stains. If influenza is suspected, a minimum total of 8 blocks or fixed tissue specimens representing samples from each of the following sites should be obtained and submitted for evaluation:

1. Central (hilar) lung with segmental bronchi
2. Right and left primary bronchi
3. Trachea (proximal and distal)
4. Representative pulmonary parenchyma from right and left lung

In addition, representative tissues from major organs should be submitted for evaluation. In particular, for patients with suspected myocarditis or encephalitis, specimens should include myocardium (right and left ventricle) and CNS (cerebral cortex, basal ganglia, pons, medulla, and cerebellum). Specimens should be included from any other organ showing significant gross or microscopic pathology.

Specimens may be submitted as:

1. Fixed, unprocessed tissue in 10% neutral buffered formalin, or
2. Tissue blocks containing formalin-fixed, paraffin-embedded specimens, or
3. Unstained sections cut at 3 microns placed on charged glass slides (10 slides per specimens)

Specimens should be sent at room temperature (**NOT FROZEN**)

Please include a copy of the autopsy report (preliminary or final if available), and a cover letter outlining a brief clinical history and the full name, title, complete mailing address, phone, and fax numbers of the submitter, in the event that CDC pathologists require further information. Referring pathologists may direct specific questions to CDC pathologists.

4. Shipping Instructions:

- a. Specimens should be submitted to CDC by state and local health departments. The Influenza A(H5) Epi/Surveillance Team should be contacted at 770-488-7100 before sending specimens for influenza A(H5) testing.
- b. When sending clinical specimens, please include the **specimen inventory sheet** ([appendix A](#)), include the assigned **CDC case ID number**, and indicate **“Human Influenza A(H5) surveillance”** on all materials and specimens sent.
- c. Please include the **CDC case ID number** on all materials forwarded to CDC. Protocols for standard interstate shipment of etiologic agents should be followed, and are available at <http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>.

d. Address for respiratory and serum specimens:

Dr. Alexander Klimov, PhD, ScD, Chief
Strain Surveillance Section
Influenza Branch, CDC
c/o DASH
1600 Clifton Road
Atlanta, GA 30333
Phone: 404-639-3387 or 3591, fax: 404-639-2334, email: AKlimov@cdc.gov

Address for autopsy specimens

Dr. Sherif Zaki, MD, PhD
Infectious Disease Pathology Activity
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Mailstop G-32, Bldg 1, Rm 2301
1600 Clifton Road
Atlanta, GA 30333
Phone: 404-639-3133
fax: 404-639-3043
email: SZaki@cdc.gov

5. ADDITIONAL INFORMATION

Any questions regarding reporting procedures or specimen shipment can be directed to the influenza special investigations team:

Influenza A(H5N1) Epi/Surveillance Team
Division of Viral and Rickettsial Diseases
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Mailstop A-32, Bldg 6, Rm 122
1600 Clifton Road
Atlanta, GA 30333
Phone: 770-488-7100, Fax: 888-232-1322
Email: eocinfluenza@cdc.gov

PHONE NUMBERS

| | |
|--|--------------|
| Reporting cases and Notification of specimen shipments | 770-488-7100 |
| Fax number for case report forms | 888-232-1322 |
| Requests for specimen testing | 770-488-7100 |
| Dr. Alexander Klimov, Strain Surveillance | 404-639-3387 |
| Dr. Sherif Zaki, Infectious Disease Pathology | 404-639-3133 |

Appendix A

CDC CASE ID:

| List specimens sent to the CDC | |
|---|---|
| Select a SOURCE* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate, bronchoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue | |
| Specimen Type #1: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | Source*: _____ Collected : <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y Date Sent: <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y |
| Specimen Type #2: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | Source*: _____ Collected : <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y Date Sent: <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y |
| Specimen Type #3: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | Source*: _____ Collected : <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y Date Sent: <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y |
| Specimen Type #4: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | Source*: _____ Collected : <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y Date Sent: <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y |
| Specimen Type #5: <input type="checkbox"/> Clinical Material <input type="checkbox"/> Extracted RNA <input type="checkbox"/> Virus Isolate | Source*: _____ Collected : <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y Date Sent: <u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> m m d d y y y y |
| Carrier: | Tracking #: |

Appendix 6

Specimen Collection Guidelines **For Influenza Specimens**

1. Do collect a throat or nasopharyngeal swab.
2. Do use collection kits provided by the Division of Laboratory Services (M4RT media and Dacron swabs)
 - Also acceptable are kits specified for viral transport. Follow guidelines suggested by the manufacturer for storage of media.
 - M4RT media is stored at room temperature until use
3. Once specimen is collected it should be refrigerated.
4. Ship specimen with ice packs and in accordance with your facilities policies (Specimen may be shipped diagnostic).
5. Submit with Viral isolation form 275. If you do not have this form you may call (502) 564-4446 and one will be faxed to you.

THINGS TO AVOID when submitting Influenza specimens:

DO NOT submit in saline

DO NOT submit using cotton swabs or swabs with wooden shafts

DO NOT submit nasal aspirates

DO NOT submit specimens at room temperature

NOTE: Specimens may be submitted on dry ice but it is not necessary.

I. RATIONALE/OVERVIEW

All state and local governments, as well as healthcare facilities, are required to have an emergency response plan that addresses all hazards. However, pandemic influenza is likely to pose unique and long-standing challenges that may not be addressed in current emergency response plans. For example, in a pandemic emergency situation, it is expected that notification and response will be initiated at the national or international level, followed by state and, finally, local levels. Because of these unique challenges, the emergency response plans of hospitals, nursing homes, and other healthcare settings should incorporate a pandemic influenza plan as an appendix to their existing plans or have a separate pandemic influenza plan. It is also recommended that physician practices develop plans to manage the anticipated large numbers of patients seeking care. Considerations include: telephone triage, separate entrances, and segregated seating for patients with ILI (Influenza-Like Illnesses).

In addition, healthcare settings may prepare by developing lists of patients, using the CDC priority groups for vaccination as a guide. Lessons learned from Hurricanes Katrina and Rita demonstrate that special populations are at risk for accessing and utilizing emergency services both in the private and public sectors. Pre-pandemic planning efforts must be made to identify special populations, as well as mechanisms to ensure community delivery of resources exist or are considered.

Much of the healthcare planning necessary for a pandemic influenza response is being met through the cooperative planning efforts of the 14 statewide Kentucky Hospital Resources Services Administration (HRSA) regions. Each region consists of health partners from hospitals, local health departments, EMS, mental health, long-term care facilities and other health-related stakeholders.

The purpose of this plan is to provide guidance to health systems in their response to pandemic influenza. Guidance is given during each phase of a pandemic and is broken down into specific sectors of the healthcare systems' response, including HRSA Planning Regions, Community Mental Health Centers and other congregate facilities with special populations.

II. GUIDELINES FOR HEALTHCARE SYSTEMS RESPONSE

(Interpandemic and Pandemic Alert Periods)

A. Healthcare System Response

The Healthcare System Response, utilizing the 14 HRSA regions throughout the state, in conjunction with other public and private sector stakeholders as appropriate, will:

1. Update and/or inventory state, regional and local medical supplies.
2. Collaborate with the appropriate agencies outside the healthcare system to inventory and identify statewide resources necessary for a pandemic influenza response.

3. Ensure that all partners in the healthcare system (i.e., hospitals, health departments, EMS, mental health centers, long-term care facilities and other health related stakeholders) have pandemic influenza plans and protocols in place.
4. Develop and coordinate recommendations on health issues related to pandemic influenza. Multiple stakeholders, including state agencies and regional/local health care systems, meet no less than quarterly to discuss pandemic influenza planning and other response issues through the HRSA regions, with most meeting on a monthly basis.
5. Review major elements of the health sector and essential non-health sector response plans.
6. Collaborate as needed with infectious disease and influenza experts to develop and revise recommendations on health-related issues.
7. Develop, based on the disease epidemiology, protective action recommendations specific to the disease to be implemented during the pandemic.
8. Estimate the impact of pandemic influenza on essential services.
9. Develop and maintain an inventory of available beds in healthcare facilities, including hospitals, nursing facilities and non-traditional settings that might serve to house sick patients as hospital overflow.
10. Alert local hospitals, health departments, EMS, long-term facilities, local health authorities, schools, community mental health centers, county emergency management coordinators and other community health partners to pandemic potential.
11. Meet at least quarterly to review the existing Pandemic Influenza Plan. The HRSA regions are responsible for assuring maintenance, updates and annual review of the plan. Healthcare members with responsibility for particular sections of the plan are responsible for coordinating the review of their sections.
12. With input from multiple stakeholders (including local and regional bioterrorism planning groups), the HRSA regions will ensure that pandemic influenza is included in planned scenarios for exercising and training purposes.
13. Conduct regular tabletop exercises to include partners outside the healthcare system as training for an all hazards/pandemic event. Also, participate in other local/regional tabletop, functional or full functional exercises that include a pandemic scenario.
14. Update regional and local authorities, other public and private sector stakeholders, including special populations and the general public, with current information and non-pharmaceutical prevention strategies.

B. HRSA Regions

HRSA Regional Groups with assistance of appropriate healthcare stakeholders will:

1. Coordinate data collection, collect data from appropriate sources, and adjust for data duplication to maintain a regional inventory of:

a. Medical personnel, including but not limited to, currently licensed physicians, physician assistants, registered nurses, licensed practical nurses, medical assistants, and others who may be trained in the event of an emergency (those with previous patient care experience who currently work outside of patient care or retired healthcare personnel).

Kentucky is implementing a new system called Kentucky Health Emergency Listing of Professionals for Surge (K HELPS). This program will manage, recruit, credential and train volunteers and professionals to respond in an emergency. Currently the Kentucky Medical Licensure Board has posted a searchable database via their website to verify all physicians with current Kentucky licenses. Although physicians and nurses will be a crucial part of the database, Kentucky's system will also include other types of volunteers needed in a medical response that are not normally considered healthcare personnel.

b. Beds (hospital and long-term care)

c. ICU capacity

d. Ventilators

e. Pharmacies and pharmacists

f. Laboratories

g. PPE (e.g., masks, gloves)

h. Specimen collection and transport materials

i. Contingency medical facilities (within jurisdiction)

j. Mortuary and funeral services

k. Social services, disaster mental health services, and faith-based services

l. Sources of medical supplies (syringes, gloves)

m. Interpreter services

2. Analyze surge capacity in public and private sectors to determine potential needs.

3. Ensure private healthcare systems have pandemic influenza plans and protocols and provide assistance where deficiencies are found.
4. Estimate the impact of pandemic influenza on healthcare services and special populations for providing and reinforcing preventive action recommendations to communities and determining pre-event health-related needs.
5. Identify locations of relative quiet/calm to be used for overflow patient care including those presenting with anxiety, psychosomatic or stress-related/induced symptoms, and strategies for the management of overflow locations (i.e., advance-planning protocols to triage overflow locations).
6. Request hospitals and community service providers, such as police and utilities, to develop and maintain contact lists of essential community services personnel (including work and home communication information) whose absence would pose a serious threat to public safety, critical infrastructure, or would significantly interfere with the ongoing response. The list should also include back-up and replacements personnel. Retired personnel may also be utilized.

C. Community Mental Health/Mental Retardation Centers

Community Mental Health/Mental Retardation Centers will:

1. Review internal emergency response plans and Disaster Mental Health Appendix to the Regional/Local Emergency Management Plan. Review shelter-in-place and evacuation procedures.
2. Update and/or inventory medical supplies.
3. Identify medical staff including back-up personnel with special emphasis on non-traditional volunteers. Identify and maintain lists of essential medical and service staff (including work and home contact information) whose absence would significantly interfere with the response and/or patient care.
4. Estimate the impact of pandemic influenza on service provision.

D. Congregate facilities serving special needs populations should follow the same recommendations as section C above.

III. GUIDELINES FOR HEALTHCARE SYSTEMS RESPONSE (Pandemic Period)

A. International identification

1. HRSA Regional Groups with assistance of appropriate healthcare stakeholder will:

- a. Encourage hospitals and congregate facilities to review and update pandemic influenza plans.
- b. Collaborate with regional and local emergency management coordinators to maintain a high level of awareness and preparedness among emergency responders and healthcare providers to include mental health.
- c. Coordinate notification of appropriate agencies, infection control practitioners, local laboratories, emergency rooms, community health providers, and community health workers within their own jurisdictions.
- d. With federal and state guidance, provide public and private healthcare providers with updated case definitions, protocols, and algorithms to assist with case finding, management, infection control, and surveillance reporting.

B. National/Kentucky Identification

1. HRSA Regional Groups with assistance of appropriate healthcare stakeholders will:
 - a. Activate emergency/pandemic influenza response plans
 - b. Collaborate with regional and local emergency management coordinators to maintain a high level of awareness and preparedness among emergency responders and healthcare providers to include mental health.
 - c. Coordinate notification of appropriate agencies, infection control practitioners, local laboratories, and emergency rooms within their own jurisdictions.
 - d. With federal and state guidance, provide public and private healthcare providers with updated case definitions, protocols, and algorithms to assist with case finding, management, infection control, and surveillance reporting.

IV. GUIDELINES FOR HEALTHCARE SYSTEM RESPONSE

(Postpandemic Period)

A. International Circulation

1. HRSA Regional Groups with assistance of appropriate healthcare stakeholders will:
 - a. Continue to collaborate with regional and local emergency management coordinators to maintain a high level of awareness and preparedness among emergency responders and healthcare providers to include mental health.

B. National/Kentucky Circulation

1. HRSA Regional Groups with assistance of appropriate healthcare stakeholders will:
 - a. Notify involved agencies of change of status to the Postpandemic Period.
2. Mental Health will:
 - a. Coordinate the assessment of the impact on mental health facilities.
 - b. It is expected that the psychosocial and financial effects of a pandemic will be felt for months if not years, hampering personal, community and agency recovery. It is the expectation that crisis counseling program services will be available for a period of at least one-year post declaration date.

KENTUCKY PANDEMIC INFLUENZA PREPAREDNESS PLAN INFECTION CONTROL SUPPLEMENT III

(This supplement is primarily based on the HHS Infection Control Supplement, but has been reviewed and accepted by infection control providers in the State of Kentucky.)

| TABLE OF CONTENTS | | PAGE |
|-------------------|---|-----------|
| I. | RATIONALE | 1 |
| II. | OVERVIEW | 1 |
| III. | RECOMMENDATIONS FOR INFECTION CONTROL IN HEALTHCARE SETTINGS | 2 |
| | A. Basic infection control principles for preventing the spread of pandemic influenza in healthcare settings | 2 |
| | B. Management of infectious patients | 3 |
| | 1. Respiratory hygiene/cough etiquette | 3 |
| | 2. Droplet precautions and patient placement | 3 |
| | C. Infection control practices for healthcare personnel | 4 |
| | 1. Personal protective equipment | 4 |
| | 2. Hand hygiene | 6 |
| | 3. Disposal of solid waste | 7 |
| | 4. Linen and laundry | 7 |
| | 5. Dishes and eating utensils | 7 |
| | 6. Patient-care equipment | 8 |
| | 7. Environmental cleaning and disinfection | 8 |
| | 8. Postmortem care | 9 |
| | 9. Laboratory specimens and practices | 9 |
| | D. Occupational health issues | 9 |
| | E. Reducing exposure of persons at high risk for complications of influenza | 9 |
| | F. Healthcare setting-specific guidance | 9 |
| | 1. Hospitals | 10 |
| | 2. Nursing homes and other residential facilities | 12 |
| | 3. Prehospital care (emergency medical services) | 13 |
| | 4. Home healthcare services | 14 |
| | 5. Outpatient medical offices | 14 |
| | 6. Other ambulatory settings | 15 |
| | G. Care of pandemic influenza patients in the home | 16 |
| | 1. Management of influenza patients | 16 |
| | 2. Management of other persons in the home | 16 |
| | 3. Infection control measures in the home | 16 |
| | H. Care of pandemic influenza patients at alternative sites | 17 |
| IV. | RECOMMENDATIONS FOR INFECTION CONTROL IN SCHOOLS AND WORKPLACES | 18 |
| V. | RECOMMENDATIONS FOR INFECTION CONTROL IN COMMUNITY SETTINGS | 18 |

I. RATIONALE

The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: vaccination, early detection and treatment with antiviral medications (as discussed elsewhere in this plan), and the use of infection control measures to prevent transmission during patient care. However, when a pandemic begins, a vaccine may not yet be widely available, and the supply of antiviral drugs may be limited. The ability to limit transmission in healthcare settings will, therefore, rely heavily on the appropriate and thorough application of infection control measures. While it is commonly accepted that influenza transmission requires close contact—via exposure to large droplets (droplet transmission), direct contact (contact transmission), or possible near-range exposure to aerosols (airborne transmission)—the relative clinical importance of each of these modes of transmission is not known.

Information contained in the Infection Control Supplement is based on the known science at the time this supplement was last updated (September 2006).

II. OVERVIEW

The Infection Control Supplement provides guidance to healthcare and public health partners on basic principles of infection control for limiting the spread of pandemic influenza. These principles (summarized in Box 1, page 19) are common to the prevention of other infectious agents spread by respiratory droplets. The Infection Control Supplement also includes guidance on the selection and use of personal protective equipment (PPE); hand hygiene and safe work practices; cleaning and disinfection of environmental surfaces; handling of laboratory specimens; and post-mortem care. The guidance also covers infection control practices related to the management of infectious patients, the protection of persons at high-risk for severe influenza or its complications, and issues concerning occupational health.

The Infection Control Supplement also provides guidance on how to adapt infection control practices in specific healthcare settings, including hospitals, nursing homes and other long-term care facilities, pre-hospital care (emergency medical services [EMS]), medical offices and other ambulatory care settings, and during the provision of professional home healthcare services. The section on hospital care covers detection of entering patients who may be infected with pandemic influenza; implementation of control measures to limit virus dissemination from respiratory secretions of infected individuals; hospitalization of pandemic influenza patients; and detection and control of nosocomial transmission.

In addition, The Infection Control Supplement includes guidance on infection control procedures for pandemic influenza patients in the home or in alternative care sites that may be established if local hospital capacity is overwhelmed by a pandemic. Finally, it includes recommendations on infection control in schools, workplaces, and community settings.

The Infection Control Supplement does not address the use of vaccines and antivirals in the control of influenza transmission in healthcare settings and the community. These issues are addressed in other supplements of the plan.

III. RECOMMENDATIONS FOR INFECTION CONTROL IN HEALTHCARE SETTINGS

The recommendations for infection control described below are generally applicable throughout the different pandemic phases. In some cases, as indicated, recommendations may be modified as the situation progresses from limited cases to widespread community illness.

A. Basic infection control principles for preventing the spread of pandemic influenza in healthcare settings

The following infection control principles apply in any setting where persons with pandemic influenza might seek and receive healthcare services (e.g. hospitals, emergency departments, outpatient facilities, residential care facilities, and homes). Details of how these principles may be applied in each healthcare setting follow.

Limit contact between infected and non-infected persons¹

- Isolate infected persons (i.e., confine patients to a defined area as appropriate for the healthcare setting).
- Limit contact between nonessential personnel and other persons (e.g., social visitors) and patients who are ill with pandemic influenza.
- Promote spatial separation in common areas (i.e., sit or stand as far away as possible—at least 3 feet—from potentially infectious persons) to limit contact between symptomatic and non-symptomatic persons.

Protect persons caring for influenza patients in healthcare settings from contact with the pandemic influenza virus.

Persons who must be in contact should:

- Wear a surgical or procedure mask² for close contact with infectious patients.
- Consider using contact and airborne precautions, including the use of N95 respirators, when appropriate (e.g., during aerosol generating procedures such as intubation and bronchoscopy).
- Wear gloves for all contact.
- Wear gowns when physical contact with patient and/or respiratory secretions or stool can be anticipated.
- Perform hand hygiene after contact with infectious patients and after removal of gloves and other PPE such as gowns, masks, or face shields.

Contain infectious respiratory secretions:

- Instruct persons who have “flu-like” symptoms (see below) to use respiratory hygiene/cough etiquette (See Box 2, page 21).
- Promote use of masks³ by symptomatic persons in common areas (e.g., waiting rooms in physician offices or emergency departments) or when being transported (e.g., in emergency vehicles).

Symptoms of influenza include sudden onset of fever, chills, headache, diffuse myalgias, prostration, sore throat, and non-productive cough. Otitis media, nausea, and vomiting are also commonly reported among children. Typical influenza (or “flu-like”) symptoms, such as fever, may not always be present in elderly patients, young children, patients in long-term care

facilities, or persons with underlying chronic illnesses

¹ During the early stages of a pandemic, laboratory-confirmation of influenza infection is recommended when possible.

² Surgical masks come in two basic types: one type is affixed to the head with two ties, conforms to the face with the aid of a flexible adjustment for the nose bridge, and may be flat/pleated or duck-billed in shape; the second type of surgical mask is pre-molded, adheres to the head with a single elastic and has a flexible adjustment for the nose bridge. Procedure masks are flat/pleated and affix to the head with ear loops. All masks have some degree of fluid resistance but those approved as surgical masks must meet specified standards for protection from penetration of blood and body fluids.

³ Coughing persons may wear either a surgical or procedure mask. However, only procedure masks come in both adult and pediatric sizes.

B. Management of infectious patients

1. Respiratory hygiene/cough etiquette

Respiratory hygiene/cough etiquette has been promoted as a strategy to contain respiratory viruses at the source and to limit their spread in areas where infectious patients might be awaiting medical care (e.g., physician offices, emergency departments).

The impact of covering sneezes and coughs and/or placing a mask on a coughing patient on the containment of respiratory secretions or on the transmission of respiratory infections has not been systematically studied. In theory, however, any measure that limits the dispersal of respiratory droplets should reduce the opportunity for transmission. Masking may be difficult in some settings (e.g., pediatrics), in which case the emphasis will be on cough etiquette.

The elements of respiratory hygiene/cough etiquette include:

- Education of healthcare facility staff, patients, and visitors on the importance of containing respiratory secretions to help prevent the transmission of influenza and other respiratory viruses.
- Posted signs in languages appropriate to the populations served with instructions to patients and accompanying family members or friends to immediately report symptoms of a respiratory infection as directed.
- Control measures for ill persons (e.g., covering the mouth/nose with a tissue when coughing and disposing of used tissues; using masks on the coughing person when they can be tolerated and are appropriate; teaching that it is important to cough into sleeve instead of hands).
- Hand hygiene after contact with respiratory secretions.
- Spatial separation, ideally at least 3 feet, of persons with respiratory infections from other persons in common waiting areas when possible.

2. Droplet precautions and patient placement

Patients with known or suspected pandemic influenza should be placed on droplet precautions for a minimum of 5 days from the onset of symptoms. Because children and immunocompromised patients may shed virus for longer periods, they may be placed on droplet precautions for the duration of their illness. Healthcare personnel should wear appropriate PPE to include eye protection. The placement of patients will vary depending on the healthcare setting

(see setting-specific guidance). If the pandemic virus is associated with diarrhea, contact precautions (i.e., gowns and gloves for all patient contact) should be added. CDC will update these recommendations if changes occur in the anticipated pattern of transmission (www.cdc.gov/flu).

C. Infection control practices for healthcare personnel

Infection control practices for pandemic influenza are the same as for other human influenza viruses and primarily involve the application of standard and droplet precautions (Box 1) during patient care in healthcare settings (e.g., hospitals, nursing homes, outpatient offices, emergency transport vehicles). This guidance also applies to healthcare personnel going into the homes of patients. During a pandemic, conditions that could affect infection control may include shortages of antiviral drugs, decreased efficacy of the vaccine, increased virulence of the influenza strain, shortages of single-patient rooms, and shortages of personal protective equipment. These issues may necessitate changes in the standard recommended infection control practices for influenza. CDC will provide updated infection control guidance as circumstances dictate. Additional guidance is provided for family members providing home care and for use in public settings (e.g., schools, workplace) where people with pandemic influenza may be encountered.

1. Personal protective equipment

a) PPE for standard and droplet precautions

PPE is used to prevent direct contact with the pandemic influenza virus. PPE that may be used to provide care includes surgical or procedure masks, as recommended for droplet precautions, and gloves and gowns, as recommended for standard precautions (Box 1). Additional precautions may be indicated during the performance of aerosol-generating procedures (see below). Information on the selection and use of PPE is provided at http://www.cdc.gov/ncidod/dhqp/gl_isolation.html.

Masks (surgical or procedure)

- Wear a mask when entering a patient's room. A mask should be worn once and then discarded. Other PPE (e.g., gloves, gown) must be removed between patients and hand hygiene immediately performed.
- Change masks when they become moist.
- Do not leave masks dangling around the neck.
- Upon touching or discarding a used mask, perform hand hygiene.

Gloves

- A single pair of patient care gloves should be worn for contact with blood and body fluids, including during hand contact with respiratory secretions (e.g., providing oral care, handling soiled tissues). Gloves made of latex, vinyl, nitrile, or other synthetic materials are appropriate for this purpose; if possible, latex-free gloves should be available for healthcare workers who have latex allergy.
- Gloves should fit comfortably on the wearer's hands.
- Remove and dispose of gloves after use on a patient; do not wash gloves for subsequent reuse.

- Perform hand hygiene after glove removal.
- If gloves are in short supply (i.e., the demand during a pandemic could exceed the supply), priorities for glove use might need to be established. In this circumstance, reserve gloves for situations where there is a likelihood of extensive patient or environmental contact with blood, stool or body fluids, including during suctioning.
- Use other barriers (e.g., disposable paper towels, paper napkins) when there is only limited contact with a patient's respiratory secretions (e.g., to handle used tissues). Hand hygiene should be strongly reinforced in this situation.

Gowns

- Wear an isolation gown, if soiling of personal clothes or uniform with a patient's blood or body fluids, including respiratory secretions, is anticipated. **Most patient interactions do not necessitate the use of gowns.** However, procedures such as intubation and activities that involve holding the patient close (e.g., in pediatric settings) are examples of when a gown may be needed when caring for pandemic influenza patients.
- A disposable gown made of synthetic fiber or a washable cloth gown may be used.
- Ensure that gowns are of the appropriate size to fully cover the clothing to be protected.
- Gowns should be worn only once and then placed in a waste or laundry receptacle, as appropriate, and hand hygiene performed. If gowns are in short supply (i.e., the demand during a pandemic could exceed the supply), priorities for their use may need to be established. In this circumstance, reinforcing the situations in which they are needed can reduce the volume used. Alternatively, other coverings (e.g., patient gowns) could be used. It is doubtful that disposable aprons would provide the desired protection in the circumstances where gowns are needed to prevent contact with influenza virus. There are no data upon which to base a recommendation for reusing an isolation gown on the same patient. To avoid possible contamination, it is prudent to limit this practice.

Goggles or face shield

Wearing goggles or a face shield for routine contact with patients with pandemic influenza is not necessary. If sprays or splatter of infectious material is likely or can be reasonably anticipated, goggles or a face shield should be worn as recommended for standard precautions. Additional information related to the use of eye protection for infection control can be found at <http://www.cdc.gov/niosh/topics/eye/eye-infectious.html>.

b) PPE for special circumstances

- **PPE for aerosol-generating procedures**

During procedures that may generate increased small-particle aerosols of respiratory secretions (e.g., endotracheal intubation, nebulizer treatment, bronchoscopy, suctioning), healthcare personnel should wear gloves, gown, face/eye protection, and consider use of higher level of respiratory protection. If possible, and when practical, use of an airborne

isolation room may be considered when conducting aerosol-generating procedures.

- **PPE for managing pandemic influenza with increased transmissibility**

The addition of airborne precautions, including respiratory protection (an N95 filtering face piece respirator or other appropriate particulate respirator), may be considered for strains of influenza exhibiting increased transmissibility, during initial stages of an outbreak of an emerging or novel strain of influenza, and as determined by other factors such as vaccination/immune status of personnel and availability of antivirals. As the epidemiologic characteristics of the pandemic virus are more clearly defined, CDC will provide updated infection control guidance, as needed.

- **Precautions for early stages of a pandemic**

Early in a pandemic, it may not be clear that a patient with severe respiratory illness has pandemic influenza. Therefore precautions consistent with all possible etiologies, including a newly emerging infectious agent, should be implemented. This may involve the combined use of airborne and contact precautions, in addition to standard precautions, until a diagnosis is established.

c) **Caring for patients with pandemic influenza**

Healthcare personnel should be particularly vigilant to avoid:

- Touching their eyes, nose or mouth with contaminated hands (gloved or ungloved). Careful placement of PPE before patient contact will help avoid the need to make PPE adjustments and risk self-contamination during use. Careful removal of PPE is also important. (See <http://www.cdc.gov/ncidod/dhqp/ppe.html>).
- Contaminating environmental surfaces that are not directly related to patient care (e.g., door knobs, light switches).

2. Hand hygiene

Hand hygiene is the single most important practice to reduce the transmission of infectious agents in healthcare settings and is an essential element of standard precautions. The term “hand hygiene” includes both handwashing with soap (either non-antimicrobial or antimicrobial) and water or use of alcohol-based products (gels, rinses, foams) containing an emollient that do not require the use of water.

- If hands are visibly soiled or contaminated with respiratory secretions, wash hands with soap (either non-antimicrobial or antimicrobial) and water.
- In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over soap (either non-antimicrobial or antimicrobial) and water because of their superior microbiocidal activity, reduced drying of the skin, and convenience.
- Always perform hand hygiene between patient contacts and after removing PPE.
- Ensure that resources to facilitate handwashing (i.e., sinks with warm and cold running water, plain or antimicrobial soap, disposable paper towels) and hand disinfection (i.e., alcohol-based products) are readily accessible in areas in which

patient care is provided. For additional guidance on hand hygiene see <http://www.cdc.gov/handhygiene/>.

3. Disposal of solid waste

Standard precautions are recommended for disposal of solid waste (regulated medical and non-medical) that might be contaminated with a pandemic influenza virus:

- Contain and dispose of contaminated regulated medical waste in accordance with facility-specific procedures and/or local or state regulations for handling and disposal of regulated medical waste, including used needles and other sharps, and non-medical waste.
- Discard as routine waste used patient-care supplies that are not likely to be contaminated (e.g., paper wrappers).
- Wear disposable gloves when handling waste. Perform hand hygiene after removal of gloves.

4. Linen and laundry

Standard precautions are recommended for linen and laundry that might be contaminated with respiratory secretions from patients with pandemic influenza:

- Place soiled linen directly into a laundry bag in the patient's room. Contain linen in a manner that prevents the linen bag from opening or bursting during transport and while in the soiled linen holding area.
- Wear gloves and gown when directly handling soiled linen and laundry (e.g., bedding, towels, personal clothing) as per standard precautions. Do not shake or otherwise handle soiled linen and laundry in a manner that might create an opportunity for disease transmission or contamination of the environment.
- Wear gloves for transporting bagged linen and laundry.
- Perform hand hygiene after removing gloves that have been in contact with soiled linen and laundry.
- Wash and dry linen according to routine standards and procedures (http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf).

5. Dishes and eating utensils

Standard precautions are recommended for handling dishes and eating utensils used by a patient with known or possible pandemic influenza:

- Wash reusable dishes and utensils in a dishwasher with recommended water temperature (http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf).
- Disposable dishes and utensils (e.g., used in an alternative care site set-up for large numbers of patients) should be discarded with other general waste.
- Wear gloves when handling patient trays, dishes, and utensils. Perform hand hygiene after removal of gloves.

6. Patient-care equipment

Follow standard practices for handling and reprocessing used patient-care equipment, including medical devices:

- Wear gloves when handling and transporting used patient-care equipment. Perform hand hygiene after removal of gloves.
- Wipe heavily soiled equipment with an EPA-approved hospital disinfectant before removing it from the patient's room. Follow current recommendations for cleaning and disinfection or sterilization of reusable patient-care equipment.
- Wipe external surfaces of portable equipment for performing x-rays and other procedures in the patient's room with an EPA-approved hospital disinfectant upon removal from the patient's room.

7. Environmental cleaning and disinfection

Cleaning and disinfection of environmental surfaces are important components of routine infection control in healthcare facilities. Environmental cleaning and disinfection for pandemic influenza follow the same general principles used in healthcare settings.

a) Cleaning and disinfection of patient-occupied rooms

(See http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf)

- Wear gloves in accordance with facility policies for environmental cleaning and wear a surgical or procedure mask in accordance with droplet precautions. Gowns are not necessary for routine cleaning of an influenza patient's room. Perform hand hygiene after removal of gloves.
- Keep areas around the patient free of unnecessary supplies and equipment to facilitate daily cleaning.
- Use any EPA-registered hospital detergent-disinfectant. Follow manufacturer's recommendations for-use dilution (i.e., concentration), contact time, and care in handling.
- Follow facility procedures for regular cleaning of patient-occupied rooms. Give special attention to frequently touched surfaces (e.g., bedrails, bedside and over-bed tables, TV controls, call buttons, telephones, lavatory surfaces including safety/pull-up bars, doorknobs, commodes, ventilator surfaces) in addition to floors and other horizontal surfaces.
- Clean and disinfect spills of blood and body fluids in accordance with current recommendations for Isolation Precautions (http://www.cdc.gov/ncidod/dhqp/gl_isolation.html).

b) Cleaning and disinfection after patient discharge or transfer

- Follow standard facility procedures for post-discharge cleaning of an isolation room.
- Clean and disinfect all surfaces that were in contact with the patient or might have become contaminated during patient care. No special treatment is necessary for window curtains, ceilings, and walls unless there is evidence of visible soiling.
- Do not spray (i.e., fog) occupied or unoccupied rooms with disinfectant. This is a potentially dangerous practice that has no proven disease control benefit.

8. Postmortem care

Follow standard facility practices for care of the deceased. Practices should include standard precautions for contact with blood and body fluids.

9. Laboratory specimens and practices

Follow standard facility and laboratory practices for the collection, handling, and processing of laboratory specimens. (See Laboratory and Surveillance Supplement I)

D. Occupational health issues

Healthcare personnel are at risk for pandemic influenza through community and healthcare-related exposures. Once pandemic influenza has reached a community, healthcare facilities must implement systems to monitor for illness in the facility workforce and manage those who are symptomatic or ill.

- Implement a system to educate personnel about occupational health issues related to pandemic influenza.
- Screen all personnel for influenza-like symptoms before they come on duty. Symptomatic personnel should be sent home until they are physically ready to return to duty.
- Healthcare personnel who have recovered from pandemic influenza should develop antibody against future infection with the same virus, and therefore should be prioritized for the care of patients with active pandemic influenza and its complications. These workers would also be well suited to care for patients who are at risk for serious complications from influenza (e.g., transplant patients and neonates).
- Personnel who are at high risk for complications of pandemic influenza (e.g., pregnant women, immunocompromised persons) should be informed about their medical risk and offered an alternate work assignment, away from influenza-patient care, or considered for administrative leave until pandemic influenza has abated in the community.

E. Reducing exposure of persons at high risk for complications of influenza

Persons who are well, but at high risk for influenza or its complications (e.g., persons with underlying diseases), should be instructed to avoid unnecessary contact with healthcare facilities caring for pandemic influenza patients (i.e., do not visit patients, and postpone nonurgent medical care).

F. Healthcare setting-specific guidance

All healthcare facilities should follow the infection control guidance above. The following guidance is intended to address setting-specific infection control issues that should also be considered.

1. Hospitals

a) Detection of persons entering the facility who may have pandemic influenza

- Post visual alerts (in appropriate languages) at the entrance to hospital outpatient facilities (e.g., emergency departments, outpatient clinics) instructing persons with respiratory symptoms (e.g., patients, persons who accompany them) to:
 - Inform reception and healthcare personnel when they first register for care, and
 - Practice respiratory hygiene/cough etiquette. Sample visual alerts are available at <http://www.cdc.gov/germstopper/materials.htm> and <http://www.cdc.gov/flu/protect/covercough.htm>
- Triage patients calling for medical appointments for influenza symptoms:
 - Discourage unnecessary visits to medical facilities.
 - Instruct symptomatic patients on infection control measures to limit transmission in the home and when traveling to necessary medical appointments.

As the scope of the pandemic escalates locally, consider setting up a separate triage area for persons presenting with symptoms of respiratory infection. Because not every patient presenting with symptoms will have pandemic influenza, infection control measures will be important in preventing further spread.

- During the peak of a pandemic, emergency departments and outpatient offices may be overwhelmed with patients seeking care. A “triage officer” may be useful for managing patient flow, including deferral of patients who do not require emergency care.
- Designate separate waiting areas for patients with influenza-like symptoms. If this is not feasible, the waiting area should be set up to enable patients with respiratory symptoms to sit as far away as possible (at least 3 feet) from other patients.

b) Control measures to limit dissemination of influenza virus from respiratory secretions of ill persons

- Post signs that promote respiratory hygiene/cough etiquette in common areas (e.g., elevators, waiting areas, cafeterias, lavatories) where they can serve as reminders to all persons in the healthcare facility. Signs should instruct ill persons to:
 - Cover the nose/mouth when coughing or sneezing.
 - Use tissues to contain respiratory secretions.
 - Dispose of tissues in the nearest waste receptacle after use.
 - Perform hand hygiene after contact with respiratory secretions. Samples of visual alerts are available at: <http://www.cdc.gov/flu/protect/covercough.htm>.
- Facilitate adherence to respiratory hygiene/cough etiquette by ensuring the availability of materials in waiting areas for patients and visitors.
 - Provide tissues and no-touch receptacles (e.g., waste containers with pedal-operated lid or uncovered waste container) for used tissue disposal.
 - Provide conveniently located dispensers of alcohol-based hand rub.
 - Provide soap and disposable towels for handwashing where sinks are available.
- Promote the use of masks and spatial separation by persons with symptoms of influenza.
 - Offer and encourage the use of either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties or elastic) by symptomatic persons to limit dispersal

- of respiratory droplets.
- Encourage coughing persons to sit as far away as possible (at least 3 feet) from other persons in common waiting areas.

c) Hospitalization of pandemic influenza patients

Patient placement

- Limit admission of influenza patients to those with severe complications of influenza who cannot be cared for outside the hospital setting.
 - Admit patients to either a single-patient room or an area designated for cohorting of patients with influenza.
- Cohorting
 - Designated units or areas of a facility should be used for cohorting patients with pandemic influenza.⁶ During a pandemic, other respiratory viruses (e.g., non-pandemic influenza, respiratory syncytial virus, parainfluenza virus) may be circulating concurrently in a community. Therefore, to prevent cross-transmission of respiratory viruses, whenever possible assign only patients with confirmed pandemic influenza to the same room or same cohort unit. At the height of a pandemic, laboratory testing to confirm pandemic influenza is likely to be limited, in which case cohorting should be based on having symptoms consistent with pandemic influenza.
 - Personnel (clinical and non-clinical) assigned to cohorted patient care units for pandemic influenza patients should not “float” or otherwise be assigned to other patient care areas. The number of personnel entering the cohorted area should be limited to those necessary for patient care and support.
 - Personnel assigned to cohorted patient care units should be aware that patients with pandemic influenza may be concurrently infected or colonized with other pathogenic organisms (e.g., *Staphylococcus aureus*, *Clostridium difficile*) and should adhere to infection control practices (e.g., hand hygiene, changing gloves between patient contact) used routinely, and as part of standard precautions, to prevent nosocomial transmission.
 - Because of the high patient volume anticipated during a pandemic, cohorting should be implemented early in the course of a local outbreak.

Patient transport

- Limit patient movement and transport outside the isolation area to medically necessary purposes.
- Consider having portable x-ray equipment available in areas designated for cohorting influenza patients.
- If transport or movement is necessary, ensure that the patient wears a surgical or procedure mask. If a mask cannot be tolerated (e.g., due to the patient’s age or deteriorating respiratory status), apply the most practical measures to contain respiratory secretions. Patients should perform hand hygiene before leaving the room.

Visitors

- Screen visitors for signs and symptoms of influenza before entry into the facility and exclude persons who are symptomatic.
- Family members who accompany patients with influenza-like illness to the hospital are assumed to have been exposed to influenza and should wear masks.
- Limit visitors to persons who are necessary for the patient's emotional well-being and care.
- Instruct visitors to wear surgical or procedure masks while in the patient's room.
- Instruct visitors on hand-hygiene practices.

Pediatrics

- Place pediatric patients in droplet precautions for the duration of illness
- Consider gowns for healthcare workers caring for infants in their arms. Aprons would not provide sufficient protection

d) Control of nosocomial pandemic influenza transmission

- Once patients with pandemic influenza are admitted to the hospital, nosocomial surveillance should be heightened for evidence of transmission to other patients and healthcare personnel. (Once pandemic influenza is firmly established in a community this may not be feasible or necessary.)
- If limited nosocomial transmission is detected (e.g., has occurred on one or two patient care units), appropriate control measures should be implemented. These may include:
 - Cohorting of patients and staff on affected units
 - Restriction of new admissions (except for other pandemic influenza patients) to the affected unit(s)
 - Restriction of visitors to the affected unit(s) to those who are essential for patient care and support
- If widespread nosocomial transmission occurs, controls may need to be implemented hospital wide and might include:
 - Restricting all nonessential persons
 - Stopping admissions not related to pandemic influenza and stopping elective surgeries

⁶ During the early stages of a pandemic, laboratory-confirmation of influenza infection is recommended when possible before cohorting patients.

2. Nursing homes and other residential facilities

Residents of nursing homes and other residential facilities will be at particular risk for transmission of pandemic influenza and disease complications. Pandemic influenza can be introduced by facility personnel and visitors. Once a pandemic influenza virus enters such facilities, controlling its spread is problematic. Therefore, as soon as pandemic influenza has been detected in the region, nursing homes and other residential facilities should implement aggressive measures to prevent introduction of the virus.

a) Prevention or delay of pandemic influenza virus entry into the facility

Control of visitors

- Post visual alerts (in appropriate languages) at the entrance to the facility restricting entry by persons who have been exposed to or have symptoms of pandemic influenza.
- Enforce visitor restrictions by assigning personnel to verbally and visually screen visitors for respiratory symptoms at points of entry to the facility.
- Provide a telephone number where persons can call for information on measures used to prevent the introduction of pandemic influenza.

Control of personnel

- Implement a system to screen all personnel for influenza-like symptoms before they come on duty.
- Symptomatic personnel should be sent home until they are physically able to return to duty.

b) Monitoring patients for pandemic influenza and instituting appropriate control measures

Despite aggressive efforts to prevent the introduction of pandemic influenza virus, persons in the early stages of pandemic influenza could introduce it to the facility. Residents returning from a hospital stay, outpatient visit, or family visit could also introduce the virus. Early detection of the presence of pandemic influenza in a facility is critical for ensuring timely implementation of infection control measures.

- Early in the progress of a pandemic in the region, increase resident surveillance for influenza-like symptoms. Notify state or local health department officials if a case(s) is suspected.
- If symptoms of pandemic influenza are apparent, implement droplet precautions for the resident and roommates, pending confirmation of pandemic influenza virus infection. **Patients and roommates should not be separated or moved out of their rooms unless medically necessary.** Once a patient has been diagnosed with pandemic influenza, roommates should be treated as close contacts.
- Cohort residents and staff on units with known or suspected cases of pandemic influenza.
- Limit movement within the facility (e.g., temporarily close the dining room and serve meals on nursing units, cancel social and recreational activities).

3. Prehospital care (emergency medical services)

Patients with severe pandemic influenza or disease complications are likely to require emergency transport to the hospital. The following information is designed to protect EMS personnel during transport.

- Screen patients requiring emergency transport for symptoms of influenza.
- Follow standard and droplet precautions when transporting symptomatic patients.
- Consider routine use of surgical or procedure masks for all patient transport when pandemic influenza is in the community.
- If possible, place a procedure or surgical mask on the patient to contain droplets expelled during coughing. If this is not possible (i.e., would further compromise respiratory status, difficult for the patient to wear), have the patient cover the

mouth/nose with tissue when coughing, or use the most practical alternative to contain respiratory secretions.

- Oxygen delivery with a non-rebreather face mask can be used to provide oxygen support during transport. If needed, positive-pressure ventilation should be performed using a resuscitation bag-valve mask.
- Unless medically necessary to support life, aerosol-generating procedures (e.g., mechanical ventilation) should be avoided during prehospital care.
- Optimize the vehicle's ventilation to increase the volume of air exchange during transport. When possible, use vehicles that have separate driver and patient compartments that can provide separate ventilation to each area.
- Notify the receiving facility that a patient with possible pandemic influenza is being transported.
- Follow standard operating procedures for routine cleaning of the emergency vehicle and reusable patient care equipment.

4. Home healthcare services

Home healthcare includes health and rehabilitative services performed in the home by providers including home health agencies, hospices, durable medical equipment providers, home infusion therapy services, and personal care and support services staff. The scope of services ranges from assistance with activities of daily living and physical and occupational therapy to wound care, infusion therapy, and chronic ambulatory peritoneal dialysis (CAPD). Communication between home healthcare providers and patients or their family members is essential for ensuring that these personnel are appropriately protected.

When pandemic influenza is in the community, home health agencies should consider contacting patients before the home visit to determine whether persons in the household have an influenza-like illness.

- If patients with pandemic influenza are in the home, consider:
 - Postponing nonessential services
 - Assigning providers who are not at increased risk for complications of pandemic influenza to care for these patients
 - Home healthcare providers who enter homes where there is a person with an influenza-like illness should follow the recommendations for standard and droplet precautions described above. Professional judgment should be used in determining whether to don a surgical or procedure mask upon entry into the home or only for patient interactions. Factors to consider include the possibility that others in the household may be infectious and the extent to which the patient is ambulating within the home.

5. Outpatient medical offices

Patients with nonemergency symptoms of an influenza-like illness may seek care from their medical provider. Implementation of infection control measures when these patients present for care will help prevent exposure among other patients and clinical and nonclinical office staff.

a) Detection of patients with possible pandemic influenza

- Post visual alerts (in appropriate languages) at the entrance to outpatient offices instructing persons with respiratory symptoms (e.g., patients, persons who accompany them) to:
 - Inform reception and healthcare personnel when they first register for care
 - Practice respiratory hygiene/cough etiquette (see www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm) Sample visual alerts may be found on CDC's SARS Web site: <http://www.cdc.gov/flu/protect/covercough.htm>
- Triage patients calling for medical appointments for influenza symptoms:
 - Discourage unnecessary visits to medical facilities.
 - Instruct symptomatic patients on infection control measures to limit transmission in the home and when traveling to necessary medical appointments.

b) Control measures for ill persons

- Post signs that promote cough etiquette in common areas (e.g., elevators, waiting areas, cafeterias, lavatories) where they can serve as reminders to all persons in the healthcare facility. Signs should instruct persons to:
 - Cover the nose/mouth when coughing or sneezing.
 - Use tissues to contain respiratory secretions.
 - Dispose of tissues in the nearest waste receptacle after use.
 - Perform hand hygiene after contact with respiratory secretions.
- Facilitate adherence to respiratory hygiene/cough etiquette. Ensure the availability of materials in waiting areas for patients and visitors.
 - Provide tissues and no-touch receptacles (e.g., waste containers with pedal-operated lid or uncovered waste container) for used tissue disposal.
 - Provide conveniently located dispensers of alcohol-based hand rub.
 - Provide soap and disposable towels for hand washing where sinks are available.
- Promote the use of procedure or surgical masks and spatial separation by persons with symptoms of influenza.
 - Offer and encourage the use of either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties or elastic) by symptomatic persons to limit dispersal of respiratory droplets.
 - Encourage coughing persons to sit at least 3 feet away from other persons in common waiting areas.

c) Patient placement

- Where possible, designate separate waiting areas for patients with symptoms of pandemic influenza. Place signs indicating the separate waiting areas.
- Place symptomatic patients in an evaluation room as soon as possible to limit their time in common waiting areas.

6. Other ambulatory settings

A wide variety of ambulatory settings provide chronic (e.g., hemodialysis units) and episodic (e.g., freestanding surgery centers, dental offices) healthcare services. When pandemic influenza is in the region, these facilities should implement control measures similar to those

recommended for outpatient physician offices. Other infection control strategies that may be utilized include:

- Screening patients for influenza-like illness by phone or before coming into the facility and rescheduling appointments for those whose care is nonemergency
- Canceling all nonurgent services when there is pandemic influenza in the community

Care of pandemic influenza patients in the home

Most patients with pandemic influenza will be able to remain at home during the course of their illness and can be cared for by other family members or others who live in the household. Anyone residing in a household with an influenza patient during the incubation period and illness is at risk for developing influenza. A key objective in this setting is to limit transmission of pandemic influenza within and outside the home. When care is provided by a household member, basic infection control precautions should be emphasized (e.g., segregating the ill patient, hand hygiene). Infection within the household may be minimized if a primary caregiver is designated, ideally someone who does not have an underlying condition that places them at increased risk of severe influenza disease. Although no studies have assessed the use of masks at home to decrease the spread of infection, use of surgical or procedure masks by the patient and/or caregiver during interactions may be of benefit.

1. Management of influenza patients

- Physically separate the patient with influenza from non-ill persons living in the home as much as possible.
- Patients should not leave the home during the period when they are most likely to be infectious to others (i.e., 5 days after onset of symptoms). When movement outside the home is necessary (e.g., for medical care), the patient should follow cough etiquette (i.e., cover the mouth and nose when coughing and sneezing) and wear procedure or surgical masks if available.

2. Management of other persons in the home

- Persons who have not been exposed to pandemic influenza and who are not essential for patient care or support should not enter the home while persons are actively ill with pandemic influenza.
- If unexposed persons must enter the home, they should avoid close contact with the patient.
- Persons living in the home with the pandemic influenza patient should limit contact with the patient to the extent possible; consider designating one person as the primary care provider.
- Household members should monitor closely for the development of influenza symptoms and contact a telephone hotline or medical care provider if symptoms occur.

3. Infection control measures in the home

- All persons in the household should carefully follow recommendations for hand hygiene (i.e., handwashing with soap (either non-antimicrobial or antimicrobial) and water or use of an alcohol-based hand rub) after contact with an influenza patient or the environment

in which care is provided.

- Although no studies have assessed the use of masks at home to decrease the spread of infection, use of surgical or procedure masks by the patient and/or caregiver during interactions may be of benefit. The wearing of gloves and gowns is not recommended for household members providing care in the home.
- Soiled dishes and eating utensils should be washed either in a dishwasher or by hand with warm water and soap. Separation of eating utensils for use by a patient with influenza is not necessary.
- Laundry can be washed in a standard washing machine with warm or cold water and detergent. It is not necessary to separate soiled linen and laundry used by a patient with influenza from other household laundry. Care should be used when handling soiled laundry (i.e., avoid “hugging” the laundry) to avoid contamination. Hand hygiene should be performed after handling soiled laundry.
- Tissues used by the ill patient should be placed in a bag and disposed with other household waste. Consider placing a bag for this purpose at the bedside.
- Normal cleaning of environmental surfaces in the home should be followed.

H. Care of pandemic influenza patients at alternative sites

If an influenza pandemic results in severe illness that overwhelms the capacity of existing healthcare resources, it may become necessary to provide care at alternative sites (e.g., schools, auditoriums, conference centers, hotels). Existing “all-hazard” plans have likely identified designated sites for this purpose. The same principles of infection control apply in these settings as in other healthcare settings. Careful planning is necessary to ensure that resources are available and procedures are in place to adhere to the key principles of infection control.

IV. RECOMMENDATIONS FOR INFECTION CONTROL IN SCHOOLS AND WORKPLACES

- In schools and workplaces, infection control for pandemic influenza should focus on:
 - Keeping sick students, faculty, and workers away while they are infectious.
 - Promoting respiratory hygiene/cough etiquette and hand hygiene as for any respiratory infection.
- The benefit of wearing masks in these settings has not been established.
- School administrators and employers should ensure that materials for respiratory hygiene/cough etiquette (i.e., tissues and receptacles for their disposal) and hand hygiene are available. Educational messages and infection control guidance for pandemic influenza are available for distribution.

V. RECOMMENDATIONS FOR INFECTION CONTROL IN COMMUNITY SETTINGS

Infection control in the community should focus on “social distancing” to decrease exposure to others and promoting respiratory hygiene/cough etiquette and hand hygiene. This could include the use of masks by persons with respiratory symptoms, if feasible. Although the use of masks in community settings has not been demonstrated to be a public health measure to decrease infections during a community outbreak, persons may choose to wear a mask as part of individual protection strategies that include cough etiquette, hand hygiene, and avoiding public gatherings. Mask use may also be important for persons who are at high risk for complications of influenza. Public education should be provided on how to use masks appropriately. Persons at high risk for complications of influenza should try to avoid public gatherings (e.g., movies, religious services, public meetings) when pandemic influenza is in the community. They should also avoid going to other public areas (e.g., food stores, pharmacies); the use of other persons for shopping or home delivery service is encouraged.

| Box 1. Summary of infection control recommendations for care of patients with pandemic influenza | |
|---|--|
| COMPONENT | RECOMMENDATIONS |
| Standard Precautions | See http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html |
| Hand Hygiene | Perform hand hygiene after touching blood, body fluids, secretions, excretions, and contaminated items; after removing gloves; and between patient contacts. Hand hygiene includes both handwashing with soap (either non-antimicrobial or antimicrobial) and water or use of alcohol-based products (gels, rinse, foams) that contain an emollient and do not require the use of water. If hands are visibly soiled or contaminated with respiratory secretions, they should be washed with soap (either non-antimicrobial or antimicrobial) and water. In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over soap (either non-antimicrobial or antimicrobial) and water because of their superior microbicidal activity, reduced drying of the skin, and convenience. |
| Personal Protective Equipment (PPE) <ul style="list-style-type: none"> ❖ Gloves ❖ Gown ❖ Face/eye protection (e.g., surgical or procedure mask and goggles or a face shield) | <p>For touching blood, body fluids, secretions, excretions, and contaminated items; for touching mucous membranes and nonintact skin</p> <p>During procedures and patient-care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated</p> <p>During procedures and patient care activities likely to generate splash or spray of blood, body fluids, secretions, excretions (i.e. patient coughing)</p> |
| Safe Work Practices | Avoid touching eyes, nose, mouth, or exposed skin with contaminated hands (gloved or ungloved), avoid touching surfaces with contaminated gloves and other PPE that are not directly related to patient care (e.g., door knobs, keys, light switches). |
| Patient Resuscitation | Avoid unnecessary mouth-to-mouth contact, use mouthpiece, resuscitation bag, or other ventilation devices to prevent contact with mouth and oral secretions. |
| Soiled Patient Care Equipment | Handle in a manner that prevents transfer of microorganisms to oneself, other and environmental surfaces, wear gloves if visibly contaminated: perform hand hygiene after handling equipment. |
| Soiled Linen and Laundry | Handle in a manner that prevents transfer of microorganisms to oneself, others, and to environmental surfaces; wear gloves (gown if necessary) when handling and transporting soiled linen and laundry; and perform hand hygiene. |
| Needles and other Sharps | Use devices with safety features when available; do not recap, bend, break or hand-manipulate used needles; if recapping is necessary, use a one-handed scoop technique, place used sharps in a puncture-resistant container. |

| Box 1. Summary of infection control recommendations for care of patients with pandemic influenza (cont.) | |
|--|---|
| COMPONENT | RECOMMENDATIONS |
| Standard Precautions (cont'd) | See http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html |
| Environmental Cleaning & Disinfection | Use EPA-registered hospital detergent-disinfectant: follow standard facility procedures for cleaning and disinfection of environmental surfaces, emphasize cleaning/disinfection of frequently touched surfaces (e.g., bed rail, phones, lavatory surfaces). |
| Disposal of Solid Waste | Contain and dispose of solid waste (regulated medical and non-medical) in accordance with facility procedures and/or local or state regulations, wear gloves when handling waste, wear gloves when handling containers, perform hand hygiene. |
| Respiratory hygiene/cough etiquette <i>Source control measures for persons with symptoms of a respiratory infection; implement at first point of encounter (e.g., triage/reception areas) within a healthcare setting</i> | Cover the mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacles; perform hand hygiene after contact with respiratory secretions; wear a mask (procedure or surgical) if tolerated; sit or stand as far away as possible (more than 3 feet) from persons who are not ill. |
| Droplet Precautions | See http://www.cdc.gov/ncidod/dhqp/gl_isolation_droplet.html |
| Patient Placement | Place patients with influenza in a private room or cohort with other patients with influenza.* Keep door closed or slightly ajar; maintain room assignments of patients in nursing homes and other residential settings; and apply droplet precautions to all persons in the room. *During the early stages of a pandemic, infection with influenza should be laboratory-confirmed, if possible. |
| Personal Protective Equipment | Wear a surgical or procedure mask for entry into patient room, wear other PPE as recommended for standard precautions. |
| Patient Transport | Limit patient movement outside of room to medically necessary purposes, have patient wear a procedure or surgical mask when outside the room. |
| Other | Follow standard precautions and facility procedures for handling linen, laundry, dishes and eating utensils, and for cleaning/disinfection of environmental surfaces and patient care equipment, disposal of solid waste, and postmortem care. |
| Aerosol-Generating Procedures | During procedures that may generate small particles of respiratory secretions (e.g., endotracheal intubation, bronchoscopy, nebulizer treatment, suctioning), healthcare personnel should wear gloves, gown, face/eye protection, and consider higher level of respiratory protection. |

Box 2. Respiratory hygiene/cough etiquette

To contain respiratory secretions, all persons with signs and symptoms of a respiratory infection, regardless of presumed cause, should be instructed to:

- Cover the nose/mouth when coughing or sneezing.
- Use tissues to contain respiratory secretions.
- Dispose of tissues in the nearest waste receptacle after use.
- Perform hand hygiene after contact with respiratory secretions and contaminated objects/materials.

Healthcare facilities should ensure the availability of materials for adhering to respiratory hygiene/cough etiquette in waiting areas for patients and visitors:

- Provide tissues and no-touch receptacles for used tissue disposal.
- Provide conveniently located dispensers of alcohol-based hand rub.
- Provide soap and disposable towels for handwashing where sinks are available.

Masking and separation of persons with symptoms of respiratory infection

During periods of increased respiratory infection in the community, persons who are coughing should be offered either a procedure mask (i.e., with ear loops) or a surgical mask (i.e., with ties) to contain respiratory secretions. Coughing persons should be encouraged to sit as far away as possible (at least 3 feet) from others in common waiting areas. Some facilities may wish to institute this recommendation year-round.

KENTUCKY INFLUENZA PANDEMIC RESPONSE PLAN CLINICAL GUIDELINES SUPPLEMENT IV

| TABLE OF CONTENTS | | |
|-------------------|---|-----------|
| | | PAGE |
| | SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR CLINICAL GUIDELINES | 1 |
| I. | RATIONALE | 3 |
| II. | OVERVIEW | 3 |
| III. | CLINICAL GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 4 |
| | A. Criteria for evaluation of patients with possible novel influenza | 4 |
| | 1. Clinical criteria | 5 |
| | 2. Epidemiologic criteria | 5 |
| | B. Initial management of patients who meet the criteria for novel influenza | 7 |
| | C. Management of patients who test positive for novel influenza | 8 |
| | D. Management of patients who test positive for seasonal influenza | 8 |
| | E. Management of patients who test negative for novel influenza | 8 |
| IV. | CLINICAL GUIDELINES FOR THE PANDEMIC PERIOD | 9 |
| | A. Criteria for evaluation of patients with possible pandemic influenza | 9 |
| | 1. Clinical Criteria | 9 |
| | 2. Epidemiologic criteria | 10 |
| | B. Initial management of patients who meet the criteria for pandemic influenza | 10 |
| | C. Clinical management of pandemic influenza patients | 12 |
| V. | APPENDICES | |
| | Appendix 1. Clinical Presentation and Complications of Seasonal Influenza | 26 |
| | Appendix 2. Clinical Presentation and Complication of Illnesses Associated with Avian Influenza A (H5N1) and Previous Pandemic Influenza Viruses | 30 |
| | Appendix 3. Guidelines for Management of Community-acquired Pneumonia, Including Post-influenza Community-acquired Pneumonia (contains Tables 2-5) | 33 |
| | Appendix 4. Clinician Fact Sheet - Influenza | 39 |
| | Appendix 5. Clinician Fact Sheet - Antivirals | 41 |
| | Appendix 6. Respiratory Etiquette Poster | 43 |

SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR CLINICAL GUIDELINES

Interpandemic and Pandemic Alert Periods

Healthcare providers should:

- Be aware of case definitions.
- Know procedures for influenza screening and laboratory testing.
- Know appropriate infection control measures.
- Know appropriate antiviral regimens for influenza A (H5N1) and other novel viruses.
- Notify health departments about suspected or confirmed novel influenza cases and fatalities.
- Collect and forward specimens to designated state and federal laboratories for the diagnosis of novel influenza strains.
- Follow public health recommendation on administration of influenza vaccine.

KDPH and local health department:

- Help educate healthcare providers about novel and pandemic influenza.

The Division of Epidemiology and Health Planning (DEHP) Influenza Coordinator will send guidelines for suspect avian influenza cases to hospital Infection Control Professionals, Local Health Department Surveillance Contacts, Local Health Department and Health Care Provider sentinel sites. Guidelines for reporting and instructions for submitting specimens will be posted on the KDPH Web site, the Health Alert Network, and published in *Kentucky Epidemiologic Notes and Reports*.

- Provide or facilitate testing and investigation of suspected novel influenza cases.

The DEHP will coordinate with the Division of Laboratory Services (DLS) to have specimens sent to the State Public Health Laboratory for testing. If the individual's condition meets the screening criteria, the State Influenza Coordinator will advise the healthcare provider to send the specimen to the State Public Health Laboratory. The State Influenza Coordinator will advise the DLS Virus Laboratory that a specimen is being sent. The DLS will test the specimen by PCR. Specimens will be sent to CDC, if necessary.

- Conduct follow-up of suspected novel influenza cases.

The State Influenza Coordinator will request a faxed copy of the screening form from the healthcare provider, and will facilitate an investigation through the Regional Epidemiologist and the Local Health Department Surveillance Contact, for the purpose of obtaining a detailed history of the suspected case and to identify contacts.

HHS agencies:

- Develop and disseminate recommendations on the use of influenza diagnostic tests, antiviral drugs, and vaccines during an influenza pandemic.
- Develop a national stockpile of antiviral drugs for use during a pandemic.
- Work with state and local health departments to investigate and manage suspected cases of human infection with avian influenza A (H5N1) or other novel strains of influenza.
- Establish case definition and reporting mechanisms.

Pandemic Period

Healthcare providers will:

- Regularly review updates on case definitions, screening, laboratory testing, and treatment algorithms for pandemic influenza.
- Follow recommendations on antiviral and vaccine use from federal, state, and local health agencies.
- Choose antiviral treatment appropriate for circulating influenza strains.
- When antiviral supplies are limited, prescribe antivirals for persons in priority groups where the need and benefit are the greatest.
- Report pandemic influenza cases or fatalities as requested by health departments.
- Collect and forward specimens for ongoing pandemic influenza surveillance as requested to designated state and federal laboratories.
- Report atypical cases, breakthrough infections while on prophylaxis, or any other abnormal cases throughout the duration of the pandemic to public health agencies.
- Follow public health recommendation on administration of influenza vaccine.

KDPH and local health departments:

State and local public health agencies will:

- Update providers regularly as the influenza pandemic unfolds.
DEHP will provide information to the Cabinet's Communications Office to be used at their discretion. Suggested information is a weekly county chart and map indicating the location and number of cases.
- Provide or facilitate testing and investigation of pandemic influenza cases.
The DEHP and DLS will coordinate facilitation of testing. The DEHP State Influenza Coordinator will facilitate an investigation in collaboration with the Regional Epidemiologists and the Local Health Department Surveillance Contacts.
- Work with CDC to investigate and report special pandemic situations.
Regional Epidemiologists and Local Health Department Surveillance Contacts will report their findings to the State Influenza Coordinator, who will communicate these findings to the CDC. The DEHP State Influenza Coordinator will contact and fax screening forms to the CDC DEOC, and obtain an assigned ID/State Number for purposes of tracking information.
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

HHS responsibilities:

- Update and disseminate national guidelines on influenza diagnostic testing and use of antiviral drugs and vaccines during the pandemic.
- Develop a pandemic influenza vaccine.
- Work with healthcare partners to refine clinical management guidelines and issue regular updates on treatment issues.
- Conduct studies to investigate pandemic influenza pathogenesis.
- Monitor pandemic influenza cases for antiviral resistance.
- Monitor antiviral drug use and inventories.
- Collect information on clinical features, outcomes, and treatments.

I. RATIONALE

Healthcare providers play an essential role in the detection of an initial case of novel or pandemic influenza in a community. Early identification and isolation of cases may help slow the spread of influenza. Clinical awareness of novel or pandemic influenza disease can also benefit the individual patient, as rapid initiation of treatment can avert potentially severe complications.

Currently there is a lack of specific clinical findings and commercially available laboratory tests to rapidly distinguish novel or pandemic influenza from seasonal influenza. In addition, it is difficult ahead of time to fully predict the clinical characteristics of a novel or pandemic influenza virus strain or the groups at highest risk for complications.

However, clinical management of patients during pandemic influenza will follow many of the same principles of patient care in cases of interpandemic (i.e. “normal”) seasonal strains of influenza. Health care workers will need to know 1) the symptoms of an influenza-like illness, 2) the strains that are circulating in the community, 3) the appropriate tests to diagnose influenza, 4) the appropriate infection control precautions, 5) how to select the correct antiviral medicine, 6) the side effects of the antiviral medicines, and 7) how to prescribe antivirals for prophylaxis (see Vaccine and Antiviral Supplement).

Additional difficulties in managing pandemic influenza include 1) differentiating seasonal strains of influenza from pandemic strains, 2) deciding which antiviral medicine would be most appropriate to use, 3) selecting the populations that would benefit most from antivirals in the face of great demands for a limited supply of antivirals, and 4) selecting the populations that would benefit most from influenza vaccine for the pandemic strain in the face of great demands for a limited supply of that influenza vaccine.

The management of influenza is based primarily on sound clinical judgment regarding the individual patient as well as the availability of local resources, such as rapid diagnostic tests, antiviral drugs, influenza vaccine, and hospital beds. Healthcare providers who are well trained in managing seasonal influenza will be better able to effectively diagnose and care for patients with pandemic influenza.

II. OVERVIEW

The Clinical Guidelines Supplement focuses on the initial screening, assessment, and management of patients who present from the community with fever and/or respiratory symptoms during the Interpandemic, Pandemic Alert, and Pandemic Periods (Box 1, page 13, defines these periods). Boxes, figures, tables, and appendices are incorporated from the November 2005 HHS Pandemic Influenza Plan (<http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>).

The Appendices add additional information on the clinical presentation and complications of influenza, the clinical features of human infection with avian influenza A (H5N1) virus, and management of secondary bacterial pneumonia during a pandemic. The appendices also contain Clinician Fact Sheets about influenza and antivirals and a respiratory etiquette poster.

During the Interpandemic and Pandemic Alert Periods, early recognition of illness caused by a novel influenza A virus strain will rely on a **combination of clinical and epidemiologic features**.

During periods in which no human infections with a novel influenza A virus strain have occurred anywhere in the world (Interpandemic Period, phases 1 or 2), or when sporadic cases of animal-to-human transmission or rare instances of limited human-to-human transmission of a novel influenza A virus strain have occurred in the world (Pandemic Alert Period, phases 3 or 4), the risk to travelers is low.

Therefore, when a traveler who is returning from an affected area and develops severe respiratory disease or an influenza-like illness, the likelihood of novel influenza A virus infection is **very low**. In this situation, the possibility of infection with seasonal human influenza viruses in returning travelers is much higher and should be considered, since human influenza A and B viruses circulate worldwide among humans year-round.

However, once local person-to-person transmission of a novel influenza A virus strain has been confirmed (Pandemic Alert Period: Phase 5), the potential for novel influenza A virus infection will be higher in an ill person who has a strong epidemiologic link to the affected area.

During the Pandemic Period (in a setting of high community prevalence), diagnosis will be more **clinically oriented** because the likelihood will be high that any severe febrile respiratory illness is pandemic influenza.

This Clinical Guidelines Supplement is current as of January 2006, and is subject to change as experience is gained. Updates will be provided, as needed, on the Kentucky Department for Public Health Web site (<http://chfs.ky.gov/dph>) and the CDC Web site (www.cdc.gov/flu/).

Other supplements in the pandemic plan may also cover topics of potential interest to clinicians.

III. CLINICAL GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

During Interpandemic and Pandemic Alert Periods, the primary goal is to quickly identify and contain cases of novel influenza. To limit evaluating an overwhelming number of patients, screening criteria should rely on a combination of clinical and epidemiologic features.

Febrile respiratory illnesses are one of the most common reasons for medical evaluation during the winter. Therefore, during the interpandemic and pandemic alert period, febrile illnesses caused by novel influenza strains are expected to be rare. Laboratory testing should be done for those with severe respiratory illness, such as pneumonia. The main features of case detection and clinical management during the Interpandemic and Pandemic Alert Periods are outlined in Figure 1.

A. Criteria for evaluation of patients with possible novel influenza

During the Pandemic Alert Period, human infections with novel influenza A viruses will be uncommon. Therefore, **both clinical and epidemiologic criteria should be met**. The criteria will be updated as needed and posted at www.cdc.gov/flu/.

1. Clinical criteria

Any suspected cases of human infection with a novel influenza virus must meet the criteria for influenza-like illness (ILI): **temperature of >100.4°F (>38°C) plus one of the following: sore throat, cough, or dyspnea.**

Because of the large number of ILI cases during a typical influenza season, during the Interpandemic and Pandemic Alert Periods laboratory evaluation for novel influenza A viruses is recommended **only** for:

- a) Hospitalized patients with severe ILI, including pneumonia, who meet the epidemiologic criteria (see below), or
- b) Non-hospitalized patients with ILI and with strong epidemiologic suspicion of novel influenza virus exposure (e.g., direct contact with ill poultry in an affected area, or close contact with a known or suspected human case of novel influenza within 10 days prior to onset of symptoms.).

Recommendations for the evaluation of patients with respiratory illnesses are provided in Box 2. Exceptions to the current clinical criteria are provided in Box 3.

2. Epidemiologic criteria

Epidemiologic criteria for evaluation of patients with possible novel influenza focus on the **risk of exposure** to a novel influenza virus with pandemic potential. Although the incubation period for seasonal influenza ranges from 1 to 4 days, the incubation periods for novel types of influenza are currently unknown and might be longer. Therefore, the maximum interval between potential exposure and symptom onset is set conservatively at 10 days.

Exposure risks — Exposure risks fall into two categories: a) travel and b) occupational.

a) Travel risks: Persons have a travel risk if they have, within 10 days prior to onset of symptoms:

- 1) recently visited or lived in an area affected by highly pathogenic avian influenza A outbreaks in domestic poultry or where a human case of novel influenza has been confirmed, **and**
- 2) either had direct contact with poultry, **or**
- 3) had close contact with a person with confirmed or suspected novel influenza. Updated listings of areas affected by avian influenza A (H5N1) and other current/recent novel strains are provided on the Web sites of the OIE (http://www.oie.int/eng/en_index.htm), WHO (www.who.int/en/), and CDC (www.cdc.gov/flu/).

Direct contact with poultry is defined as: 1) touching birds (well-appearing, sick, or dead), or 2) touching poultry feces or surfaces contaminated with feces, or 3) consuming uncooked poultry products (including blood) in an affected area. Close contact with a person from an infected area with confirmed or suspected novel influenza is defined as being within 3 feet (1 meter) of that person during their illness. Because specific testing for human infection with avian influenza A (H5N1) might not be locally available in an affected area, persons reporting close contact in an affected area with a person suffering from a severe, yet unexplained, respiratory illness should also be evaluated.

Human influenza viruses circulate worldwide and year-round, including in countries with outbreaks of avian influenza A (H5N1) among poultry. Therefore, during the Interpandemic and Pandemic Alert Periods, human influenza virus infection can be a cause of ILI among returned travelers at any time of the year, including during the summer in the United States. This includes travelers returning from areas affected by poultry outbreaks of highly pathogenic avian influenza

A (H5N1) in Asia. As of May 2006, such persons are currently more likely to have infection with human influenza viruses than with avian influenza A (H5N1) viruses.

b) Occupational risks

Persons at occupational risk for infection with a novel strain of influenza include:

- 1) persons who work on farms or live poultry markets
- 2) persons who process or handle poultry infected with known or suspected avian influenza viruses
- 3) workers in laboratories that contain live animal or novel influenza viruses
- 4) healthcare workers in direct contact with a suspected or confirmed novel influenza case.

Information on limiting occupational risk is provided on the Occupational Health and Safety Administration (OSHA) Web site at: www.osha.gov/dsg/guidance/avian-flu.html.

During the Interpandemic and Pandemic Alert Periods, when there is no sustained human-to-human transmission of any novel influenza viruses, **direct contact** with animals such as poultry in an affected area or close contact with a case of suspected or confirmed human novel influenza is **required** for further evaluation.

During the Pandemic Alert Period, Phases 3 and 4, the majority of human cases of novel influenza will result from avian-to-human transmission (see Box 1). Therefore, a history of direct contact with poultry (well-appearing, sick, or dead), consumption of uncooked poultry or poultry products, or direct exposure to environmental contamination with poultry feces in an affected area will be important to ascertain.

During the Pandemic Alert Period, Phase 5, a history of close contact with an ill person suspected or confirmed to have novel influenza in an affected area will be even more important.

Other avian influenza A viruses

Although the epidemiologic criteria for novel influenza are based on recent human cases of avian influenza A (H5N1), they are intended for use in the evaluation of suspected cases of infection with any novel influenza A virus strain.

Other avian influenza A viruses that have caused human disease include the highly pathogenic viruses H7N7 and H7N3 and the low pathogenic viruses H9N2 and H7N2. Some of these human cases have occurred in Europe (Netherlands) and North America (Canada and the United States). Therefore, the same high-risk exposures defined above for avian influenza A (H5N1) also apply to other avian influenza A viruses.

A strong epidemiologic link to an avian influenza outbreak in poultry, even in areas that have not experienced poultry outbreaks of avian influenza A (H5N1), may raise the index of suspicion for human infection with avian influenza A viruses.

In the future, other animal hosts (in addition to poultry) or novel influenza A virus subtypes (in addition to H5N1) might become significantly associated with human disease. If such events occur, this guidance will be updated.

B. Initial management of patients who meet the criteria for novel influenza

When a patient meets both the clinical and epidemiologic criteria for a suspected case of novel influenza, healthcare personnel should initiate the following activities:

1. Implement infection control precautions for novel influenza, including Respiratory Hygiene/Cough Etiquette. Patients should be placed on **Droplet Precautions** for a **minimum of 5 days** unless there is full resolution of illness or another etiology has been identified before that period has elapsed. Healthcare personnel should wear surgical or procedure **masks** on entering a patient's room, as per Droplet Precautions. They should also wear **gloves, eye protection and gowns when indicated** for Standard Precautions (See Infection Control supplement III Table 1). Patients should be admitted to a single-patient room, and patient movement and transport within the hospital should be limited to medically necessary purposes (see also Infection Control Supplement).
2. **Notify the local health department or KDPH.** Report each patient who meets the clinical and epidemiologic criteria for a suspected case of novel influenza to the state or local health department as quickly as possible to facilitate initiation of public health measures (see Laboratory and Surveillance Supplement). Designate one person as a point of contact to update public health authorities on the patient's clinical status.
3. **Obtain clinical specimens** for novel influenza A virus testing and notify the local and state health departments to arrange testing. Testing of suspected novel or pandemic influenza will be directed by public health authorities (see Laboratory and Surveillance Supplement for more detailed guidelines).
 - a. Where feasible, collect of the following respiratory specimens for novel influenza A virus testing: 1) nasopharyngeal swab; 2) throat swab; 3) tracheal aspirate (for intubated patients); and 4) nasal swab, aspirate or wash.
 - b. Store specimens at 4°C in viral transport media until transported or shipped for testing. Acute (within 7 days of illness onset) and convalescent serum specimens (2–3 weeks after the acute specimen and at least 3 weeks after illness onset) should be obtained and refrigerated at 4°C or frozen at minus 20–80°C. Serological testing for novel influenza virus infection can be performed only at CDC.
 - c. Immediately notify their local health departments of their intention to ship clinical specimens from suspected cases of human infection with a novel influenza A virus, to ensure that the specimens are handled under proper biocontainment conditions.
 - d. Novel influenza A viruses can be confirmed by RT-PCR or virus isolation from tissue cell culture with subtyping. However, RT-PCR for testing of novel influenza viruses cannot be performed by a hospital laboratory and is available only at state public health laboratories and CDC. Viral culture of specimens from suspected novel influenza cases should be attempted **only** in laboratories that meet the biocontainment conditions for BSL-3 with enhancements or higher.
 - e. Rapid influenza diagnostic tests and immunofluorescence (indirect fluorescent antibody staining [IFA] or direct fluorescent antibody staining [DFA]) may be used to detect seasonal influenza, but **should not be used to confirm or exclude novel influenza during the Pandemic Alert Period.** Rapid influenza tests have relatively low sensitivity for detecting seasonal influenza, and their ability to detect novel influenza subtypes is unknown. Such tests can identify influenza A viruses but cannot distinguish between human infection with seasonal and novel influenza A viruses. A negative rapid influenza test result does **not** necessarily

exclude human infection with either seasonal or novel influenza A viruses. A positive rapid influenza test result could be a false positive or represent infection with either seasonal or novel influenza A viruses. Therefore, both negative and positive rapid influenza test and immunofluorescence results should be interpreted with caution, and RT-PCR testing for influenza viruses should be performed. (See Laboratory and Surveillance Clinical Guidelines Supplement for further information on rapid diagnostic testing).

- f. Acute and convalescent serum samples and other available clinical specimens (respiratory, blood, and stool) should be saved and refrigerated or frozen for additional testing until a specific diagnosis is made.
4. **Evaluate alternative diagnoses.** An alternative diagnosis should be based only on laboratory tests with high positive-predictive value (e.g., blood culture, viral culture, PCR, Legionella urinary antigen, pleural fluid culture, transthoracic aspirate culture). If an alternate etiology is identified, the possibility of **co-infection** with a novel influenza virus may still be considered if there is a strong epidemiologic link to exposure to novel influenza.
 5. **Decide on inpatient or outpatient management.** The decision to hospitalize a suspected novel influenza case will be based on the physician's clinical assessment and assessment of risk and whether adequate precautions can be taken at home to prevent the potential spread of infection.
 - a. Patients cared for at home should be separated from other household members as much as possible.
 - b. All household members should carefully follow recommendations for hand hygiene, and tissues used by the ill patient should be placed in a bag and disposed with other household waste (Box 4).
 - c. Although no studies have assessed the use of masks at home to decrease the spread of infection, use of surgical or procedure masks by the patient and/or caregiver during interactions may be of benefit.
 - d. Separation of eating utensils for use by a patient with influenza is not necessary, as long as they are washed with warm water and soap (Box 4).
 6. **Initiate antiviral treatment as soon as possible**, even if laboratory results are not yet available. Clinical trials have shown that these drugs can decrease the illness due to seasonal influenza duration by several days when they are initiated **within 48 hours of illness onset**. The clinical effectiveness of antiviral drugs for treatment of novel influenza is unknown, but it is likely that the earlier treatment is initiated, the greater the likelihood of benefit. During the Pandemic Alert Period, available virus isolates from any case of novel influenza will be tested for resistance to the currently licensed antiviral medications. (See Vaccine and Antiviral Supplement for antiviral information).
 7. **Assist public health officials with identifying exposed contacts.** After consulting with KDPH or local public health officials, clinicians might be asked to help identify persons exposed to the suspected novel influenza case-patient (particularly healthcare workers). In general, persons in close contact with the case-patient at any time beginning one day before the onset of illness are considered at risk. Close contacts might include household and social contacts, family members, workplace or school contacts, fellow travelers, and/or healthcare providers.

C. Management of patients who test positive for novel influenza

If a patient is confirmed to have an infection with a novel influenza virus:

1. Continue antiviral treatment
2. Continue all isolation and infection control precautions
3. Isolate patients with novel influenza from seasonal influenza patients.

In addition to prior vaccination against seasonal influenza, such measures may decrease the risk of co-infection and viral genetic reassortment.

D. Management of patients who test positive for seasonal influenza

Many people who are suspected to have a novel influenza will be found to have seasonal human influenza, particularly during the winter season. It should be recognized that human influenza viruses circulate among people worldwide throughout the year, including in affected areas with poultry outbreaks of avian influenza A viruses.

For patients with confirmed seasonal influenza, maintain Standard and Droplet Precautions, and continue appropriate antiviral treatment for a full treatment course (e.g., 5 days).

E. Management of patients who test negative for novel influenza

The sensitivity of the currently available tests for detecting novel influenza viruses in clinical specimens has not been thoroughly evaluated, so false-negative test results may occur. Therefore, if test results are negative but the clinical and epidemiologic suspicion for a novel influenza virus remains high, continue antiviral treatment and isolation procedures. Test results could be negative for influenza viruses for several reasons:

1. Some patients may have an alternate etiology to explain their illness. The general work-up for febrile respiratory illnesses described below should evaluate the most common alternate causes.
2. A certain number of truly infected cases might also test falsely negative, due to specimen collection conditions, to viral shedding that is not detectable, or to sensitivity of the test.

Interpretation of negative testing results should be tailored to the individual patient in consultation with hospital infection control and infectious disease specialists, as well as the state or local health department and CDC. In hospitalized patients who test negative for novel influenza but have no alternate diagnosis established, novel-influenza-directed management should be continued if clinical suspicion is high and there is a strong epidemiologic link to exposure to novel influenza.

When influenza tests are negative and an alternative diagnosis is established, isolation precautions and antiviral drug therapy for novel influenza may be discontinued based on clinician's assessment if:

1. There is no strong epidemiologic link
2. An alternative diagnosis is made using a test with a high positive-predictive value
3. The clinical manifestations are explained by the alternative diagnosis.

IV. CLINICAL GUIDELINES FOR THE PANDEMIC PERIOD

During the Pandemic Period, the primary goal of rapid detection is to appropriately identify and triage cases of pandemic influenza. During this period, outpatient clinics and emergency departments might be overwhelmed with suspected cases, restricting the time and laboratory

resources available for evaluation. In addition, if the pandemic influenza virus exhibits transmission characteristics similar to those of seasonal influenza viruses, illnesses will likely spread throughout the community too rapidly to allow the identification of obvious exposures or contacts.

Evaluation will therefore focus predominantly on **clinical** and **basic laboratory** findings, with less emphasis on laboratory diagnostic testing (which may be in short supply) and **epidemiologic criteria**. Nevertheless, clinicians in communities without pandemic influenza activity might consider asking patients about recent travel from a community with pandemic influenza activity or close contact with a suspected or confirmed pandemic influenza case. The main features of clinical management during the Pandemic Period are outlined in Figure 2.

A. Criteria for evaluation of patients with possible pandemic influenza

1. Clinical criteria

Suspected cases of pandemic influenza virus infection should meet the criteria for an ILI: **temperature of >100.4°F (>38°C) plus one of the following: sore throat, cough, or dyspnea.**

Although past influenza pandemics have most frequently resulted in respiratory illness, the next pandemic influenza virus strain might present with a different clinical syndrome (see Appendix 1 and Appendix 2). During a pandemic, updates on other clinical presentations will be provided at: www.pandemicflu.gov and www.cdc.gov/flu/.

Recommendations for general evaluation of patients with ILI are provided in Box 2. Exceptions to the clinical criteria are provided in Box 3.

2. Epidemiologic criteria

During the Pandemic Period, an exposure history will be marginally useful for clinical management when disease is widespread in a community. In addition, there will be a relatively high likelihood that any case of ILI during that time period will be pandemic influenza. Once pandemic influenza has arrived in a particular locality, **clinical criteria will be sufficient** for classifying the patient as a **suspected** pandemic influenza case.

B. Initial management of patients who meet the criteria for pandemic influenza

When a patient meets the criteria for a suspected case of pandemic influenza, healthcare personnel should initiate the following activities:

1. **Report** according to local and state health department recommendations for patients who meet the criteria for pandemic influenza. See Clinical Guidelines Supplement 1 for guidance on case reporting during the Pandemic Period.
2. If the patient is hospitalized, implement **infection control precautions** for pandemic influenza, including Respiratory Hygiene/Cough Etiquette (see Infection Control Supplement, Box 2).
 - a. Place the patient on Droplet Precautions for a minimum of 5 days from the onset of symptoms.
 - b. Healthcare personnel should wear surgical or procedure masks on entering a patient's room, as per Droplet Precautions
 - c. Healthcare personnel should wear gloves and gowns, when indicated, as per Standard Precautions (Box 1, Infection Control Supplement 3).

- d. Patients should be admitted to either a single-patient room or an area designated for cohorting of patients with influenza.
 - e. Patient movement and transport outside the isolation area should be limited to medically necessary purposes (see Table 1, Infection Control).
 3. **Limit hospital admission** of patients should be limited to those with severe complications who cannot be cared for outside the hospital setting, especially once a pandemic is underway.
 4. Obtain **clinical specimens**, as clinically indicated (see Box 2).
 - a. Once pandemic influenza has arrived in a community, influenza testing will likely not be needed for most patients.
 - b. Work in conjunction with health departments to perform laboratory testing in a subset of pandemic influenza cases, as part of ongoing virologic surveillance (see Laboratory and Surveillance Supplement).
 - c. Influenza diagnostic testing should be considered before initiating treatment with antivirals (see Vaccine and Antiviral Supplement).
 - d. See Laboratory and Surveillance Supplement for guidelines for pandemic influenza virus testing.
 - e. As with seasonal influenza, RT-PCR and virus isolation from tissue culture will be the most accurate methods for diagnosing pandemic influenza.
 - f. Specimens should generally include combined nasopharyngeal aspirates or nasal swabs, and throat swabs, stored at 4°C in viral transport media.
 - g. BSL-2 conditions should be sufficient for viral culture of clinical specimens from suspected pandemic influenza patients during the Pandemic Period.
 5. **Know how to properly use rapid diagnostic tests** for influenza
 - a. Rapid tests and immunofluorescence may be helpful for initial clinical management, including cohorting and treatment, but have relatively low sensitivity for detecting seasonal influenza, and their ability to detect pandemic influenza viruses is unknown.
 - b. The sensitivity of rapid diagnostic tests will likely be higher in specimens collected within two days of illness onset, in children, and when tested at clinical laboratories that perform a high volume of testing.
 - c. During a pandemic a negative rapid test may be a false negative. Therefore test results need to be interpreted within the overall clinical context. For example, it may not be optimal to withhold antiviral treatment from a seriously ill high-risk patient on the basis of a negative test; however, in a setting of limited antiviral drug availability, treatment decisions in less high-risk situations could be based on test results.
 - d. The risk of a false-negative test also must be taken into account in making cohorting decisions.
 - e. Rapid diagnostic testing should not preclude more reliable testing, if available.
 - f. See Laboratory and Surveillance Clinical Guidelines Supplement for further information on rapid diagnostic testing.
 6. **Decide on inpatient or outpatient management.** The decision to hospitalize a suspected pandemic influenza case will be based on the physician's clinical assessment of the patient as well as the availability of hospital beds and personnel. Guidelines on cohorting and infection control for admitted patients can be found in Infection Control Supplement.

- a. High priority for admission
 - i. An unstable patient.
 - ii. Patients with high-risk conditions (see Appendix 1) might also warrant special attention, such as observation or close follow-up, even if disease is mild.
- b. Appropriate for home management with follow-up.
 - i. Well-appearing young children with fever alone.
- c. See Vaccine and Antiviral Supplement for inpatient and outpatient antiviral treatment strategies.

7. Infection control for home care

- a. Patients cared for at home should be separated from other household members as much as possible.
- b. All household members should carefully follow recommendations for hand hygiene, and tissues used by the ill patient should be placed in a bag and disposed with other household waste (Box 4).
- c. Infection within the household may be minimized if a primary caregiver is designated. The primary caregiver would ideally be someone who does not have an underlying condition that places them at increased risk of severe influenza disease.
- d. Using a surgical or procedure mask by the patient or caregiver during interactions may be of benefit.
- e. Separation of eating utensils for use by a patient with influenza is not necessary, as long as they are washed with warm water and soap (Box 4).

C. Clinical management of pandemic influenza patients

See Vaccine and Antiviral Supplement for current antiviral information and treatment strategies. In addition to the use of antivirals, clinical management of severe influenza should address supportive care and the rapid identification and treatment of secondary complications.*

1. Provide CDC with virus isolates from persons who fail treatment or antiviral prophylaxis, as these strains may more likely be drug resistant.
 2. Do not give aspirin or other salicylate-containing product to children aged < 18 years with suspected or confirmed pandemic influenza because of an increased risk of Reye syndrome in this age group (characterized by acute encephalopathy and liver failure).
 3. Monitor for complications. Complications related to seasonal human influenza occur more commonly in persons with certain underlying medical conditions, such as chronic respiratory or cardiovascular disease and extremes of age, and are described in Appendix 1. Limited data are available on risk factors and complications related to infection with novel influenza viruses, and these may change as individual strains evolve.
 4. Review the summary of the clinical presentations and complications associated with recent influenza A (H5N1) viruses in Appendix 2.
 5. Be aware that post-influenza community-acquired pneumonia will likely be a commonly encountered complication, and be aware of recommended methods for diagnosis and treatment. Guidance on the management of influenza-related pneumonia is in Appendix 3.
- Ribavirin and immunomodulatory therapies, such as steroids, are not approved by the FDA for treatment of severe influenza of any type and are investigational at this time.

These agents frequently have severe adverse effects, such as bone marrow and hepatic toxicity, while the benefits of these therapies are unknown.

Box 1. Risk of Novel Influenza in Persons with Severe Respiratory Disease or Influenza-like Illness during the Interpandemic and Pandemic Alert Periods

Clinicians should recognize that human influenza A and B viruses and other respiratory viruses circulate year-round among people throughout the world, including in countries affected by outbreaks of avian influenza A viruses in poultry. Seasonal human influenza A and B community outbreaks occur in temperate climates of the northern and southern hemisphere, and human influenza activity may occur year-round in subtropical and tropical regions. Outbreaks of human influenza can occur among travelers during any time of the year, including periods of low influenza activity in the United States (e.g., summer)

Phases 1, 2: Interpandemic Period
 A novel influenza A virus has been detected in animals but not in humans. During these phases, the risk of human infection with a novel influenza A virus strain is extremely low. The risk of human infection with human influenza viruses or other viruses is much higher in persons living in or traveling to affected areas.

Phases 3, 4: Pandemic Alert Period
 A novel influenza A virus has been detected in humans through sporadic animal-to-human transmission in an affected area (e.g., direct contact with infected poultry), and few cases of limited, local human-to-human transmission have occurred (small clusters of cases). During these phases, the risk of human infection with a novel influenza A virus strain is very low. The risk of human infection with human influenza viruses or other viruses is much higher in persons living in or traveling to affected areas

Phase 5: Pandemic Alert Period
 A novel influenza A virus has been detected in humans in larger clusters in an affected area, suggesting that the virus is becoming better adapted to spread among people. During this period, the risk of human infection with a novel influenza A virus strain is higher, depending on specific exposures, in persons living in or traveling to affected areas. Human infection with human influenza viruses or other viruses will occur and should still be considered.

Box 2. Clinical Evaluation of Patients with Influenza-like Illness during the Interpandemic and Pandemic Alert Periods

- Patients who require hospitalization for an influenza-like illness for which a definitive alternative diagnosis is not immediately apparent* should be questioned about: 1) travel to an area affected by avian influenza A virus outbreaks in poultry, 2) direct contact with poultry, 3) close contact with persons with suspected or confirmed novel influenza, or 4) occupational exposure to novel influenza viruses (such as through agricultural, health care, or laboratory activities).
- Patients may be screened on admission for recent seasonal influenza vaccination and pneumococcal vaccination. Those without a history of immunization should receive these vaccines before discharge, if indicated.
- Patients meeting the epidemiologic criteria for possible infection with a novel strain of influenza should undergo a routine diagnostic work-up, guided by clinical indications. Appropriate personal protective equipment should be used when evaluating patients with suspected novel influenza, including during collection of specimens.**
- Diagnostic testing for a novel influenza A virus should be initiated as follows:
 - Collect all of the following specimens: nasopharyngeal swab, nasal swab, wash, or aspirate, throat swab, and tracheal aspirate (if intubated), and place into viral transport media and refrigerate at 4°C until specimens can be transported for testing.
 - Immediately contact the local and state health departments to report the suspected case and to arrange novel influenza testing by RT-PCR.

RT-PCR testing is not available in hospital laboratories and must be performed at a qualified laboratory such as a state health department laboratory or the CDC Influenza Laboratory. Viral culture should be performed only at biosafety level 3 [BSL-3] with enhancements (see Laboratory Supplement).

- Depending on the clinical presentation and the patient's underlying health status, other initial diagnostic testing might include:
 - Pulse oximetry
 - Chest radiograph
 - Complete blood count (CBC) with differential
 - Blood cultures
 - Sputum (in adults), tracheal aspirate, and pleural effusion aspirate (if an effusion is present) Gram stain and culture
 - Antibiotic susceptibility testing (encouraged for all bacterial isolates)
 - Multivalent immunofluorescent antibody testing or PCR of nasopharyngeal aspirates or swabs for common viral respiratory pathogens, such as influenza A and B, adenovirus, parainfluenza viruses, and respiratory syncytial virus, particularly in children
 - In adults with radiographic evidence of pneumonia, *Legionella* and pneumococcal urinary antigen testing
 - If clinicians have access to rapid and reliable testing (e.g., PCR) for *M. pneumoniae* and *C. pneumoniae*, adults and children <5 yrs with radiographic pneumonia should be tested.
 - Comprehensive serum chemistry panel, if metabolic derangement or other end-organ involvement such as liver or renal failure is suspected.

*Further evaluation and diagnostic testing should also be considered for outpatients with strong epidemiologic risk factors and mild or moderate illness (see Box 3).

**Healthcare personnel should wear surgical or procedure masks on entering a patient's room (Droplet Precautions), as well as gloves and gowns, when indicated (Standard Precautions) (see Table and Infection Control Supplement).

Box 3. Special Situations and Exceptions to the Clinical Criteria

Persons with a high risk of exposure—For persons with a high risk of exposure to a novel influenza virus (e.g., poultry worker from an affected area,* caregiver of a patient with laboratory-confirmed novel influenza, employee in a laboratory that works with live novel influenza viruses), epidemiologic evidence might be enough to initiate further measures, even if clinical criteria are not fully met. In these persons, early signs and symptoms—such as rhinorrhea, conjunctivitis, chills, rigors, myalgia, headache, and diarrhea—in addition to cough or sore throat, may be used to fulfill the clinical criteria for evaluation.

High-risk groups with atypical symptoms—Young children, elderly patients, patients in long-term care facilities, and persons with underlying chronic illnesses might not have typical influenza-like symptoms, such as fever. When such patients have a strong epidemiologic risk factor, novel influenza should be considered with almost any change in health status, even in the absence of typical clinical features. Conjunctivitis has been reported in patients with influenza A (H7N7) and (H7N3) infections. In young children, gastrointestinal manifestations such as vomiting and diarrhea might be present. Infants may present with fever or apnea alone, without other respiratory symptoms, and should be evaluated if there is an otherwise increased suspicion of novel influenza.

*Updated lists of affected areas are provided at the Web sites of the OIE (http://www.oie.int/eng/en_index.htm), WHO (www.who.int/en/), and CDC (www.cdc.gov/flu/).

Box 4. Home Care Infection Control Guidance for Pandemic Influenza Patients and Household Members

Most patients with pandemic influenza will be able to remain at home during the course of their illness and can be cared for by family members or others who live in the household. Anyone who has been in the household with an influenza patient during the incubation period is at risk for developing influenza. A key objective in this setting is to limit transmission of pandemic influenza within and outside the home.

Management of influenza patients in the home

- Physically separate the patient with influenza from non-ill persons living in the home as much as possible.
- Patients should not leave the home during the period when they are most likely to be infectious to others (i.e., 5 days after onset of symptoms). When movement outside the home is necessary (e.g., for medical care), the patient should follow respiratory hygiene/cough etiquette (i.e., cover the mouth and nose when coughing and sneezing) and should wear a mask.

Management of other persons in the home

- Persons who have not been exposed to pandemic influenza and who are not essential for patient care or support should not enter the home while persons are still having a fever due to pandemic influenza.
- If unexposed persons must enter the home, they should avoid close contact with the patient.
- Persons living in the home with the patient with pandemic influenza should limit contact with the patient to the extent possible; consider designating one person as the primary care provider.
- Household members should be vigilant for the development of influenza symptoms. Consult with healthcare providers to determine whether a pandemic influenza vaccine, if available, or antiviral prophylaxis should be considered.

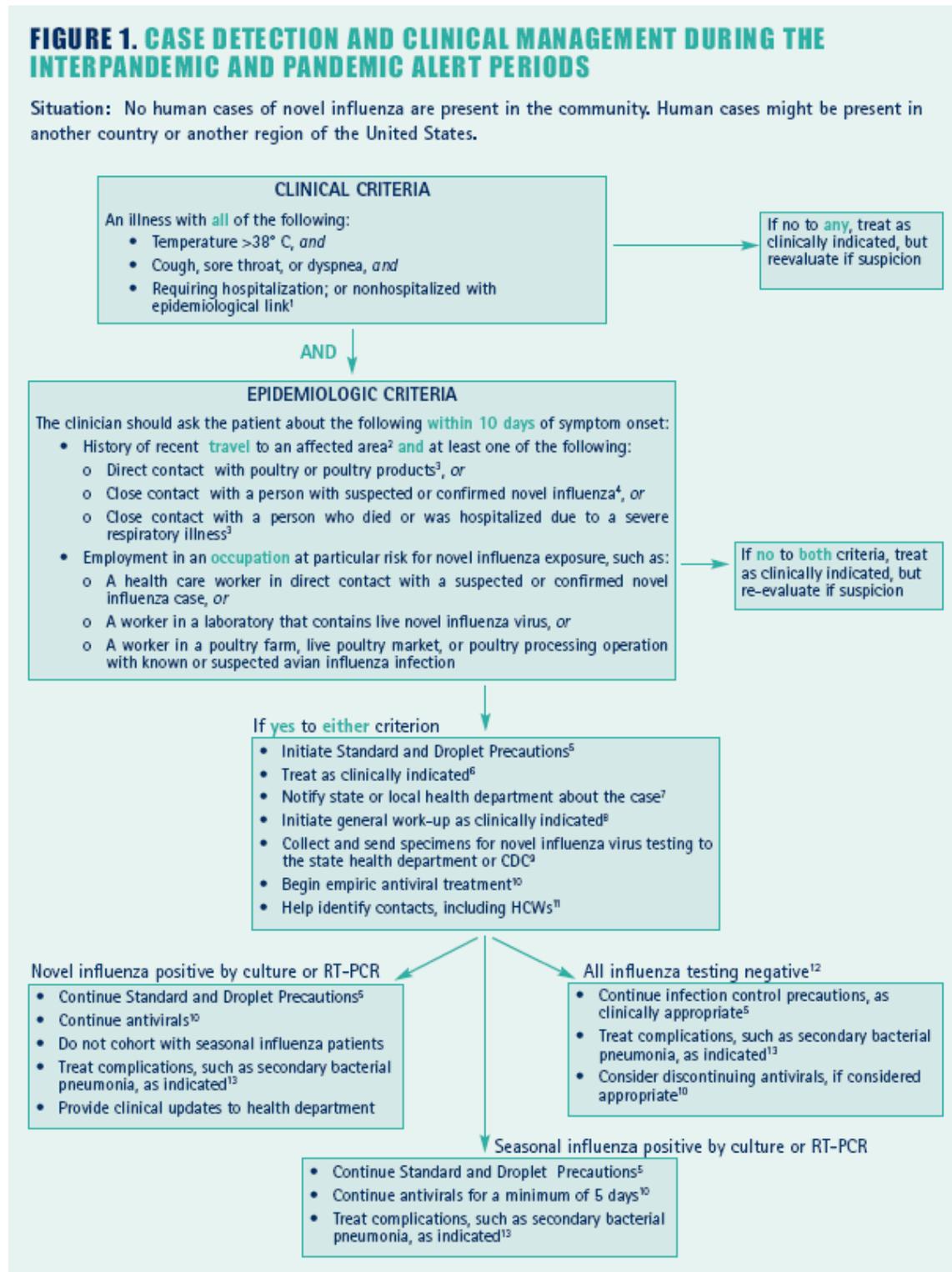
Infection control measures in the home

- All persons in the household should carefully follow recommendations for hand hygiene (i.e., hand washing with soap and water or use of an alcohol-based hand rub) after contact with an influenza patient or the environment in which they are receiving care.
- Although no studies have assessed the use of masks at home to decrease the spread of infection, using a surgical or procedure mask by the patient or caregiver during interactions may be beneficial.
- Soiled dishes and eating utensils should be washed either in a dishwasher or by hand with warm water and soap. Separation of eating utensils for use by a patient with influenza is not necessary.

Box 4. Home Care Infection Control Guidance for Pandemic Influenza Patients and Household Members – con.

- Laundry may be washed in a standard washing machine with warm or cold water and detergent. It is not necessary to separate soiled linen and laundry used by a patient with influenza from other household laundry. Care should be used when handling soiled laundry (i.e., avoid “hugging” the laundry) to avoid self-contamination. Hand hygiene should be performed after handling soiled laundry.
- Tissues used by the ill patient should be placed in a bag and disposed of with other household waste. Consider placing a bag for this purpose at the bedside.
- Environmental surfaces in the home should be cleaned using normal procedures

Figure 1. Case Detection and Clinical Management during the Interpandemic and Pandemic Alert Periods

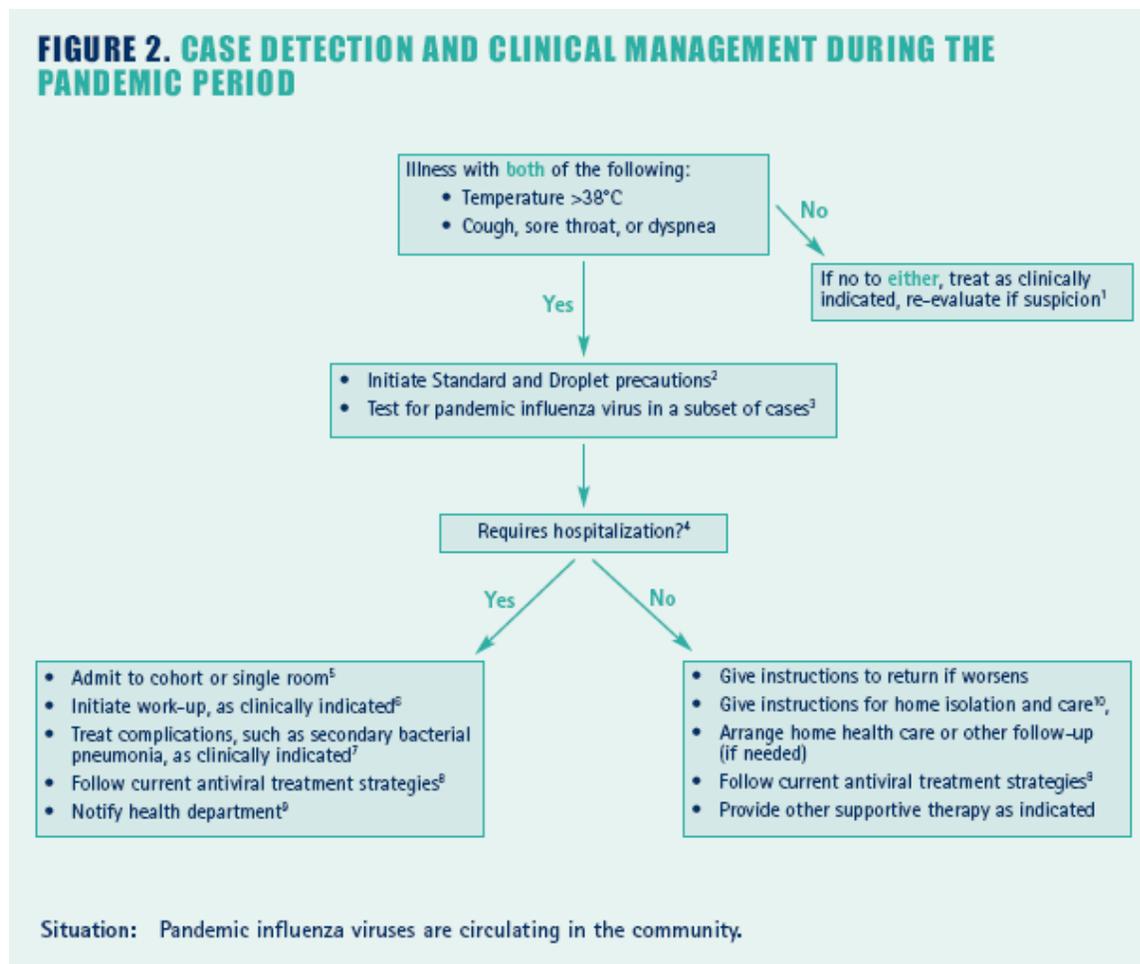


Footnotes to Figure 1:

1. Further evaluation and diagnostic testing should also be considered for outpatients with strong epidemiologic risk factors and mild or moderate illness. (See Box 2).
2. Updated information on areas where novel influenza virus transmission is suspected or documented is available on the CDC Web site at www.cdc.gov/travel/other/avian_flu_ah5n1_031605.htm and on the WHO Web site at www.who.int/en/.
3. For persons who live in or visit affected areas, close contact includes touching live poultry (well-appearing, sick or dead) or touching or consuming uncooked poultry products, including blood. For animal or market workers, it includes touching surfaces contaminated with bird feces. In recent years, most instances of human infection with a novel influenza A virus having pandemic potential, including influenza A (H5N1), are thought to have occurred through direct transmission from domestic poultry. A small number of cases are also thought to have occurred through limited person-to-person transmission or consumption of uncooked poultry products. Transmission of novel influenza viruses from other infected animal populations or by contact with surfaces contaminated with feces remains a possibility. These guidelines will be updated as needed if alternate sources of novel influenza viruses are suspected or confirmed.
4. Close contact includes direct physical contact, or approach within 3 feet (1 meter) of a person with suspected or confirmed novel influenza.
5. Standard and Droplet Precautions should be used when caring for patients with novel influenza or seasonal influenza (See Infection Control Supplement). Information on infection precautions that should be implemented for all respiratory illnesses (i.e., Respiratory Hygiene/Cough Etiquette) is provided at: www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm
6. Hospitalization should be based on all clinical factors, including the potential for infectiousness and the ability to practice adequate infection control. If hospitalization is not clinically warranted, and treatment and infection control is feasible in the home, the patient may be managed as an outpatient. The patient and his or her household should be provided with information on infection control procedures to follow at home (Box 3). The patient and close contacts should be monitored for illness by local public health department staff.
7. Guidance on how to report suspected cases of novel influenza is provided in Laboratory and Surveillance Supplement.
8. The general work-up should be guided by clinical indications. Depending on the clinical presentation and the patient's underlying health status, initial diagnostic testing might include:
 - Pulse oximetry
 - Chest radiograph
 - Complete blood count (CBC) with differential
 - Blood cultures
 - Sputum (in adults), tracheal aspirate, pleural effusion aspirate (if pleural effusion is present) Gram stain and culture
 - Antibiotic susceptibility testing (encouraged for all bacterial isolates)
 - Multivalent immunofluorescent antibody testing or PCR of nasopharyngeal aspirates or swabs for common viral respiratory pathogens, such as influenza A and B, adenovirus, parainfluenza viruses, and respiratory syncytial virus, particularly in children
 - In adults with radiographic evidence of pneumonia, *Legionella* and pneumococcal urinary antigen testing

- If clinicians have access to rapid and reliable testing (e.g., PCR) for *M. pneumoniae* and *C. pneumoniae*, adults and children <5 yrs with radiographic pneumonia should be tested.
 - Comprehensive serum chemistry panel, if metabolic derangement or other end-organ involvement, such as liver or renal failure, is suspected See Box 2 for additional details.
9. Guidelines for novel influenza virus testing can be found in Laboratory and Surveillance Supplement. All of the following respiratory specimens should be collected for novel influenza A virus testing: nasopharyngeal swab; nasal swab, wash, or aspirate; throat swab; and tracheal aspirate (for intubated patients), stored at 4° C in viral transport media; and acute and convalescent serum samples.
 10. Strategies for the use of antiviral drugs are provided in Vaccine and Antiviral Supplement.
 11. Guidelines for the management of contacts in a healthcare setting are provided in Healthcare Planning Supplement.
 12. Given the unknown sensitivity of tests for novel influenza viruses, interpretation of negative results should be tailored to the individual patient in consultation with the local health department. Novel influenza directed management may need to be continued, depending on the strength of clinical and epidemiologic suspicion. Antiviral therapy and isolation precautions for novel influenza may be discontinued on the basis of an alternative diagnosis. The following criteria may be considered for this evaluation:
 - Absence of strong epidemiologic link to known cases of novel influenza
 - Alternative diagnosis confirmed using a test with a high positive-predictive value
 - Clinical manifestations explained by the alternative diagnosis
 13. Guidance on the evaluation and treatment of suspected post-influenza community-associated pneumonia is provided in Appendix 3.

Figure 2. Case Detection and Clinical Management during the Pandemic Period



Footnotes to Figure 2:

1. Antiviral therapy and isolation precautions for pandemic influenza should be discontinued on the basis of an alternative diagnosis only when both the following criteria are met:
 - Alternative diagnosis confirmed using a test with a high positive-predictive value, and
 - Clinical manifestations entirely explained by the alternative diagnosis
2. Standard and Droplet Precautions should be used when caring for patients with novel influenza or seasonal influenza (Table 4 in Infection Control Supplement). Information on infection precautions that should be implemented for all respiratory illnesses (i.e., Respiratory Hygiene/Cough Etiquette) is provided at: www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm
3. Guidance on laboratory testing during the Pandemic Period can be found in Laboratory and Surveillance Supplement. Generally, specimens should include respiratory samples (e.g., nasopharyngeal wash/aspirate; nasopharyngeal, nasal or oropharyngeal swabs, or tracheal aspirates) stored at 4°C in viral transport media.

Routine laboratory confirmation of clinical diagnoses will be unnecessary as pandemic activity becomes widespread in a community. CDC will continue to work with state health laboratories to conduct virologic surveillance to monitor antigenic changes and antiviral resistance in the pandemic virus strains throughout the Pandemic Period.

4. The decision to hospitalize should be based on a clinical assessment of the patient and the availability of hospital beds and personnel.
5. Guidelines on cohorting can be found in Infection Control Supplement. Laboratory confirmation of influenza infection is recommended when possible before cohorting patients.
6. The general work-up should be guided by clinical indications. Depending on the clinical presentation and the patient's underlying health status, initial diagnostic testing might include:
 - Pulse oximetry
 - Chest radiograph
 - Complete blood count (CBC) with differential
 - Blood cultures
 - Sputum (in adults) or tracheal aspirate Gram stain and culture
 - Antibiotic susceptibility testing (encouraged for all bacterial isolates)
 - Multivalent immunofluorescent antibody testing of nasopharyngeal aspirates or swabs for common viral respiratory pathogens, such as influenza A and B, adenovirus, parainfluenza viruses, and respiratory syncytial virus, particularly in children
 - In adults with radiographic evidence of pneumonia, *Legionella* and pneumococcal urinary antigen testing
 - If clinicians have access to rapid and reliable testing (e.g., PCR) for *M. pneumoniae* and *C. pneumoniae*, adults and children <5 yrs with radiographic pneumonia should be tested.
 - Comprehensive serum chemistry panel, if metabolic derangement or other end-organ involvement, such as liver or renal failure, is suspected See Box 2 for additional details.
7. Guidance on the evaluation and treatment of community acquired pneumonia and suspected post-influenza community-acquired bacterial pneumonia are provided in Appendix 3.
8. Strategies for the use of antiviral drugs are provided in Vaccine and Antiviral Supplement.
9. Guidance on the reporting of pandemic influenza cases is found in Laboratory and Surveillance Supplement.
10. Patients with mild disease should be provided with standardized instructions on home management of fever and dehydration, pain relief, and recognition of deterioration in status. Patients should also receive information on infection control measures to follow at home (Box 4). Patients cared for at home should be separated from other household members as much as possible. All household members should carefully follow recommendations for hand hygiene, and tissues used by the ill patient should be placed in a bag and disposed of with other household waste. Infection within the household may be minimized if a primary caregiver is designated; ideally, someone who does not have an underlying condition that places them at increased risk of severe influenza disease. Although no studies have assessed the use of masks at home to decrease the spread of infection, using a surgical or procedure mask by the patient or caregiver during interactions may be beneficial. Separation of eating utensils for use by a patient with influenza is not necessary, as long as they are washed with warm water and soap. Additional information on measures to limit the spread of pandemic influenza in the home and community can be found in Infection Control and Disease Transmission Supplements.

Figure 3. Management of Community-Acquired Pneumonia during an Influenza Pandemic: Adults

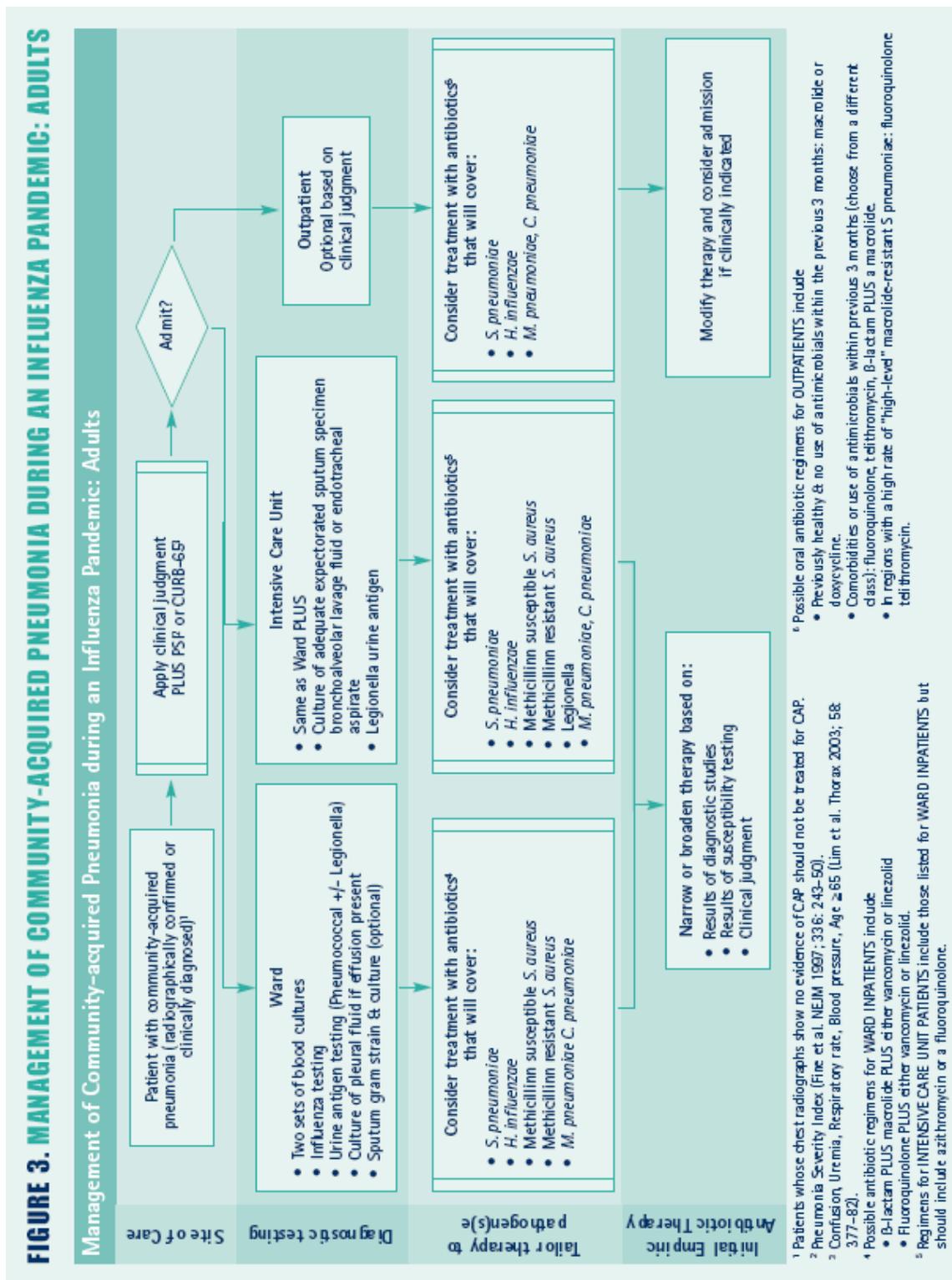
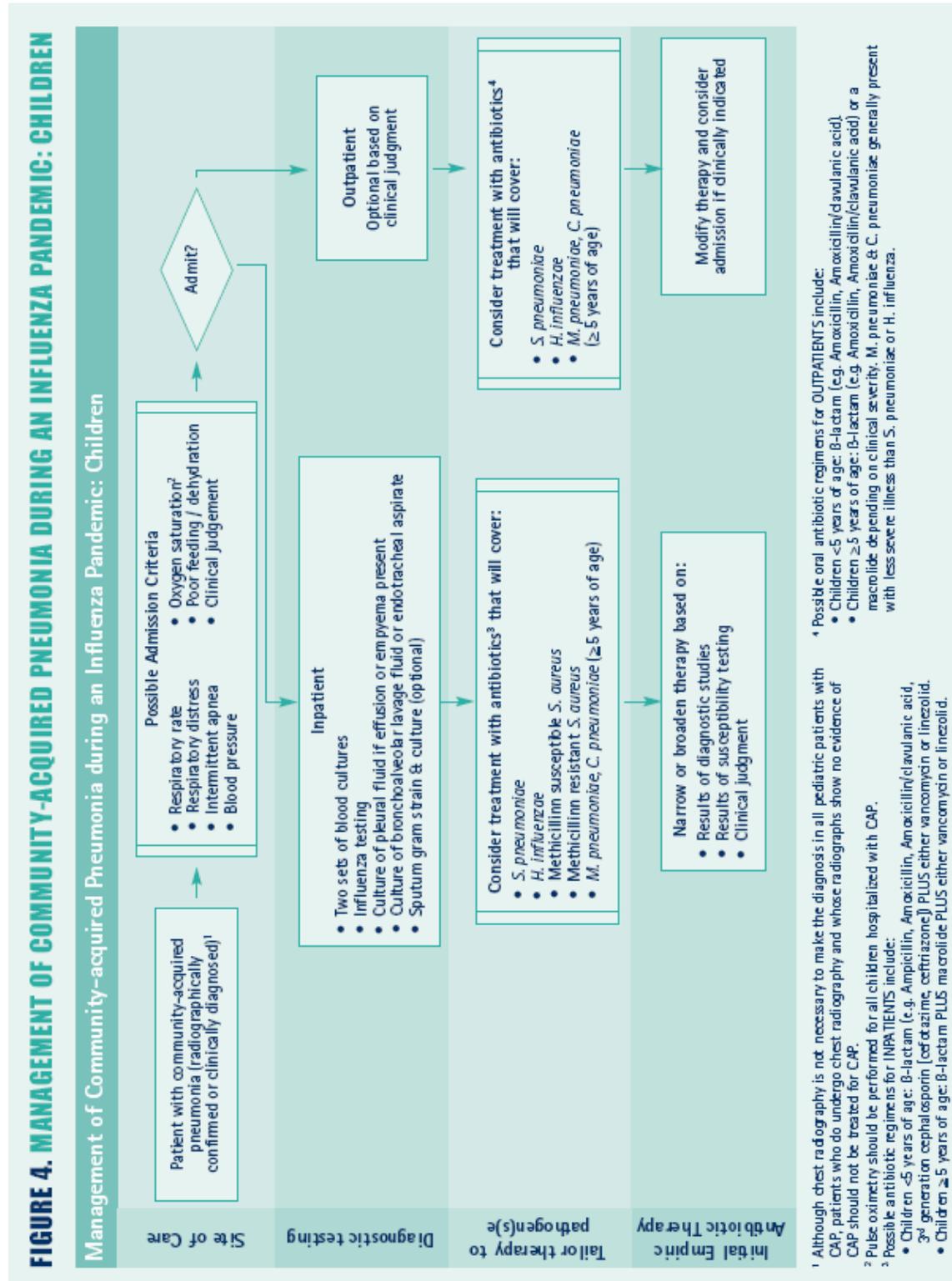


Figure 4: Management of Community Acquired Pneumonia during an Influenza Pandemic: Children



Appendix 1.

Clinical Presentation and Complications of Seasonal Influenza

Although often quite characteristic, the clinical picture of seasonal influenza can be indistinguishable from illness caused by other respiratory infections. The frequent use of non-specific terms such as "flu" and "influenza-like illness" makes the clinical diagnosis of influenza even more indefinite. Even when the diagnosis of influenza is confirmed, management can be challenging, as influenza virus infection can result in subclinical infection, mild illness, uncomplicated influenza, or exacerbation of underlying chronic conditions to fulminant deterioration, and can result in a wide variety of complications.

This appendix provides a brief description of the common presentations and complications of seasonal human influenza. Novel and pandemic influenza viruses might, however, cause quite different clinical syndromes than seasonal influenza. For instance, seasonal influenza-related complications more commonly affect those at the extremes of age, whereas previous pandemics resulted in disproportionate morbidity and mortality in young and previously healthy adults. It will be essential to describe and disseminate the clinical features of novel or pandemic influenza cases as soon as they are identified.

Presentation of Seasonal Influenza

- A typical case of uncomplicated seasonal influenza begins abruptly and is manifested by systemic symptoms such as fever, chills, myalgias, anorexia, headache, and extreme fatigue. Fever typically lasts 2–3 days and usually reaches 38–40°C, but can be higher (particularly in children).
- Respiratory tract symptoms such as nonproductive cough, sore throat, and upper respiratory congestion occur at the same time, although these may be overshadowed by systemic complaints.
- Physical examination typically reveals fever, weakness, mild inflammation of the upper respiratory tract, and rare crackles on lung examination, but none of these findings is specific for influenza.
- In uncomplicated illness, major symptoms typically resolve after a limited number of days, but cough, weakness, and malaise can persist for up to 2 weeks.
- In the elderly and in infants, the presenting signs can include respiratory symptoms with or without fever, fever only, anorexia only, lassitude, or altered mental status. In children, fevers are often higher than in adults and can lead to febrile seizures. Gastrointestinal manifestations (e.g., vomiting, abdominal pain, and diarrhea) occur more frequently in children. Fever or apnea without other respiratory symptoms might be the only manifestations in young children, particularly in neonates.

At times, influenza can be difficult to distinguish from illnesses caused by other respiratory pathogens on the basis of symptoms alone. Fever and cough, particularly in combination, are modestly predictive of influenza in unvaccinated adults, as is the combination of fever, cough, headache, and pharyngitis in children.

Other constitutional signs and symptoms, such as chills, rigors, diaphoresis, and myalgias, are also suggestive. The positive predictive value of any clinical definition is strongly dependent on the level of influenza activity and the presence of other respiratory pathogens in the community.

Routine laboratory findings for seasonal influenza

No routine laboratory test results are specific for influenza. Leukocyte counts are variable. Severe leukopenia and thrombocytopenia have been described in fulminant cases. Leukocytosis of >15,000 cells/mL should raise suspicion for a secondary bacterial process. Comprehensive laboratory testing might reveal other influenza-related complications (see Complications below).

Differential diagnosis

The fever and respiratory manifestations of seasonal influenza are not specific and can occur with several other pathogens, such as respiratory syncytial virus (RSV), parainfluenza viruses, adenoviruses, human metapneumovirus, rhinoviruses, coronaviruses, and *Mycoplasma pneumoniae*.

In contrast to influenza, most of these pathogens do not usually cause severe disease, particularly in previously healthy adults. However, RSV and parainfluenza viruses can lead to severe respiratory illness in young children and the elderly and should be considered in the differential diagnosis if circulating in the community. Even if an alternate etiology is determined, viral or bacterial co-infections can still be a possibility.

Often the clinician can diagnose seasonal influenza with reasonable certainty in the absence of laboratory testing due to the tendency for influenza to occur in community epidemics and to affect persons of all ages. Nevertheless, a definitive diagnosis requires laboratory testing.

Rapid influenza diagnostic tests and immunofluorescence testing using a panel of respiratory pathogens aid in the clinical management of patients with suspected influenza. Further information on diagnostic testing for influenza can be found at <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>.

Complications

Groups at risk for complications of influenza

The following groups are currently recognized to be at higher risk for complications of seasonal influenza (e.g., hospitalization; death) compared to healthy older children and younger adults (see Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005; 54: 1-40 <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5408a1.htm>).

- Persons aged 65 years and older
- Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions
- Adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma
- Adults and children who required regular medical follow-up or hospitalization during the previous year because of chronic metabolic diseases (including diabetes mellitus), renal

dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by infection with human immunodeficiency virus [HIV])

- Children and adolescents (aged 6 months–18 years) who are receiving long-term aspirin therapy (and are therefore at risk for Reye syndrome)
- Pregnant women
- All children aged <2 years
- All persons with conditions that can compromise respiratory function or the handling of respiratory secretions, or that can increase the risk of aspiration

Excluding the last group, in 2003 approximately 85 million persons in the United States belonged to one or more of these target groups.

Types of influenza complications

1. Respiratory exacerbations. Worsening of underlying chronic diseases are the most common serious complications of influenza. Complications are frequently related to underlying respiratory disease, such as chronic obstructive pulmonary disease (COPD). In some cases, typical influenza symptoms might be brief or minimal compared to the exacerbation of the underlying disease, particularly in the elderly.
2. Secondary bacterial pneumonia. This common complication is characterized by an initial improvement in influenza symptoms over the first few days followed by a return of fever, along with a productive cough and pleuritic chest pain. Findings include lobar consolidation on chest x-ray and, in adults, sputum smears positive for leukocytes and bacteria. The most commonly isolated pathogens are *Streptococcus pneumoniae*, *Staphylococcus aureus*, group A Streptococcus, and *Haemophilus influenzae*.
3. Primary influenza viral pneumonia. A prominent feature of previous influenza pandemics, primary influenza viral pneumonia is currently a relatively rare outcome of seasonal influenza in adults. In contrast, children with pneumonia are more likely to have a viral etiology, including influenza than a bacterial cause. Primary influenza pneumonia usually begins abruptly, with rapid progression to severe pulmonary disease within 1–4 days. Physical and radiologic findings are consistent with diffuse interstitial and/or alveolar disease, including bilateral inspiratory crackles on auscultation and diffuse pulmonary infiltrates on chest radiographs. Hypoxia and hemoptysis indicate a poor prognosis, and recovery can take up to 1–2 weeks.
4. Mixed viral-bacterial pneumonia. This is slightly more common than primary viral pneumonia, and, although mixed pneumonia may have a slower progression, the two are often indistinguishable. Bacterial pathogens in mixed infections are similar to those found in secondary bacterial pneumonias.
5. Bronchiolitis due to influenza. This occurs more commonly in children, with a clinical picture similar to that of RSV or parainfluenza virus infections.
6. Croup. Influenza can cause croup (laryngotracheobronchitis) in children, and, although influenza viruses are a less common etiology than other respiratory viruses, the illness can be more severe.

7. Otitis media & sinusitis. Children with influenza can also develop otitis media, due to either direct viral infection or secondary bacterial involvement. Similarly, bacterial sinusitis can develop in older children and adults with influenza.
8. Cardiovascular complications. A range of cardiovascular problems can occur, most commonly as an exacerbation of an underlying condition such as congestive heart failure. Pregnant women and children with congenital heart defects can also experience worsening cardiac function during an influenza illness. Cardiac inflammation, such as myocarditis and pericarditis, can be found occasionally, although clinical manifestations are rare. Available reports suggest that myocarditis might have occurred more frequently during pandemic years. Influenza virus is not typically identified in heart tissue, suggesting that the host inflammatory response might play a role. Although influenza has been associated in rare instances with sudden death possibly due to cardiac arrhythmia, this outcome has been difficult to investigate.
9. Gastrointestinal symptoms. Gastrointestinal involvement is uncommon in adults with seasonal influenza; it is more commonly reported in children. Manifestations can include vomiting and diarrhea, sometimes leading to significant dehydration. Transient hepatic inflammation can occur in rare circumstances.
10. Myositis related to influenza. This is another complication more commonly found in children. It is also more frequently associated with influenza B than with influenza A. Involvement may be limited to pain and weakness of the lower extremities but sometimes can progress to rhabdomyolysis and renal failure.
11. Encephalopathy. Influenza-associated encephalopathy, characterized by an acute alteration in mental status within the first few days of fever onset, is a recently recognized complication of influenza in children. Most reports of influenza-associated encephalopathy have been in Japanese children, but the condition has been reported sporadically in other countries, including the United States. The syndrome can include seizures, neurologic deficits, obtundation, and coma. While most children recover completely, some cases can result in permanent sequelae or death. This condition might be due to an abnormal host inflammatory response without viral infection of the central nervous system.
12. Other neurologic complications. Uncomplicated self-limited febrile seizures can occur with high fever, usually occurring in younger children. Guillain-Barré syndrome and transverse myelitis have been reported to occur in very rare instances after influenza, but no definite etiologic relationship has been established.
13. Reye syndrome. This is characterized by an acute encephalopathy combined with hepatic failure in the absence of inflammation in either the brain or the liver. Hepatic involvement includes fatty infiltration, hypoglycemia, and hyperammonemia, whereas neurologic manifestations include cerebral edema, delirium, coma, and respiratory arrest. Reye syndrome was found to be associated with the use of aspirin in children; its incidence has decreased dramatically since the 1980s after aspirin use was discouraged in children.

14. Systemic complications. Seasonal influenza can be associated with systemic symptoms, such as sepsis and shock. Sepsis caused by invasive co-infection with *Staphylococcus aureus*, including methicillin-resistant *S. aureus* (MRSA), or other bacteria, such as *Neisseria meningitidis*. Toxic shock syndrome with bacterial co-infection has also been reported.

Appendix 2.

Clinical Presentation and Complications of Illnesses Associated With Avian Influenza A (H5N1) and Previous Pandemic Influenza Viruses

Human infections with different avian influenza A viruses have emerged and caused mild to severe illness in recent years, including H9N2, H7N7, H7N3, and H7N2. One novel subtype, influenza A (H5N1), has repeatedly caused limited outbreaks of severe and fatal human disease in recent years and therefore has been of particular concern.

Human infection with avian influenza A (H5N1)

The H5N1 subtype first came to widespread public attention in 1997, when a poultry outbreak of highly pathogenic avian influenza A (H5N1) in Hong Kong caused illness in 18 humans. These cases were the first identified instances of direct avian-to-human transmission of an avian influenza A virus that led to severe disease.

Clinical features ranged from asymptomatic infection or mild upper respiratory symptoms to severe pneumonia and death. Most cases presented with fever, headache, malaise, myalgia, sore throat, cough, and rhinorrhea; a few persons also had conjunctivitis or gastrointestinal distress. Seven persons, mostly children, developed only mild upper respiratory infections, whereas 11 developed severe primary viral pneumonia with rapid deterioration. Most patients in this latter group developed lymphopenia; six developed acute respiratory distress syndrome (ARDS), and five developed multi-organ system failure. Other abnormalities included pulmonary hemorrhage, renal dysfunction, liver failure, pancytopenia, hemophagocytosis, and Reye syndrome (with aspirin ingestion). Notably, none of the patients had secondary bacterial pneumonia. Six of the 18 infected persons eventually died.

Avian influenza A (H5N1) resurfaced in Hong Kong in February 2003, in a father and son returning from Fujian Province, China. Both presented with influenza-like symptoms, chest radiograph abnormalities, and lymphopenia. The father's status rapidly deteriorated, and he developed severe lung involvement and hemophagocytosis; the 8-year-old son recovered. Of note, the father's 7-year-old daughter had also died of a pneumonia-like illness while in China, but the cause of her illness was not determined. The boy reported close contact with live chickens during his visit to China, but no definite source for H5N1 was found.

The most recent human outbreak of avian influenza A (H5N1) has been ongoing since December 2003. This outbreak has been associated with an extensive H5N1 epizootic among poultry in Asia. Transmission continues to be predominantly from birds to humans, although a few instances of limited human-to-human transmission have been suspected.

Reports published from Vietnam and Thailand describe the early confirmed H5N1 cases from this outbreak. These reports characterize human illness with avian influenza A (H5N1) virus infection as a primarily respiratory febrile illness that progresses to severe disease in a high proportion of cases. Among 10 Vietnamese patients,¹ all were previously healthy children or young adults (mean age, 13.7 years) who presented to medical attention with fever, cough, and dyspnea. None of the patients had other respiratory symptoms, such as sore throat or rhinorrhea, but seven developed diarrhea. Significant lymphopenia was observed in all 10 cases, and moderate thrombocytopenia occurred. All 10 had marked abnormalities on chest radiograph, and eight patients—all of whom eventually died—required mechanical ventilation for respiratory failure. Respiratory cultures suggested bacterial pneumonia in two patients.

Of 12 cases described from Thailand,² seven were aged <14 years, and all but one were previously healthy. All of the patients developed fever, cough, and dyspnea, and six patients were reported with myalgia and diarrhea. Decreased leukocyte counts were reported in seven cases, thrombocytopenia occurred in four cases, and increased serum liver enzymes were found in eight. All patients had negative blood cultures. They all had abnormal chest radiographs; nine developed respiratory failure with ARDS, whereas five developed cardiac failure, four had renal failure, and eight ultimately died. In the Vietnamese and Thai cases, respiratory deterioration occurred a median of 5 days after symptom onset, but the range was quite wide.

Whereas all patients described above presented with pulmonary symptoms, subsequently published case reports suggest that other clinical syndromes can occur with H5N1 infection.^{3,4,5} In one report, a 39-year-old female with confirmed H5N1 from Thailand was initially admitted with symptoms of fever, vomiting, and diarrhea, and was found to have significant lymphopenia. She developed shortness of breath approximately 12 days after illness onset and soon progressed to ARDS and death.

A 4-year-old male from Vietnam presented for medical attention with severe diarrhea, developed acute encephalitis with coma, and died soon thereafter. Although avian influenza A (H5N1) was later detected in throat, stool, serum, and cerebrospinal fluid specimens, the patient had no respiratory symptoms at presentation. This patient's 9-year-old sister died of a similar illness a few days before his illness began, but no H5N1 testing was performed. Asymptomatic H5N1 infection, detected by seroconversion, has been reported. Updated information on avian influenza can be found at http://www.who.int/csr/disease/avian_influenza/en/.

Illnesses associated with previous pandemic viruses
Since most people do not have previous immunity to novel influenza A viruses, an influenza pandemic results in an increased rate of severe disease in a majority of age groups. Nevertheless,

¹ Tran TH, Nguyen TL, Nguyen TD, Luong TS, Pham PM, Nguyen VC, et al. Avian influenza A (H5N1) in 10 patients in Vietnam. *N Engl J Med*. 2004;350:1179-88.

² Chotpitayasunondh T, Ungchusak K, Hanshaoworakul W, Chunsuthiwat S, Sawanpanyalert P, Kijphati R, et al. Human disease from influenza A (H5N1), Thailand, 2004. *Emerg Infect Dis*. 2005;11:201-9.

^{3,4,5} de Jong MD, Bach VC, Phan TQ, Vo MH, Tran TT, Nguyen BH, et al. Fatal avian influenza A (H5N1) in a child presenting with diarrhea followed by coma. *N Engl J Med*. 2005;352:686-91.

Apisarnthanarak A, Kitphati R, Thongphubeth K, Patoomanunt P, Anthanont P, Auwanit W, et al. Atypical avian influenza (H5N1). *Emerg Infect Dis* 2004;10:1321-4

Beigel JH, Farrar J, Hayden FG, Hyer R, de Jong MD, Lochindrat S, et al. Avian influenza A (H5N1) infection in humans. *N Eng J Med*. 2005 Sep 29;353(13):1374-85.

the three pandemics of the past century demonstrated significant variability in terms of morbidity.

The 1918–19 pandemic was particularly notable in affecting young, healthy adults with severe illness. A significant proportion of patients developed fulminant disease, accompanied by a striking perioral cyanosis, leading to death within a few days. Postmortem examinations in these patients frequently revealed denuding tracheobronchitis, pulmonary hemorrhage, or pulmonary edema. Others survived the initial illness, only to die of a secondary bacterial pneumonia, usually due to *Streptococcus pneumoniae*, *Staphylococcus aureus*, group A Streptococcus, or *Haemophilus influenzae*.

The clinical features of the subsequent pandemics of 1957–58 and 1968–69 were also typical of influenza-like illness, including fever, chills, headache, sore throat, malaise, cough, and coryza, but were milder compared to the 1918–19 pandemic. On a population level, the impact of influenza in 1957–58 was only one-tenth that observed in 1918–19, and the excess death rate in 1968–69 was only half that observed during 1957–58. However, death rates were elevated among the chronically ill and the elderly, and the occurrence of severe complications, such as primary viral pneumonia, was notably increased in healthy young adults during the 1957–58 pandemic, particularly in pregnant women.

Implications for the next pandemic

The characteristic clinical features of the next influenza pandemic cannot be predicted. It is reasonable to assume that most affected persons will have the typical features of influenza (e.g., fever, respiratory symptoms, myalgia, malaise). However, past pandemics have varied considerably with regard to severity and associated complications.

Illnesses caused by novel influenza viruses such as avian influenza A (H5N1) might predict the potential characteristics of pandemic influenza, but H5N1 has not adapted to spread easily among humans, and its presentation and severity might change as the virus evolves. Even as the next pandemic begins and spreads, the characteristic features might change, particularly if successive waves occur over several months.

Given this potential for a dynamic clinical picture, it will be important for clinicians and public health partners to work together to disseminate updated and authoritative information to the healthcare community on a regular basis.

Appendix 3.

Guidelines For Management of Community-Acquired Pneumonia, Including Post-Influenza Community-Acquired Pneumonia

Rationale

Post-influenza bacterial community-acquired pneumonia will likely be a common complication during the next pandemic and might affect approximately 10% of persons with pandemic influenza, based on data from previous influenza pandemics. Assuming that pandemic influenza will affect about 15%–35% of the U.S. population, approximately 4.4 to 10.2 million cases of post-influenza bacterial community-acquired pneumonia could occur.

Post-influenza bacterial community-acquired pneumonia often presents as a return of fever, along with a productive cough and pleuritic chest pain, after an initial improvement in influenza symptoms over the first few days. Findings include lobar consolidation on chest x-ray and, in adults, sputum smear positive for leukocytes and bacteria. As with other bacterial infections, leukocytosis with increased immature forms may be present, but this finding is neither sensitive nor specific.

The most common etiologies of post-influenza bacterial pneumonia are *Streptococcus pneumoniae*, *Staphylococcus aureus*, group A Streptococcus, and *Haemophilus influenzae*.

Primary viral pneumonia, with abrupt onset and rapid progression, is more common than bacterial pneumonia in children, yet rare in adults. Physical and radiologic findings in viral pneumonia are consistent with interstitial and/or alveolar disease and include bilateral inspiratory crackles and diffuse infiltrates.

Mixed viral-bacterial pneumonia is slightly more common than primary viral pneumonia, but they are often indistinguishable. Bacterial pathogens in mixed infections are similar to those found in secondary bacterial pneumonias.

Droplet and Standard Precautions are currently recommended for community-acquired pneumonia of bacterial etiology.¹

Treatment of community-acquired pneumonia, including post-influenza bacterial community-acquired pneumonia will pose challenges for clinicians during a pandemic. Secondary bacterial pneumonia following influenza virus infection will be difficult to distinguish from community-acquired pneumonia that is not preceded by influenza.

Current guidelines for the treatment of adult community-acquired pneumonia (CAP) during the Interpandemic Period de-emphasize the use of diagnostic testing for pathogen-directed treatment and favor empiric therapy with safe and effective broad-spectrum antibacterials, especially extended-spectrum macrolides and fluoroquinolones. However, these antibacterials will likely be in short supply during a pandemic.

¹ Centers for Disease Control and Prevention. Guidelines for preventing health-care-associated pneumonia, 2003 recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. *Respir Care*. 2004;49(8):926-39.

The guidelines in this appendix are therefore designed to assist clinicians in managing patients with community-acquired pneumonia, including post-influenza bacterial community-acquired pneumonia, in a setting of high patient volume and limited clinical resources, where the pressure to treat empirically will likely be even greater than during the Interpandemic Period.

These recommendations are from the November 2005 HHS Pandemic Influenza Plan (<http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>).

For adults, the guidance draws heavily from the current draft guidelines for the management of CAP developed jointly by the Infectious Diseases Society of America (IDSA)² and the American Thoracic Society (ATS).³ For children, the guidance incorporates recommendations from the British Thoracic Society (BTS),⁴ a published review⁵ and expert opinions

Prevention

Preventing pneumococcal pneumonia by maximizing vaccination coverage against *Streptococcus pneumoniae for at risk individuals* is important during the Interpandemic, Pandemic Alert, and Pandemic Periods. Current guidelines on the use of the 23-valent pneumococcal polysaccharide vaccine among adults⁶ and the 7-valent pneumococcal conjugate vaccine among children⁷ are available.

Site of care: inpatient versus outpatient

Adults

IDSA-ATS draft guidelines recommend the use of severity scores, such as the Pneumonia PORT Severity Index (PSI) and the CURB-65 system, to determine which patients can be safely treated as outpatients (Tables 2–5). The use of these or other similar systems could be extremely important during the next pandemic, as hospital beds will be in short supply. However, these systems should be used as guidance and not replace the judgment of the individual clinician.

Children

Current guidelines provide indicators for hospitalization of children with CAP. For infants, the indications include temperature >38.5 C, respiratory rate (RR) >70 breaths per minute, chest retractions (indrawing), nasal flaring, hypoxia, cyanosis, intermittent apnea, grunting, and poor feeding. Indications for hospitalization among older children include temperature >38.5 C, RR >50, chest retractions, nasal flaring, hypoxia, cyanosis, grunting, and signs of dehydration.

As with pandemic influenza, the decision to hospitalize for post-influenza bacterial community-acquired pneumonia during the Pandemic Period will rely on the physician's clinical assessment of the patient as well as availability of personnel and hospital resources. Although an unstable

² Mandell LA, Bartlett JG, Dowell SF, File TM Jr, Musher DM, Whitney C; Infectious Diseases Society of America. Update of practice guidelines for the management of community-acquired pneumonia in immunocompetent adults. *Clin Infect Dis*. 2003; 37(11):1405-33.

³ Niederman MS, Mandell LA, Anzueto A, Bass JB, Broughton WA, Campbell GD, et al. American Thoracic Society. Guidelines for the management of adults with community-acquired pneumonia. Diagnosis, assessment of severity, antimicrobial therapy, and prevention. *Am J Respir Crit Care Med*. 2001;163(7):1730-54.

⁴ British Thoracic Society Standards of Care Committee. British Thoracic Society guidelines for the management of community acquired pneumonia in childhood. *Thorax*. 2002;57(suppl 1):i1-24.

⁵ McIntosh, K. Community-acquired pneumonia in children. *N Engl J Med*. 2002;346:429-37.

⁶ CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 1997;46(RR-8).

⁷ Prevention of pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep*. 2000;49(RR-9).

patient will be considered a high priority for admission, patients with certain high-risk conditions (see Appendix 1) might also warrant special attention. Home management with follow-up might be appropriate for well-appearing young children with fever alone.

Diagnostic testing

Adults

Generally, the etiologies associated with CAP during the Interpandemic Periods will continue to occur during a pandemic. Familiarity with the appropriate use of available diagnostic tests is therefore a key feature of clinical preparedness.

1. Look for *S. pneumoniae* and *S. aureus*. Draft IDSA-ATS guidelines recommend obtaining appropriate specimens for etiologic diagnosis whenever such an etiology would alter clinical care. Since the most common etiologies of post-influenza bacterial community-acquired pneumonia [*S. pneumoniae* and *S. aureus*, including community-acquired methicillin-resistant *S. aureus* (CA-MRSA)] are treated differently, diagnostic testing should be performed to the extent feasible to distinguish among these pathogens.
2. Do additional tests for hospitalized patients.
 - a. Blood cultures, pneumococcal urine antigen testing, and pleural fluid aspiration with Gram stain and culture should be considered.
 - b. Since sputum Gram stain and culture is highly dependent on patient and technical conditions, these are considered optional for hospitalized but non-severe patients.
 - c. For patients admitted to an ICU, consider aspiration of endotracheal secretions for Gram stain and bacterial culture.

Children

Diagnostic studies for identifying bacterial pneumonia in young children are severely limited.

1. Blood cultures should be obtained from all children suspected of having post-influenza bacterial community-acquired pneumonia.
2. Sputum samples are rarely useful in children. However, if tracheal or pleural fluid aspirates are available, they should be submitted for Gram stain and bacterial culture.
3. If pleural effusions are present, they should be aspirated and submitted for Gram stain and culture.
4. Test antibiotic susceptibility testing of any bacterial isolates to direct treatment, where feasible.

Antibiotic treatment

Adults

and

children

Antibiotics will likely be in short supply during the Pandemic Period, particularly those needed to treat CAP. Therefore, use of empiric therapy for all persons with post-influenza bacterial community-acquired pneumonia may not be feasible.

1. Antimicrobial therapy is best managed by culture and susceptibility testing of appropriate clinical specimens, and by awareness of local antibiotic susceptibility patterns. (See Figures 1 and 2 for additional clinical management algorithms and information.)
2. A history of a preceding influenza-like illness, especially when pandemic influenza is circulating in the community, might help to select those patients more likely to have viral rather than bacterial respiratory infection.
3. Empiric therapy should be directed toward the most likely etiologies of post-influenza bacterial community-acquired pneumonia.

4. Concurrent antiviral treatment should also be considered, depending on the timing and presentation of illness, the clinical status of the patient, and the availability of antivirals (see Vaccine and Antiviral Supplement).

**Clinical Guidelines Supplement. Appendix 3. Table 2.
Pneumonia PORT Severity Index (PSI) Calculation**

| Patient Characteristic | | Points Assigned |
|--|--------|---|
| Demographic Factor | | |
| Male | Female | Age Number of years Number of years–10 |
| Nursing home resident | | +10 |
| Comorbid illnesses | | |
| Neoplastic disease | | +30 |
| Liver disease | | +20 |
| Congestive heart failure | | +10 |
| Cerebrovascular disease | | +10 |
| Renal disease | | +10 |
| Physical examination finding | | |
| Altered mental status | | +20 |
| Respiratory rate >30 breaths/minute | | +20 |
| Systolic blood pressure <90 mm Hg | | +20 |
| Temperature <35 C or >40 C | | +15 |
| Pulse >125 beats/minute | | +10 |
| Laboratory and /or radiographic finding | | |
| Arterial pH <7.35 | | +30 |
| Blood urea nitrogen >30 mg/dl | | +20 |
| Sodium <130mmol/l | | +20 |
| Glucose >250 mg/dl | | +10 |
| Hematocrit <30% | | +10 |
| <90% by pulse oximetry <60mm Hg by arterial blood gas | | Hypoxemia: OR+10 |
| Pleural effusion on baseline radiograph | | +10 |

**Clinical Guidelines Supplement. Appendix 3. Table 3.
Pneumonia Severity Index Risk Classification**

| PSI Risk Class | Characteristics and Points | Recommended Site of Care |
|----------------|--|------------------------------|
| I | Age >50 years + no comorbid conditions, normal range vital signs, normal mental status | Outpatient |
| II | <70 | Outpatient |
| III | 71–90 | Outpatient / Brief inpatient |
| IV | 91–130 | Inpatient |
| V | 130 | Inpatient |

**Clinical Guidelines Supplement5. Appendix 3. Table 4.
CURB-65 Scoring System**

| Characteristic | Points |
|--|--------|
| Confusion ¹ | +1 |
| Urea >7mmol/l (20mg/dl) | +1 |
| Respiratory rate >30 breaths per minute | +1 |
| Blood pressure (Systolic <90 or diastolic <60 mm Hg) | +1 |
| Age >65 years | +1 |

1 Based on a specific mental test or disorientation to person, place, or time.

**Clinical Guidelines Supplement. Appendix 3. Table 5.
Recommended site of care based on CURB-65 system**

| Number of Points | Recommended Site of Care |
|------------------|------------------------------|
| 0–1 | Outpatient |
| 2 | Admit to medical ward |
| 3–5 | Admit to medical ward or ICU |

Appendix 4. Clinician Fact Sheet: Influenza

Epidemiology

- **Human** disease is caused by influenza A or influenza B viruses
- Ongoing minor antigenic changes require yearly vaccination in the fall
- Knowing the currently circulating strain aids in decisions regarding antiviral treatment and prophylaxis

Clinical Presentation

- High fever, chills, prostration, muscle aches, sore throat, coryza, cough; at times, also vomiting and diarrhea

Differential Diagnosis

- Febrile respiratory illnesses such as bacterial pneumonia, mycoplasma, adenovirus, avian influenza (e.g. influenza A H5N1), and SARS

Laboratory

- Rapid testing of nasopharyngeal swabs for influenza
- Consider NP swab for respiratory viral culture (if positive, allows for further typing of isolate)
- Do not order routine viral **culture** if novel influenza A virus infection is suspected

Infection control

- Droplet precautions (mask within 3-6 feet)
- Routine standard precautions and good handwashing before & after patient contact

Treatment & Prophylaxis

- Antivirals shorten the course of illness when given within the first 1-2 days of influenza symptoms
- CDC recommended against the use of amantadine & rimantadine for the 2005-2006 and the 2006-2007 influenza seasons

| | Amantadine (Symmetrel®) | Rimantadine (Flumadine®) | Oseltamivir (Tamiflu®) | Zanamivir (Relenza®) |
|----------------------------------|-----------------------------------|------------------------------------|----------------------------------|---|
| Effective for Influenza A | NOT RECOMMENDED | | Yes | Yes |
| Effective for Influenza B | No | No | Yes | Yes |
| Mode | Oral | Oral | Oral | Inhaled |
| Treatment | ≥ 1 y.o. | ≥ 13 y.o. | ≥ 1 y.o. | ≥ 7 y.o. |
| Prophylaxis | ≥ 1 y.o. | ≥ 1 y.o. | ≥ 1 y.o. | Not licensed – 2006 Updated information in ACIP Influenza Recommendations |

Follow CDC recommendations for ages and contraindications

July 2006 ACIP Recommendations on “[Prevention and Control of Influenza](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm?s_cid=rr5510a1_e),
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm?s_cid=rr5510a1_e]

Remember Pneumovax® or Prevnar® pneumococcal vaccine for high-risk individuals.

Influenza Vaccine Recommendations for 2005-2006 season

Inactivated intramuscular shot [Multiple manufacturers]:

- 1) Ages \geq 50 y.o.
- 2) All children ages 6 mo.-23 mo.
- 3) Household contacts and out-of-home caretakers of infants < age 6 mo.
- 4) Ages 2 y.o.-64 y.o. with a chronic medical conditions (e.g. heart disease, lung disease, asthma, diabetes, kidney disease, immunosuppression, etc.)
- 5) Pregnant during influenza season.
- 6) Children age 6 mo.-18 y.o. on chronic aspirin therapy.
- 7) Health care workers (HCW) with direct patient care.
- 8) Residents in nursing home or long-term care facility.
- 9) **Anyone** wishing to reduce their risk of influenza.

Live attenuated influenza vaccine (LAIV) [FluMist™]:

- Healthy, nonpregnant people ages 5 y.o. through 49 y.o., including close contacts of infants and many health care workers

Pediatric pointers

- Children aged 6 months to less than 9 years old receiving any influenza vaccine for the first time need two doses of vaccine administered at least one month apart..
 - Two inactivated shots should be spaced \geq 4 weeks apart
 - Two LAIV doses, given only to those children age five years to less than nine years, should be separated by 6-10 weeks
- Notify local or county health department for pediatric influenza deaths.

Staphylococcal and MRSA disease associated with influenza

- MRSA is becoming a community-acquired infection
- Coagulase positive *Staphylococcus* secondary respiratory infections are more likely with influenza
- During the 2003-2004 season, CDC reported severe illness and death associated with influenza and MRSA
- Physicians caring for patients who have influenza and worsening respiratory status requiring IV antibiotics should consider using **vancomycin** for staphylococcal coverage until culture results are available and/or clinical improvement occurs
- Many oral antibiotics do not cover MRSA
- Oral antibiotics that may be effective against MRSA
 - Trimethoprim-sulfamethoxazole
 - Poor against *Streptococcus pneumoniae*
 - Avoid in pregnancy
 - Clindamycin (Good against *Streptococcus pneumoniae*)

For More Information

- KDPH Web site (<http://chfs.ky.gov/dph/default.htm>)
- Centers for Disease Control and Prevention Web site at www.cdc.gov/flu
- MMWR July 29, 2005 "Treatment and Control of Influenza" at
- <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5408a1.htm>
- July 2006 ACIP Recommendations on "Prevention and Control of Influenza, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm?s_cid=rr5510a1_e

Appendix 5. Clinician Fact Sheet: Antivirals

Four antiviral drugs are licensed for treatment and chemoprophylaxis

- Antivirals shorten the course of illness when given within the first 1-2 days of influenza symptoms
- Avoid antivirals in pregnant women unless benefit outweighs risk
- Though usually effective for influenza A, this season amantadine and rimantadine are not recommended in the U.S. due to high levels of resistance

| | Amantadine (Symmetrel®) | Rimantadine (Flumadine®) | Oseltamivir (Tamiflu®) | Zanamivir (Relenza®) |
|----------------------------------|-----------------------------------|------------------------------------|----------------------------------|---|
| Effective for Influenza A | NOT RECOMMENDED | | Yes | Yes |
| Effective for Influenza B | No | No | Yes | Yes |
| Mode | Oral | Oral | Oral | Inhaled |
| Treatment | ≥ 1 y.o. | ≥ 13 y.o. | ≥ 1 y.o. | ≥ 7 y.o. |
| Prophylaxis | ≥ 1 y.o. | ≥ 1 y.o. | ≥ 1 y.o. | N/A --2006 Updated information in ACIP Influenza Recommendations |

Priority groups for treatment with antiviral medicines

- Any person with a potentially life-threatening influenza-related illness
- Any person at high risk for serious complications of influenza and who is within the first 2 days of illness onset

Priority groups for chemoprophylaxis with antiviral medicines

- All residents and workers during an institutional outbreak
- All persons at high risk of serious influenza complications if they are exposed to a known or suspected case of influenza

Consider antiviral use in these patients if local supplies are adequate:

Chemoprophylaxis

- Persons in communities where influenza viruses are circulating (influenza outbreak usually lasts 6-8 weeks)
- Persons at high risk of serious complications who cannot get vaccinated. Persons at high risk of serious complications who have been vaccinated but have not had time to mount an immune response to the vaccine. In adults, chemoprophylaxis should occur for 2 weeks after vaccination.
- Persons with immunosuppressive conditions who are not expected to mount an adequate antibody response to influenza vaccine.
- Health-care workers with direct patient care responsibilities who have not been vaccinated

Treatment

- Infected adults and children aged ≥ 1 year who do not have conditions placing them at high risk for serious complications secondary to influenza infection.

Length of Antiviral Treatment and Chemoprophylaxis

| | Treatment Length | Chemoprophylaxis Length | | |
|--------------------|------------------------------------|--------------------------------|------------------------|-----------------|
| | | After exposure | Institutional outbreak | After vaccine** |
| Amantadine | NOT RECOMMENDED (ACIP 2006) | | | |
| Rimantadine | | | | |
| Oseltamivir | 5 days | 7 days | Until outbreak over | 2 weeks |
| Zanamivir | | N/A | N/A | N/A |

*Until afebrile 1-2 days ** If antiviral prophylaxis is desired for high-risk individuals during the time immunity is developing

Pediatric Pointers

- Children ≤ 9 years old who have never had an influenza vaccine need 2 doses of influenza vaccine, ≥ 1 month apart to be optimally protected. Therefore, if a high-risk child is vaccinated when there is influenza in the community, antiviral prophylaxis may need to be continued for 6 weeks for optimal protection.
- For pediatric antiviral use where no liquid formulation is available, open the capsule or crush the tablet, and give the appropriate dose in cherry syrup.

ANTIVIRAL MEDICINES

Amantadine [100 mg capsule; 50 mg/5 mL syrup] - **NOT RECOMMENDED (ACIP 2006)**

Rimantadine [100 mg tablet; 50 mg/5 mL syrup] -- **NOT RECOMMENDED (ACIP 2006)**

Oseltamivir (Tamiflu®) [75 mg tablet; 60 mg/5 mL suspension]

- Treatment and prophylaxis of influenza A & B in ≥ 12 months old.
- Treatment: 75 mg PO **twice daily** for 5 days.
- Lower dose in children based on weight:
 - ≤ 15 kg, 30 mg BID;
 - $>15-23$ kg, 45 mg BID;
 - $>23-40$ kg, 60 mg BID;
 - >40 kg, 75 mg PO BID.
- Prophylaxis: 75 mg PO **once daily**
- Side effects: nausea & vomiting
- Reduce dose to 75 mg every other day when CrCl 10-30 mL/min
-

Zanamivir (Relenza®) [Inhaler]

- Treatment of influenza A & B in ≥ 7 years of age.
- Inhalation (10 mg) twice daily for 5 days.
- Side effects: Bronchospasm

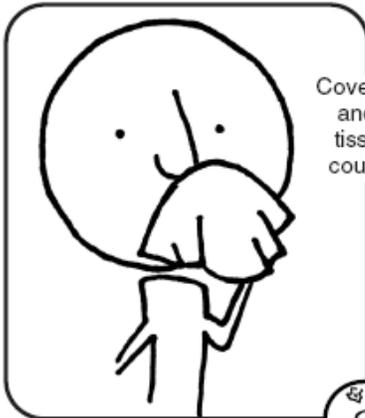
For more detailed information about each antiviral medication

See <http://www.cdc.gov/flu/professionals/treatment>

Appendix 6.
Respiratory Etiquette Poster

Stop the spread of germs that make you and others sick!

Cover your Cough



Cover your mouth and nose with a tissue when you cough or sneeze

or
cough or sneeze into your upper sleeve, not your hands.



Put your used tissue in the waste basket.



You may be asked to put on a surgical mask to protect others.

Clean your Hands

after coughing or sneezing.



Wash with soap and water

or
clean with alcohol-based hand cleaner.



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**KENTUCKY PANDEMIC INFLUENZA PREPAREDNESS PLAN
VACCINE DISTRIBUTION AND USE SUPPLEMENT V**

| TABLE OF CONTENTS | | |
|--------------------------|---|-------------|
| | | PAGE |
| | SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE | 1 |
| I. | RATIONALE | 2 |
| II. | OVERVIEW | 2 |
| III. | GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 2 |
| | A. Vaccination Against Seasonal Influenza Virus Strains | 2 |
| | B. Responsibility of the Department for Public Health | 3 |
| | C. Responsibility of the Local Health Departments | 3 |
| | | 4 |
| IV. | PREPAREDNESS PLANNING FOR VACCINATION AGAINST A PANDEMIC INFLUENZA STRAIN | 4 |
| | A. Vaccination of Priority Groups | 4 |
| | B. Responsibility of the Department for Public Health | 4 |
| | C. Responsibility of the Local Health Departments | 4 |
| | | |
| V. | VACCINE DISTRIBUTION | 4 |
| | A. Distribution to Local Health Departments | 5 |
| | B. Distribution to Private Providers | 5 |
| | C. Second Dose Vaccination | 6 |
| | D. Contingency Plan for IND Use | 6 |
| | E. Vaccine Monitoring and Data Collection | 7 |
| | F. Vaccine Effectiveness | 7 |
| | G. Vaccine Supply and Distribution | 7 |
| | H. Kentucky’s Immunization Registry | 7 |
| | I. Vaccine Coverage | 8 |
| | J. Vaccine Safety | 8 |
| | | |
| VI. | RECOMMENDATIONS FOR THE PANDEMIC PERIOD | 9 |
| | A. Before a Vaccine is Available | 9 |
| | B. When a Vaccine Becomes Available | 10 |
| | | |
| VII. | APPENDICES | |
| | APPENDIX A: Recommendations for Prioritization of Pandemic Influenza Vaccine | 11 |

SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE

Interpandemic and Pandemic Alert Periods

A. Department for Public Health/Local Health Departments

- Work with healthcare partners and other stakeholders to develop state-based plans for vaccine effectiveness, safety, distribution and use.

Pandemic Period

A. After the first reports of pandemic influenza are confirmed and before a pandemic vaccine becomes available

1. Department for Public Health/Local Health Department will:

- Work with healthcare partners and other stakeholders to distribute, deliver, and administer vaccines to designated groups if stockpiled influenza vaccine of the pandemic subtype is available,
- Mobilize healthcare partners, and prepare to activate state-based plans for distributing and administering vaccines.
- Keep the healthcare and public health workforce up-to-date on projected timelines for availability of vaccines against pandemic influenza.
- Review modifications, if any, to recommendations on vaccinating priority groups.
- Accelerate training in vaccination and vaccine monitoring for public health staff and for partners responsible for vaccinating priority groups.
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

B. After a vaccine becomes available

1. Department for Public Health/Local Health Departments will:

- Work with healthcare partners and other stakeholders to distribute, deliver, and administer pandemic vaccines to priority groups.
- Monitor vaccine supplies, distribution, and use.
- Monitor and investigate adverse events.
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated.
- Provide updated information to the public via the news media.
- Work with federal partners to evaluate vaccine-related response activities when the pandemic is over.

I. RATIONALE

The initial response to an influenza pandemic will include medical care, community containment and personal protective measures, and targeted use of antiviral drugs. Before a vaccine containing the circulating pandemic virus strain becomes available, pre-pandemic vaccine from stockpiles (if available for the pandemic subtype or partially cross-protective to the circulating virus) may be considered for persons in designated priority groups. Once a vaccine against the circulating pandemic virus strain becomes available, its distribution and delivery will be a major focus of pandemic response efforts to:

- Ensure efficient and equitable distribution of pandemic vaccine, according to priority lists.
- Rapidly determine vaccine effectiveness.
- Provide ongoing and timely monitoring of vaccine coverage.
- Provide ongoing and timely monitoring of vaccine safety.

II. OVERVIEW

The Vaccine Supplement provides recommendations to state and local partners and other stakeholders on planning for the different elements of a pandemic vaccination program. The recommendations for the Interpandemic and Pandemic Alert Periods focus on planning for vaccine distribution, vaccination of priority groups, monitoring of adverse events, tracking of vaccine supply and administration, vaccine coverage and effectiveness studies, communications, legal preparedness, and training. The recommendations for the Pandemic Period focus on working with healthcare partners to implement plans for vaccination against pandemic influenza and initiate monitoring activities.

Additional issues that might be of interest to healthcare partners that administer vaccine are addressed in the Healthcare Planning Supplement.

III. GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

A. Vaccination Against Seasonal Influenza Virus Strains

During the Interpandemic Period, the Department for Public Health in coordination with local health departments will work with healthcare partners to:

1. Enhance levels of seasonal influenza vaccination in groups at risk for severe influenza and in healthcare workers.
 - The success of the pandemic influenza vaccination program will be determined in large part by the strength of state and local vaccination programs during the Interpandemic Period. Higher annual vaccination rates will foster increased familiarity with and public confidence in influenza vaccines, increased manufacturing capacity for influenza vaccines, and strengthened distribution channels.

2. Enhance levels of pneumococcal polysaccharide vaccination for whom it is recommended.
 - Increased use of pneumococcal polysaccharide vaccine may decrease rates of secondary bacterial infections during a pandemic. Because large-scale pneumococcal vaccination might not be feasible once a pandemic occurs, the Interpandemic Period and Pandemic Alert is the ideal time to deliver this preventive measure. Pneumococcal vaccine is indicated for most persons for whom influenza vaccine is recommended.

B. Responsibility of the Department for Public Health

- Provide guidance to local health departments during seasonal epidemics of influenza regarding vaccine procurement, effectiveness, safety, distribution and use.
- Use the Health Alert Network during seasonal epidemics of influenza to provide an open line of communication to local health departments in regard to state-wide vaccine supply.
- Provide guidance to the general population during seasonal epidemics of influenza regarding vaccine effectiveness and availability using the Cabinet for Health and Family Services' influenza Web address (www.chfs.ky.gov/KDPH/Influenza.htm) and an influenza telephone hotline (502-564-5353).
- Conduct frequent meetings of the Seasonal Influenza Committee within the Department for Public Health to monitor state-wide vaccine distribution, administration and potential shortages.
- Communicate vaccine prioritization to local health departments, private providers and the general public in the event of a vaccine shortage.
- Work with stakeholders (Schools of Public Health, long term care facilities, private providers, employer groups and other health related organizations) to strengthen influenza and pneumococcal vaccination efforts.

C. Responsibility of the Local Health Departments

- Conduct county-wide assessments for seasonal epidemics of influenza regarding vaccine procurement by long term care facilities, hospitals and private physicians to determine anticipated vaccine supply.
- Provide vaccine inventory and administration data to the Department for Public Health utilizing the Health Alert Network.
- Provide information and education to the population regarding vaccine effectiveness, vaccine supply and prioritization of vaccine.
- Emphasize the importance of late season vaccination and fully utilize vaccine supply.
- Provide pneumococcal vaccination to eligible individuals.
- Exercise mass vaccination plans in preparation for a potential pandemic.
- Develop a partnership with other community healthcare providers in regard to influenza vaccination.

IV. PREPAREDNESS PLANNING FOR VACCINATION AGAINST A PANDEMIC INFLUENZA STRAIN

A. Vaccination of Priority Groups

During a pandemic, changes may be made based on the characteristics of the causative virus (e.g., transmissibility, virulence, initial geographic distribution, age-specific attack rates, and complication rates) and on vaccine effectiveness. The Department for Public Health will comply with the National Vaccine Advisory Committee (NVAC) and Advisory Committee on Immunization Practices (ACIP) Recommendations for Prioritization of Pandemic Influenza Vaccine as they apply to Kentucky residents. Any changes in the NVAC/ACIP recommendations will be reflected in the Kentucky Recommendations for Prioritization of Pandemic Influenza Vaccine (Appendix 1) issued in the Kentucky Pandemic Influenza Preparedness and Response Plan.

B. The following activities will be the Responsibility of the Department for Public Health:

- In collaboration with Regional Epidemiologists, Public Health Preparedness Planners and Local Health Departments, KDPH will enumerate essential priority groups at the state level.
- Provide guidance to local health departments and other healthcare providers on any changes made to priority groups due to the epidemiology of the novel virus.
- Educate professional organizations and other stakeholders about the need for priority groups and the rationale for the groups currently recommended.

C. The following activities will be the responsibility of the Local Health Departments:

- Identify and enumerate recommended priority groups at the local level.
- Develop a plan on how persons in priority groups would be identified at vaccination clinics and how vaccine would most efficiently be provided to those groups.
- Provide education on priority groups and rationale to healthcare providers and residents in the community.

V. VACCINE DISTRIBUTION

HHS is working to expand pandemic influenza vaccine production capacity and will signal to manufacturers when to shift from annual to pandemic vaccine production and assure that pandemic vaccine is produced at full capacity.

At the onset of an influenza pandemic, HHS, in concert with U.S. Congress in collaboration with the states, will work with the pharmaceutical industry to acquire vaccine directed against the pandemic strain. Distribution of pandemic vaccine to health departments and providers will occur via private-sector vaccine distributors or directly via manufacturer. Only stockpiled pre-pandemic vaccine would be distributed by the

federal government, if used. Due to the uncertainty of the method of distribution, multiple methods of distribution are accounted for in this plan.

A. Distribution to Local Health Departments

If vaccine is delivered to the Department for Public Health in coordination with the federal government or directly from vaccine manufacturers, the following distribution plan will be activated:

- Receipt of vaccine by the state and distribution to local health departments/districts will follow the guidelines set forth in Kentucky Emergency Operations Plan Appendix M-10 (Strategic National Stockpile Program).
- If vaccine is delivered to local health departments/districts directly from vaccine manufacturers, the following activities will be the responsibility of the local health departments/districts:
 - Local health departments/districts will provide vaccination to persons in priority groups.
 - Local health departments/districts will activate established and exercised plans for mass vaccination while ensuring efficient and equitable distribution of pandemic vaccine, according to priority lists.
 - Maintain strategies and equipment to ensure vaccine security issues, cold chain requirements, and transport and storage issues.
 - Identify locations for vaccination clinics that will be operated by health departments and enter into memoranda of agreement with organizations that agree to provide vaccinators or other staff.
 - Develop procedures for collecting, removing, and disposing of used syringes, needles, and other vaccination supplies
 - Develop a plan for training vaccinators and other staff responsible for mass vaccination.
 - Develop strategies for vaccinating hard-to-reach populations
- Local health departments/districts plans should also specifically address the delivery of pandemic vaccine to medically underserved and migrant populations to improve equity in access within priority groups and, later, the general population.

B. Distribution to Private Providers

If vaccine is administered by private-sector organizations or providers at offices, clinics, or other sites, KDPH will be responsible for the following:

- Providing vaccination information to healthcare providers regarding priority groups, vaccine safety and effectiveness, storage and handling, etc.
- Utilize Immunization Program field staff to collect and redistribute unused vaccine from healthcare providers who have met their priority vaccination goals.
- Monitoring vaccine administration so that it follows existing plans on priority groups based on data submitted by local health departments/districts.

Local health departments/districts will be responsible for the following:

- Providing vaccination information to healthcare providers regarding priority groups, vaccine safety and effectiveness, storage and handling, etc.
- Collecting data from vaccinating providers on inventory, vaccine administration, priority group eligibility screening, etc.
- Reporting collected information to the KDPH via the Health Alert Network, utilizing the format described in the “Vaccine Monitoring and Data Collection” portion of this supplement.

C. Second Dose Vaccinations

A vaccine against pandemic influenza will likely require two doses, administered at least a month apart, to provide a level of immunity comparable to that obtained with seasonal influenza vaccines. Recommendations on the number of required doses and the timing of the second dose will be issued once immunogenicity trials have been completed.

If two doses are required to achieve immunity, it will be necessary to ensure that vaccinated persons return for the second dose. KDPH along with local health departments/districts will be responsible for the following:

- Arrange for information about the need for a second dose to be provided at the time of vaccination.
- Ensure that planning for vaccine procurement and distribution to clinics and other facilities accounts for the need to use portions of future shipments for second doses, thus reducing the number of available first doses.
- Use immunization registry or another system that would accomplish the goals of pandemic vaccination.

D. Contingency Plan for Investigational New Drug (IND) Use

State and local health departments should be prepared to distribute unlicensed vaccines (if needed) under FDA’s IND provisions. Unlicensed vaccines might be needed, for example, if pandemic spread is rapid and standard vaccine efficacy and safety tests are not completed before the response.

IND provisions require strict inventory control and record-keeping, completion of a signed consent form from each vaccine recipient, and mandatory reporting of specified types of adverse events. IND provisions also require approval from Institutional Review Boards (IRBs) in hospitals, health departments, and other vaccine-distribution venues. The FDA regulations permit the use of a national or "central" IRB. A treatment IND is one IND mechanism that FDA has available for use and is especially suited for large scale use of investigational products.

As an alternative to IND use of an unapproved antiviral drug, HHS may utilize the drug product under Emergency Use Authorization procedures as described in the FDA draft Guidance "Emergency Use Authorization of Medical Products".

E. Vaccine Monitoring and Data Collection

To ensure optimal use of a new pandemic influenza vaccine, state and local health departments should be prepared to collect data on vaccine effectiveness, vaccine supply and distribution, vaccine coverage, and vaccine safety.

F. Vaccine Effectiveness

Vaccine effectiveness will be assessed by comparing rates of influenza-related illness, hospitalization, and/or death among vaccinated and unvaccinated persons. These studies will be implemented by CDC in collaboration with healthcare and university partners and with state and local health departments that participate in influenza surveillance systems.

G. Vaccine Supply and Distribution

Mechanisms for tracking vaccine supply and distribution will depend on how vaccine is purchased and distributed. Tracking will be implemented by state and local health authorities who will have the major responsibility for allocation decisions and will be working in association with CDC and vaccine producers. Data also will be obtained from vaccine producers and commercial distributors.

- Vaccine tracking and coverage information may be used by federal, state, and local decision makers to estimate adverse event rates based on the number of doses administered and to determine if vaccine is being administered according to established priority groups for pandemic vaccine (especially in the early phases of vaccination). Data will be collected from individual providers, collated at the local and state levels, and reported to federal authorities on a scheduled routine basis.
- The Kentucky Immunization Registry may be adapted to track coverage with pandemic influenza vaccine. Kentucky may also use a vaccine database that will be supplied by CDC. At a minimum, tracking data should include:
 - Number of doses administered, by date and age, priority group, and state or county (or zip code)
 - Number of doses that represent second doses, as applicable

Currently, the Department for Public Health utilizes the Health Alert Network to collect inventory and administration data for seasonal influenza and barring further instruction from CDC, would continue to utilize that method in a pandemic.

H. Kentucky's Immunization Registry

Kentucky's Immunization Registry is being developed by the Department for Public Health and should be operational in 2007. The Immunization Registry will be a confidential, population-based, computerized system for maintaining information

regarding vaccinations. The Registry will include persons in the geographic area of the Commonwealth of Kentucky and will provide a single data source for all community vaccination partners, offering benefits to parents, communities, and health-care providers. The Registry will electronically store data on all core data elements that are recommended and approved by the NVAC. A Registry record will be created within 6 weeks of birth for each newborn child in Kentucky. The Registry will enable access to and retrieval of vaccination information at the time of encounter and will produce official immunization certificates; Encounter information will be received and processed within 1 month of vaccine administration. The Registry will automatically determine the routine childhood vaccination(s) needed, in compliance with current ACIP recommendations when an individual presents for a scheduled vaccination. Individuals will be automatically identified when due or late for vaccination(s) to enable the production of reminder/recall notifications. Immunization coverage reports will be automatically produced and stratified by providers, age groups, and geographic area. Electronic data will be exchanged with external systems using Health Level 7 standards. State-of-the-art technology will protect the confidentiality of stored healthcare data and will ensure the confidentiality and security of healthcare information contained.

The Immunization Registry will be architecturally connected to and functionally interoperable with the Kentucky Electronic Disease Surveillance System (KY-EDSS), which is the Commonwealth's implementation of the federal initiative called the National Electronic Disease Surveillance System (NEDSS). This system is designed to detect infectious disease outbreaks rapidly, to facilitate the electronic transfer of appropriate clinical information from external systems to the Department for Public Health, to reduce the provider burden in the provision of information, and to enhance both the timeliness and quality of information provided. The Immunization Registry provides application software functionality for the KY-EDSS to monitor and report information about vaccine preventable diseases. In turn, the NEDSS Logical Data Model includes many database tables and relationships that are used to support immunization efforts.

Effective use of the Immunization Registry during an infectious disease emergency requires a high emphasis on electronically maintaining associated demographic (home and occupation), contact (communicable disease tracing), clinical, geospatial and event (threat, facility, etc.) data in forms that can be readily associated, re-linked and processed. Automated record linking capabilities are specifically designed to facilitate data exchange between partners. During an infectious disease emergency, public health agencies will be able to use Immunization Registry components to manage case contacts given prophylaxis, help identify populations at high risk and persons who are under-vaccinated, monitor the progress of prophylaxis, produce summary reports on outcomes, and support provider and consumer education.

I. Vaccine Coverage

CDC will work with states to develop a system for monitoring vaccination rates at regular intervals, using a pre-existing population-based survey tool (e.g., Behavioral Risk Factor

Surveillance System) that provides national and state-level estimates and complements the vaccine tracking systems described above.

J. Vaccine Safety

In response to vaccine safety, the Kentucky Immunization Program will use a system to report and investigate adverse events following immunization (AEFI) with a pandemic influenza vaccine. The following activities will be the responsibility of the Department for Public Health:

- Any person in the state of Kentucky (private citizen, private provider or health department) may fill out and send a Vaccine Adverse Event and Reporting System (VAERS) form to the Department for Public Health.
- VAERS forms are available at local health departments or by contacting the Immunization Program at the Department for Public Health.
- The Immunization Program VAERS Coordinator, who serves as the state's contact with federal government staff overseeing VAERS, will collect the VAERS form, review for completion and assign a specific Kentucky number for each report.
- The specific Kentucky (KY) number can have identifiers attached to track specific cases.
- After a KY number is assigned, the VAERS form will then be submitted to the VAERS central office via the Internet, by fax, or by mail.
- The hard copy of the VAERS form is kept on file for future follow-up.

Adverse events related to use of IND vaccines may be reported through other mechanisms in addition to or in place of VAERS, in accordance with specific regulatory or policy requirements. Adverse events will also be monitored through the Vaccine Safety Datalink (<http://www.cdc.gov/nip/vacsafe/default.htm#VSD>), a network of seven geographically diverse health maintenance organizations through which active surveillance vaccine safety studies are conducted. Another potential resource for vaccine safety research is CDC's Clinical Immunization Safety Assessment (CISA) network (<http://www.vaccinesafety.org/CISA/index.htm>).

VI. RECOMMENDATIONS FOR THE PANDEMIC PERIOD

A. Before a Vaccine is Available

Before a vaccine becomes available, state and local health departments should:

- Meet with partners and stakeholders to review the major elements of the state's vaccine distribution plan.
- Modify the plan to account for possible updated interim recommendations on priority groups, projected vaccine supplies and timelines for availability, and staffing estimates for mass vaccination.

- Notify the medical community about the status of the plan and the expected availability of vaccines.
- Work with healthcare partners and other stakeholders to distribute, deliver, and administer vaccines to designated groups if stockpiled vaccine of the pandemic subtype is available.
- Update and disseminate public information on the production, distribution, and use of pandemic influenza vaccine before it becomes available.
- Conduct training for public health staff and partners involved in distributing and administering vaccines.

B. When a Vaccine Becomes Available

- Once a vaccine is ready for distribution, state and local health departments should work with healthcare and community partners to activate plans to:
 - Vaccinate persons in priority groups, in accordance with existing recommendations.
 - Provide a second dose, if required for immunity.
 - Monitor vaccine supply, distribution, and use.
 - Monitor and investigate adverse events.
 - Continue communication with partners and the public.
- After priority groups have been vaccinated and additional vaccine stocks become available, public health authorities should phase-in vaccination for the remainder of the population, based on age or other criteria that will ensure fair, equitable, and orderly distribution. HHS will issue national recommendations to aid in this process.
- After the pandemic has ended, state and local health departments should evaluate all response activities, including vaccine tracking and delivery, adverse event monitoring, and communications.

APPENDIX A

Recommendations for Prioritization of Pandemic Influenza Vaccine

The following recommendations are reflective of the prioritization recommendations set forth by the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) in the Department for Health and Human Services (HHS) Pandemic Influenza Plan. Although the advisory committees considered potential priority groups broadly, the main expertise of the members was in health and public health. The primary goal of a pandemic response was to decrease health impacts including severe morbidity and death. A secondary pandemic response goal was to minimize societal and economic impacts. However, as other sectors are increasingly engaged in pandemic planning, additional considerations may arise. The advisory committee reports explicitly acknowledge the importance of this, for example highlighting the priority for protecting critical components of the military. Finally, HHS has recently initiated outreach to engage the public and obtain a broader perspective into decisions on priority groups for pandemic vaccine and antiviral drugs. Though findings of the outreach are preliminary, a theme that has emerged is the importance of limiting the effects of a pandemic on society by preserving essential societal functions.

The Kentucky Department for Public Health (KDPH) recommendations for prioritization will continue to reflect the recommendations set forth by the Centers for Disease Control and Prevention (CDC) and the HHS. We recognize the potential for alterations of these recommendations in the case of a pandemic depending upon the epidemiology of a novel strain and will reiterate the need to refer to national recommendations for changes that may occur.

The Constitution of the Commonwealth of Kentucky affords the Governor of Kentucky, or his designee, the discretionary ability to restructure the prioritization during an influenza pandemic. In addition, the recommendations for prioritization of vaccination may be further modified at a local level by the chief elected official.

A. Critical Assumptions

The recommendations were based on the following critical assumptions:

- **Morbidity and mortality.** The greatest risk of hospitalization and death—as during the 1957 and 1968 pandemics and annual influenza—will be in infants, the elderly, and those with underlying health conditions. In contrast, during the 1918 pandemic, most deaths occurred in young adults, highlighting the need to reconsider the recommendations at the time of the pandemic based on the epidemiology of disease.
- **Healthcare system.** The healthcare system will be severely taxed if not overwhelmed due to the large number of illnesses and complications from influenza requiring hospitalization and critical care. CDC models estimate increases in hospitalization and intensive care unit demand of more than 25% even in a moderate pandemic.

- **Workforce.** During a pandemic wave in a community, between 25% and 30% of persons will become ill during a 6 to 8 week outbreak. Among working-aged adults, illness attack rates will be lower than in the community as a whole. A CDC model suggests that at the peak of pandemic disease, about 10% of the workforce will be absent due to illness or caring for an ill family member. Impacts will likely vary between communities and work sites and may be greater if significant absenteeism occurs because persons stay home due to fear of becoming infected.
- **Critical infrastructure.** Only limited information was available from which to assess potential impacts on critical infrastructure sectors such as transportation and utility services. Because of changes in business practices and the complexity of networks, information from prior pandemics was not considered applicable.
- **Vaccine production capacity.** The U.S.-based vaccine production capacity was assumed at 3 to 5 million doses (15 mcg) per week with 3 to 6 months needed before the first doses are produced. Two doses per person were assumed to be required for protection. Subsequent results of a National Institute of Health (NIH) clinical trial of influenza A (H5N1) vaccine suggest that higher doses of antigen will be needed to elicit a good immune response; thus, the assumptions made by the committee could potentially substantially exceed the amount of vaccine that would be produced.

Vaccine Priority Group Recommendations*

| Tier | Subtier | Population | Rationale |
|------|---------|---|---|
| 1 | A | <ul style="list-style-type: none"> • Medical workers and public health workers who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators | <ul style="list-style-type: none"> • Healthcare workers are required for quality medical care (studies show outcome is associated with staff-to-patient ratios). There is little surge capacity among healthcare sector personnel to meet increased demand |
| 1 | B | <ul style="list-style-type: none"> • Persons > 65 years with 1 or more influenza high-risk conditions, not including essential hypertension • Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertension • Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year | <ul style="list-style-type: none"> • These groups are at high risk of hospitalization and death. Excludes elderly in nursing homes and those who are immunocompromised and would not likely be protected by vaccination |

| | | | |
|---|---|--|--|
| 1 | C | <ul style="list-style-type: none"> • Pregnant women • Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine • Household contacts of children <6 month olds | <ul style="list-style-type: none"> • In past pandemics and for annual influenza, pregnant women have been at high risk; vaccination will also protect the infant who cannot receive vaccine. • Vaccination of household contacts of immunocompromised and young infants will decrease risk of exposure and infection among those who cannot be directly protected by vaccination |
| 1 | D | <ul style="list-style-type: none"> • Public health emergency response workers critical to pandemic response • Key government leaders | <ul style="list-style-type: none"> • Critical to implement pandemic response such as providing vaccinations and managing/monitoring response activities • Preserving decision-making capacity also critical for managing and implementing a response |

| Tier | Subtier | Population | Rationale |
|------|---------|---|--|
| 2 | A | <ul style="list-style-type: none"> • Healthy 65 years and older • 6 months to 64 years with 1 high-risk condition • 6-23 months old, healthy | <ul style="list-style-type: none"> • Groups that are also at increased risk but not as high risk as population in Tier 1B |
| 2 | B | <ul style="list-style-type: none"> • Other public health emergency responders • Public safety workers including police, fire, 911 dispatchers, and correctional facility staff • Utility workers essential for maintenance of power, water, and sewage system functioning • Transportation workers transporting fuel, water, food, and medical supplies as well as public ground public transportation • Telecommunications/IT | <ul style="list-style-type: none"> • Includes critical infrastructure groups that have impact on maintaining health (e.g., public safety or transportation of medical supplies and food); implementing a pandemic response; and on maintaining societal functions |

| | | | |
|---|--|--|--|
| | | for essential network operations and maintenance | |
| 3 | | <ul style="list-style-type: none"> • Other key government health decision-makers • Funeral directors/embalmers | <ul style="list-style-type: none"> • Other important societal groups for a pandemic response but of lower priority |
| 4 | | <ul style="list-style-type: none"> • Healthy persons 2-64 years not included in above categories | <ul style="list-style-type: none"> • All persons not included in other groups based on objective to vaccinate all those who want protection |

*The committee focused its deliberations on the U.S. civilian population. ACIP and NVAC recognize that Department of Defense (DOD) needs should be highly prioritized. DoD Health Affairs indicates that 1.5 million service members would require immunization to continue current combat operations and preserve critical components of the military medical system. Should the military be called upon to support civil authorities domestically, immunization of a greater proportion of the total force will become necessary. These factors should be considered in the designation of a proportion of the initial vaccine supply for the military.

Other groups also were not explicitly considered in these deliberations on prioritization. These include American citizens living overseas, non-citizens in the U.S., and other groups providing national security services such as the border patrol and customs service.

B. Definitions and rationales for priority groups

1. Healthcare workers and essential healthcare support staff

a) Definition
 Healthcare workers (HCW) with direct patient contact (including acute-care hospitals, nursing homes, skilled nursing facilities, urgent care centers, physician’s offices, clinics, home care, blood collection centers, and EMS) and a proportion of persons working in essential healthcare support services needed to maintain healthcare services (e.g. dietary, housekeeping, admissions, blood collection center staff, etc.). Also included are healthcare workers in public health with direct patient contact, including those who may administer vaccine or distribute influenza antiviral medications, and essential public health support staff for these workers.

b) Rationale
 The pandemic is expected to have substantial impact on the healthcare system with large increases in demand for healthcare services placed on top of existing demand. HCW will be treating influenza-infected patients and will be at risk of repeated exposures. Further, surge capacity in this sector is low. To encourage continued work in a high-exposure setting and to help lessen the risk of healthcare workers transmitting influenza to other patients and HCW family members, this group was highly prioritized. In addition, increases in bed/nurse ratios have been associated with increases in overall patient mortality. Thus, substantial absenteeism may affect overall patient care and outcomes.

2. Groups at high risk of influenza complications

a) Definition
Persons 2-64 years with a medical condition for which influenza vaccine is recommended and all persons 6-23 months and 65 years and older. Excludes nursing home residents and severely immunocompromised persons who would not be expected to respond well to vaccination.

b) Rationale
These groups were prioritized based on their risk of influenza-related hospitalization and death and also their likelihood of vaccine response. Information from prior pandemics was used whenever possible, but information from interpandemic years was also considered. Nursing home residents and severely immunocompromised persons would be prioritized for antiviral treatment and/or prophylaxis and vaccination of healthcare workers and household contacts who are most likely to transmit influenza to these high risk groups.

3. Critical infrastructure

a) Definitions and rationale
Those critical infrastructure sectors that fulfill one or more of the following criteria:

- Have increased demand placed on them during a pandemic
- Directly support reduction in deaths and hospitalization;
- Support the healthcare sector and other emergency services
- Supply basic necessities and services critical to support of life and healthcare or emergency services.

Groups included in critical infrastructure are needed to respond to a pandemic and to minimize morbidity and mortality, and include the following sectors:

- Key government leaders and health decision-makers who will be needed to quickly move policy forward on pandemic prevention and control efforts
- Public safety workers (firefighters, police, and correctional facility staff, including dispatchers) are critical to maintaining social functioning and order and will contribute to a pandemic response, for example by ensuring order at vaccination clinics and responding to medical emergencies
- Utility service workers (water, power, and sewage management) are prioritized as the services they provide are also essential to the healthcare system as well as to preventing additional illnesses from lack of these services unrelated to a pandemic.
- Transportation workers who maintain critical supplies of food, water, fuel, and medical equipment and who provide public transportation, which is essential for provision of medical care and transportation of healthcare workers to work and transportation of ill persons for care
- Telecommunication and information technology services critical for maintenance and repairs of these systems are also essential as these systems are now critical for accessing and delivering medical care and in support of all other critical infrastructure
- Mortuary services will be substantially impacted due to the increased numbers of deaths from a pandemic and the fact that impact will be high in the elderly, a growing segment of the population

4. Public health emergency response workers

a) Definition

This group includes persons who do not have direct patient care duties, but who are essential for surveillance for influenza, assessment of the pandemic impact, allocation of public health resources for the pandemic response, development and implementation of public health policy as part of the response, and development of guidance as the pandemic progresses.

b) Rationale

Persons in this sector have been critical for past influenza vaccine pandemics and influenza vaccine shortages and little surge capacity may be available during a public health emergency such as a pandemic.

5. Persons in skilled nursing facilities

a) Definition

Patients residing in skilled nursing facilities. Not included in this group are persons in other residential settings (e.g., assisted living) who are more likely to be mobile, in a setting that is less closed, and have decentralized healthcare.

b) Rationale

This group was not prioritized for vaccine because of the medical literature finding of poor response to vaccination and occurrence of outbreaks even in the setting of high vaccination rates. Other studies have suggested that vaccination of healthcare workers may be a more effective strategy to prevent influenza in this group. Further, surveillance for influenza can be conducted in this group and antiviral medications used widely for prophylaxis and treatment. Ill visitors and staff should also be restricted from visiting nursing home facilities during outbreaks of pandemic influenza. This strategy for pandemic influenza vaccine differs from the interpandemic vaccination strategy of aggressively vaccinating nursing home residents. The rationale considers several factors: 1) these populations are less likely to benefit from vaccine than other groups who are also at high risk; 2) other prevention strategies feasible for this group are not possible among other high-risk groups; 3) the overall morbidity and mortality from pandemic is likely to severely impact other groups of persons who would be expected to have a better response to the vaccine; and 4) a more severe shortage of vaccine is anticipated.

6. Severely immunocompromised persons

a) Definition

Persons who are undergoing or who have recently undergone bone marrow transplantation and others with severe immunodeficiency (e.g., AIDS patients with CD4 counts <50, children with SCID syndrome, recent bone marrow transplant patients). The numbers of persons in these categories is likely much smaller than the anticipated number assumed in tiering above, but sources for more specific estimates have not been identified.

b) Rationale

These groups have a lower likelihood of responding to influenza vaccination. Thus, strategies to prevent severe influenza illness in this group should include vaccination of healthcare workers and household contacts of severely immunocompromised persons and

use of antiviral medications. Consideration should be given to prophylaxis of severely immunocompromised persons with influenza antivirals and early antiviral treatment should they become infected.

7. Children <6 months of age

a) Rationale
Influenza vaccine is poorly immunogenic in children <6 months and the vaccine is currently not recommended for this group. In addition, influenza antiviral medications are not FDA-approved for use in children <1 year old. Thus, vaccination of household contacts and out-of-home caregivers of children <6 months is recommended to protect this high-risk group. Influenza vaccine administered to pregnant women may provide some protection to children for several months after their birth.

C. Other discussion

There was substantial discussion on priority for children. Four potential reasons were raised for making vaccination of children a priority:

1. At the public engagement session, many participants felt that children should have high priority for vaccination.
2. Children play a major role in transmitting infection, and vaccinating this group could slow the spread of disease and indirectly protect others.
3. Children have strong immune systems and will respond well to vaccine whereas vaccination of the elderly and those with illnesses may be less effective.
4. Some ethical frameworks would support a pediatric priority.

ACIP and NVAC did not make children a priority (other than those included in tiers, because of their underlying diseases [Tiers 1B and 2A] or as contacts of high-risk persons [Tier 1C]) for several reasons:

- Healthy children have been at low risk for hospitalization and death in prior pandemics and during annual influenza seasons.
- It is uncertain whether vaccination of children will decrease transmission and indirectly protect others. Studies that show this impact or mathematical models that predict it rely on high vaccination coverage that may not be possible to achieve given limited supplies in a pandemic.
- The committees recognize that this is an area for further scientific work; that children may be a good target population for live-attenuated influenza vaccine (FluMist®) if it is available; and that education of the public will be needed to provide the rationale for the recommendations.

**KENTUCKY PANDEMIC INFLUENZA PREPAREDNESS PLAN
ANTIVIRAL DISTRIBUTION AND USE SUPPLEMENT VI**

| TABLE OF CONTENTS | | |
|--------------------------|---|-------------|
| | | PAGE |
| | SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR ANTIVIRAL DISTRIBUTION AND USE | 1 |
| I. | RATIONALE | 2 |
| II. | OVERVIEW | 2 |
| III. | GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | 2 |
| | A. Use of Antivirals in Management of Cases of Novel Influenza | 2 |
| | B. Use of Antivirals for Treatment | 3 |
| | C. Use of Antivirals for Prophylaxis of Contacts | 3 |
| | d. Use of Antivirals for Containment of Disease Clusters | 3 |
| IV. | PREPAREDNESS PLANNING FOR USE OF ANTIVIRALS DURING PANDEMIC | 4 |
| | A. National Recommendations on Use of Antivirals During a Pandemic | 4 |
| | B. State Level Planning | 4 |
| | C. Procurement | 4 |
| | D. Establishing Priority Groups | 5 |
| | E. Distributing and Dispensing Antivirals to Priority Groups | 5 |
| | F. Vaccine Monitoring and Data Collection | 6 |
| | G. Contingency Planning for Investigational New Drug (IND) Use | 8 |
| V. | RECOMMENDATIONS FOR THE PANDEMIC PERIOD | 8 |
| | A. When pandemic influenza is reported abroad | 9 |
| | B. When there is limited transmission of pandemic influenza in the United States | 9 |
| | C. When there is widespread transmission of pandemic influenza in the United States | 10 |
| VI. | APPENDICES | |
| | APPENDIX 1: Recommendations on Pandemic Antiviral Use | 11 |
| | | |

ANTIVIRAL DISTRIBUTION AND USE SUPPLEMENT VI

SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR ANTIVIRAL DISTRIBUTION AND USE

Interpandemic and Pandemic Alert Periods

Department for Public Health/Local Health Departments

- Use antivirals in medical management of cases of novel strains of influenza
- Procure and maintain local stockpiles of antiviral drugs if/when funding permits
- Develop state-based plans for distribution and use of antiviral drugs during a pandemic

Pandemic Period

Department for Public Health/Local Health Departments

- Prepare to activate state-based plans for distributing and administering antivirals to persons in priority groups.
- Review modifications, if any, to interim recommendations on antiviral prophylaxis in selected groups or circumstances.
- Accelerate training on appropriate use of antiviral drugs among public health staff and healthcare partners.
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

If pandemic influenza is detected in the United States, state and local health departments will work with healthcare partners to:

- Distribute and deliver stockpiled supplies of antivirals, as appropriate, to healthcare facilities that will administer them to priority groups.
- Work with HHS to monitor antiviral drug use and effectiveness.
- Work with HHS to monitor and investigate adverse events.
- Provide updated information to the public via the news media.

I. RATIONALE

Drugs with activity against seasonal influenza viruses (“antivirals”) in 2005-2006 and 2006-2007 include the neuraminidase inhibitors (*oseltamivir* and *zanamivir*). The adamantanes (*amantadine* and *rimantadine*) were ineffective against recent seasonal influenza viruses. Appropriate use of these agents during an influenza pandemic may reduce morbidity and mortality and diminish the overwhelming demands that will be placed on the healthcare system. Antivirals might also be used during the Pandemic Alert Period in limited attempts to contain small disease clusters and potentially slow the spread of novel influenza viruses. A huge and uncoordinated demand for antivirals early in a pandemic could rapidly deplete national and local supplies. Preparedness planning for optimal use of antiviral stocks is therefore essential.

II. OVERVIEW

The Antiviral Supplement provides recommendations to state and local partners on the distribution and use of antiviral drugs for treatment and prophylaxis during an influenza pandemic. Stockpiled antivirals will be supplied from the federal level. State and local stockpiles will depend upon funding and availability. The Interpandemic and Pandemic Alert Period recommendations focus on preparedness planning for the rapid distribution and use of antiviral drugs (e.g., distribution to priority groups, legal preparedness, training, and data collection on use, effectiveness, safety, and the development of drug resistance). These recommendations also cover the use of antiviral drugs in the management and containment of cases and clusters of infection with novel strains of influenza, including influenza A (H5N1) and other strains with pandemic potential.

The Pandemic Period recommendations focus on the local use of antiviral drugs in three situations:

1. When pandemic influenza is sporadically reported in the United States (without evidence of spread in the United States)
2. When there is limited transmission of pandemic influenza in the United States
3. When there is widespread transmission in the United States. National recommendations for optimal use of limited stocks of antivirals will be updated throughout the course of an influenza pandemic to reflect new epidemiologic and laboratory data. Interim recommendations will also be updated as an effective influenza vaccine becomes available.

Additional issues that may be of interest to healthcare partners who administer antiviral drugs are outlined in the Healthcare Planning Supplement.

III. GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

A. Use of Antivirals in Management of Cases of Novel Influenza

Influenza infections may be due to:

1. Interpandemic (i.e., ‘normal’) seasonal strains of influenza A
2. Novel strains of influenza that do not appear to be easily transmissible but could be precursors to human pandemic strains (e.g., influenza A [H5N1] viruses)
3. Novel strains of influenza that demonstrate person-to-person transmission and therefore have pandemic potential (e.g., a new human pandemic strain)

In this supplement, the term “novel strains of influenza” is used to refer to avian or animal influenza strains that can infect humans (like avian influenza A [H5N1]) and new or re-emergent human influenza viruses that cause cases or clusters of human disease. Criteria for early detection and identification of novel strains of influenza are discussed in the Clinical Guidelines Supplement.

B. Use of Antivirals for Treatment

A patient with a suspected case of avian influenza A (H5N1) or another novel strain of influenza should be isolated as described in the Transmission of Disease Supplement and treated in accordance with the clinical algorithm for the Pandemic Alert Period provided in the Healthcare Planning Supplement. As of fall 2005, the recommendation for treatment includes the use of oseltamivir or zanamivir, administered as early as possible and ideally within 48 hours after onset of symptoms. These neuraminidase inhibitors are preferred because the majority of avian influenza A (H5N1) viruses currently affecting humans are resistant to amantadine and rimantadine, and resistance to these drugs typically develops rapidly when they are used for treatment of influenza. Although resistance to zanamivir and oseltamivir can be induced in influenza A and B viruses *in vitro*, multiple passages in cell culture are usually required to produce neuraminidase inhibitor resistance, in contrast with adamantane resistance, which can develop after a single passage. Because the neuraminidase inhibitors have different binding sites for the enzyme, cross-resistance between zanamivir- and oseltamivir-resistant viruses is variable.

C. Use of Antivirals for Prophylaxis of Contacts

State and local health departments, in consultation with CDC, will consider whether it is necessary and feasible to trace a patient’s close contacts and provide them with postexposure antiviral prophylaxis. Close contacts may include family, schoolmates, workmates, healthcare providers, and fellow passengers if the patient has been traveling. If deemed necessary by public health authorities, these persons may receive post-exposure prophylaxis with oseltamivir, as zanamivir is not currently indicated for prophylaxis. Zanamivir is now recommended for chemoprophylaxis.

If the exposure to the novel influenza virus strain occurs during the regular influenza season, the patient's healthcare contacts (who may also care for persons with seasonal influenza) should be vaccinated against seasonal influenza to reduce the possible risk of co-infection and reassortment of seasonal and novel strains.

D. Use of Antivirals for Containment of Disease Clusters

In special circumstances, state and local health departments could consider "targeted antiviral prophylaxis" as a community-based measure for containing small clusters of infection with novel strains of influenza. This measure could be implemented in small, well-defined settings such as the initial introduction of a virus with pandemic potential into a small community or a military base. However, once a pandemic is underway, such a strategy would not represent an efficient use of limited antiviral supplies.

Because targeted antiviral prophylaxis would require rapid delivery and administration of substantial stocks of antiviral drugs, its feasibility should be evaluated in light of antiviral drug supply and interim recommendations on antiviral drug use during a pandemic. Targeted antiviral prophylaxis would involve investigation of disease clusters, administration of antiviral treatment to persons with confirmed or suspected cases of pandemic influenza, and provision of drug prophylaxis to all persons in the affected community. Targeted antiviral prophylaxis would also require intensive case-finding in the affected area as well as effective communication with the affected community.

IV. PREPAREDNESS PLANNING FOR USE OF ANTIVIRALS DURING PANDEMIC

A. National Recommendations on Use of Antivirals During a Pandemic

The Department for Health and Human Services (HHS) is working with private-sector partners to increase production of antivirals and to procure additional stocks of antivirals for the Strategic National Stockpile (SNS) (<http://www.HHS.gov/nvpo/pandemicplan/>). Despite these efforts, demand for antivirals during an influenza pandemic is likely to far outstrip supplies available in stockpiles or through usual channels of distribution.

- A list of priority groups for receiving antiviral treatment or prophylaxis and the rationale for prioritization are provided in the NVAC/ACIP Recommendations Appendix. During an actual pandemic, these recommendations could be modified, based on the characteristics of the causative virus (e.g., drug susceptibilities, initial geographic distribution, fatality rate, age-specific morbidity and mortality rates) and the effectiveness of implemented strategies.

B. State-Level Planning

- State-based planning for antiviral includes:

- Obtaining antiviral drugs from national, state, and local stockpiles if available, and their distribution to priority groups by healthcare providers
- Data collection on drug use,
- Drug-related adverse events
- Drug resistance.

C. Procurement

Examples of planning steps for state-level procurement of antivirals include:

- Estimating the quantities of antiviral drugs that will be needed for treatment and prophylaxis of priority groups (see below)
- Identifying sources of antiviral drugs (e.g., federal supplies from the SNS and if available state stockpiles and private sector).

The establishment of state, local, or institutional stockpiles should take into account the expiration dates of the purchased material. All drugs are marked with an expiration date, based on review of stability data, at the time of manufacture. However, when purchased, the drugs might have been stored for some time in warehouses so that the time to expiration might be shorter than the time from initial manufacture to expiration date. Moreover, one shipment might consist of several batches with different expiration dates. Antivirals maintained in the national stockpile may be tested for potency and dating extended under the U.S. Food and Drug Administration's (FDA) shelf life extension program. Currently, state stockpiles are not included in this program.

D. Establishing Priority Groups

Based on interim recommendations on priority groups for antiviral treatment and prophylaxis (NVAC/ACIP Recommendations), state and local health authorities should determine how certain priority groups (e.g., public safety workers, essential service providers, and key decision makers) will be defined in their jurisdictions. These recommendations and enumerations can be found in the Recommendations on Antiviral Use portion of the state pandemic plan.

E. Distributing and Dispensing Antivirals to Priority Groups

Planning steps for distribution of antivirals to priority groups might include:

- Estimating the size and needs of priority groups in local jurisdictions, using interim recommendations
- Assessing antiviral stocks available at the state, local, and hospital levels if available
- Establishing a mechanism to request antivirals from the federal stockpile, if needed (see below)
- Activating pre-existing plans for the transport, receipt, storage, security, tracking, and delivery of:

- Antiviral stocks for use in treatment to hospitals, clinics, nursing homes, alternative care facilities, and other healthcare institutions. Prompt dispensing to point-of-care locations is crucial, because clinical efficacy for these agents has been demonstrated when treatment begins within 48 hours of the onset of symptoms.
- Antiviral stocks for use in post-exposure prophylaxis (e.g., for direct contacts of infected patients)
- Antiviral stocks for use in prophylaxis (e.g., if recommended for healthcare workers, public safety workers, and essential service providers)
- Considering the use of standing orders for treatment of certain priority groups, such as hospitalized patients and healthcare workers
- Developing a communication plan to explain the rationale for establishing these target groups

The decision to deploy federal assets from the SNS during an influenza pandemic will be made by HHS officials, as it would be during any public health emergency. Each state and federal agency with direct patient care responsibilities should designate a representative (e.g., the state epidemiologist or public health director) to make emergency requests for federal assets in the SNS.

Federal supplies of antivirals will be delivered to a site designated by state planners in each state or large city (e.g., state health department; existing SNS receipt, storage, staging site). State SNS coordinators should provide logistical guidance on the receipt and distribution of federal assets to priority groups.

Kentucky's SNS plan can be found in Kentucky Emergency Operations Plan Appendix M-10 (Strategic National Stockpile Program).

F. Monitoring and Data Collection

To ensure optimal use of antiviral drugs during an influenza pandemic, state and local health departments and healthcare partners should work with federal officials and collect data on:

- Distribution of state or federal supplies of antiviral drugs
- Occurrence of adverse events following administration of antiviral drugs

State and local departments could also participate in federal efforts to collect data on:

- Effectiveness of treatment and prophylaxis
- Development of drug resistance

(1) Distribution. Allocation and distribution of antiviral drugs from state and local health departments to drug delivery or dispensing sites will be established based on state and local pandemic plans. Health departments should develop strategies to

monitor drug distribution and use, assessing whether drugs are being effectively targeted to priority groups and whether distribution is equitable within those groups (e.g., among racial and ethnic minorities and persons of different socioeconomic levels).

(2) Antiviral effectiveness. Studies to evaluate the effectiveness of antiviral drug use during a pandemic will be conducted by federal agencies in collaboration with state and local health departments and other healthcare and academic partners. The effectiveness of antiviral therapy and prophylaxis will be assessed by comparing rates of severe influenza-related illness and death among treated and untreated persons and among persons who did and did not receive prophylaxis. Analyses of antiviral drug effectiveness should take into account characteristics that will vary among individuals and those that may vary over time, such as diagnostic practices, length of time to initiate therapy, and changes in the pandemic virus.

(3) Adverse events. Serious adverse events associated with the use of antiviral drugs for prophylaxis and treatment of influenza should be reported to the FDA, using the MedWatch monitoring program. During an influenza pandemic, state and local health departments can assist in this effort by providing protocols and information to healthcare providers and encouraging hospitals to download MedWatch forms (available at <http://www.fda.gov/medwatch/>) for distribution to patients. Adverse events reported to MedWatch are collated and analyzed by the FDA's Adverse Events Reporting System (AERS).

Use of antivirals will be much greater during a pandemic than during a regular influenza season. To help improve the detection of serious adverse effects (especially rare effects or effects in vulnerable populations), additional efforts to encourage recognition and reporting of adverse events will be needed. These efforts might include:

- Active monitoring for adverse events observed at emergency rooms, through the National Electronic Injury Surveillance System Cooperative Adverse Drug Event project (NEISS-CADE)
- Local campaigns to educate healthcare workers about the recognition and reporting of adverse events
- Distribution of MedWatch forms and descriptions of known adverse events to each end-user who receives antiviral drugs

In addition, the CDC, FDA, and AHRQ will explore the use of existing drug-monitoring systems that have access to individual health utilization records that may

allow active, population-based surveillance for adverse events following the use of antivirals for treatment or prophylaxis.

(4) Antiviral drug resistance. CDC will work with state and local partners to monitor the development of resistance to antivirals. Because resistance to M2 inhibitors may involve a single base pair change, resistance may develop rapidly if these drugs are used widely. Information about resistance to M2 inhibitors (i.e. the adamantanes and neuraminidase inhibitors) can be found in the July 2005 recommendations of the ACIP (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>).

Global surveillance for neuraminidase resistance during a pandemic will also be conducted by the Neuraminidase Inhibitor Susceptibility Network (NISN). The global NISN was established in 1999 to address public health and regulatory concerns regarding the potential emergence and consequences of drug resistance in influenza viruses following the introduction of the influenza neuraminidase inhibitor (NI) class of antiviral agents. The Network includes representatives of each of the four World Health Organization (WHO) global influenza reference laboratories and scientists from regions of the world where increasing use of these drugs is anticipated.

CDC will test the drug susceptibilities of viruses isolated from different age groups and geographic groups over the course of the pandemic (see Antiviral Effectiveness above). State and local health departments should encourage clinicians to obtain specimens from patients who develop severe disease while receiving treatment or prophylaxis. State health departments should provide these specimens on a periodic basis, preferably after testing them by RT-PCR, viral culture, or rapid diagnostic testing to confirm the presence of novel strains of influenza A.

Surveillance for antiviral resistance may be particularly important during the later stages of the pandemic, especially if M2 inhibitor agents (i.e. adamantanes) have been widely used. Under these circumstances, the detection of widespread M2 inhibitor resistance might require a re-evaluation of priorities for prophylaxis and treatment.

G. Contingency Planning for Investigational New Drug (IND) Use

State and local health departments should be prepared to distribute unlicensed antiviral drugs (if needed) under FDA's Investigational New Drug (IND) provisions. IND provisions require strict inventory control and recordkeeping, completion of a signed consent form from each person who receives the medication, and mandatory reporting of specified types of adverse events. IND provisions also require approval of the protocol and consent form by an Institutional Review Board (IRB). The FDA regulations permit the use of a national or "central" IRB. A treatment IND is one IND mechanism that FDA has available for use and is especially suited for large scale use of investigational products (http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr_99.html).

As an alternative to IND use of an unapproved antiviral drug, HHS may utilize the drug product under Emergency Use Authorization procedures as described in the FDA draft *Guidance Emergency Use Authorization of Medical Products* <http://www.fda.gov/cber/gdlns/emerase.pdf>

V. RECOMMENDATIONS FOR THE PANDEMIC PERIOD

Interim recommendations for use of antivirals may be updated throughout the course of an influenza pandemic to reflect current epidemiologic and laboratory data. Interim recommendations may also be updated as an effective influenza vaccine becomes available.

A. When pandemic influenza is reported abroad, or sporadic pandemic influenza cases are reported in the United States, without evidence of spread

If an influenza pandemic has begun in other countries, state and local health departments should:

- Use antiviral drugs in the management of persons infected with novel strains of influenza and their contacts.
- Work with healthcare partners to consider providing antiviral prophylaxis to persons at highest risk for pandemic influenza. Examples of such persons include:
 - Public health workers who investigate suspected cases of pandemic influenza
- Meet with local partners and stakeholders to review the state-based antiviral drug distribution plan. As part of this effort, state and local partners could:
 - Modify the distribution plan to take into account possible updated recommendations on target groups and updated information on projected supplies of antiviral drugs.
 - Notify the medical community about the status of the plan and the availability of antiviral drugs.
 - Disseminate public health guidelines that encourage drug-use practices that help minimize the development of drug resistance.
 - Provide the public with information on interim recommendations and their rationale for the use of antiviral drugs during an influenza pandemic.
- Work with federal partners to monitor the safety and effectiveness of drugs and ensure that available antivirals are used in accordance with federal and local recommendations.

B. When there is limited transmission of pandemic influenza in the United States

When there is limited transmission of pandemic influenza in the United States, state and local health departments should:

- Activate state-based plans for targeting antiviral drugs to priority groups for prophylaxis and treatment.

- Request antiviral drugs, as needed, from previously identified sources, including the SNS.
- Continue to work with healthcare partners to ensure appropriate use of antivirals in the medical management of early cases and contacts.
- Work with federal partners to begin monitoring the safety and effectiveness of drugs and ensure that available antivirals are used in accordance with federal and local recommendations.

C. When there is widespread transmission of pandemic influenza in the United States

When transmission of pandemic influenza has become widespread, the paramount goals of antiviral use will be to treat those at highest risk of severe illness and death, and to preserve the delivery of healthcare and other essential critical services through early treatment and limited prophylaxis.

After a vaccine becomes available, antiviral drugs may be used to protect persons who have an inadequate vaccine response (e.g., the elderly and those with underlying immunosuppressive disease) as well as persons with contraindications to vaccination, such as anaphylactic hypersensitivity to eggs or other vaccine components.

Until the pandemic has waned, state and local health departments should continue to work with healthcare and federal partners to monitor the safety and effectiveness of antivirals and to encourage appropriate drug use practices that help minimize the development of drug resistance.

APPENDIX A

Recommendations on Pandemic Antiviral Use

The following recommendations are reflective of the National Vaccine Advisory Committee (NVAC) recommendations issued on July 19, 2005. NVAC recognizes that recommendations for antiviral drug use will need to be reconsidered at the time of a pandemic when information of the available drug supply, epidemiology of disease, and impacts on society are known. Kentucky will comply with recommendations set forth by NVAC, the Department for Health and Human Services (HHS), and the Centers for Disease Control and Prevention (CDC) and will implement any changes made by these agencies to the recommendations on pandemic antiviral use. The committee considered the primary goals of a pandemic response to decrease health impacts including severe morbidity and death. Minimizing societal and economic impacts were considered secondary and tertiary goals.

A. Critical Assumptions

Assumptions regarding groups at highest risk during a pandemic and impacts on the healthcare system and other critical infrastructures are the same as those underlying the vaccine priority recommendations. Additional assumptions specific for antiviral drugs included:

- Treatment with a neuraminidase inhibitor (oseltamivir [Tamiflu®] or zanamivir [Relenza®]) will be effective in decreasing risk of pneumonia, will decrease hospitalization by about half (as shown for interpandemic influenza), and will also decrease mortality.
- Antiviral resistance to the adamantanes (amantadine and rimantadine) may limit their use during a pandemic.
- The primary source of antiviral drugs for a pandemic response will be the supply of antiviral drugs that have been stockpiled. Before annual influenza seasons about 2 million treatment courses of oseltamivir are available in the U.S. U.S.-based production of oseltamivir is being established; expected capacity is projected at about 1.25 million courses per month.
- Treating earlier after the onset of disease is most effective in decreasing the risk of complications and shortening illness duration. Generally, treatment should be given within the first 48 hours.
- Assumptions for the amount of antiviral drug needed for defined priority groups is based on the population in those groups and assumptions that 35% of persons in the priority groups will have influenza-like illness and 75% will present within the first 48 hours and be eligible for treatment. For persons admitted to the hospital, the committee assumed that 80% would be treated, as the 48-hour limit may sometimes be relaxed in more ill patients.
- Unlike vaccines, where each tier would be protected in turn as more vaccine is produced, for antiviral drugs, the number of priority groups that can be covered would be known at the start of the pandemic based on the amount of drug that is

stockpiled. Additional supply that would become available during the pandemic could provide some flexibility.

Table D-2: Antiviral Drug Priority Group Recommendations*

| | Group | Estimated population (millions) | Strategy** | # Courses (millions) | | Rationale |
|---|---|---------------------------------|------------|----------------------|------------|--|
| | | | | For target group | Cumulative | |
| 1 | Patients admitted to hospital*** | 10.0 | T | 7.5 | 7.5 | Consistent with medical practice and ethics to treat those with serious illness and who are most likely to die. |
| 2 | Health care workers (HCW) with direct patient contact and emergency medical service (EMS) providers | 9.2 | T | 2.4 | 9.9 | Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand. |
| 3 | Highest risk outpatients—immunocompromised persons and pregnant women | 2.5 | T | 0.7 | 10.6 | Groups at greatest risk of hospitalization and death; immunocompromised cannot be protected by vaccination. |
| 4 | Pandemic health responders (public health, vaccinators, vaccine and antiviral manufacturers), public safety (police, fire, corrections), and government decision-makers | 3.3 | T | 0.9 | 11.5 | Groups are critical for an effective public health response to a pandemic. |
| 5 | Increased risk outpatients—young children 12-23 months old, persons | 85.5 | T | 22.4 | 33.9 | Groups are at high risk for hospitalization and death. |

| | Group | Estimated population (millions) | Strategy** | # Courses (millions) | | Rationale |
|----|---|---------------------------------|------------|----------------------|------------|---|
| | | | | For target group | Cumulative | |
| | >65 yrs old, and persons with underlying medical conditions | | | | | |
| 6 | Outbreak response in nursing homes and other residential settings | NA | PEP | 2.0 | 35.9 | Treatment of patients and prophylaxis of contacts is effective in stopping outbreaks; vaccination priorities do not include nursing home residents. |
| 7 | HCWs in emergency departments, intensive care units, dialysis centers, and EMS providers | 1.2 | P | 4.8 | 40.7 | These groups are most critical to an effective healthcare response and have limited surge capacity. Prophylaxis will best prevent absenteeism. |
| 8 | Pandemic societal responders (e.g., critical infrastructure groups as defined in the vaccine priorities) and HCW without direct patient contact | 10.2 | T | 2.7 | 43.4 | Infrastructure groups that have impact on maintaining health, implementing a pandemic response, and maintaining societal functions. |
| 9 | Other outpatients | 180 | T | 47.3 | 90.7 | Includes others who develop influenza and do not fall within the above groups. |
| 10 | Highest risk outpatients | 2.5 | P | 10.0 | 100.7 | Prevents illness in the highest risk groups for hospitalization and death. |

| | Group | Estimated population (millions) | Strategy** | # Courses (millions) | | Rationale |
|----|--|---------------------------------|------------|----------------------|------------|---|
| | | | | For target group | Cumulative | |
| 11 | Other HCWs with direct patient contact | 8.0 | P | 32.0 | 132.7 | Prevention would best reduce absenteeism and preserve optimal function. |

*The committee focused its deliberations on the domestic U.S. civilian population. NVAC recognizes that Department of Defense (DoD) needs should be highly prioritized. A separate DoD antiviral stockpile has been established to meet those needs. Other groups also were not explicitly considered in deliberations on prioritization. These include American citizens living overseas, non-citizens in the U.S., and other groups providing national security services such as the border patrol and customs service.

**Strategy: Treatment (T) with oseltamivir [Tamiflu®] requires a total of 10 capsules and is defined as 1 course. Post-exposure prophylaxis (PEP) also requires a single course. Prophylaxis (P) with oseltamivir [Tamiflu®] is assumed to require 40 capsules (4 courses) though more may be needed if community outbreaks last for a longer period.

***There are no data on the effectiveness of treatment at hospitalization. If stockpiled antiviral drug supplies are very limited, the priority of this group could be reconsidered based on the epidemiology of the pandemic and any additional data on effectiveness in this population.

B. Definitions and rationale for draft priority groups

1. Persons admitted to hospital with influenza infection

a) Definition
 Persons admitted to acute care facilities (traditional or non-traditional with a clinical diagnosis of influenza; laboratory confirmation not required). Excludes persons admitted for a condition consistent with a bacterial superinfection (e.g., lobar pneumonia developing late after illness onset) or after viral replication and shedding has ceased (e.g., as documented by a negative sensitive antigen detection test)

b) Strategy
 Treatment within 48 hours of symptom onset.

c) Rationale
 This group is at greatest risk for severe morbidity and mortality. Although there are no data to document the impacts of antiviral drug treatment among persons who already suffer more severe influenza illness, benefit is biologically plausible in persons with evidence of ongoing virally mediated pathology (e.g., diffuse pneumonia, ARDS). Providing treatment to those who are most ill is also consistent

with standard medical practices, would be feasible to implement, and would be acceptable to the public.

d) Population size
The number of persons admitted to hospital in an influenza pandemic would vary substantially depending on the severity of the pandemic and on the ability to expand inpatient capacity, if needed.

e) Unresolved issues
More specific guidance should be provided to healthcare workers on implementing antiviral treatment, including when and when not to treat. In some persons with severe illness, the ability to take oral medication or its absorption may be important issues. For infants <1 year old admitted to hospital, decisions about whether to treat with antiviral drugs may depend on the child's age and potential risk versus benefit as the neuraminidase inhibitors are not licensed for use in infants. If possible, data on time from symptom onset to hospital admission, current use of antiviral drug treatment among inpatients, and its impacts should be collected during interpandemic influenza seasons.

2. Healthcare workers and emergency medical service providers who have direct patient contact

a) Definition
Persons providing direct medical services in inpatient and outpatient care settings. Includes doctors, nurses, technicians, therapists, EMS providers, laboratory workers, other care providers who come within 3 feet of patients with influenza, and persons performing technical support functions essential to quality medical care.

b) Strategy
Treatment within 48 hours of symptom onset.

c) Rationale
Maintaining high quality patient care is critical to reduce health impacts of pandemic disease and to prevent adverse outcomes from other health conditions that will present for care during the pandemic period. Treatment of healthcare providers will decrease absenteeism due to influenza illness and may decrease absenteeism from fear of becoming ill, given the knowledge that treatment can prevent serious complications of influenza. Good data exist documenting the impacts of early treatment on duration of illness and time off work, and on the occurrence of complications such as lower respiratory infections. Treating healthcare providers is feasible to implement, especially for inpatient care providers who can be provided drugs through the occupational health clinic. It also would be acceptable to the public, who would recognize the importance of maintaining quality healthcare and would understand that persons with direct patient contact are putting themselves at increased risk.

d) Population size
There are about 12.6 million persons designated as healthcare workers by the Bureau of Labor Statistics and about 820,000 EMS providers. Among HCWs, two-thirds are estimated to provide direct patient care services.

e) Unresolved issues
Further work is needed to hone definitions and estimate population sizes.

Implementation issues include the approach to identifying healthcare providers who would be eligible for treatment and where the treatment would be provided, particularly for outpatient care providers.

3. Outpatients at highest risk for severe morbidity or mortality from influenza infection

a) Definition
The ACIP defines groups at high risk (or increased risk) of complications from influenza infection during annual outbreaks based on age (6-23 months and >65 years) and underlying illnesses. Among this population of about 88 million persons, some can be identified who are at highest risk of severe disease and death. These include persons with hematopoietic stem cell transplants (HSCT) and solid organ transplants; those with severe immunosuppression due to cancer therapy or hematological malignancy; persons receiving immunosuppressive therapy for other illnesses (e.g., rheumatoid arthritis); persons with HIV infection and a CD4 count <200; persons on dialysis; and women who are in the second or third trimester of pregnancy.

b) Strategy
Treatment within 48 hours of symptom onset.

c) Rationale
Of the large group of persons who are at increased risk of severe disease or death from influenza, these groups represent the population at highest risk and who are least likely to be protected by vaccination. Studies show that neuraminidase inhibitor therapy decreases complications and hospitalizations from influenza in high-risk persons and one unpublished study shows a significant decrease in mortality among patients who have undergone a hematopoietic stem cell transplant.

d) Population size
About 150,000 persons have had an HSCT or solid organ transplant. Assuming that the period of severe immunosuppression after a cancer diagnosis lasts for 1 year, the population targeted with non-skin, non-prostate cancers would equal the incidence of about 1.35 million persons. Based on a birth cohort of 4.1 million, a 28-week risk period during the second and third trimesters, and an 8-week pandemic outbreak in a community, there would be about 400,000 pregnant women included in this risk group. Further work is needed to estimate the size of other immunosuppressed groups.

e) Unresolved issues
Specific definition of included groups and population sizes.

4. Pandemic health responders, public safety workers, and key government decision-makers

a) Definition
Public health responders include those who manufacture vaccine and antiviral drugs; persons working at health departments who are not included as healthcare workers; and those who would be involved in implementing pandemic vaccination or other response components. Public safety workers include police, fire, and corrections personnel. Key government decision-makers include chief executives at federal, state, and local levels.

- b) Strategy
Treatment within 48 hours of symptom onset.
- c) Rationale
Preventing adverse health outcomes and social and economic impacts in a pandemic depend on the ability to implement an effective pandemic response. Early treatment of pandemic responders will minimize absenteeism and ensure that vaccination and other critical response activities can be maintained. Implementing early treatment for public health workers and vaccine manufacturers is feasible at workplace settings. Public safety workers prevent intentional and unintentional injuries and death, are critical to maintaining social functioning, and will contribute to a pandemic response, for example by ensuring order at vaccination clinics. A small number of decision-makers at federal, state, and local levels are needed to for an effective pandemic response.
- d) Population size
An estimated 40,000 workers who produce pandemic vaccine and antiviral drugs in the U.S.; ~300,000 public health workers who would not be included in the HCW category; 3 million public safety workers; and a small number of government decision-makers.
- e) Unresolved issues
Need to define the exact composition and size of this group.

5. Outpatients at increased risk of severe morbidity or mortality from influenza

- a) Definition
For planning purposes, this group would include those currently designated as high-risk groups, except for those who have been categorized as being at highest-risk and included in a separate category. This increased-risk group includes persons 6-23 months and >65 years old, or who have underlying illnesses defined by the ACIP as associated with increased risk. Definition of this group may change based on the epidemiology of the pandemic.
- b) Strategy
Treatment within 48 hours of symptom onset.
- c) Rationale
Early treatment has been shown to significantly decrease lower respiratory infections and reduce the rate of hospitalization in elderly and high-risk populations. By extrapolation and based on the results of one small uncontrolled study, significant reductions of mortality can be expected as well. As these risk groups are familiar to the public given recommendations for annual vaccination, communication would be easy and acceptability high.
- d) Population size
About 85.5 million persons are included in this group. Although all are at increased risk of annual influenza compared with the healthy under-65 year old population, there are different levels of increased risk for severe complications and death within this category. Further stratification may be possible based on several parameters including number of underlying conditions; recent hospitalization for a high-risk condition, pneumonia, or influenza; and age.

e) Unresolved issues
Stratifying this group into those at greater and lesser risk may be important if antiviral supplies are limited. Implementing treatment will be challenging given that it should be provided at the initial point of care to accrue the greatest benefit from early therapy.

6. Outbreak control

a) Definition
Use of antiviral drugs to support public health interventions in closed settings where an outbreak of pandemic influenza is occurring.

b) Strategy
Treatment of cases and post-exposure prophylaxis of contacts (once daily antiviral medication for 10 days).

c) Rationale
Influenza outbreaks in nursing homes are associated with substantial mortality and morbidity. Nursing home residents also are less likely to respond to vaccination. Post-exposure prophylaxis has been shown to be effective in stopping influenza outbreaks in closed settings.

d) Population size
The number of outbreaks that may occur during a pandemic is unclear. Measures should be implemented to prevent outbreaks including limiting visitors, vaccination of staff, furloughing non-critical staff, and screening and exclusion for illnesses consistent with influenza.

e) Unresolved issues
Should this policy also be implemented in prisons or other settings where explosive spread of illness may occur but the risk for severe complications is not high?

7. Healthcare workers in ER, ICU, EMS, and dialysis settings

a) Definition
Includes all staff in these settings who are required for effective functioning of these health care units.

b) Strategy
Prophylaxis

c) Rationale
Optimally effective functioning of these units is particularly critical to reducing the health impacts of a pandemic. Prophylaxis will minimize absenteeism in these critical settings.

d) Population size
Need to obtain population estimates.

e) Unresolved issues
Population sizes

8. Pandemic societal responders and healthcare workers who have no direct patient contact

a) Definition
This group includes persons who provide services that must be sustained at a

sufficient level during a pandemic to maintain public well-being, health, and safety. Included are workers at healthcare facilities who have no direct patient contact but are important for the operation of those facilities; utility (electricity, gas, water), waste management, mortuary, and some transport workers.

b) Strategy
Treatment within 48 hours of symptom onset.

c) Rationale
Maintaining certain key functions is important to preserve life and decrease societal disruption. Heat, clean water, waste disposal, and corpse management all contribute to public health. Ensuring functional transportation systems also protects health by making it possible for people to access medical care and by transporting food and other essential goods to where they are needed.

d) Population size
Within these broad categories, there are about 2 million workers at healthcare facilities who have no direct patient contact; 730,000 utility workers; 320,000 waste management workers; 62,000 in mortuary services; and 2.3 million in transportation. Not all occupations within these categories would be classified as pandemic societal responders. Estimates are that 35% of this population will develop illness and present within 48 hours of onset regardless of pandemic severity.

e) Unresolved issues
Need to stratify within these groups to identify who fills specific pandemic societal response functions and to assess whether those functions could still operate if a substantial proportion of the workforce became ill during a 6-8 week pandemic outbreak within a community. Implementation issues need to be addressed, especially with respect to how persons would be identified as falling within this priority group when presenting for treatment and where that treatment would be provided.

9. Other outpatients

a) Definition
Includes persons not in one of the earlier priority groups.

b) Strategy
Treatment within 48 hours of illness onset.

c) Rationale
Treatment reduces the risk of complications and mortality, reduces duration of illness and shortens time off work, and decreases viral shedding and transmission. If sufficient antiviral supplies are available, providing treatment to all who are ill achieves equity and will be most acceptable to the public.

d) Population size
There are an estimated 180 million persons who are not included in previously targeted groups.

e) Unresolved issues
Consider whether there are any strata that can be defined within this population.

C. Additional NVAC recommendations on antiviral drugs for pandemic influenza

In addition to recommendations for priority groups, NVAC unanimously adopted the following recommendations:

- Sufficient drugs should be stockpiled to address top priorities. NVAC recommends that the minimum stockpile size be about 40 million courses, allowing coverage of the top 7 priority groups.
- Oseltamivir should be the primary drug stockpiled, but some zanamivir also should be obtained as it is effective against some oseltamivir-resistant strains, may be preferred for treatment of pregnant women, and supporting two manufacturers enhances security against supply disruptions. Approximately 10% of the stockpile should be zanamivir if feasible and cost effective. No additional adamantanes should be stockpiled.
- Antiviral drugs can also be used as part of an international effort to contain an initial outbreak and prevent a pandemic. Use to slow disease spread early in a pandemic may be useful but requires large amounts of drug.
- Critical research should be conducted to support development and implementation of recommendations for pandemic influenza antiviral drug use, including:
 - Impact of treatment at hospital admission on outcome
 - Optimal treatment dose for H5N1 and other potential pandemic strains
 - Sensitivity and use of rapid diagnostic tests for H5N1 and other influenza strains with pandemic potential
 - Safety and pharmacokinetics of oseltamivir among infants <1 year old
 - Investigation of the impact of other drugs (new antiviral agents and other classes such as statins) on influenza
- Additional work with public and private sector groups should be done to further hone definitions of target groups and their estimated population sizes, and to provide further guidance on antiviral drug distribution and dispensing.

**KENTUCKY INFLUENZA PANDEMIC RESPONSE PLAN
COMMUNITY CONTAINMENT SUPPLEMENT VII**

| TABLE OF CONTENTS | | |
|--------------------------|--|-------------|
| | | PAGE |
| I. | RATIONALE/OVERVIEW | 1 |
| II. | GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT | 1 |
| | A. Nonpharmaceutical Interventions | 4 |
| | B. Triggers for Initiating Use of Nonpharmaceutical Interventions | 9 |
| | C. Duration of Implementation of Nonpharmaceutical Interventions | 10 |
| | D. Planning to Minimize Consequences of Community Mitigation Strategy | 11 |
| III. | GENERAL GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT AND PREVENTION INTERPANDEMIC AND PANDEMIC ALERT PERIODS: | 12 |
| | A. Department for Public Health Responsibilities | 12 |
| | B. Local Health Departments Responsibilities | 13 |
| IV. | GENERAL GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT AND PREVENTION PANDEMIC PERIOD: | 14 |
| | A. Department for Public Health Responsibilities | 14 |
| | B. Local Health Department Responsibilities | 15 |
| V. | MANAGING TRAVEL-RELATED RISK OF DISEASE TRANSMISSION INTERPANDEMIC AND PANDEMIC ALERT PERIODS: | 15 |
| | A. Department for Public Health Responsibilities | 15 |
| | B. Local Health Departments Responsibilities | 16 |
| VI. | LEGAL AUTHORITY FOR PUBLIC HEALTH EMERGENCIES: | 17 |
| | A. Kentucky Revised Statutes | 17 |
| VII. | APPENDICES | |
| | Appendix 1. Prioritization Tier Groups | 18 |
| | Appendix 2. Travel Industry | 19 |
| | Appendix 3. Protocols Developed for International Flights | 19 |
| | Appendix 4. Isolation and Quarantine Locations | 20 |
| | Appendix 5. School Notification-Concerning Communicable Disease: | 20 |

Community Containment

I. RATIONALE / OVERVIEW

The objective of this supplement is to provide guidance on the most effective combinations of pharmaceutical and nonpharmaceutical interventions to reduce the risk of transmission of novel influenza A viruses, particularly subtype H5N1 (a causative agent of avian influenza) that may cause an influenza pandemic. The supplement is divided into three major areas: Community Disease Containment, Prevention and Managing Travel-Related Risk of Disease Transmission and Legal Authority for Public Health Emergencies. The first two major areas provide guidance for the state and local health departments depending on the stages of the pandemic. This supplement contains appendices that address vaccine and antiviral prioritization, travel industry guidelines, protocols for international flights, isolation and quarantine information, school notification-concerning communicable disease and interim guidance from the CDC on nonpharmaceutical interventions.

The Kentucky Department for Public Health (KDPH) will implement recommendations from the “Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions” (Appendix 6) before explosive growth of an epidemic. This will mitigate the effects of an influenza pandemic on the population of Kentucky. KDPH will execute the pandemic mitigation interventions described based upon the pandemic severity index and other guidance received by the CDC.

II. GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT:

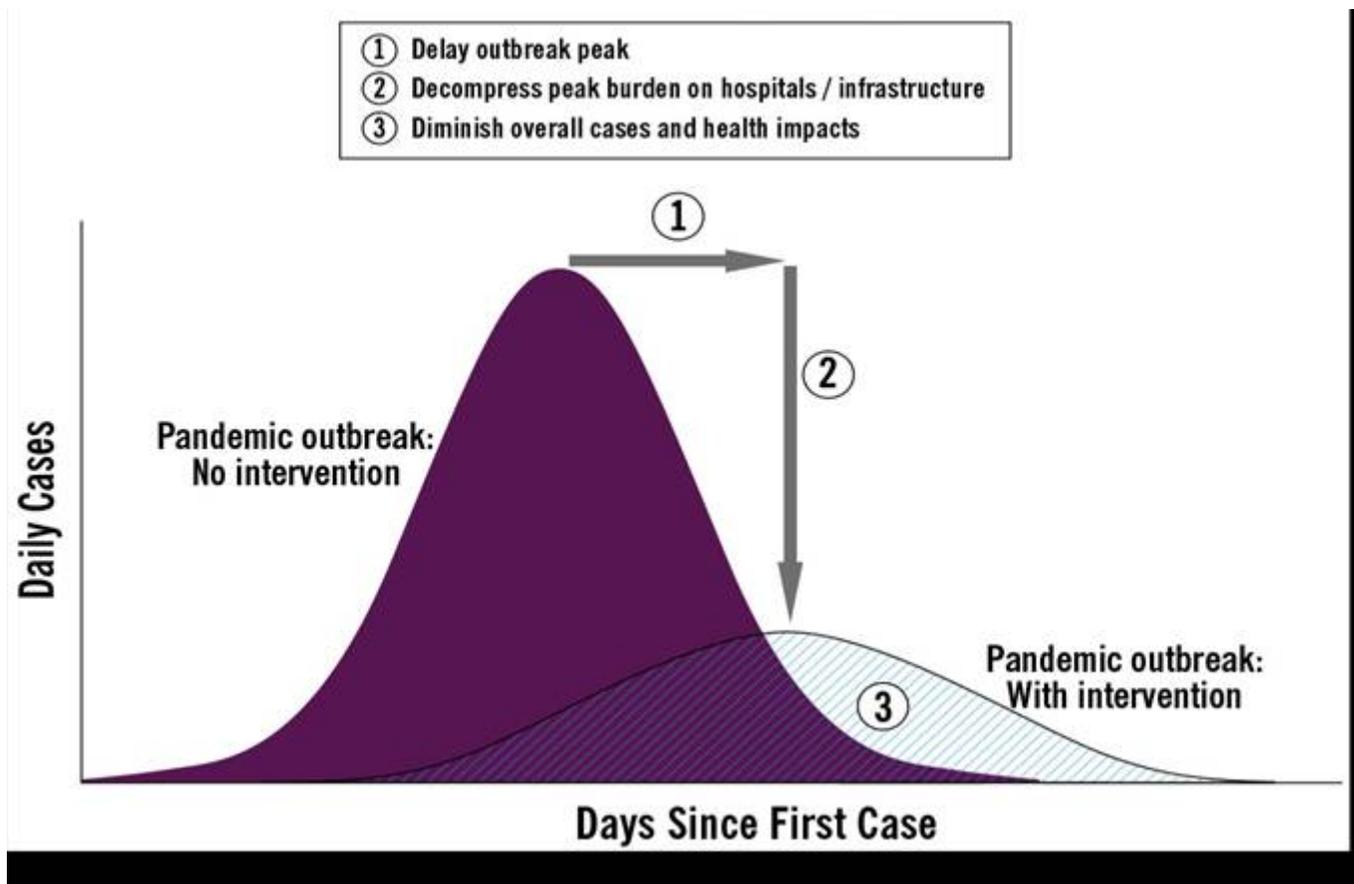
The overarching public health imperative is to reduce morbidity and mortality in a pandemic. The primary strategies for combating influenza are:

1. Vaccination
2. Treatment of infected individuals and prophylaxis of exposed individuals with influenza antiviral medications
3. Implementation of infection control and social distancing measures.

Because it is highly unlikely that a vaccine would be available at the start of a pandemic and the fact that vaccine and antivirals are likely to be in short supply, nonpharmaceutical interventions will be the best countermeasure. The goals of community mitigation are listed below and summarized in Figure 1:

1. Delay outbreak peak
2. Decompress peak burden on hospitals/infrastructure
3. Diminish overall cases and health impacts

Figure 1. Goals of Community Mitigation

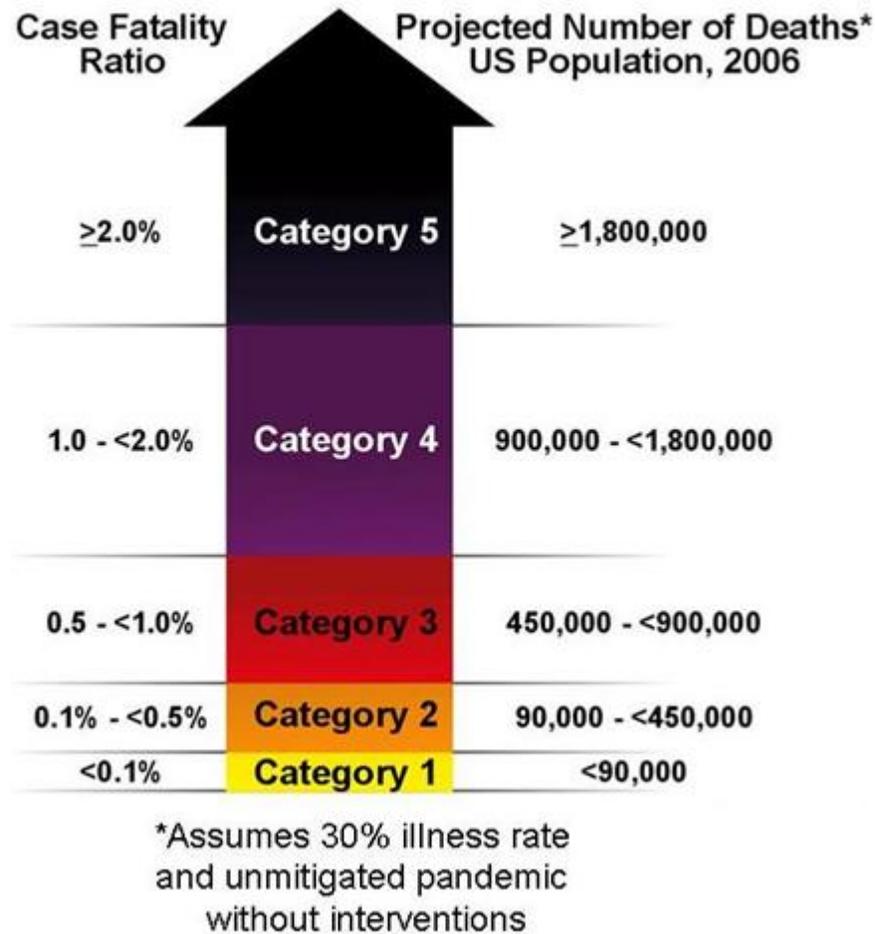


Based on research done by the CDC, community containment is based upon early, targeted, layered mitigation strategies involving multiple partially effective nonpharmaceutical measures initiated early and maintained consistently during an epidemic wave. Decisions about what interventions should be used during a pandemic should be based on the severity of the event, its impact on specific subpopulations, the expected benefits of the intervention, the feasibility of success in modern society, the direct and indirect costs, and the consequences of critical infrastructure, healthcare delivery and society. Some interventions such as prolonged dismissal of students from school are not necessary during a less severe pandemic. The Pandemic Severity Index is a tool created by the CDC for pre-pandemic planning efforts based primarily on case fatality ratio. Pandemic severity is described within five discrete categories of increasing severity (Category 1 to Category 5). Figure 3 below depicts the new Pandemic Severity Index. Figure 2 below provides categorization of pandemic severity by epidemiological characteristics.

Figure 2. Pandemic Severity Index by Epidemiological Characteristics

| Characteristics | Pandemic Severity Index | | | | |
|--|---|---------------------|-------------------|-----------------------|---------------|
| | Category 1 | Category 2 | Category 3 | Category 4 | Category 5 |
| Case Fatality Ratio (percentage) | <0.1 | 0.1 - <0.5 | 0.5 - <1.0 | 1.0 - <2.0 | ≥ 2.0 |
| Excess Death Rate (per 100,000) | <30 | 30 - <150 | 150 - <300 | 300 - <600 | ≥600 |
| Illness Rate (percentage of the population) | 20 - 40 | 20 - 40 | 20 - 40 | 20 - 40 | 20 - 40 |
| Potential Number of Deaths (based on 2006 U.S. population) | <90,000 | 90,000- <450,000 | 450,000- <900,000 | 900,000- <1.8 million | ≥1.8 million |
| 20 th Century U.S. Experience | Seasonal Influenza (Illness rate 5-20%) | 1957, 1968 Pandemic | None | None | 1918 Pandemic |

Figure 3. Pandemic Severity Index



A. Nonpharmaceutical Interventions

Community containment is based upon early, targeted, layered mitigation strategies involving multiple partially effective nonpharmaceutical measures initiated early and maintained consistently during an epidemic wave. These interventions are based on severity index and include:

1. Isolation and treatment (as appropriate) with influenza antiviral medications of all persons with confirmed or probable pandemic influenza. Isolation may occur in the home or healthcare setting, depending on the severity of the individual's illness and/or the current capacity of the healthcare infrastructure.
2. Voluntary home quarantine of members of households with confirmed or probable influenza case(s) and consideration of combining this intervention with

the prophylactic use of antiviral medications, providing sufficient quantities of effective medications exist and that a feasible means of distributing them is in place.

3. Dismissal of students from schools (including public and private schools as well as colleges and universities) and school-based activities and closure of childcare programs, coupled with protecting children and teenagers through social distancing in the community to achieve reductions of out-of-school social contacts and community mixing.
4. Use of social distancing measures to reduce contact between adults in the community and workplace, including, for example, cancellation of large public gatherings and alteration of workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible without disrupting essential services. Enable institution of workplace leave policies that align incentives and facilitate adherence with the nonpharmaceutical interventions (NPIs) outlined above.

Recommendations for these nonpharmaceutical measures are summarized in Figure 4 below.

Figure 4. Summary of the Community Mitigation Strategy by Pandemic Severity

| Interventions* by Setting | Pandemic Severity Index | | |
|--|---------------------------|-----------------------|-------------------------|
| | 1 | 2 and 3 | 4 and 5 |
| Home | | | |
| Voluntary isolation of ill at home (adults and children); combine with use of antiviral treatment as available and indicated | Recommend †§ | Recommend †§ | Recommend †§ |
| Voluntary quarantine of household members in homes with ill persons¶ (adults and children); consider combining with antiviral prophylaxis if effective, feasible, and quantities sufficient | Generally not recommended | Consider ** | Recommend ** |
| School | | | |
| Child social distancing | | | |
| -dismissal of students from schools and school based activities, and closure of child care programs | Generally not recommended | Consider: ≤4 weeks †† | Recommend: ≤12 weeks §§ |
| -reduce out-of school social contacts and community mixing | Generally not recommended | Consider: ≤4 weeks †† | Recommend: ≤12 weeks §§ |
| Workplace / Community | | | |
| Adult social distancing | | | |
| -decrease number of social contacts (e.g., encourage teleconferences, alternatives to face-to-face meetings) | Generally not recommended | Consider | Recommend |
| -increase distance between persons (e.g., reduce density in public transit, workplace) | Generally not recommended | Consider | Recommend |
| -modify, postpone, or cancel selected public gatherings to promote social distance (e.g., stadium events, theater performances) | Generally not recommended | Consider | Recommend |
| -modify work place schedules and practices (e.g., telework, staggered shifts) | Generally not recommended | Consider | Recommend |

The following interventions are taken from “Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions”.

Voluntary Isolation of Ill Persons

The goal of this intervention is to reduce transmission by reducing contact between persons who are ill and those who are not. Ill individuals not requiring hospitalization would be requested to remain at home voluntarily for the infectious period, approximately 7-10 days after symptom onset. This would usually be in their homes, but could be in a home of a friend or relative. Voluntary isolation of ill children and adults at home is predicated on the assumption that many ill individuals who are not critically ill can and will need to be cared for in the home. In addition, this intervention may be combined with the use of influenza antiviral medications for treatment (as appropriate), as long as such medications are effective and sufficient in quantity and that feasible plans and protocols for distribution are in place.

Requirements for success include prompt recognition of illness, appropriate use of hygiene and infection control practices in the home setting (specific guidance is forthcoming and will be available on www.pandemicflu.gov); measures to promote voluntary compliance (e.g., timely and effective risk communications); commitment of employers to support the recommendation that ill employees stay home; and support for the financial, social, physical, and mental health needs of patients and caregivers. In addition, ill individuals and their household members need clear, concise information about how to care for an ill individual in the home and when and where to seek medical care. Special consideration should be made for persons who live alone, as many of these individuals may be unable to care for themselves if ill.

Voluntary Quarantine of Household Members of Ill Persons

The goal of this intervention is to reduce community transmission from members of households in which there is a person ill with pandemic influenza. Members of households in which there is an ill person may be at increased risk of becoming infected with a pandemic influenza virus. As determined on the basis of known characteristics of influenza, a significant proportion of these persons may shed virus and present a risk of infecting others in the community despite having asymptomatic or only minimally symptomatic illness that is not recognized as pandemic influenza disease. Thus, members of households with ill individuals may be recommended to stay home for an incubation period, 7 days (voluntary quarantine) following the time of symptom onset in the household member. If other family members become ill during this period, the recommendation is to extend the time of voluntary home quarantine for another incubation period, 7 days from the time that the last family member becomes ill. In addition, consideration may be given to combining this intervention with provision of influenza antiviral medication to persons in quarantine if such medications are effective and sufficient in quantity and if a feasible means of distributing them is in place.

Requirements for success of this intervention include the prompt and accurate identification of an ill person in the household, voluntary compliance with quarantine by household members, commitment of employers to support the recommendation that employees living in a household with an ill individual stay home, the ability to provide needed support to households that are under voluntary quarantine, and guidance for infection control in the home. Additionally, adherence to ethical principals in use of quarantine during pandemics, along with proactive anti-stigma measures should be assured.

Child Social Distancing

The goal of these interventions is to protect children and to decrease transmission among children in dense classroom and non-school settings and, thus, to decrease introduction into households and the community at large. Social distancing interventions for children include dismissal of students from classrooms and closure of childcare programs, coupled with protecting children and teenagers through social distancing in the community to achieve reductions of out-of-school social contacts and community mixing. Childcare facilities and schools represent an important point of epidemic amplification, while the children themselves, for reasons cited above, are thought to be efficient transmitters of disease in any setting. The common sense desire of parents to protect their children by limiting their contacts with others during a severe pandemic is congruent with public health priorities, and parents should be advised that they could protect their children by reducing their social contacts as much as possible.

However, it is acknowledged that maintaining the strict confinement of children during a pandemic would raise significant problems for many families and may cause psychosocial stress to children and adolescents. These considerations must be weighed against the severity of a given pandemic virus to the community at large and to children in particular. Risk of introduction of an infection into a group and subsequent transmission among group members is directly related to the functional number of individuals in the group. Although the available evidence currently does not permit the specification of a “safe” group size, activities that recreate the typical density and numbers of children in school classrooms are clearly to be avoided. Gatherings of children that are comparable to family-size units may be acceptable and could be important in facilitating social interaction and play behaviors for children and promoting emotional and psychosocial stability.

A recent study of children between the ages of 25 and 36 months found that children in group care with six or more children were 2.2 times as likely to have an upper respiratory tract illness as children reared at home or in small-group care (defined as fewer than six children). If a recommendation for social distancing of children is advised during a pandemic and families must nevertheless group their children for pragmatic reasons, it is recommended that group sizes be held to a minimum and that mixing between such groups be minimized (e.g., children should not move from group to group or have extended social contacts outside the designated group).

Requirements for success of these interventions include consistent implementation among all schools in a region being affected by an outbreak of pandemic influenza, community and parental commitment to keeping children from congregating out of school, alternative options for the education and social interaction of the children, clear legal authorities for decisions to dismiss students from classes and identification of the decision-makers, and support for parents and adolescents who need to stay home from work. Interim recommendations for pre-pandemic planning for this intervention include a three-tiered strategy: 1) no dismissal of students from schools or closure of childcare facilities in a Category 1 pandemic; 2) short-term (up to 4 weeks) dismissal of students and closure of childcare facilities during a Category 2 or Category 3 pandemic; and 3) prolonged (up to 12 weeks) dismissal of students and closure of childcare facilities during a severe influenza pandemic (Category 4 or Category 5). The conceptual thinking behind this recommendation is developed more fully in Section VII, *Duration of Implementation of Nonpharmaceutical Interventions*.

Colleges and universities present unique challenges in terms of pre-pandemic planning because many aspects of student life and activity encompass factors that are common to both the child school environment (e.g., classroom/dormitory density) and the adult sphere (e.g., commuting longer distances for university attendance and participating in activities and behaviors associated with an older student population). Questions remain with regard to the optimal strategy for managing this population during the early stages of an influenza pandemic.

The number of college students in the United States is significant. There are approximately 16.6 million college students attending both 2- and 4-year universities, a large number of whom live away from home. Of the 8.3 million students attending public or private 4-year colleges and universities, less than 20 percent live at home with their parents.

At the onset of a pandemic, many parents may want their children who are attending college or university to return home from school. Immediately following the announcement of an outbreak, colleges and universities should prepare to manage or assist large numbers of students departing school and returning home within a short time span. Where possible, policies should be explored that are aligned with the travel of large numbers of students to reunite with family and the significant motivations behind this behavior. Pre-pandemic planning to identify those students likely to return home and those who may require assistance for imminent travel may allow more effective management of the situation. In addition, planning should be considered for those students who may be unable to return home during a pandemic.

Adult Social Distancing

Social distancing measures for adults include provisions for both workplaces and the community and may play an important role in slowing or limiting community transmission pressure. The goals of workplace measures are to reduce transmission within the workplace and thus into the community at large, to ensure a safe working

environment and promote confidence in the workplace, and to maintain business continuity, especially for critical infrastructure. Workplace measures such as encouragement of telework and other alternatives to in-person meetings may be important in reducing social contacts and the accompanying increased risk of transmission. Similarly, modifications to work schedules, such as staggered shifts, may also reduce transmission risk.

Within the community, the goals of these interventions are to reduce community transmission pressures and thus slow or limit transmission. Cancellation or postponement of large gatherings, such as concerts or theatre showings, may reduce transmission risk. Modifications to mass transit policies/ridership to decrease passenger density may also reduce transmission risk, but such changes may require running additional trains and buses, which may be challenging due to transit employee absenteeism, equipment availability, and the transit authority's financial ability to operate nearly empty train cars or buses.

Requirements for success of these various measures include the commitment of employers to providing options and making changes in work environments to reduce contacts while maintaining operations; whereas, within communities, the support of political and business leaders as well as public support is critical.

B. Triggers for Initiating Use of Nonpharmaceutical Interventions

Identifying the optimal time for initiation of nonpharmaceutical interventions will be challenging as implementing measures prior to a pandemic may result in economic and social hardship and compliance fatigue while implementing measures after extensive spread may limit health benefits. Identification of key personnel, critical resources and processes is very important during a pandemic. Figure 5 below introduces the terms Alert, Standby and Active to reflect key steps in escalation of response action.

Figure 5. Triggers for Implementation of Mitigation Strategies by Pandemic Severity Index and U.S. Government Stages

| Pandemic Severity Index | WHO Phase 6, U.S. Government Stage 3* | WHO Phase 6, U.S. Government Stage 4† and First human case in United States | WHO Phase 6, U.S. Government Stage 5§ and First laboratory-confirmed cluster in State or region¶ |
|--------------------------------|--|--|---|
| 1 | Alert | Standby | Activate |
| 2 and 3 | Alert | Standby | Activate |
| 4 and 5 | Standby** | Standby/Activate †† | Activate |

*Widespread human outbreaks in multiple locations overseas.

†First human case in North America.

§Spread throughout the United States.

¶Recommendations for regional planning acknowledge the tight linkages that may exist between cities and metropolitan areas that are not encompassed within state boundaries.

**Standby applies. However, Alert actions for Category 4 and 5 should occur during WHO Phase 5, which corresponds to U.S. Government Stage 2.

††Standby/Activate Standby applies unless the laboratory-confirmed case cluster and community transmission occurs within a given jurisdiction, in which case that jurisdiction should proceed directly to Activate community interventions defined in Table 2.

Alert includes notification of critical systems and personnel of impending activation, Standby includes initiation of decision-making processes for imminent activation, including mobilization of resources and personnel, and Activate refers to implementation of the specified pandemic mitigation measures.

C. Duration of Implementation of Nonpharmaceutical Interventions

The total duration for intervention measures will depend on the severity of the pandemic and the duration of the pandemic wave in the community. (The average pandemic wave is about 6-8 weeks). Monitoring of excess mortality, case fatality ratios or other surrogate markers over time will be important for determining the optimal duration. The table below provides guidance on the duration of dismissal of students:

- No dismissal of students from schools or closure of childcare facilities in a Category 1 pandemic

- Short-term (up to 4 weeks) dismissal of students and closure of childcare facilities during a Category 2 or Category 3 pandemic
- Prolonged (up to 12 weeks) dismissal of students and closure of childcare facilities during a severe influenza pandemic (Category 4 or Category 5 pandemic)

D. Planning to Minimize Consequences of Community Mitigation Strategy

The major areas of concern derive from the recommendation to dismiss children from school and closure of childcare programs. The concerns include 1) the economic impact to families; 2) the potential disruption to all employers, including businesses and governmental agencies; 3) access to essential goods and services; and 4) the disruption of school-related services (e.g., school meal programs). Other interventions, such as home isolation and voluntary home quarantine of members of households with ill persons, would also contribute to increased absenteeism from work and affect both business operations and employees. These issues are of particular concern for vulnerable populations who may be disproportionately impacted.

Solutions or strategies for minimizing the impact of dismissal of students from school and closure of childcare programs and workplace absenteeism are summarized below: 1) employing child-minding strategies to permit continued employment; 2) employing flexible work arrangements to allow persons who are minding children or in quarantine to continue to work; 3) minimizing the impact on household income through income replacement; and 4) ensuring job security.

Communities and families with school-age children who rely on school meal programs should anticipate and plan as best they can for a disruption of these services and school meal programs for up to 12 weeks. Local government and faith-based and community leaders are being encouraged to work closely with nutrition program administrators at the local, State, and Federal level to:

- Develop plans to address community nutrition assistance needs during a pandemic
- Identify nutrition program adaptations needed to respond to social distancing, voluntary quarantines, and possible disruption of the normal food supply
- Address challenges related to the supply and delivery of food through commercial markets
- Identify current program flexibilities/authorities and determine if others are needed

III. GENERAL GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT AND PREVENTION — INTERPANDEMIC AND PANDEMIC ALERT PERIODS:

A. Department for Public Health Responsibilities

A novel influenza A virus has been detected in animals but not in humans. During these phases, the risk of human infection with a novel influenza A virus strain is extremely low but would become much higher in persons living in or traveling to affected areas.

Notify Local Health Departments through Kentucky Health Alert Network (HAN) as “heads up” warning and encourage public information the following guidelines to reduce the transmission of disease:

- Hand washing: wash hands after touching blood, bodily fluids, secretions, excretions, and contaminated items, whether or not gloves are worn. Wash hands immediately after gloves are removed, between patients’ contacts, and when otherwise indicated to avoid transfer of microorganisms to other patients or environments.
- Use plain non-antimicrobial soap for routine hand washing
- Wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water when hands are visibly soiled.
- When hands are not visibly soiled, use an **alcohol-based hand rub** or waterless antiseptic agent when soap and water are not immediately available.
- Use respiratory hygiene/ cough etiquette

Control measures for persons with symptoms of a respiratory infection; implement at first point of encounter (e.g., triage/ reception areas within a healthcare setting).

Cover the mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacles; perform hand hygiene after contact with respiratory secretions; wear a mask (procedure or surgical) if tolerated; sit or stand as far away as possible (more than 3 feet) from persons who are ill.

1. Personal Protective Equipment (PPE):

- **Gloves:** Wear gloves (clean, non-sterile gloves are adequate) when touching blood, body fluids, secretions, excretions, and contaminated items. Put on clean gloves just before touching mucous membranes and non-intact skin. Change gloves between tasks and procedures on the same patient after contact with material that may contain a high concentration of microorganisms. Decontaminate hands after removing gloves.
- **Gown:** Wear a gown during procedures and patient care activities when contact of clothing or exposed skin with blood or body fluids, secretions, and excretions is anticipated.
- **Face/ eye protection** (e.g., surgical or procedure mask and goggles or face shield). Use face/ eye protection during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.

2. Safe Work Practices:

- Avoid touching eyes, nose, mouth or exposed skin with contaminated hands (gloved or ungloved).
- Avoid touching surfaces that are not directly related to patient care (e.g., door knobs, keys, light switches) with contaminated gloves and other PPE.

3. Environmental cleaning and disinfection:

- Use EPA-registered hospital detergent-disinfectant; follow standard facility procedures for cleaning and disinfection of environmental surfaces; emphasize cleaning/disinfection of frequently touched surfaces (e.g., bed rails, phones, lavatory surfaces).
- Disposal of solid waste: Contain and dispose of solid waste (regulated medical and non-medical) in accordance with facility procedures and local or state regulations; wear gloves when handling waste; wear gloves when handling waste containers; perform hand hygiene after waste disposal.
- Soiled patient care equipment: Handle in a manner that prevents transfer of microorganisms to oneself, others, and environmental surfaces; wear gloves if handling visibly contaminated equipment; perform hand hygiene after handling equipment.
- Soiled linen and laundry: Handle in a manner that prevents transfer of microorganisms to oneself, others, and to environmental surfaces; wear gloves (gown if necessary) when handling and transporting soiled linen and laundry; and perform hand hygiene after handling soiled lines and laundry.

B. Local Health Departments Responsibilities:

- Implement guidelines set out by state and local pandemic influenza plan using standard precautions for hand washing techniques, PPE, and reduction of spread of disease.
- Standard precautions using proper hand washing techniques (e.g., wash hands after touching blood, bodily fluids, secretions, excretions, and contaminated items, whether or not gloves are worn. Wash hands immediately after gloves are removed, between patient contacts, tasks, and procedures.)
- Standard procedures followed for reduction of spread of disease through respiratory hygiene/ cough etiquette; covering the mouth/nose when sneezing/coughing; using tissues and dispose in no-touch receptacles; perform hand hygiene after contact with respiratory secretions; wear a mask (procedure or surgical) if necessary.
- Educate general public in ways to reduce the spread of disease; Public Service Announcements (PSAs) in local newspapers and television; flyers and hand outs for school visits, posters displayed in waiting rooms of LHD describing proper techniques for hand washing, cough/sneeze etiquette.

- Receive and provide vaccine/anti-viral medications direct (probably) from manufacturers for at risk populations using prioritization Tier groups established through state and local pandemic flu plan (see Appendix A).

III GENERAL GUIDELINES FOR COMMUNITY DISEASE CONTAINMENT AND PREVENTION — PANDEMIC PERIOD:

A. Department for Public Health Responsibilities:

During this period:

- A novel influenza A virus has been detected in humans through sporadic animal to human transmission in an affected area (e.g. direct contact with infected poultry), and few cases of limited, local human-to-human transmission have occurred (small clusters of cases).
- A novel influenza A virus has been detected in humans in larger clusters in an affected area, suggesting that the virus is becoming better adapted to spread among people.
- Human infection with human influenza viruses or other viruses will occur and should still be considered.

KDPH will continue efforts used during earlier periods and:

- Regularly consult updates on case definitions, screening, laboratory testing, and treatment algorithms for pandemic influenza noting if any of the following have occurred within the state:
- Issue medical alerts on (HAN) for medical personnel, public health workers and LHDs.
- Through the Division of Communications, (Commissioner and /or Governor’s office) provide medical information and background to general public via public service announcements listed on radio, television and specific websites for self isolation / quarantine.
- Begin early with first and fewest cases reported to help slow spread of disease. Issue information on guidelines, transmission and spread of virus.
- Individuals who are sick, have been exposed, or are caring for an individual who is sick should “self- isolate” or “self quarantine” themselves for a period of ten days until the possibility of transmission has passed.
- Suspend communal gatherings, (e.g., ballgames, school, church, shopping malls, and other social functions).
- Limit travel to a minimum thus reducing the possibility of transmission of virus during pandemic period.
- Travel to known infected areas should be avoided at all times during pandemic period.

B. Local Health Departments will continue efforts used during earlier periods and:

- Implement standard precautions and procedures for reduction and spread of disease.
- Encourage respiratory hygiene/ cough etiquette in the community

- Control measures for persons with symptoms of a respiratory infection; implement at first point of encounter (e.g., triage/ reception areas within a healthcare setting).
 - Cover the mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacles; perform hand hygiene after contact with respiratory secretions; wear a mask (procedure or surgical) if tolerated; sit or stand as far away as possible (more than 3 feet) from persons who are ill.
- Hand washing: wash hands after touching blood, bodily fluids, secretions, excretions, and contaminated items, whether or not gloves are worn. Wash hands immediately after gloves are removed, between patients' contacts, and when otherwise indicated to avoid transfer of microorganism to other patients or environments.
- Use plain non-antimicrobial soap for routine hand washing.
- Wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water when hands are visibly soiled.
- When hands are not visibly soiled, use an **alcohol-based hand rub** or waterless antiseptic agent when soap and water are not immediately available.

IV. MANAGING TRAVEL-RELATED RISK OF DISEASE TRANSMISSION INTER-PANDEMIC AND PANDEMIC ALERT PERIOD:

A. Department for Public Health Responsibilities:

- Provide public health information to LHD for travelers who visit counties where avian or animal influenza strains that can infect humans (e.g., influenza A (H5N1) or human strains with pandemic potential have been reported
- KDPH will work closely with U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS) and Kentucky Department of Agriculture to prevent the importation of influenza- infected birds and animals into the United States
- KDPH will work closely with travel industry (airlines, cruise ships, bus lines) to educate them on procedures for identifying and managing arriving ill passengers and to notify KDPH of suspected cases (see appendix B)
- Local Health Department Inter-pandemic and Pandemic Alert Period:
 - Distribute travel health alert notices to general public especially passengers planning to visit affected countries
 - Post travel health alert notices in airports, bus terminals, travel agencies
 - Distribute health alert notices to prominent places of business such as county court houses, public schools, doctor's offices, hospitals, Emergency Medical Services (EMS)
- Department for Public Health Pandemic Period:
 - Minimize travel-related disease transmission using various containment strategies
 - Suspend social gatherings in areas known to have Influenza A virus (H5N1) (e.g., ballgames, church meetings, concerts, shopping malls)

- Suspend travel into and from known infected areas having Influenza A virus (H5N1)
- Post alerts for LHD informing them of areas that are under quarantine due to infection of Influenza A virus (H5N1)
- Issue travel health precautions and warnings
- Avoid travel to high risk settings and communities where transmission is occurring
- Postpone nonessential travel during pandemic period
- Provide guidance on infection control procedures for travel industry, (e.g., airplanes, ships, busses) to separate ill passengers from other passengers and provide ill passenger with a mask or tissues to prevent viral spread via coughing
- Recommend the cancellation of nonessential travel to other countries or areas affected by Influenza A virus (H5N1)
- Isolate ill passengers arriving on domestic flights and quarantine passengers and crew following protocols developed for international flights (see Appendix C)
- KDPH will work closely with Governor’s office, Kentucky Department of Transportation and state Emergency Operations Center (EOC_ concerning closing mass transit systems (e.g., buses, trains)
- KDPH will work closely with Governor’s office, Kentucky Department of Transportation and state EOC concerning closing interstate bus and train routes

B. Local Health Department Responsibilities:

- Stress proper hand washing techniques, especially when frequenting public places (e.g., restaurants, churches, schools, bus and airport terminals).
- During periods of increased respiratory infection in the community, persons who are coughing should wear either a procedure mask or a surgical mask to contain respiratory secretions or be encouraged to sit as far away as possible (at least 3 feet) from others in common waiting areas.
- LHD should notify local authorities of individuals who have traveled to known areas of infection and have possibly been exposed to influenza A virus and who are under self-isolation/ quarantine. Each quarantined person should receive a preliminary medical assessment and should be interviewed to ascertain their travel and exposure histories.
- LHD should quarantine travel contacts (i.e., passengers, crew, response workers) only when there is a high probability that the ill passenger is infected with a novel influenza strain that is transmitted between people. If a decision is made to initiate quarantine, persons who cannot be quarantined at home should be housed in a pre-designated temporary care facility until the diagnosis of the ill passenger is confirmed or disproved (see Appendix D).
- LHD Regional Epidemiologist or infection control nurses should monitor “hot zones” and outbreaks of individuals with influenza like symptoms until definitive diagnosis is confirmed.

- Minimize travel-related disease transmission using containment strategies and then evaluate the need to implement or terminate travel-related containment measures as the pandemic evolves.

V. LEGAL AUTHORITY FOR PUBLIC HEALTH EMERGENCIES:

A. KY Revised Statutes

- KRS 39A. 100(1), Kentucky State Law states; (1) In the event of the occurrence or threatened or impending occurrence of any of the situations or events contemplated by KRS 39A.010 (et seq.), the Governor may declare, in writing, that a state of emergency exists. Conditions enumerated in KRS 30A.010 include “threats to public safety and health”.
- KRS 214.020 Cabinet to adopt regulations and take other action to prevent spread of disease. When the Cabinet for Health Services believes that there is a probability that any infectious or contagious disease will invade this state, it shall take such action and adopt and enforce such rules and regulations as it deems efficient in preventing the introduction or spread of such infectious or contagious disease or diseases within the state, and to accomplish these objects shall establish and strictly maintain quarantine and isolation at such places as it deems proper.
- 902 KAR 2:050 Control procedures; application. Relates to: KRS 211.180. 214.020 Statutory Authority: KRS 195.040, 211.090 Necessity, Function, and Conformity: KRS 211.180 mandates the Cabinet for Human Resources to implement a statewide program for the detection, prevention and control of communicable diseases. This regulation insures the application of control procedures necessary to prevent transmission of communicable diseases after the sources of infection are identified.
- KRS 158-160 Notification to school by parent or guardian of child’s medical condition threatening school safety – Exclusion of child with communicable disease from school – Closing of school during epidemic.

Appendix 1: Prioritization Tier Groups:

Vaccine

- Tier 1 A: vaccine and antiviral manufacturers and others essential to manufacturing and critical support; medical workers and public health workers who are involved in direct patient contact
- Tier 1 B: persons > 65 years with 1 or more influenza high-risk conditions and residents in long term care facilities; persons 6 months to 64 years with 2 or more influenza high risk conditions; persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high risk condition in the past year
- Tier C: Pregnant women; household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine; household contacts of children less than 6 months old
- Tier D: Public health emergency response workers critical to pandemic response; key government leaders
- Tier 2 A: Healthy 65 years and older; 6 months to 64 years with 1 high risk condition; 6- 23 months old, healthy
- Tier 2 B: other public health emergency responders; public safety workers including police, fire, 911 dispatchers, and correctional facility staff; utility workers essential for maintenance of power, water, and sewage system functioning; transportation workers transporting fuel, water, food, and medical supplies; telecommunications/ IT for essential network operations and maintenance
- Tier 3: Other key government health decision makers; funeral directors/ embalmers
- Tier 4: Healthy person 2-64 years not included in the above categories

Anti-viral Prioritization

- Patients admitted to hospital
- Health care workers (HCW) with direct patient contact and EMS providers
- Highest risk outpatients -immunocompromised persons and pregnant women
- Pandemic health responders (public health, vaccinators, vaccine and antiviral manufacturers), public safety (police, fire, corrections), and government decision-makers
- Increased risk outpatients –young children 12-23 months old, persons older than 65 years and persons with underlying medical conditions
- Outbreak response in nursing homes and other residential settings
- HCW in emergency departments, intensive care units, dialysis centers and EMS providers
- Pandemic societal responders (e.g., critical infrastructure groups as defined in the vaccine priorities) and HCW without direct patient contact
- Other outpatients
- Highest risk outpatients
- Other HCW with direct patient contact

Appendix 2: Travel Industry:

Interim Guidance for Airline Flight Crews and Persons Meeting Passengers Arriving from areas with Avian Influenza; Updated March 13

http://www.cdc.gov/travel/other/avian_flu_ig_airlines_021804.htm

Interim Guidance for Airline Cleaning Crew, Maintenance Crew, and Baggage/Package and Cargo Handlers for Airlines Returning from Areas Affected by Avian Influenza A (H5N1)- Updated March 13

http://www.cdc.gov/travel/other/avian_flu_airlines_cleaning_update_120505.htm

Kentucky Department of Tourism -<http://travel.ky.gov>

Appendix 3: Protocols Developed for International Flights:

In collaboration with law enforcement authorities and other partners, public health officials and quarantine officers should develop protocols for managing ill arriving passengers identified by airplane or cruise ship personnel. The protocols should include provisions for:

- Meeting flights or ships with a reported ill passenger
- Establishing notification procedures and communication links among organizations involved in the response
- Reporting potential cases to health authorities both local and state
- Providing a medical assessment of the ill traveler and referral for evaluation and care
- Separating the ill traveler from other passengers during the initial medical assessment
- Transporting the ill traveler to a designated healthcare facility
- Identifying other ill passengers and separating them from passengers who are not sick
- Transporting and quarantining contacts, if necessary
- Enforcing isolation and quarantine, if necessary, when ill travelers or their contacts are uncooperative

Appendix 4: Isolation and Quarantine Locations:

Home isolation and quarantine: Determine the situations and attendant types of monitoring that will occur for people in home isolation and quarantine

- *Self monitoring:* Patient status is monitored by the individual
- *Active monitoring:* Patient status is monitored in-person, via telephone, or other (video) methods by LHD personnel (e.g., infection control nurse, epidemiologist, regional epidemiologist)
- *Other:* Any other type of monitoring that may occur
- *Temporary quarantine:* a few days, or until the results of diagnostic test become available
- *Longer-term quarantine:* up to 10 days if a diagnosis of pandemic influenza is confirmed

Hospital and special facility: If influenza pandemic results in severe illness overwhelming the capacity of existing healthcare resources, it may become necessary to provide care at alternative sites (e.g., schools, auditoriums, conference centers, hotels). The same principles of infection control apply in these settings as in other healthcare settings.

Support for persons in isolation: Essential services (e.g., food, water, sanitary needs) will be provided to persons quarantined in alternative designated sites. (Alternative means other than hospital, special facility or home)

Appendix 5: School Notification-Concerning Communicable Disease:

158.160 Notification to school by parent or guardian of child's medical condition threatening school safety- Exclusion of child with communicable disease from school- Closing of school during epidemic.

(1) A parent, legal guardian, or other person or agency responsible for a student shall notify the student's school if the student has any medical condition which is defined by the Cabinet for Health Services in administrative regulation as threatening the safety of the condition becomes known and upon each subsequent enrollment by the student in a school. The principal, guidance counselor, or other school official who has knowledge of the medical condition shall notify the student's teachers in writing of the nature of the medical condition.

**KENTUCKY INFLUENZA PANDEMIC RESPONSE PLAN
COMMUNICATIONS SUPPLEMENT VIII**

| TABLE OF CONTENTS | | |
|--------------------------|--|-------------|
| | | PAGE |
| I. | RATIONALE/OVERVIEW | 1 |
| II. | GUIDELINES FOR INTERPANDEMIC PERIOD: | 1 |
| | A. State Responsibilities | 1 |
| | 1. Internal Communication | 1 |
| | 2. Public Information | 3 |
| | B. County Responsibilities | 4 |
| | 1. Internal Communication | 4 |
| | 2. Public Information | 4 |
| III. | GUIDELINES FOR THE PANDEMIC PERIOD | 5 |
| | A. State Responsibilities | 5 |
| | 1. Internal Communication | 5 |
| | 2. Public Information | 5 |
| | B. County Responsibilities | 7 |
| | 1. Internal Communication | 7 |
| | 2. Public Information | 7 |
| IV. | GUIDELINES FOR THE POST PANDEMIC PERIOD | 8 |
| | A. State Responsibilities | 8 |
| | 1. Internal Communication | 8 |
| | 2. Public Information | 8 |
| | B. County Responsibilities | 9 |
| | 1. Internal Communication | 9 |
| | 2. Public Information | 9 |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

COMMUNICATIONS SUPPLEMENT

I. RATIONALE/OVERVIEW

Effective and timely communication is critical before, during and after an influenza pandemic. This section provides information about the role of communications and outlines state and local responsibilities that would be used to provide timely, accurate and credible information to staff, the public, the news media, healthcare providers and other groups in responding appropriately to outbreak situations and complying with public health measures.

The pandemic communication strategy is broken down into three periods (interpandemic, pandemic, and postpandemic), corresponding to the phases of pandemic influenza outbreak as outlined by the World Health Organization (WHO). The communication plan will evolve concurrently with the pandemic periods and in conjunction with the Cabinet for Health and Family Services (CHFS) Emergency Communications Plan for public information.

II. GUIDELINES FOR INTERPANDEMIC PERIOD

A. State Responsibilities:

1. Internal Communication:

The Department for Public Health shall communicate with other key agencies about pandemic influenza activity. The agencies to be notified include, but are not limited to:

- Members of the Pandemic Influenza Planning Committee
- Healthcare agencies (hospitals, long term care facilities, assisted living, etc)
- Other State Agencies (KYEM, KOHS, CJPS, KDA, etc.)
- Local public health jurisdictions
- Other appropriate organizations (*e.g.*, Red Cross, CDC, FDA, KMA, KNA)
- Infection Control Professionals
- Media
- Public health agencies of border states

The Department for Public Health shall utilize any of the following means, by protocol, to conduct such communications:

- Health Alert Network
- Satellite Radio Communications
- E-mail
- Fax
- Land Line Phone
- Mobile Phone Communications
- Web Based Communications
- Interactive Television (ITV)
- Tele Health Network (Proact) and Public Health Network

The Department for Public Health shall test all means of communications on a periodic basis to assure redundant communication capabilities in the event of a public health emergency.

2. Public Information:

- Assess readiness to meet communications needs in preparation for an influenza pandemic, including regular review, exercise and update of the CHFS Emergency Communications Plan.
- Plan and coordinate emergency communication activities with private industry, education and non-profit partners.
- Provide public health communications staff and key spokespersons training on risk communications for use during an influenza pandemic.
- Identify and train lead subject-specific spokespersons.
- Ensure existence of a demographic profile of the community to include special needs populations and language minorities and ensure that the needs of these populations are addressed in the operation plan.
- Test the communication operational plan that addresses the needs of targeted public, private sector, governmental, public health, medical and emergency response audiences to include the CHFS Kentucky Outreach and Information Network (KOIN), designed to send public information to Kentucky's special populations; identify priority channels of communication; delineate the network of communication personnel, including identifying lead subject-specific spokespersons and persons trained in risk communication; and links to other communication networks.
- Develop and maintain up-to-date communications contacts of key stakeholders and exercise the plan to provide regular updates as the influenza pandemic unfolds.
- Address rumors and false reports regarding pandemic influenza threats.
- Confirm any contingency contracts needed for communications resources during a pandemic.
- Implement and maintain, as appropriate, community resources, such as hotlines and Web site, to respond to local questions from the public and professional groups.
- Prepare basic communications resources in advance, and plan to update them during a pandemic.
- Ensure the provision of redundant communication systems/channels that allow for the expedited transmission and receipt of information.
- Messages will be crafted to help educate the public about personal preparedness methods and include the expertise of behavior health experts.
- Address the needs of special populations (vulnerable and hard-to-reach) in the operational plan.
- Work with healthcare partners and other stakeholders to develop state-based plans for vaccine effectiveness, safety, distribution and use.
- Develop and maintain a strong working relationship with other agencies, healthcare partners and stakeholders.

B. County Responsibilities:

1. Internal Communication:

The local public health jurisdictions shall communicate with local agencies and KDPH about pandemic influenza activity. The agencies to be notified include, but are not limited to:

- Members of the local Pandemic Influenza Planning Committee
- Healthcare agencies (hospitals, long term care facilities, assisted living, etc.)
- Other local governmental agencies
- Bordering public health jurisdictions
- Other appropriate organizations (*e.g.*, Red Cross, CDC, FDA)
- Infection control professionals
- Media

The Local public health jurisdictions shall utilize any of the following means to conduct such communications:

- Health Alert Network
- Satellite Radio Communications
- E-mail
- Fax
- Land Line Phone
- Mobile Phone Communications
- Web Based Communications
- Interactive Television (ITV)
- Tele Health Network (Proact) and Public Health Network

The local public health jurisdictions shall test all means of communications on a periodic basis to assure redundant communication capabilities in the event of a public health emergency.

2. Public Information:

- Assess readiness to meet communications needs in preparation for an influenza pandemic, including regular review, exercise and update of communications plans.
- Plan and coordinate emergency communication activities with private industry, education and non-profit partners.
- Ensure existence of a demographic profile of the community to include special needs populations and language minorities and ensure that the needs of these populations are addressed in the operation plan.
- Test the communication operational plan that addresses the needs of targeted public, private sector, governmental, public health, medical and emergency response audiences; identify priority channels of communication; delineate the network of communication personnel, including identifying lead subject-specific spokespersons and persons trained in risk communication; and links to other communication networks.
- Develop and maintain up-to-date communications contacts of key stakeholders and exercise the plan to provide regular updates as the influenza pandemic unfolds.
- Address rumors and false reports regarding pandemic influenza threats.
- Confirm any contingency contracts needed for communications resources during a pandemic.

- Implement and maintain, as appropriate, community resources, such as hotlines and Web site, to respond to local questions from the public and professional groups.
- Prepare basic communications resources in advance (fact sheets, news release templates, message maps, public service announcements (PSAs)), and plan to update them during a pandemic.
- Ensure the provision of redundant communication systems/channels that allow for the expedited transmission and receipt of information.
- Messages will be crafted to help educate the public about personal preparedness methods and include the expertise of behavior health experts.
- Work with healthcare partners and other stakeholders to develop county-based plans for vaccine effectiveness, safety, distribution and use.

III. GUIDELINES FOR PANDEMIC PERIOD

A. State Responsibilities

1. Internal Communication:

Upon pandemic virus notification, the Department for Public Health shall implement contingency plans to assure hardware, software, and personnel capabilities are sufficient to manage the increased volume of communications and to assure the ability of disseminating vital information on a timely basis.

The Department for Public Health shall communicate with other key agencies about the pandemic virus notification and pandemic influenza activity utilizing tested communication systems. The agencies to be notified include, but are not limited to:

- Members of the Pandemic Influenza Planning Committee
- Healthcare agencies (hospitals, long term care facilities, assisted living, etc.)
- Other state agencies (KYEM, KOHS, CJPS, KDA, etc.)
- Local public health jurisdictions
- Other appropriate organizations (*e.g.*, Red Cross, CDC, FDA, KMA, KNA)
- Infection control professionals
- Media
- Public health agencies of border states

The Department for Public Health shall be the primary agency responsible for distributing Pandemic Event sensitive material to identified stakeholders, including but not limited to, any federal guidance from the CDC.

2. Public Information:

- Activate emergency communications plans including information hotlines and the formation of the Joint Information Center (JIC). Provide accurate, honest and timely information on the pandemic to the public and media through news releases and press conferences that is consistent with national, state and local public health messages. Information should describe what is known and unknown, as well as interim guidance to formulate decisions to help protect public health.

- Accurate, useful and consistent messages will be developed, coordinated and released among federal, state, and local health officials to help avoid confusion that can undermine public trust, raise fear and anxiety, and impede response measures. Communications services and key messages will be tailored to specific local audiences. News media reports will be monitored and public inquiries to identify emerging issues, rumors and misperceptions will be promptly addressed. Translate public health messages for non-English speaking persons. Send out messages for special population members through the KOIN.
- Health departments should provide information to healthcare providers, state and local government officials, and the news media concerning:
 - Rationale for prioritization and list of priority groups (see Part 1, Appendix D).
 - Phasing of vaccination, if any, after priority groups have been vaccinated.
 - When and where vaccination is available.
 - The importance of vaccination given likelihood of subsequent pandemic waves, particularly if public interest in vaccination has decreased.
 - As noted above, state and local health departments should be prepared to disseminate information on vaccine use to healthcare providers who purchase private stocks of pandemic influenza vaccine. In addition, all vaccine providers will need vaccine information sheets that describe the risks and benefits of, and contraindications to, vaccination.
- In coordination with epidemiologic and medical personnel, obtain and track information daily on the numbers and location of newly hospitalized cases, newly quarantined persons, and hospitals with pandemic influenza cases. These reports will be used to determine priorities among community outreach and education efforts, and to prepare for updates to media organizations in coordination with federal partners.
- Contact key community partners and implement frequent update briefings.
- As appropriate, implement and maintain community resources, such as hotlines and emergency communications Web site to respond to local questions from the public and professional groups. Include a link to the www.pandemicflu.gov Web site.
- State and local health departments should be prepared to disseminate information on vaccine use to healthcare providers who purchase private stocks of pandemic influenza vaccine. All vaccine providers will require vaccine information sheets that describe the risks and benefits of, and contraindications to, vaccination.
- Update and disseminate public information on the production, distribution, and use of pandemic influenza vaccine before it becomes available.
- Coordinate with state and local governments to develop guidelines to assure the public of the safety of the food supply and mitigate the risk of exposure from wildlife.

A. County Responsibilities:

1. Internal Communication:

The Local public health jurisdictions shall communicate with local agencies and KDPH about the pandemic virus notification and pandemic influenza activity. The agencies to be notified include, but are not limited to:

- Members of the local Pandemic Influenza Planning Committee
- Healthcare agencies (hospitals, long term care facilities, assisted living, etc.)
- Other Local governmental agencies
- Bordering public health jurisdictions
- Other appropriate organizations (*e.g.*, Red Cross, CDC, FDA)
- Infection control professionals
- Media

The Local public health jurisdictions shall be the primary agency responsible for distributing pandemic event sensitive material to identified community stakeholders, including but not limited to, any state or federal guidance from KDPH or the CDC.

2. Public Information:

- Activate emergency communications plans including the formation of the local JIC. Provide accurate, honest and timely information on the pandemic to the public and media. Information should describe what is known and unknown, as well as interim guidance to formulate decisions to help protect public health.
- Messages will be developed, coordinated and released among federal, state, and local health officials to help avoid confusion that can undermine public trust, raise fear and anxiety, and impede response measures. Communications services and key messages will be tailored to specific local audiences. Rumors and misperceptions will be promptly addressed. Translate public health messages for non-English speaking persons.
- Health departments should provide information to healthcare providers, state and local government officials, and the news media on:
 - Rationale for prioritization and list of priority groups (see Part 1, Appendix D).
 - Phasing of vaccination, if any, after priority groups have been vaccinated.
 - When and where vaccination is available.
 - The importance of vaccination given likelihood of subsequent pandemic waves, particularly if public interest in vaccination has decreased.
 - As noted above, local health departments should be prepared to disseminate information on vaccine use to healthcare providers who purchase private stocks of pandemic influenza vaccine. In addition, all vaccine providers will need vaccine information sheets that describe the risks and benefits of, and contraindications to, vaccination.
- In coordination with epidemiologic and medical personnel, obtain and track information daily on the numbers and location of newly hospitalized cases, newly quarantined persons, and hospitals with pandemic influenza cases. These reports will be used to

determine priorities among community outreach and education efforts, and to prepare for updates to media organizations in coordination with state and federal partners.

- Contact key community partners and implement frequent update briefings.
- As appropriate, implement and maintain community resources, such as hotlines and emergency communications Web site to respond to local questions from the public and professional groups. Include a link to the www.pandemicflu.gov Web site.
- Local health departments should be prepared to disseminate information on vaccine use to healthcare providers who purchase private stocks of pandemic influenza vaccine. All vaccine providers will need vaccine information sheets that describe the risks and benefits of, and contraindications to, vaccination.
- Update and disseminate public information on the production, distribution, and use of pandemic influenza vaccine before it becomes available.
- Coordinate with state government to develop guidelines to assure the public of the safety of the food supply and mitigate the risk of exposure from wildlife.

III. GUIDELINES FOR POSTPANDEMIC PERIOD

A. State Responsibilities

1. Internal Communications:

The Department for Public Health shall communicate with other key agencies about pandemic influenza activity and continued pandemic surveillance. The agencies to be notified include, but are not limited to:

- Members of the Pandemic Influenza Planning Committee
- Healthcare agencies (hospitals, long term care facilities, assisted living, etc.)
- Other State Agencies (KYEM, KOHS, CJPS, KDA, etc.)
- Local public health jurisdictions
- Other appropriate organizations (*e.g.*, Red Cross, CDC, FDA, KMA, KNA)
- Infection control professionals
- Media
- Public health agencies of border states

The Department for Public Health shall be the primary agency responsible for distributing post-pandemic event materials to identified stakeholders, including but not limited to, any federal guidance from the CDC.

2. Public Information:

- Staff will participate in an after action review both internally and in conjunction with other response partners to identify areas for improvement and provide recognition to individuals and plans that worked well.
- Continue to maintain regular contact with response partners in order to continue successful communications network for future events.

- Follow-up feedback will be solicited from the KOIN and a post-event communication evaluation worksheet will be completed.
- All necessary improvements will be added to the CHFS Emergency Communications Plan for use in future events.

B. County Responsibilities:

1. Internal Communication:

The Local public health jurisdictions shall communicate with local agencies and KDPH about the pandemic influenza activity and continued pandemic surveillance. The agencies to be notified include, but are not limited to:

- Members of the local Pandemic Influenza Planning Committee
- Healthcare agencies (hospitals, long term care facilities, assisted living, etc.)
- Other local governmental agencies
- Bordering public health jurisdictions
- Other appropriate organizations (*e.g.*, Red Cross, CDC, FDA)
- Infection control professionals
- Media

The Local public health jurisdictions shall be the primary agency responsible for distributing post-pandemic event material to identified community stakeholders, including, but not limited to, any state or federal guidance from KDPH or the CDC.

2. Public Information:

- Staff will participate in an after action review assessment both internally and in conjunction with other response partners to identify areas for improvement and provide recognition to individuals and plans that worked well.
- Continue to maintain regular contact with partners involved in response effort in order to continue successful communications network for future events.
- All necessary improvements will be added to the county emergency communications plan for use in future events.

**KENTUCKY COMMUNITY CRISIS RESPONSE BOARD
 PANDEMIC INFLUENZA PREPAREDNESS PLAN
 PSYCHOSOCIAL CONSIDERATIONS SUPPLEMENT IX**

| TABLE OF CONTENTS | | |
|--------------------------|--|-------------|
| | | PAGE |
| I. | RATIONALE/OVERVIEW | 1 |
| II. | SCOPE OF OPERATIONS | 1 |
| III. | SITUATION AND ASSUMPTIONS | 1 |
| IV. | CONCEPT OF OPERATIONS | 2 |
| V. | GUIDELINES FOR RESPONSE PHASES | 4 |
| | A. Interpandemic Phases 1 and 2 | 4 |
| | B. Pandemic Alert Phase 3 | 4 |
| | C. Pandemic Alert Phase 4 | 4 |
| | D. Pandemic Alert Phase 5 | 4 |
| | E. Pandemic Phase 6 | 5 |
| | F. Second or Subsequent Waves | 5 |
| | G. Postpandemic Period | 5 |

**PSYCHOSOCIAL CONSIDERATIONS
KENTUCKY COMMUNITY CRISIS RESPONSE BOARD
INFLUENZA PANDEMIC RESPONSE**

I. RATIONALE / OVERVIEW

This supplement to the Kentucky Pandemic Influenza Response Plan addresses the all-hazards approach the Kentucky Community Crisis Response Board (KCCRB) will take in response to situations as they relate to the psychological and behavioral effects of pandemic influenza.

From the past, we know that psychosocial considerations are an important part of a public health emergency. According to the September 2003 report, *SARS: Lessons from the first epidemic of the 21st century* prepared by the Directorate of Intelligence of the Central Intelligence Agency, (unclassified) "...understanding and managing the public's psychological and behavioral reactions to an unexpected outbreak of infectious disease are integral to successful response and containment."

KCCRB is responsible for periodically reviewing and updating this plan to ensure that information contained within the document is consistent with current knowledge and changing infrastructure. While this supplement serves as a guide specifically for influenza intervention activities during a pandemic, the judgment of public health leadership based on knowledge of the specific virus may alter the strategies that have been outlined. Priorities of KCCRB during pandemic influenza will be to assess, coordinate and deliver essential disaster behavioral health services as needed.

II. SCOPE OF OPERATIONS

All persons affected by disaster, whether impacted civilian populations or personnel assigned to emergency oriented missions within Kentucky, will have available to them the services of the KCCRB and the Kentucky Community Crisis Response Team (KCCRT).

KCCRB will operate within the established incident command structure.

III. SITUATION AND ASSUMPTIONS

- An influenza pandemic in Kentucky will present a massive test of the emergency preparedness system. Advance planning for Kentucky's emergency response could save lives and prevent substantial economic loss.
- A pandemic will pose significant threats to human infrastructure responsible for critical community services due to widespread absenteeism.
- Many geographic areas within Kentucky and its neighboring jurisdictions may be affected simultaneously. Localities should be prepared to rely on their own resources to respond. The effect of pandemic influenza on individual communities will be relatively prolonged (weeks to months) in comparison to other types of disasters.
- Kentucky's healthcare and behavioral health delivery systems will be significantly taxed by the increased demand for services precipitated by a

prolonged event. Healthcare workers and other first responders may be at higher risk of exposure and illness than the general population, further straining the healthcare system.

- Widespread illness in the community could increase the likelihood of sudden and potentially significant shortages of personnel in other sectors who provide critical public safety services.
- An effective response to an influenza pandemic will require the coordinated efforts of a wide variety of organizations, private as well as public.
- Disasters, by their inherent conditions, produce the need for behavioral health response. Responding to the psychological and emotional impact of disasters for everyone involved is an integral part of a comprehensive and effective disaster response and recovery strategy. Therefore, a behavioral health response should be made available to individuals at various venues such as home, school, shelter, hospital, and isolation/quarantine areas.
- Individuals psychologically impacted often include those involved in treating the physical casualties. In fact, disaster responders, including medical personnel, are a high-risk group for developing stress and trauma-related disorders. Certain members of the workforce (e.g. healthcare workers) may be at increased risk of infection. Those workers at increased risk of infection are an especially vulnerable group due to a real or perceived increased risk of becoming infected themselves, and/or transmitting infection to their friends and families. In addition to assuring access to personal protective equipment, vaccination and prophylactic treatments for first responders and frontline healthcare workers, healthcare organizations need to direct attention to mitigating the stress-related psychological effects of disaster response on these individuals. Hence, there is a particular need for sensitivity to personal concerns and obligations when workers, for instance, may be separated from their families and loved ones for long hours and even days.
- An influenza pandemic may pose substantial short-term and long-term physical, personal, social, and emotional challenges to individuals and/or the community at large.
- In an influenza pandemic, there may be short and/or long term effects on the behavioral health of individuals due to direct experience with sick and dying loved ones, and on the population as a whole. The particular behavioral health needs of marginalized populations such as homeless people also need to be considered. Along with additional pandemic-related behavioral health needs of the community, providing care for those with pre-existing mental illness will need to continue.

IV. CONCEPT OF OPERATIONS

KCCRB will organize mental health response into a comprehensive network to conduct Emergency Support Function #8 - mitigation of the psychosocial impact of any mass casualty incident in coordination with Local Management Entities (LMEs), Red Cross, faith-based entities, KCCRT cadre of trained volunteers, KCCRB recognized teams, and private behavioral health partners. Provision of local behavioral response will be administered as available resources permit.

Because some or all of the state-level resources may quickly be exhausted, KCCRB may need to request assistance from Federal Emergency Management Agency (FEMA), the National Disaster Medical System (NDMS) and other states through the Emergency Management Assistance Compact. NDMS consists of the Disaster Medical Assistance Team, the Disaster Mortuary Operation Response Team, Medical Support Unit, Mental Health and Stress Management teams, and the Veterinary Medical Assistance Team. To this end, KCCRB will:

- Conduct assessments relating to space and site resource inventories to determine the availability of staff at shelters, schools, gymnasiums, nursing homes, day care centers, and other potential sites for aggregate care.
- Assess related behavioral health needs of community, victims, families, behavioral health consumers, and emergency workers and their families, in cooperation with local/regional behavioral health centers.
- Provide oversight and coordination of a state response by promoting psychological first aid and resilience for victims and their families as well as first responders and healthcare workers.
- Provide outreach workers with literature and educational materials, for community-wide distribution, on the human response to disaster and stress reduction and self-help information. Support public health community education efforts.
- Be mindful of the “contagion” factor, thus warranting coordination with a Public Information Officer to assist in providing accurate information to the public. It may be necessary to do “virtual” behavioral health response via media (TV, radio, newspaper). This will include press releases that address fear and other psychological reactions to an influenza pandemic.
- Educate healthcare providers, behavioral health responders and the public about the side effects of antivirals.
- Provide assistance to the Kentucky Cabinet for Health and Family Services that will:
 - Provide information and education via phone line for the community
 - Assure consumers’ behavior health concerns are addressed
 - Provide multilingual information as needed
- In the event of a Presidential Declaration of disaster, initiate the application process for federal funding by applying for all FEMA funded disaster crisis counseling assistance grants. Prepare mandated reports for the federal government.
- Institutionalize psychosocial support services in order to help workers manage emotional stress during the response to an influenza pandemic and to resolve related personal, professional and family issues.
- Train behavioral healthcare staff and first responders on how to:
 - Help victims of a disaster emergency deal with the trauma directly associated with an emergency or disaster
- Provide immediate support
- Make appropriate referrals for continuing services.

- Create a plan for continuity of KCCRB operations in case of increased workload or staff losses during a pandemic

(For more information on psychosocial considerations and information needs for healthcare workers, refer to US DHHS Pandemic Influenza Plan, *Supplement 11: Workforce Support*)

V. GUIDELINES FOR RESPONSE PHASES

It is expected that an influenza pandemic will occur in the phases listed below. In actual practice, the distinction between the various phases of pandemic influenza may be blurred or occur in a matter of hours, underscoring the need for flexibility. The response for KCCRB is detailed in each phase.

A. Interpandemic Phases 1 and 2

- Identify private and public sector disaster behavioral health responding partners in the planning process. Foster coordination and participation among private and public sector partners in the planning process.
- Work with agencies to develop contingency plans for large-scale public health disasters like an influenza pandemic.
- Coordinate planning with federal agencies and other neighboring states.
- Provide education and planning guidance to responding disaster behavioral health partners and the community on preparing for and responding to an influenza pandemic.
- Identify major gaps in current ability to effectively respond to an influenza pandemic. Explore possible avenues for addressing and resolving gaps.

B. Pandemic Alert Phase 3

- Notify Local Management Entities (LME) and community partners of the pandemic alert phase 3 (human infections with a new influenza subtype).
- Designate an official contact person to receive updates.

C. Pandemic Alert Phase 4

- Update LME and community disaster behavioral health partners of Pandemic Alert Phase 4 (small clusters of human-to-human transmission of new influenza subtype).
- Monitor bulletins from CDC, WHO, and HAN regarding clinical updates, as appropriate
- Review and update pandemic influenza response and contingency plans.

D. Pandemic Alert Phase 5

- Notify LME and community disaster behavioral health partners of the potential for an influenza pandemic in Kentucky to ensure adequacy of behavioral health response.
- Continue to review pandemic influenza response and contingency plans for large scale public health disasters

- Monitor bulletins from CDC, WHO, and HAN regarding clinical updates as appropriate

E. Pandemic Phase 6

- Implement contingency plans for large-scale public health disasters.
- Ensure a designated agency contact available to receive updates from KCCRB
- Provide regular updates to LMEs and community disaster behavioral health partners about gaps in agency services.
- Coordinate use of available disaster behavioral health resources during pandemic, including private, public and volunteer resources.
- Coordinate disaster behavioral health activities with other stated and federal health agencies.
- Assess effectiveness of local response and available local capacity.
- Monitor response of KCCRB during pandemic, re-allocate resources as needed
- Apply for FEMA grants as needed.
- Monitor bulletins from CDC, WHO, and HAN regarding clinical updates as appropriate

F. Second or Subsequent Waves

- Continue all activities listed under Pandemic Phase 6.
- Review, evaluate and modify as needs, the local pandemic response
- Monitor resources and staffing needs.

G. Postpandemic Period

- Assess state and local capacity to resume normal behavioral health functions.
- Assess fiscal impact of pandemic response.
- Modify the pandemic influenza response and contingency plans based on lessons learned.

REFERENCES

Appendix M-1, North Carolina Division of Mental Health/Developmental Disabilities/Substance Abuse Services Influenza Pandemic Response Plan
 Center for Mental Health Services. (2004). *Mental Health Response to Mass Violence and Terrorism: A Training Manual*. HHS Pub. No. SMA 3959. Rockville, MD.

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WEBLINKS

KCCRB <http://kccrb.ky.gov/>

American Psychiatric Association. www.psych.org/disasterpsych

American Psychological Association Help Center www.apahelpcenter.org

National Center for PTSD, Department of Veterans' Affairs www.ncptsd.va.gov/

National Child Traumatic Stress Network www.nctsnet.org