

DRAFT

2. DHMH OPERATIONAL PLAN FOR PANDEMIC INFLUENZA 47

2.1. Overview 47

DHMH Roles and Responsibilities in Statewide Preparedness and Response

2.2 Legal Authorities 49

2.3 Pandemic Influenza Functional Area Guidance 58

| | |
|--|-----|
| 1. Planning and Coordination _____ | 58 |
| 2. Surveillance and Laboratory Testing _____ | 61 |
| 3. Healthcare Planning _____ | 99 |
| 4. Infection Control _____ | 128 |
| 5. Clinical Guidelines _____ | 156 |
| 6. Vaccine Procurement, Distribution, and Use _____ | 202 |
| 7. Antiviral Drug Procurement, Distribution, and Use _____ | 211 |
| 8. Travel-Related Disease Control and Community Prevention _____ | 223 |
| 9. Communications _____ | 242 |
| 10. Workforce Support _____ | 257 |

3. ADDENDUMS 260

| | |
|--------------------------------------|-----|
| 1. Definition of Terms _____ | 261 |
| 2. Resources and References _____ | 268 |
| 3. Emergency Points of Contact _____ | 270 |

2. DHMH OPERATIONAL PLAN FOR PANDEMIC INFLUENZA

2.1. Overview

This section of the Maryland Pandemic Influenza Plan expands on the roles and responsibilities of DHMH covered in the first section of this Plan, Maryland Strategy. It also provides guidance in ten public health functional areas in accordance with *Part 2: Public Health Guidance for State and Local Partners* from the *HHS Pandemic Influenza Plan*. Within each functional area, activities by the state and local health departments are described by pandemic phase. The first functional area includes a section on legal authorities.

This guidance will be updated and distributed as necessary. Like the Strategy, it complements existing Maryland plans for normal and emergency operations. Where useful, references to such plans will be indicated.

DHMH Roles and Responsibilities in Statewide Preparedness and Response

During an influenza pandemic, DHMH will act as the overall lead agency for ESF 8 Health and Medical Services. In this capacity, DHMH will coordinate the provision of emergency response (e.g., pre-hospital, hospital, and other) at the state level during a pandemic. DHMH will address the public health ramifications associated with the pandemic including the restoration of public health functions, defining the epidemiology of the pandemic, the administration of vaccinations and antiviral agents, among other public health issues. ESF 8 also has relevance to the following branches:

- Response
- Human needs
- Intelligence
- Services and support
- Recovery
- Logistics

As warranted by the pandemic threat and phase, DHMH will establish a Departmental Command Center. Like the SEOC, this structure will allow DHMH to monitor pandemic influenza response, address policy and resource issues, coordinate with Federal and State agencies and officials, and develop public information.

DRAFT

The DHMH Command Center will be comprised of members of the Department of Health and Mental Hygiene and draw upon employees from every Administration and Office. Office of Public Health Preparedness and Response along with the Community Health Administration, Epidemiology and Disease Control Program. It will implement public health emergency preparedness and response plans for pandemic influenza and provide guidance to local and private sector organizations involved in pandemic influenza planning and response. In addition, DHMH Command Center will advise the Secretary of DHMH and coordinate with the DHMH liaison at the SEOC.

Activities by state and local health departments are described by pandemic phase within each of the following ten functional areas:

1. Planning, Coordination and Legal Authorities
2. Surveillance and Laboratory Testing
3. Healthcare Planning
4. Infection Control
5. Clinical Guidelines
6. Vaccine Procurement, Distribution, and Use
7. Antiviral Drug Procurement, Distribution, and Use
8. Travel-Related Disease Control and Community Prevention
9. Communications
10. Psychosocial Workforce Support

DRAFT

2.2 Legal Authorities:

A Guide to Maryland Laws Governing Public Health Emergency Preparedness and Response

(from the DHMH Draft Isolation and Quarantine Guidelines, Draft Version 2, March 1, 2006)

When a novel influenza virus or pandemic occurs, there are several steps that may be taken by the State to prevent or stem the spread of illness. The Maryland laws, statutes, and legal provisions summarized in this section provide the Governor, the Secretary of DHMH, and the State and local health departments the authority to take the essential steps required to mitigate a pandemic. These provisions range from laws regarding quarantine and isolation to procedures for closing businesses and schools, and empower the State and the DHMH to prepare and respond to a public health emergency.

LEGAL AUTHORITY

Md. Code Ann., Public Safety (“Public Safety”), Title 14, Subtitle 3A, Governor’s Health Emergency Powers provide the Governor of Maryland with the legal authority to address a catastrophic health emergency (CHE). Under Public Safety § 14-3A-01(b), a catastrophic health emergency is defined as “a situation in which extensive loss of life or serious disability is threatened imminently because of exposure to a deadly agent.” A deadly agent is defined in Public Safety § 14-3A-01(c) as one of a wide range of biological, chemical, or radiological items that could potentially cause extensive loss of life or serious disability. Table 4 summarizes the categories and provides specific examples of some of the deadly agents that are set forth in this section.

Powers of the Governor

Public Safety §§ 14-3A-01 to 14-3A-08 grants the Governor authority to act with health emergency powers. The Governor can declare a catastrophic health emergency, issue a proclamation and issue orders under the proclamation.

The Governor has the power to declare a catastrophic health emergency under Public Safety § 14-3A-02. If the Governor determines that a catastrophic health emergency exists, then the Governor will issue a proclamation. Public Safety §14-3A-02(a). The proclamation will include: the nature of the catastrophic health emergency, the areas threatened and the conditions that led to the catastrophic health emergency or the conditions that made possible the termination of the emergency. Public Safety § 14-3A-02 (b)(1)-(3). The proclamation will last for 30 days after the issuance and is renewable by the Governor for successive 30-day periods during the catastrophic health emergency. Public Safety § 14-3A-02 (c)(2)-(3). The Governor will rescind the issued proclamation when the Governor

DRAFT

2.2 Legal Authorities, cont.

determines that the catastrophic health emergency no longer exists. Public Safety § 14-3A-02 (c)(1).

During the proclamation the Governor can order:

- a health care provider to participate in disease surveillance, treatment and suppression efforts and to comply with the directives of the Secretary or other designated official. Public Safety §14-3A-03(c).
- an evacuation, closing, or decontamination of any facility. Public Safety 14-3A-03(d)(1).
- individuals to remain indoors or refrain from congregating if necessary and reasonable to save lives or prevent exposure to a deadly agent. Public Safety §14-3A-03(d)(2).

Additionally, the Governor can issue orders to the Secretary of the Department of Health and Mental Hygiene (“Secretary”) or other designated official under Public Health § 14-3A-03.

Powers of the Secretary of the Department of Health and Mental Hygiene

Health-General § 18-905, Annotated Code of Maryland, provides legal authority for the Secretary to order individuals under certain circumstances to go to and remain in isolation and quarantine sites without a gubernatorial CHE proclamation and order.

Health-General Article, §§ 18-901 to 18-908, grant the Secretary authority to act during a catastrophic health emergency. This authority is codified in the Code of Maryland (“COMAR”) 10.59.01 Care of Individuals Isolated or Quarantined Due to a Deadly Agent. During a catastrophic health emergency, the Secretary can also receive orders from the Governor under Public Safety § 14-3A-03.

After the Governor issues a proclamation, the Governor may also issue orders to the Secretary or other designated official under Public Safety §14-3A-03 (b)-(d) granting the power to:

- seize immediately anything needed to respond to the medical consequences of the catastrophic health emergency work collaboratively with health care providers.
- control, restrict, or regulate the use, sale, dispensing, distribution, or transportation of anything needed to respond to the consequences of the catastrophic health emergency.
- require individuals to submit to medical examination or testing.

DRAFT

2.2 Legal Authorities, cont.

- require individuals to submit to vaccination or medical treatment unless the vaccination or treatment will cause serious harm to the individual.
- establish places of treatment, isolation and quarantine.
- require individuals to go to and remain in places or isolation or quarantine until they no longer pose a risk of transmitting the condition or disease to the public.

The Secretary, or other designated official, has the authority under Public Safety § 14-3A-05 to issue a directive for isolation and quarantine. The content of the directive given to an individual or group of individuals placed in isolation or quarantine shall include the following, according to Public Safety § 14-3A-05(b):

- the identity of the individual or group of individuals that are subject to isolation or quarantine.
- the premises that are subject to isolation or quarantine.
- the date and time when the isolation or quarantine starts.
- the suspected deadly agent causing the outbreak or disease if known.
- the justification for the isolation or quarantine.
- the availability of a hearing to contest the directive.

The directive shall be in writing and given to the individual or group of individuals before the directive takes place. Public Safety § 14-3A-05 (b)(2) . If a written directive is impractical, then the Secretary, or other designated official, shall use the best possible means available to ensure that the affected individual(s) are fully informed of the directive. Public Safety § 14-3A-05(b)(3).

The Secretary, or other designated, official also has the authority under Health-General § 18-902(1)-(3) to:

- continuously evaluate and modify existing disease surveillance procedures in order to detect a catastrophic health emergency.
- investigate actual or potential exposures to a deadly agent.
- treat, prevent, or reduce the spread of the disease or outbreak believed to have been caused by the exposure to a deadly agent.

Delegated authority by the Secretary

The Secretary has the authority in Section 2-102(b)(2) of Health-General to establish guidelines and procedures to promote the orderly and efficient administration of the department. Thus, to ensure continuity of the Department's essential business functions when the Secretary is temporarily unavailable, the Secretary established an Emergency Delegation of Authority and a Limited Delegation of the Secretary's Public Health Emergency Authority .

DRAFT

2.2 Legal Authorities, cont.

Powers of the Health Officer

COMAR 10.59.01 outlines the authority of the health officer during a catastrophic health emergency. Under this title, the health officer shall:

- recommend to the Secretary, a suitable place for isolation or quarantine based on: the seriousness of the disease; the route or routes of transmission of the disease; the contagiousness of the disease; precedents in the practice of public health; the behavior, neurological development and condition, physical condition of the individual being isolated or quarantined; and the access to needed support services at the site. COMAR 10.59.03D(1)-(2).
- arrange for and provide, if needed, transportation for an individual to be isolated or quarantined. COMAR 10.59.03E.
- monitor an isolated or quarantined individual by phone call, home visit, or other means to ensure that the isolated or quarantined individual stays in the designated facility at all times during the period of isolation or quarantine, except in an emergency such as fire, natural disaster, or evacuation by a county, State, or federal agency of the area for any other reason. COMAR 10.59.03F.
- ensure that an isolation or quarantine facility has at a minimum: electricity; hot and cold potable water; hand-washing facilities; toilets; heat; telephone access; and means for discarding trash and wastes. COMAR 10.59.03H.
- ensure that an individual in isolation or quarantine has access to at a minimum: food; medical supplies; medications; and medical care including psychological care. COMAR 10.59.03I.
- provide information to an isolated or quarantined individual, without compromising the health of the isolated or quarantined individual or the people caring for the isolated or quarantined individual, by: assessing the language needs of the isolated or quarantined individual; translating both oral and written communications and documentation; and monitoring to assure that the isolated or quarantined individual is not treated in a discriminatory manner. COMAR 10.59.03J.
- determine whether the individual has any cultural or religious beliefs that would interfere with medical care during quarantine or isolation and to the extent feasible, make arrangements to accommodate these beliefs, without compromising the health of the isolated or quarantined individual or the people caring for the isolated or quarantined individual. COMAR 10.59.03K.

DRAFT

2.2 Legal Authorities, cont.

ISOLATION AND QUARANTINE ORDERS

Under Health-General §18-905, the Secretary, or other designated official, may order isolation of an individual who may have a deadly communicable disease such as isolation or quarantine of an individual potentially exposed to a deadly agent or infectious disease. When the Secretary issues an order in compliance with Health-General §18-905 (b), the Secretary may order an individual into isolation or quarantine at: a health care facility; the individual's home; or a non-health care facility.

An individual in isolation or quarantine shall, according to COMAR 10.59.03L:

- follow all written and verbal instructions provided by the Department and the local health department;
 - notify and receive approval from the local health officer in advance of relocation to a new isolation or quarantine site, except in an emergency such as fire, natural disaster, or evacuation of the area by a county, State, or federal agency for any other reason; and
 - notify the health officer immediately upon relocation to a new location, in the event of an emergency such as fire, natural disaster, or evacuation of the area by a county, State, or federal agency for any other reason.
- COMAR 10.59.03L.

An individual in isolation or quarantine may not leave the isolation or quarantine site without notification of the health officer, except in an emergency such as fire, natural disaster, or evacuation by a county, State, or federal agency of the area for any other reason. COMAR 10.59.03M. If evacuation from the site occurs in an emergency, an isolated or quarantined individual shall notify the health officer immediately by a phone call or any other means possible and follow instructions given by the health officer. COMAR 10.59.03G.

Isolation Orders

1. Verbal Orders for Routine Isolation

- Individuals requiring isolation should first be advised of this requirement and of the measures that must be followed. Within 24 hours of providing an individual or group of individuals with a verbal order for isolation, the Health Officer will send a letter describing the terms and conditions of the isolation. In addition, enclosed with the letter will be a fact sheet on the disease of concern, procedures to be followed to comply with the isolation order, and contact numbers of the

DRAFT

2.2 Legal Authorities, cont.

LHD. All information provided is to be written in “plain language” and to be culturally appropriate.

- If an individual fails to comply with the isolation requirements, that individual will be served a mandatory written isolation order. All individuals requiring isolation in a non-hospital setting are required to sign an Isolation Agreement (to be developed).

2. Written Orders

- Written orders would be needed if the individual is not compliant with the verbal order, or if the need for isolation is related to an outbreak or pandemic
- Written orders will need to be obtained from the Secretary
- If the Health Officer or other designee cannot obtain the isolation order signed by the Secretary in person, an order faxed from the Secretary’s office with his signature is acceptable.
- Although the Secretary’s office has the capability to provide an electronic signature, legally it may not be the most robust method and is discouraged for use on the isolation orders at this time.

3. Process for Obtaining Written Isolation Orders

- In accordance with Health-General, Sections 18-905(a) (1) (ii) and (b), written “Isolation Orders” for the specific disease of concern will be issued by the Secretary. These orders will be issued in collaboration with the local Health Officer.
- Local health departments requiring a written “Isolation Order” should contact the DHMH Office of Epidemiology and Disease Control Programs (EDCP) during regular business hours (410-767-6700) or the On Call Physician (410-407-6154) after hours and on weekends. If the appropriate DHMH individual cannot be reached through either method, DHMH should be contacted via the DHMH operator (410-795-7365).
- Should an individual appeal an isolation order, DHMH will immediately notify the Office of the Attorney General (OAG), so that appropriate legal adjudication can commence.
- Should a local health department have knowledge of an individual violating a written isolation order, the local health department should immediately teleconference DHMH EDCP with the appropriate local law enforcement agency so that law enforcement actions can be initiated.

DRAFT

2.2 Legal Authorities, cont.

Quarantine Orders

As with isolation, under Health-General §18-905, the Secretary may order quarantine of an individual or a group of individuals who may have a deadly communicable disease such as: H5N1 avian influenza or if potentially exposed to a deadly agent. However, as with isolation, most individuals needing quarantine will not need to be issued a written “Quarantine Order”.

1. Verbal Orders for Routine Quarantine

- Individuals requiring quarantine should first be advised of this requirement and of the measures that must be followed. Within 24 hours of providing an individual or group of individuals with a verbal order for quarantine, the Health Officer will send a letter describing the terms and conditions of the quarantine. In addition, enclosed with the letter will be a fact sheet on the disease of concern, procedures to be followed to comply with the verbal quarantine order, and contact numbers of the LHD. All information provided is to be written in “plain language” and to be culturally appropriate.
- If an individual fails to comply with the quarantine requirements, that individual will be served a mandatory written quarantine order. All individuals requiring quarantine in a non-hospital setting are required to sign a Quarantine Agreement (to be developed).

2. Written Orders for Quarantine

- Written orders would be needed if the individual is not compliant with the verbal order, or if the need for quarantine is related to an outbreak or pandemic
- Written orders will need to be obtained from the Secretary
- If the Health Officer or other designee cannot obtain the quarantine order signed by the Secretary in person, an order faxed from the Secretary’s office with his signature is acceptable.
- Although the Secretary’s office has the capability to provide an electronic signature, legally it may not be the most robust method and is discouraged for use on the quarantine orders at this time.

3. Obtaining Written Quarantine Orders

- Issuing “Quarantine Orders” is the responsibility of DHMH. All written “Quarantine Orders” will be issued by the Secretary. Local health departments requiring a written “Quarantine Order” should contact DHMH EDCP.

DRAFT

2.2 Legal Authorities, cont.

- Should an individual appeal a quarantine order, DHMH will immediately notify the Office of the Attorney General (OAG), so that appropriate legal adjudication can commence.
- Should a local health department have knowledge of an individual violating a written quarantine order, the local health department should immediately contact DHMH EDCP. A teleconference will be convened with DHMH EDCP, the local health department(s) and with the appropriate local law enforcement agency so that law enforcement actions can be initiated.

The Secretary may quarantine an individual in a health care facility due to a pre-existing medical condition of the individual being quarantined or when a health care facility is more appropriate than the individual's home because of medical conditions of family members residing in the individual's home. COMAR 10.59.05A. The administrator of a health care facility shall, under COMAR 10.59.05B:

- Follow the health care facility's procedures and protocol for quarantine; and
- Consult with and receive approval from the Secretary before transferring the patient to another site or discharging the patient from the health care facility.

ENFORCEMENT OF ISOLATION AND QUARANTINE

The Secretary, or other designated official, may issue an order requiring individuals whom the Secretary has reason to believe have been exposed to a deadly agent to seek appropriate and necessary evaluation and treatment. Health-General § 18-905(a)(1)(i). An individual who fails to comply with an order, requirement, or directive issued by the Secretary or other designee is guilty of a misdemeanor and may be fined up to \$5,000, imprisoned up to a year or both. Public Safety Article § 14-3A-08 and Health-General §18-907(a)(1)-(2).

A health care facility that fails to comply with an order, requirement, or directive issued by Secretary or other designee may face a civil penalty up to \$3,000 for each offense. Health-General § 18-907(b).

A health care practitioner who fails to comply with an order, requirement, or directive issued by Secretary or other designee may have their licensee or certification holder on probation, suspended or revoked or may face a civil penalty up to \$3,000 for each offence. Health-General §18-907.

DRAFT

2.2 Legal Authorities, cont.

In addition, Health-General §18-905 grants the authority to the Secretary to order any law enforcement officer of the State or a subdivision to enforce orders issued under Health-General, Title 18, subtitle 9, Catastrophic Health Emergency Disease Surveillance and Response Program.

2.3 Pandemic Influenza Functional Area Guidance

1. Planning and Coordination

- I. Overview**
- II. Incident Management Structure and Process**
- III. Pandemic Influenza Coordinating Committee**
- IV. Activities by Pandemic Period**

I. Overview

This section describes the Maryland State Department of Health and Mental Hygiene's (DHMH) Pandemic Influenza Planning and Coordination procedures. Because the response to pandemic influenza will use the same command and control system developed for other public health emergencies, this section highlights activities specific to pandemic influenza.

II. Incident Management Structure and Process

During emergencies, DHMH coordinates response activities by using an incident management system, superimposed over the normal department organizational structure. In emergencies, the DHMH's Office of Preparedness and Response manages the traditional functions of a departmental emergency operations center within DHMH's existing systems to facilitate an integrated and comprehensive response. These functions include: coordinating regional, state, and federal public health resources, aid, and response; coordinating public information; coordinating with state elected officials, the State and local EOCs, and other organizations. Other DHMH staff may be identified to augment the Office of Preparedness and Response.

III. Pandemic Influenza Coordinating Committee

Before a pandemic occurs, a Pandemic Influenza Coordinating Committee (PICC) will be formed by the Governor's Office. The PICC will officially approve the Maryland Pandemic Influenza Plan and oversee the planning process. The PICC will confirm state agency and department roles and responsibilities in a pandemic and ensure each agency and department has a plan for continuity of operations during a pandemic.

DRAFT

1. Planning and Coordination cont.

IV. Activities by Pandemic Period

Interpandemic Period

State Health Department:

- Activate the Pandemic Influenza Coordinating Committee.

State and Local Health Departments:

- Ensure that pandemic influenza plans are developed, either as an annex or supplement to the existing All Hazard Emergency Operations Plans, or as stand-alone plans.
- Identify, address and resolve crucial gaps in infrastructure and resources, laws and/or statutes that may interfere with an effective response.
- Develop and maintain lists, including contact information, of partners, resources, and facilities.
- Establish and maintain relationships with, and contact information for, key communications partners; facilitate risk communication training for the same.
- Coordinate planning activities with bordering jurisdictions and special populations as appropriate.
- Develop a community response plan for pandemic influenza in collaboration with local partners, including law enforcement, first responders, healthcare facilities, mental health professionals, local businesses, and the legal community.
- Meet with appropriate partners and stakeholders and review major elements of the Pandemic Influenza Plan and evaluate level of preparedness
- Review, exercise, and modify pandemic influenza plans on a periodic basis.
- Conduct WebEOC initial and refresher training on a regular basis. Include the use of WebEOC in exercises.
- Confirm availability of facilities for mass vaccination, mass casualty, etc.

DRAFT

1. Planning and Coordination cont.

- Develop a continuity of operations plan that identifies essential functions and services, such as surveillance, and outlines how these will be maintained with significant staff absenteeism.
- Ensure communications redundancy and interoperability with key partners.

Pandemic Period

State Health Department:

- Interface with appropriate counterparts at the national level.
- Participate in HHS/CDC public information briefings.
- Participate in a Joint Information Center (JIC), or schedule daily media briefings to update information and discuss response activities.

State and Local Health Departments:

- Monitor staffing needs.
- Coordinate activities with neighboring jurisdictions, as appropriate.
- Schedule internal, partner, and media briefings as necessary to update information and discuss response activities.
- Activate call centers and implement targeted strategies to reach all audiences, including utilizing the Emergency Alert System (EAS) system, if necessary.
- Document expenses of pandemic response.

DRAFT

2. Surveillance and Laboratory Testing

- I. Overview**
- II. Components of Surveillance for Human Infection**
- III. Criteria for Assessing and Reporting Possible Pandemic Influenza Cases**
- IV. Laboratory Diagnosis of Human Pandemic Influenza**
- V. Epidemiologic Surge Capacity**
- VI. Activities by Pandemic Phase**

Appendices:

- 2-A. CDC Updated Novel Influenza Surveillance and Reporting Criteria**
- 2-B. DHMH Protocols for Collecting and Transporting Specimens**
- 2-C. DHMH Laboratory Contact Numbers**
- 2-D. CDC Specimen Testing Guidelines**
- 2-E. Novel Influenza Case Report Form**
- 2-F. Quick Reference Chart for Diagnostic Testing**
- 2-G. Influenza Diagnostic Assays For Pandemic Influenza**
- 2-H. Reference Testing Guidelines**
- 2-I. Laboratory Biosafety Guidelines**
- 2-J. Rapid Diagnostic Testing**

I. Overview

Established local and statewide surveillance systems are fundamental for detecting influenza activity, identifying the circulating strains, and monitoring the burden of influenza morbidity and mortality. Influenza virus circulates yearly, with the season in the United States identified as October through May. Early identification of novel influenza strains is integral for early identification and intervention to prevent a pandemic.

Enhancing existing influenza surveillance networks can lead to rapid detection of a novel virus strain with pandemic potential. For the purposes of this Plan, the terms 'novel virus strain' or 'novel influenza' include highly pathogenic avian influenza (HPAI) strains with evidence of more than occasional human cases and some capacity

DRAFT

2. Surveillance and Laboratory Testing cont.

for human to human transmission such as the H5N1 strain currently circulating in Asia, Africa and Europe.

II. Components of Surveillance

Surveillance for Human Infection

Maryland routinely conducts surveillance for influenza, including virologic and disease surveillance, through a variety of methods from multiple partners throughout the state. Information compiled includes laboratory testing data, nosocomial outbreak reports, influenza-like illness by age group, hospitalizations, and pediatric deaths. These routine systems could be enhanced during an influenza pandemic.

- **Virologic Surveillance:**

Surveillance of influenza viruses aim to identify and characterize circulating strains to inform annual vaccine formulation and to identify and characterize strains with pandemic potential. The DHMH State Laboratory is equipped and trained to use PCR to detect novel influenza viruses, including H5N1 and other avian influenza strains. Any positive results for novel influenza viruses would be sent to CDC for confirmatory testing.

- **Outpatient Surveillance:**

Outpatient surveillance for influenza in Maryland includes the sentinel provider network and syndromic surveillance in emergency rooms. Approximately a dozen healthcare providers across Maryland participate in the sentinel provider network (SPN), a collaborative effort among state health departments, healthcare providers, and CDC. During the influenza season, May through October, these health care providers voluntarily report the number of weekly outpatient visits for influenza-like illness (ILI) by age group. This data is analyzed weekly to assess influenza-like illness morbidity in the outpatient setting. CDC develops and maintains reporting materials and systems, serves as a data repository, and provides feedback to the states.

In addition to SPN, syndromic surveillance collects information about illnesses in Maryland emergency room patients. Visits are grouped into syndromes, including febrile respiratory syndrome, to categorize clinical presentations of patients seeking medical care in hospital emergency rooms.

DRAFT

2. Surveillance and Laboratory Testing cont.

- **Hospital Surveillance:**

Nosocomial outbreak reporting: Acute care and long-term care facilities are required throughout the year to report any increased incidence in respiratory illness, including suspected and confirmed influenza outbreaks.

Through the Emerging Infections Program (EIP) project, laboratory-confirmed pediatric influenza hospitalizations are monitored in certain hospitals.

In addition, hospitals in Maryland are required by regulation to report pneumonia in a health care worker that results in hospitalization.

- **Mortality Surveillance:**

As part of the 122 cities surveillance system for pneumonia and influenza deaths, Baltimore City reports weekly the total number of deaths and those with influenza or pneumonia listed as a contributing cause of death. In addition, as of October 2004, pediatric deaths due to confirmed influenza are nationally notifiable.

State-level Assessment of Influenza Activity

Maryland provides to CDC weekly assessments of the overall level of influenza activity (i.e. none, sporadic, local, regional, or widespread) in the state. These assessments are used to compare the extent of influenza activity from state to state.

DRAFT

2. Surveillance and Laboratory Testing cont.

Definitions of the Influenza Activity Levels

| Activity Level | ILI activity/Outbreaks | | Laboratory data |
|--|--|------------|---|
| No activity | Low | And | No lab confirmed cases |
| Sporadic | Not increased | And | Isolated lab-confirmed cases |
| | Not increased | And | OR Lab confirmed outbreak in one institution* |
| Local | Increased ILI in 1 region; ILI activity in other regions is not increased | And | Recent (within the past 3 weeks) lab evidence of influenza in region with increased ILI |
| | 2 or more institutional outbreaks (ILI or lab confirmed) in 1 region; ILI activity in other regions is not increased | And | OR Recent (within the past 3 weeks) lab evidence of influenza in region with the outbreaks; virus activity is no greater than sporadic in other regions |
| Regional (doesn't apply to states with ≤4 regions) | Increased ILI in ≥2 but less than half of the regions | And | Recent (within the past 3 weeks) lab confirmed influenza in the affected regions |
| | Institutional outbreaks (ILI or lab confirmed) in ≥2 and less than half of the regions | And | OR Recent (within the past 3 weeks) 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 (within the past 3 weeks) lab confirmed influenza in the state. |

* Institution includes nursing home, hospital, prison, school, etc.

▪ **Other Surveillance:**

While influenza is not a reportable disease in Maryland, two clinical laboratories report to DHMH all laboratory positive results of influenza.

Veterinary Surveillance:

In Maryland, surveillance for avian influenza in poultry and poultry industry workers is conducted by the Maryland Department of Agriculture (MDA) and the poultry industry. Diagnostic testing is performed by MDA and industry laboratories, with confirmatory testing by the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services at the National Veterinary Services Laboratories in Ames, Iowa.

DRAFT

2. Surveillance and Laboratory Testing cont.

In addition, surveillance for avian influenza among wild birds is the responsibility of the Maryland Department of Natural Resources.

III. Criteria for Assessing and Reporting Possible Pandemic Influenza Cases

DHMH will continue to develop and distribute to healthcare providers the current CDC and DHMH recommendations for enhanced surveillance, case reporting, and laboratory testing.

Assessment

Criteria for assessment may need to be modified throughout the pandemic phases according to the circulating virus and the known epidemiology of the infection at that time. CDC's current criteria is in Appendix 2-A.

Reporting

It is anticipated that individual case reporting will not be feasible once pandemic influenza has been confirmed in Maryland. Surveillance during the pandemic period will focus on data collection mechanisms to assess morbidity and mortality. Select individual case investigations may need to be conducted to guide prevention and control recommendations.

Once a novel strain detected abroad exhibits sustained human-to-human transmission (WHO Phase 6), recommendations for further intensified virologic and disease surveillance will be issued and might include recommendations for stepped-up disease surveillance at ports of entry.

Clinicians should immediately contact the DHMH when they suspect a human case of infection with an avian or animal strain of influenza or with any other novel human influenza strain. Clinical algorithms for managing patients with possible novel influenza infection are provided in **Functional Area 5, Clinical Guidelines**.

DRAFT

2. Surveillance and Laboratory Testing cont.

State and local health departments should in turn immediately report to CDC any influenza cases that:

- Test positive for a novel influenza subtype, *or*
- Meet the enhanced surveillance case definition in effect at that time, *and*
- Cannot be subtyped in the state public health laboratory because appropriate reagents or biocontainment equipment is not available

Reference testing guidelines for potential pandemic strains of influenza are provided in Appendix 2-G.

IV. Laboratory Diagnosis of Human Pandemic Influenza

The following summarizes the procedures for submitting samples to the DHMH State Laboratory. Submitters should also familiarize themselves with the testing capability of their local laboratory and utilize that facility when appropriate services are available. It should be noted that the laboratory procedures used for testing may change depending on the characteristics of the pandemic strain. The DHMH State Laboratory will communicate with the CDC and forward samples and isolates for confirmatory testing when appropriate. Tests for influenza virus include viral culture, polymerase chain reaction (PCR), rapid antigen testing, and immunofluorescence. Serologic tests are used to retrospectively diagnose infection. Specific guidance about DHMH specimen collection and transport protocols and CDC's guidelines for Specimen Testing are in Appendix 2-C. In addition, the following is the link to the World Health Organization's Field Operating Guide for Collecting, Preserving, and Shipping Specimens for the Diagnosis of Avian Influenza:

http://www.who.int/csr/resources/publications/surveillance/WHO_CDS_EPR_ARO_2006_1/en/index.html

Specimen Collection Overview

- Appropriate specimens for testing include: nasal wash /aspirate, nasopharyngeal swab, throat swab, bronchoalveolar lavage, tracheal aspirate, pleural fluid tap, sputum, and autopsy specimens (see HHS: Pandemic influenza plan [Part 2, Supplement 2]).
- Specimens from living patients optimally should be collected within 4 days after illness onset.
- Some rapid test kits require specific specimen types and storage/transport methods.

DRAFT

2. Surveillance and Laboratory Testing cont.

- Nasopharyngeal swabs, nasal washes, and nasal aspirates are considered to be more sensitive than throat swabs for culture of most respiratory viruses, including convention influenza strains, and are preferred for children younger than 2 years of age.
- Pharyngeal swabs collected 4 to 8 days after onset of illness may be more sensitive for detection of influenza A (H5N1) than nasal swabs (see [References](#): WHO: Writing Committee of WHO Consultation on Human Influenza A/H5NI 2005).
- Only sterile Dacron or rayon swabs with plastic shafts should be used. Calcium alginate swabs or swabs with wooden sticks should not be used.
- Viral transport media should be used for nasopharyngeal and oropharyngeal swabs and specimens should be maintained at refrigerator temperature (4°C to 8°C) until testing is performed. Freezing at 70°C is best for maintaining viability during extended storage.
- With regard to autopsy specimens, large airways have the highest yield for immunohistochemistry (IHC) tests. Eight blocks or fixed-tissue specimens from each of the following sites should be obtained. Fixed tissue should be transported at room temperature (not frozen); fresh unfixed tissue should be frozen.
 - Central (hilar) lung with segmental bronchi
 - Right and left primary bronchi
 - Trachea (proximal and distal)
 - Representative pulmonary parenchyma from right and left lung
- Infection control precautions should be observed during specimen collection.
- Specimen collection procedures for animals have been described by the World Health Organization (WHO) (see [References](#): WHO: Manual on animal influenza diagnosis and surveillance).
- Clinical laboratories should contact their DHMH if they receive specimens from patients with possible novel influenza suspected on the basis of clinical and epidemiologic criteria.
- DHMH will send specimens to CDC if the patient meets clinical and epidemiologic criteria and (1) tests positive for influenza A by reverse transcriptase polymerase chain reaction (RT-PCR) or rapid testing or (2) tests negative for influenza A by rapid testing and RT-PCR is not available. If the DHMH Laboratories do not have capacity for testing avian strains by indirect

DRAFT

2. Surveillance and Laboratory Testing cont.

Immunofluorescence (IFA) or RT-PCR, the DHMH Laboratories will send untypable influenza isolates to CDC.

V. Epidemiologic Surge Capacity

During the inter-pandemic phase, epidemiologic investigation of any suspect and confirmed human novel influenza virus infections will be extensive to attempt to limit transmission. If a novel strain of influenza strain that is capable of person-to-person transmission is suspected in Maryland, staff may need to be mobilized in a short time frame to conduct surveillance activities, outbreak investigations, contact tracing, and to implement control measures. As a supplement to local health department staff, DHMH Office of Preparedness and Response; the Community Health Administrator, Epidemiology and Disease Control Program may be utilized.

Other local and state public health staff may need to be mobilized and receive just in time training to assist with case investigations, contact tracing, and ensuring control measures are being implemented.

Once an influenza pandemic has been confirmed, public health epidemiologic resources may need to be diverted from intense case investigation and contact tracing to tracking the geographic distribution of illness, calculating the morbidity and mortality, and determining the overall epidemiology of the outbreak. This will be critical to target public health resources and modify prevention and control measures.

VI. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State Health Department:

- Develop materials and help educate healthcare providers about novel and pandemic influenza.
- Provide consultation to LHDs and healthcare providers, as needed, on suspect novel influenza cases.
- Provide updated surveillance information and materials to LHDs.
- In conjunction with the Office of the Chief Medical Examiner (OCME), develop a mechanism for receiving timely information on avian influenza related causes of death if needed for epidemiological investigation.

DRAFT

2. Surveillance and Laboratory Testing cont.

- Continue to recruit medical providers to participate in the CDC Influenza Sentinel Provider Network.
- Maintain current influenza surveillance systems to monitor morbidity and mortality.
- Isolate and subtype influenza viruses all year round.
- Improve capacity for rapid identification of unusual influenza strains.
- Identify critical resources for epidemiologic surge capacity to include personnel needed to assist with epidemiological investigations.
- Establish and maintain (update) contact lists, including other agencies involved in non-human animal disease control (e.g., MDA, DNR, USDA state offices).
- Continue routine sample testing for influenza and subtype, as appropriate.
- Send unusual or suspected cases of novel influenza virus to CDC Reference Laboratory for confirmatory and special tests.
- Ensure that primers are available to sub-type all influenza A viruses.
- Ensure that sufficient quantities of all diagnostic reagents are available for the laboratory's needs.
- Develop a reporting system for hospitals to report daily aggregate data on the number of suspected and confirmed influenza-associated deaths. It is anticipated that this will be the primary method to collect daily data necessary to monitor the mortality of the pandemic.

Local Health Departments:

- Help educate healthcare providers about novel and pandemic influenza.
- Distribute to healthcare providers the current CDC recommendations for enhanced surveillance for the detection of the first cases of the pandemic virus in their jurisdictions.
- Provide consultation and investigation of suspected novel influenza cases to healthcare providers in conjunction with the state health department.
- Consult on collection of specimens of suspected novel influenza testing.

DRAFT

2. Surveillance and Laboratory Testing cont.

- Facilitate the transfer of specimens to the DHMH State Laboratory.
- Conduct follow-up of suspected novel influenza cases, including contact investigations.
- Identify critical resources for epidemiologic surge capacity.
- Establish and maintain (update) contact lists.
- Investigate community outbreaks of influenza-like illness.
- Assist with identifying medical providers willing to participate in the CDC Influenza Sentinel Provider Network

Pandemic Period

State Health Department:

- Update LHDs and providers regularly throughout the influenza pandemic.
- Work with LHDs to coordinate testing.
- Work with LHDs to investigate and report special pandemic situations.
- Analyze surveillance data to monitor trends in influenza activity.
- Implement enhanced surveillance for detection of the first cases.
- Send unusual or suspected cases of novel influenza virus to CDC Reference Laboratory for confirmatory and special tests.
- Increase surveillance and laboratory activities and testing as needed and share results with key stakeholders.
- Implement enhanced disease surveillance at points of entry to Maryland if an influenza pandemic begins outside the United States.
- Communicate to all partners the heightened need for timely and complete surveillance data.
- Provide mortality data to CDC as needed to help guide national response measures.
- Participate in national and international surveillance activities as indicated.

DRAFT

2. Surveillance and Laboratory Testing cont.

- Augment or scale back surveillance as appropriate. Enhanced surveillance will be conducted during the introduction, initial spread, and first waves of a pandemic. Over time, as more persons are exposed, the pandemic strain is likely to become a routinely circulating influenza A subtype. When that happens, the activities of Maryland's influenza surveillance system may revert to the frequency and intensity typically seen during interpandemic influenza seasons. The return to interpandemic surveillance will occur as soon as feasible, and the change will be communicated to all surveillance partners.

Local Health Departments:

- Update providers regularly throughout the influenza pandemic.
- Provide or facilitate testing and investigation of pandemic influenza cases.
- Work with DHMH to investigate and report special pandemic situations.
- Conduct enhanced surveillance activities.
- Communicate to all partners the heightened need for timely and complete surveillance data.

DRAFT

Appendix 2-A CDC Updated Surveillance Criteria

CDC recommends maintaining the enhanced surveillance efforts practiced currently by state and local health departments, hospitals, and clinicians to identify patients at increased risk for avian influenza A (H5N1). Guidance for enhanced surveillance was first described in a HAN update issued on February 3, 2004 and most recently updated on February 4, 2005.

Testing for avian influenza A (H5N1) virus infection is recommended for:

A patient who has an illness that:

- Requires hospitalization or is fatal; AND
- Has or had a documented temperature of $\geq 38^{\circ}\text{C}$ ($\geq 100.4^{\circ}\text{F}$); AND
- Has radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternate diagnosis has not been established; AND
- Has at least one of the following potential exposures within 10 days of symptom onset:
 - A. History of travel to a country with influenza H5N1 documented in poultry, wild birds, and/or humans,[†] AND had at least one of the following potential exposures during travel:
 - o Direct contact with (e.g., touching) sick or dead domestic poultry;
 - o Direct contact with surfaces contaminated with poultry feces;
 - o Consumption of raw or incompletely cooked poultry or poultry products;
 - o Direct contact with sick or dead wild birds suspected or confirmed to have influenza H5N1;
 - o Close contact (approach within 1 meter [approx. 3 feet]) of a person who was hospitalized or died due to a severe unexplained respiratory illness;
 - B. Close contact (approach within 1 meter [approx. 3 feet]) of an ill patient who was confirmed or suspected to have H5N1;
 - C. Worked with live influenza H5N1 virus in a laboratory.

DRAFT

Appendix 2-A cont. CDC Updated Surveillance Criteria

Testing for avian influenza A (H5N1) virus infection can be considered on a case-by-case basis, in consultation with local and state health departments, for:

- A patient with mild or atypical disease‡ (hospitalized or ambulatory) who has one of the exposures listed above (criteria A, B, or C); OR
- A patient with severe or fatal respiratory disease whose epidemiological information is uncertain, unavailable, or otherwise suspicious but does not meet the criteria above (examples include: a returned traveler from an influenza H5N1-affected country whose exposures are unclear or suspicious, a person who had contact with sick or well-appearing poultry, etc.)

Clinicians should contact their local or state health department as soon as possible to report any suspected human case of influenza H5N1 in the United States.

† For a listing of influenza H5N1-affected countries, visit the CDC website at <http://www.cdc.gov/flu/avian/outbreaks/current.htm>; the OIE website at http://www.oie.int/eng/en_index.htm; and the WHO website at http://www.who.int/csr/disease/avian_influenza/en/.

‡ For example, a patient with respiratory illness and fever who does not require hospitalization, or a patient with significant neurologic or gastrointestinal symptoms in the absence of respiratory disease.

DRAFT

Appendix 2-B

DHMH Procedure for Collection and Transport of Viral Throat Specimens for Respiratory Outbreaks

- Obtain viral throat swab kits from DHMH Laboratories Administration, Outfit Room, by calling (410) 767- 6120 or your local health department. Before using a kit, be sure to check the expiration date on the viral transport media on a regular basis.

- Complete the accompanying VIROLOGY form (DHMH-72). Be sure to include:
 - Person's first and last name.

 - Specify virus that is suspected, or for which testing is desired, on the blank line following "Virologic Test desired." Do NOT write vague instructions such as "viral culture," or "respiratory viruses." By naming the virus, you ensure that the laboratory will do the work that is desired, which will provide more meaningful results to the health care provider.

 - Outbreak number assigned by DHMH (if applicable). This should be written in the blank space of the form near the submitter information.

 - Clinical diagnosis. Note "influenza" if that is suspected as the clinical diagnosis

- Open sterile swabs provided in kit. Hold two swabs together and swab the posterior pharynx and tonsillar areas vigorously with swabs.

- Immerse swabs, tips first, in media and break off the top portion of the shaft that extends beyond the length of the tube. The entire remaining swab should fit in the tube without applying pressure to the lid when the lid is secured.

- Label the specimen tube with the patient's first and last names *exactly as the name was written on the lab slip*. Federal clinical laboratory regulations require unambiguous identification on all specimens, meaning that the patient identifiers on the lab slip and tube must match. Specimens that are received with no identification on the collection tube that exactly corresponds to the

DRAFT

Appendix 2-B cont.

DHMH Procedure for Collection and Transport of Viral Throat Specimens for Respiratory Outbreaks

identifier on the lab slip will not be tested. It is in the best interest of the patient, the health care provider, and the laboratory that all specimens sent to the laboratory be clearly and unequivocally labeled.

- Refrigerate specimens immediately after collection, and then transport them to the laboratory using cool packs to maintain a cold temperature. Alternatively, the specimen can be frozen at -70°C, which requires a specialized freezer. DO NOT freeze specimen in a regular, household-type freezer as this will not keep the specimen cold enough. Specimens frozen at -70°C should be shipped to the lab on dry ice. If no dry ice is available, specimens should not be frozen after collection, but should be kept cool as outlined earlier in this paragraph. Because of the mess created when it melts, do not use wet ice to keep specimens cold during transit.
 - Note to local health departments: If facilitating the transport of viral throat specimens to DHMH Virology Laboratory, please double check specimens to ensure that all proper laboratory paperwork and corresponding tube labels have been completed .
 - Specimens should be transported to DHMH Virology Laboratory, 201 W. Preston St, Baltimore, MD 21201.

PLEASE NOTE – Failure to follow proper procedures may render a specimen unsatisfactory for testing.

DRAFT

APPENDIX 2-C. DHMH Laboratory Contact Numbers

| | | | |
|--|---|---|--|
| For Daily Reporting, The Contact People Are: | | | |
| Dr Jack DeBoy | 1.410-767-6100 | 1.800.538.4186 | jdeboy@dhmh.state.md.us |
| Dr Bob Myers | 1.410-767-5772 | 1.800.465.6287 | myersr@dhmh.state.md.us |
| Dr Julie Kiehlbauch | 1.410.767.3427 | 1.800.538.7924 | kiehlbauchj@dhmh.state.md.us |
| Mr. Jim Svrjctet/Jill Santacroce | 1.410.767.6096 | | svrjctetj@dhmh.state.md.us santacrocej@dhmh.state.md.us |
| For Emergency Calls, All Text Message Pagers: | | | |
| BT Lab emergency pager Mr. Jim Svrjctet/Jill Santacroce | | 1.410.471.0595 | 4104710595@archwireless.net |
| | | | |
| For Emergency Technical Review | | | |
| Dr Bob Myers | 410-767-5772 | 1.800.465.6287 | 8004656287@archwireless.net |

DRAFT

Appendix 2-D CDC Specimen Testing Guidelines, Updated June 2006

- Oropharyngeal swab specimens and lower respiratory tract specimens (e.g., bronchoalveolar lavage or tracheal aspirates) are preferred because they appear to contain the highest quantity of virus for influenza H5N1 detection, as determined on the basis of available data. Nasal or nasopharyngeal swab specimens are acceptable, but may contain less virus and therefore not be optimal specimens for virus detection.
- Detection of influenza H5N1 is more likely from specimens collected within the first 3 days of illness onset. If possible, serial specimens should be obtained over several days from the same patient.
- Bronchoalveolar lavage is considered to be a high-risk aerosol-generating procedure. Therefore, infection control precautions should include the use of gloves, gown, goggles or face shield, and a fit-tested respirator with an N-95 or higher rated filter. A loose-fitting powered air-purifying respirator (PAPR) may be used if fit-testing is not possible (for example, if the person has a beard). Detailed guidance on infection control precautions for health care workers caring for suspected influenza H5N1 patients is available.||
- Swabs used for specimen collection should have a Dacron tip and an aluminum or plastic shaft. Swabs with calcium alginate or cotton tips and wooden shafts are not recommended.§ Specimens should be placed at 4°C immediately after collection.
- For reverse-transcriptase polymerase chain reaction (RT-PCR) analysis, nucleic acid extraction lysis buffer can be added to specimens (for virus inactivation and RNA stabilization), after which specimens can be stored and shipped at 4°C. Otherwise, specimens should be frozen at or below -70°C and shipped on dry ice. For viral isolation, specimens can be stored and shipped at 4>°C. If specimens are not expected to be inoculated into culture within 2 days, they should be frozen at or below -70°C and shipped on dry ice. Avoid repeated freeze/thaw cycles.
- Influenza H5N1-specific RT-PCR testing conducted under Biosafety Level 2 conditions¶ is the preferred method for diagnosis. All state public health laboratories, several local public health laboratories, and CDC are able to perform influenza H5N1 RT-PCR testing, and are the recommended sites for initial diagnosis.

DRAFT

Appendix 2-D cont.

CDC Specimen Testing Guidelines, Updated June 2006

- Viral culture should NOT be attempted on specimens from patients suspected to have influenza H5N1, unless conducted under Biosafety Level 3 conditions with enhancements.¶
- Commercial rapid influenza antigen testing in the evaluation of suspected influenza H5N1 cases should be interpreted with caution. Clinicians should be aware that these tests have relatively low sensitivities, and a negative result would not exclude a diagnosis of influenza H5N1. In addition, a positive result does not distinguish between seasonal and avian influenza A viruses.
- Serologic testing for influenza H5N1-specific antibody, using appropriately timed specimens, can be considered if other influenza H5N1 diagnostic testing methods are unsuccessful (for example, due to delays in respiratory specimen collection). Paired serum specimens from the same patient are required for influenza H5N1 diagnosis: one sample should be tested within the first week of illness, and a second sample should be tested 2-4 weeks later. A demonstrated rise in the H5N1-specific antibody level is required for a diagnosis of H5N1 infection. Currently, the microneutralization assay, which requires live virus, is the recommended test for measuring H5N1-specific antibody. Any work with live wild-type highly pathogenic influenza H5N1 viruses must be conducted in a USDA-approved Biosafety Level 3 enhanced containment facility. Visit <http://www.cdc.gov/flu/h2n2bsl3.htm> for more information about procedures and facilities recommended for manipulating highly pathogenic avian influenza viruses.

¶ Interim recommendations for infection control in health-care facilities caring for patients with known or suspected avian influenza are available at <http://www.cdc.gov/flu/avian/professional/infect-control.htm>.

§ Specimens can be transported in viral transport media, Hanks balanced salt solution, cell culture medium, tryptose-phosphate broth, veal infusion broth, or sucrose-phosphate buffer. Transport media should be supplemented with protein, such as bovine serum albumin or gelatin, to a concentration of 0.5% to 1%.

¶ Information regarding Laboratory Biosafety Level Criteria can be found at <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3.htm>.

DRAFT

**Appendix 2-E
Novel Influenza Case Report Form**



Human Influenza A (H5)

Human Influenza A (H5) Domestic Case Screening Form

CDC Case ID:

| | | | |
|---|--|--------------------------------|--------|
| 1. Reported By | | | |
| Date reported to state or local health department: <u> </u> / <u> </u> / <u> </u> <small>m m d d y y y y</small> | | State/ local Assigned Case ID: | |
| Last Name: | | First Name: | |
| State: | Affiliation: | Email: | |
| Phone 1: | Phone 2: | Fax: | |
| 2. Patient Information | | | |
| City of Residence: | | County: | State: |
| Age at onset: <u> </u> <small>Year(s)</small> <input type="checkbox"/> <small>Month(s)</small> | Race: <i>(Choose One)</i> <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> White <input type="checkbox"/> Asian <input type="checkbox"/> Unknown <input type="checkbox"/> Black <input type="checkbox"/> Native Hawaiian/Other Pacific Islander | | |
| Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female | Ethnicity: <input type="checkbox"/> Non Hispanic <input type="checkbox"/> Hispanic | | |
| 3. Optional Patient Information | | | |
| Last Name: | | First Name: | |
| 4. Signs and Symptoms | | | |
| A. Date of symptom onset: <u> </u> / <u> </u> / <u> </u> <small>m m d d y y y y</small> | | | |
| B. What symptoms and signs did the patient have during the course of illness? (check all that apply) | | | |
| Fever > 38° C (100.4° F) | Feverish (temperature not taken) | Conjunctivitis | |
| Cough | Headache | Shortness of breath | |
| Sore throat | Other (specify): _____ | | |
| C. Was a chest X-ray or chest CAT scan performed? <input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | |
| If yes*, did the patient have radiographic evidence of pneumonia or respiratory distress syndrome (RDS)? <input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown | | | |

February 19, 2004

Page 1 of 5

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
SAFER • HEALTHIER • PEOPLE™**

DRAFT

Appendix 2-E Novel Influenza Case Report Form

Influenza A (H5) Domestic Case Screening Form 1.0
(continued from previous page)

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? <input type="checkbox"/> Yes* <input type="checkbox"/> No** <input type="checkbox"/> Unknown If yes*, please fill in arrival and departure dates for all countries that apply. **If patient did not travel outside U.S., skip to question 6. | | | | | |
| Country | Arrival Date | Departure Date | Country | Arrival Date | Departure Date |
| Afghanistan | | | Myanmar (Burma) | | |
| Bangladesh | | | Nepal | | |
| Brunei | | | North Korea | | |
| Cambodia | | | Oman | | |
| China | | | Pakistan | | |
| Hong Kong | | | Papua New Guinea | | |
| India | | | Philippines | | |
| Indonesia | | | Saudi Arabia | | |
| Iran | | | Singapore | | |
| Iraq | | | South Korea | | |
| Israel | | | Syria | | |
| Japan | | | Taiwan | | |
| Jordan | | | Thailand | | |
| Laos | | | Turkey | | |
| Lebanon | | | Viet Nam | | |
| Macao | | | Yemen | | |
| 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 | | | | | |

DRAFT

Appendix 2-E Novel Influenza Case Report Form

Influenza A (H5) Domestic Case Screening Form 1.0
(continued from previous page)

CDC ID:

| 6. Exposure for Non Travelers | |
|---|---|
| <p>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?</p> <p>If yes*, was the contact a confirmed or suspected H5 case patient?</p> <p>If yes*: CDC ID: _____ STATE ID: _____</p> | <p><input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown</p> <p><input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown</p> |

Laboratory Evaluation

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

DRAFT

Appendix 2-E Novel Influenza Case Report Form

Influenza A (H5) Domestic Case Screening Form 1.0
(continued from previous page)

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, broncheoalveolar 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 | 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 | 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 | 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 | 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 | 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: | | |
| | | |

Appendix 2-F Quick Reference Chart, Diagnostic Tests

| Procedure | Influenza Types Detected | Acceptable Specimens | Time for Results | Rapid result available |
|--|--------------------------|--|------------------------|------------------------|
| QUICK REFERENCE CHART OF INFLUENZA DIAGNOSTIC TESTS¹ (From: <i>Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)</i> , MMWR 2004;53(RR-6):1-40. | | | | |
| Viral culture | A and B | nasal wash/aspirate, NP swab,2 nasal aspirate, nasal swab and throat swab, sputum | 5-10 days ² | No |
| Immunofluorescence | A and B | nasal wash/aspirate, NP swab,2 nasal aspirate, nasal swab and throat swab, sputum | 2-4 hours | No |
| Antibody Staining | A and B | nasal wash/aspirate, NP swab,2 nasal aspirate, throat swab, bronchial wash, nasal aspirate, sputum | Hours | No |
| RT-PCR ⁵ | A and B | paired acute/convalescent serum samples ⁶ | >2 weeks | No |
| Rapid Diagnostic Tests | | | | |
| Directigen Flu A ⁷ (Becton-Dickinson) | A | NP swab,2 throat swab, nasal wash, nasal aspirate | See insert | Yes |
| Directigen Flu A+B ^{7,9} (Becton-Dickinson) | A and B | NP swab,2 throat swab, nasal wash, nasal aspirate | See insert | Yes |
| FLU OIA ⁷ (Thermo Electron) | A and B ⁸ | NP swab,2 throat swab, nasal aspirate, sputum | See insert | Yes |
| FLU OIA A/B ^{7,9} (Thermo Electron) | A and B | NP swab,2 throat swab, nasal aspirate, sputum | See insert | Yes |
| XPECT Flu A/B ^{7,9} (Remel) | A and B | Nasal wash, NP swab,2 throat swab | See insert | Yes |
| NOW Flu A Test ^{7,9} | A | Nasal wash, NP swab,2 | See insert | Yes |
| NOW Flu B Test ^{7,9} (Binax) | B | Nasal wash, NP swab,2 | See insert | Yes |
| QuickVue Influenza Test ⁸ (Quidel) | A and B ⁸ | NP swab,2 nasal wash, nasal aspirate | See insert | Yes |
| QuickVue Influenza A+B Test ⁸ (Quidel) | A and B ⁸ | NP swab,2 nasal wash, nasal aspirate | See insert | Yes |
| SAS Influenza A ^{7,9} | B | NP wash,2 NP aspirate ² | See insert | Yes |
| SAS Influenza B ^{7,9} | B | NP wash,2 NP aspirate ² | See insert | Yes |
| ZstatFlu ⁸ (Zyme Ix) | A and B ⁸ | throat swab | See insert | Yes |

¹ The list might not include all FDA-approved test kits.

² NP = nasopharyngeal

³ Shell-vial culture, if available, may reduce time for results to 2 days.

⁴ Does not distinguish between influenza A and B virus infections.

⁵ RT-PCR = reverse-transcription polymerase chain reaction

⁶ A fourfold or greater rise in antibody titer from the acute - (collected within the first week of illness) to the convalescent-phase sample (collected 2-4 weeks after the acute sample) indicates recent infection.

⁷ Moderately complex test that requires specific laboratory certification

⁸ CLIA-waived test. Can be used in any office setting. Requires a certificate of waiver or higher laboratory certification

⁹ Distinguishes between influenza A and B virus infections.

Disclaimer: Use of trade names or commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan, November 2005

DRAFT

Appendix 2-G Influenza Diagnostic Assays

Among the several types of assays used to detect influenza, rapid antigen tests, reverse-transcription polymerase chain reaction (RT-PCR), viral isolation, immunofluorescence assays (IFA), and serology are the most commonly used. The sensitivity and specificity of any test for influenza will vary by the laboratory that performs the test, the type of test used, and the type of specimen tested. A chart that lists influenza diagnostic procedures and commercially available rapid diagnostic tests follows more detailed descriptions provided below.

- **Virus Isolation**

- **Biocontainment level: Interpandemic and Pandemic Alert Periods – BSL-3 with enhancements; Pandemic Period – BSL-2**

Virus isolation is a highly sensitive and very useful technique when the clinical specimens are of good quality and have been collected in a timely manner (optimally within 3 days of the start of illness). Isolation of a virus in cell culture along with the subsequent identification of the virus by immunologic or genetic techniques are standard methods for virus diagnosis. Virus isolation amplifies the amount of virus from the original specimen, making a sufficient quantity of virus available for further antigenic and genetic characterization and for drug-susceptibility testing if required. Virus isolation is considered the “gold standard” for diagnosis of influenza virus infections.

Highly pathogenic avian influenza (HPAI) viruses are BSL-3 agents. During the Interpandemic and Pandemic Alert Periods, laboratories should attempt to culture HPAI viruses—as well as other influenza viruses with pandemic potential—only under BSL-3 conditions with enhancements in order to optimally reduce the risk of a novel influenza virus subtype spreading to persons or animals. During the Pandemic Period, biocontainment of BSL-2 is appropriate to prevent laboratory-acquired infection and the virus will already be widespread.

In recent years, the use of cell lines has surpassed the use of embryonated eggs for culturing of influenza viruses, although only viruses grown in embryonated eggs are used as seed viruses for vaccine production. Because standard isolation procedures require several days to yield results, they should be used in combination with the spin-amplification shell-vial method. The results of these assays can be obtained in 24–72 hours, compared to an average of 4.5 days using standard culture techniques. Spin-amplification should not be performed using 24-well plates because of increased risk of cross-contamination. The most

DRAFT

Appendix 2-G cont. Influenza Diagnostic Assays

effective combination of cell lines recommended for public health laboratories is primary rhesus monkey for standard culture, along with Madin Darby Canine Kidney (MDCK) in shell vial.⁽¹⁾ The use of these two cell lines in combination has demonstrated maximum sensitivity over time for recovery of evolving influenza strains. Some clinical laboratories have recently reported good isolation rates using commercially available cell-line mixed-cell combinations; however, data are lacking on the performance of these mixed cells with new subtypes of Influenza A viruses.

Appropriate clinical specimens for virus isolation include nasal washes, nasopharyngeal aspirates, nasopharyngeal and throat swabs, tracheal aspirates, and bronchoalveolar lavage. Ideally, specimens should be collected within 72 hours of the onset of illness.

Viral culture isolates are used to provide specific information regarding circulating influenza subtypes and strains. This information is needed to compare current circulating influenza strains with vaccine strains, to guide decisions on influenza treatment and chemoprophylaxis, and to select vaccine strains for the coming year. Virus isolates also are needed to monitor HHS Pandemic Influenza Plan the emergence of antiviral resistance and of novel influenza A subtypes that might pose a pandemic threat. During outbreaks of influenza-like illness, viral culture may help identify other causes of illness when influenza is not the etiology (except when using MDCK cells or the MDCK shell-vial technique).

▪ Immunofluorescence Assays

- **Biocontainment level: BSL-2 when performed directly on clinical specimens; if used on cultures for earlier detection of virus, biocontainment recommendations for viral culture apply**

Direct (DFA) or indirect (IFA) immunofluorescence antibody staining of virus-infected cells is a rapid and sensitive method for diagnosis of influenza and other viral infections. DFA and IFA can also be used to type and subtype influenza viruses using commercially available monoclonal antibodies specific for the influenza virus HA. The sensitivity of these methods is greatly influenced by the quality of the isolate, the specificity of the reagents used, and the experience of the person(s) performing, reading, and interpreting the test.

¹ The shell-vial technique is described in: *Manual of Clinical Virology*, 3rd edition. Steven Specter, Richard Hodinka, and Stephen Young, eds. ASM Press, 2000.

DRAFT

Appendix 2-G cont. Influenza Diagnostic Assays

Although IFA can be used to stain smears of clinical specimens directly, when rapid diagnosis is needed it is preferable to first increase the amount of virus through growth in cell culture. For HPAI isolates, attempts to culture the virus should be made only under BSL-3 conditions with enhancements.

- **Reverse-Transcription Polymerase Chain Reaction (RT-PCR)**
 - **Biocontainment level: BSL-2**

PCR can be used for rapid detection and subtyping of influenza viruses in respiratory specimens. Because the influenza genome consists of single-stranded RNA, a complementary DNA (cDNA) copy of the viral RNA must be synthesized using the reverse-transcriptase (RT) enzyme prior to the PCR reaction.

Laboratories can obtain CDC protocols and sequences of primers and probes for rapid RT-PCR detection of human and avian HA subtypes of current concern at the APHL website (available for members only). These protocols use real-time RT-PCR methods with fluorescent-labeled primers that allow automatic, semi-quantitative estimation of the input template. The RT-PCR results are analyzed and archived electronically, without the need for gel electrophoresis and photographic recording. A large number of samples may be analyzed at the same time, reducing the risk of carry-over contamination.

As with all PCR assays, interpretation of real-time RT-PCR tests must account for the possibility of false-negative and false-positive results. False-negative results can arise from poor sample collection or degradation of the viral RNA during shipping or storage. Application of appropriate assay controls that identify poor-quality samples (e.g., an extraction control and, if possible, an inhibition control) can help avoid most false-negative results. (2)

The most common cause of false-positive results is contamination with previously amplified DNA. The use of real-time RT-PCR helps mitigate this problem by operating as a contained system. A more difficult problem is the cross-contamination that can occur between specimens during collection, shipping, and aliquoting in the laboratory. Use of multiple negative control samples in each assay and a well-designed plan for confirmatory testing can help ensure that laboratory contamination is detected and that negative specimens are not inappropriately identified as influenza-positive.

2 CDC is working with the private sector to provide inactivated RNA virus for use as RT-PCR controls for influenza A (H5) testing in LRN laboratories. CDC is working with USDA to resolve any permit issues that might affect the ability of LRN members to use these controls.

DRAFT

Appendix 2-G cont. Influenza Diagnostic Assays

Specimens that test positive for a novel subtype of influenza virus should be forwarded to CDC for confirmatory testing. (Due to the possibility of contamination, it is important to provide original clinical material.) All laboratory results should be interpreted in the context of the clinical and epidemiologic information available on the patient.

- **Rapid Diagnostic Tests**

- **Biocontainment level: BSL-2**

Commercial rapid diagnostic tests can be used in outpatient settings to detect influenza viruses within 30 minutes. These rapid tests differ in the types of influenza viruses they can detect and in their ability to distinguish among influenza types. Different tests can 1) detect influenza A viruses only (including avian strains); 2) detect both influenza A and B viruses, without distinguishing between them; or 3) detect both influenza A and B viruses and distinguish between them.

The types of specimens acceptable for use (i.e., nasal wash/aspirate, nasopharyngeal swab, or nasal swab and throat swab) also vary by test. The specificity and, in particular, the sensitivity of rapid tests are lower than for viral culture and vary by test and specimen tested. The majority of rapid tests are >70% sensitive and >90% specific. Thus, as many as 30% of samples that would be positive for influenza by viral culture may give a negative rapid test result with these assays.

When interpreting results of a rapid influenza test, physicians should consider the level of influenza activity in the community. When influenza prevalence is low, positive rapid test results should be independently confirmed by culture or RT-PCR. When influenza is known to be circulating, clinicians should consider confirming negative tests with viral culture or other means because of the lower sensitivity of the rapid tests. Package inserts and the laboratory performing the test should be consulted for more details regarding use of rapid diagnostic tests. Additional information on diagnostic testing is provided at: <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>. Detailed information on the use of rapid diagnostics tests is provided in Appendix 2-I.

Appendix 2-G cont. Influenza Diagnostic Assays

▪ Serologic Tests (3)

Hemagglutination Inhibition (HAI)

o Biocontainment level: BSL-2

Serologic testing can be used to identify recent infections with influenza viruses. It can be used when the direct identification of influenza viruses is not feasible or possible (e.g., because clinical specimens for virus isolation cannot be obtained, cases are identified after shedding of virus has stopped, or the laboratory does not have the resources or staff to perform virus isolation).

Since most human sera contain antibodies to influenza viruses, serologic diagnosis requires demonstration of a four-fold or greater rise in antibody titer using paired acute and convalescent serum samples. HAI is the preferred diagnostic test for determining antibody rises. In general, acute-phase sera should be collected within one week of illness onset, and convalescent sera should be collected 2–3 weeks later.

There are two exceptions in which the collection of single serum samples can be helpful in the diagnosis of influenza. In investigations of outbreaks due to novel viruses, testing of single serum samples has been used to identify antibody to the novel virus. In other outbreak investigations, antibody test results from single specimens collected from persons in the convalescent phase of illness have been compared with results either from age-matched persons in the acute phase of illness or from non-ill controls. In such situations, the geometric mean titers between the two groups to a single influenza virus type or subtype can be compared. In general, these approaches are not optimal, and paired sera should be collected whenever possible.

Because HAI titers of antibodies in humans infected with avian influenza viruses are usually very low or even undetectable, more sensitive serologic tests, such as microneutralization, may be needed.

³ Enzyme-linked immunoassay (EIA) is not included on this list because of non-specificity issues. Complement fixation is not included because it is currently out of use.

DRAFT

Appendix 2-G cont. Influenza Diagnostic Assays

- **Microneutralization Assay**

- **Biocontainment level: Interpandemic and Pandemic Alert Periods – BSL-3 with enhancements; Pandemic Period – BSL-2**

The virus neutralization test is a highly sensitive and specific assay for detecting virus-specific antibody in animals and humans. The neutralization test is performed in two steps: 1) a virus-antibody reaction step, in which the virus is mixed with antibody reagents, and 2) an inoculation step, in which the mixture is inoculated into a host system (e.g. cell cultures, embryonated eggs, or animals). The absence of infectivity constitutes a positive neutralization reaction and indicates the presence of virus-specific antibodies in human or animal sera.

The virus neutralization test gives the most precise answer to the question of whether or not a person has antibodies that can neutralize the infectivity of a given virus strain. The neutralization test has several additional advantages for detecting antibody to influenza virus. First, the assay primarily detects antibodies to the influenza virus HA and thus can identify functional, strain-specific antibodies in animal and human serum. Second, since infectious virus is used, the assay can be developed quickly upon recognition of a novel virus and before suitable purified viral proteins become available for use in other assays.

The microneutralization test is a sensitive and specific assay for detecting virus-specific antibody to avian influenza A (H5N1) in human serum and potentially for detecting antibody to other avian subtypes. Microneutralization can detect H5-specific antibody in human serum at titers that cannot be detected by HAI. Because antibody to avian influenza subtypes is presumably low or absent in most human populations, single serum samples can be used to screen for the prevalence of antibody to avian viruses. However, if infection of humans with avian viruses is suspected, the testing of paired acute and convalescent sera in the microneutralization test would provide a more definitive answer regarding the occurrence of infection. Conventional neutralization tests for influenza viruses based on the inhibition of cytopathogenic effect (CPE)-formation in MDCK cell cultures are laborious and rather slow, but in combination with rapid culture assay principles the neutralization test can yield results within 2 days. For HPAI viruses, neutralization tests should be performed at BSL-3 enhanced conditions.

DRAFT

Appendix 2-H Reference Testing Guidelines for Potential Pandemic Strains of Influenza

State and local laboratories may conduct initial testing on patient specimens for influenza A or potential highly pathogenic strains, if laboratory capacity is available. Due to the spread of avian influenza A (H5N1) in poultry in Asia, laboratories should be on the alert for avian and human H5 viruses. Procedures for diagnosis of human cases of influenza A (H5N1) are provided in Appendix 2-A. Influenza A viruses other than currently circulating H1 and H3 subtypes should also be considered as potentially pandemic if detected in humans.

State and local laboratories should send specimens to CDC if:

- A sample tested by the state or local laboratory is positive for H5 or another novel subtype; OR

NOTE: A laboratory should test for influenza A (H5) only if it is able to do so by PCR or has a BSL-3-enhanced facility for influenza A(H5) viral culture.

- A sample from a patient who meets the clinical and epidemiologic criteria for possible infection with a potentially pandemic virus is positive for influenza A by RT-PCR or rapid antigen detection, is negative for influenza A(H1) and A(H3), and the referring jurisdiction is not equipped to test for specific strains; OR
- The referring jurisdiction is not equipped to test samples for novel influenza viruses by RT-PCR and is requesting testing at CDC.

Shipping procedures for potential pandemic strains of influenza are provided in Appendix 2-B.

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

DRAFT

Appendix 2- Laboratory Biosafety Guidelines

HANDLING AND PROCESSING SPECIMENS OR ISOLATES OF NOVEL INFLUENZA STRAINS

Key Guidance

- Commercial antigen detection testing for influenza may be conducted under BSL-2 containment conditions if a Class II biological safety cabinet is used.
- Clinical specimens from suspected novel influenza cases may be tested by RT-PCR using standard BSL-2 work practices in a Class II biological safety cabinet for initial processing of patient specimens.
- If a specimen is confirmed positive for influenza A (H5N1) by RT-PCR, additional testing should be performed only under BSL-3 conditions with enhancements. CDC's Influenza Branch should be informed immediately by DHMH through the CDC Director's Emergency Operations Center (DEOC) at 770-488-7100.
- A detailed description of recommended facilities, practices, and protective equipment for the various laboratory biosafety levels can be found in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual at www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm
- BSL-3 with enhancements and Animal Biosafety Level 3 include: all BSL-3 practices, procedures, and facilities, plus the use of negative-pressure, HEPA-filtered respirators or positive air-purifying respirators, and clothing change and personal showering protocols. Additional practices and/or restrictions may be added as conditions of USDA-APHIS permits. Registration of personnel and facilities with the Select Agent Program is required for work with highly pathogenic avian influenza (HPAI) viruses, which are classified as agricultural select agents.
- State and local public health laboratories may test clinical specimens from suspected novel influenza cases by RT-PCR using standard BSL-2 work practices in a Class II biological safety cabinet. Commercial rapid antigen detection testing may also be conducted under BSL-2 biocontainment conditions.

DRAFT

Appendix 2-I cont. Laboratory Biosafety Guidelines

- Highly pathogenic avian influenza A (H5) and A (H7) viruses are classified as select agents. USDA regulations require that these viruses (as well as exotic low pathogenic avian influenza viruses) be handled under BSL-3 laboratory containment conditions, with enhancements (i.e., controlled-access double-door entry with change room and shower, use of respirators, decontamination of all wastes, and showering of all personnel). Laboratories that work with these viruses must be certified by USDA.
- Laboratories should not perform virus isolation on respiratory specimens from patients who may be infected with an avian influenza virus unless stringent BSL-3 enhanced containment conditions can be met and diagnostic work can be kept separate from studies with other human influenza A viruses (i.e., H1 or H3). Therefore, respiratory virus cultures should not be performed in most clinical laboratories. Cultures for patients suspected of having influenza A (H5N1) infection should be sent only to state laboratories with appropriate BSL-3 with enhancement containment facilities or to CDC.

Appendix 2- J Rapid Diagnostic Testing for Influenza

The following information in this appendix is designed to assist clinicians and clinical laboratory directors in the use of rapid diagnostic tests during inter-pandemic influenza seasons. During an influenza pandemic, one or more of these tests may be sensitive and specific enough to be used by clinicians to supplement clinical diagnoses of pandemic influenza. However, clinicians should be reminded that a negative test result might not rule out pandemic influenza and should not affect patient management or infection control decisions.

I. INFORMATION FOR CLINICIANS

A. Background

Rapid diagnostic tests for influenza can help in the diagnosis and management of patients who present with signs and symptoms compatible with influenza. They also are useful for helping to determine whether institutional outbreaks of respiratory disease might be due to influenza. In general, rapid diagnostic testing for influenza should be done when the results will affect a clinical decision. Rapid diagnostic testing can provide results within 30 minutes.

B. Reliability and interpretation of rapid test results

The reliability of rapid diagnostic tests depends largely on the conditions under which they are used. Understanding some basic considerations can minimize being misled by false-positive or false-negative results. Median sensitivities of rapid diagnostic tests are generally ~70%–75% when compared with viral culture, but median specificities of rapid diagnostic tests for influenza are approximately 90%–95%. False-positive (and true negative) results are more likely to occur when disease prevalence in the community is low, which is generally at the beginning and end of the influenza season. False-negative (and true positive) results are more likely to occur when disease prevalence is high in the community, which is typically at the height of the influenza season.

C. Minimizing the occurrence of false results

- Use rapid diagnostic tests that have high sensitivity and specificity.
- Collect specimens as early in the illness as possible (within 4–5 days of symptom onset).
- Follow the manufacturer's instructions, including those for handling of specimens.

DRAFT

Appendix 2- J cont. Rapid Diagnostic Testing for Influenza

- Consider sending specimens for viral culture when:
 - Community prevalence of influenza is low and the rapid diagnostic test result is positive, or
 - Disease prevalence is high but the rapid diagnostic test result is negative. (Contact your DHMH for information about influenza activity.)

D. For further information

- Information about influenza is available at the CDC influenza website (www.cdc.gov/flu) or from the CDC Flu Information Line (800-CDC-INFO [English and Spanish]; 800-243-7889 [TTY]).
- For more information about influenza diagnostics, contact your state laboratory or state health department (<http://www.cdc.gov/other.htm#states>).
- Additional resources:
 - Association of Public Health Laboratories:
http://www.aphl.org/Public_Health_Labs/index.cfm
 - Weekly U.S. influenza activity reports:
<http://www.cdc.gov/flu/weekly/fluactivity.htm>
 - CDC Clinician Outreach and Communication Activity:
<http://www.bt.cdc.gov/coca/index.asp>
 - CDC website: <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>

II. INFORMATION FOR CLINICAL LABORATORY DIRECTORS

A. Background

Rapid diagnostic tests for influenza are screening tests for influenza virus infection; they can provide results within 30 minutes. The use of commercial influenza rapid diagnostic tests by laboratories and clinics has increased substantially in recent years. At least ten rapid influenza tests have been approved by the U.S. Food and Drug Administration (FDA) (see Appendix 2-E). Rapid tests differ in some important respects. Some can identify influenza A and B viruses and distinguish between them; some can identify influenza A and B viruses but cannot distinguish between them. Some tests are waived from

Appendix 2- J cont.
Rapid Diagnostic Testing for Influenza

requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Most tests can be used with a variety of specimen types, but sensitivity and specificity can vary with specimen type. FDA approval is based upon specific specimen types.

Rapid tests vary in terms of sensitivity and specificity when compared with viral culture. Product insert information and research publications indicate that median sensitivities are approximately 70%–75% and median specificities are approximately 90%–95%.

Specimens to be used with rapid tests generally should be collected as close as possible to the start of symptoms and usually no more than 4–5 days later in adults. In very young children, influenza viruses can be shed for longer periods; therefore, in some instances, testing for a few days after this period may still be useful. Test sensitivity will be greatest in children, who generally have higher viral titers, if the specimen is obtained during the first 2 days of illness, and if the clinician or laboratory has more experience performing the test. The quality of the specimen tested also is critical for test sensitivity.

B. Accuracy depends on disease prevalence

The positive and negative predictive values of rapid tests vary considerably depending on the prevalence of influenza in the community. False-positive (and true negative) influenza test results are more likely to occur when disease prevalence is low, which is generally at the beginning and end of the influenza season. False-negative (and true positive) influenza test results are more likely to occur when disease prevalence is high, which is typically at the height of the influenza season.

Clinical considerations when influenza prevalence is low

When disease prevalence is low, the positive-predictive value (PPV) is low and false-positive test results are more likely. By contrast, the negative-predictive value (NPV) is high when disease prevalence is low, and negative results are more likely to be truly negative.

If flu prevalence is...and specificity is.. then PPV is... false-positive rate is...

| | | | |
|-----------------|------------|------------------|-------------------|
| VERY LOW (2.5%) | POOR (80%) | V. POOR (6%–12%) | V. HIGH (88%–94%) |
| VERY LOW (2.5%) | GOOD (98%) | POOR (39%–56%) | HIGH (44%–61%) |
| MODERATE (20%) | POOR (80%) | POOR (38%–56%) | HIGH (44%–62%) |
| MODERATE (20%) | GOOD (98%) | GOOD (86%–93%) | LOW (7%–14%) |

**Appendix 2- J cont.
Rapid Diagnostic Testing for Influenza**

Interpretation of positive results should take into account the clinical characteristics of the case-patient. If an important clinical decision is affected by the test result, the rapid test result should be confirmed by another test, such as viral culture or PCR.

Clinical considerations when influenza prevalence is high

When disease prevalence is relatively high, the NPV is low and false-negative test results are more likely. By contrast, when disease prevalence is high, the PPV is high and positive results are more likely to be true.

If flu prevalence is... and sensitivity is... then NPV is... false-negative rate is...

| | | | |
|----------------|------------|-------------------|----------------|
| MODERATE (20%) | POOR (50%) | MOD (86%–89%) | MOD (11%–14%) |
| MOD (20%) | HIGH (90%) | V. GOOD (97%–99%) | V. LOW (2%–3%) |
| HIGH (40%) | POOR (50%) | MOD(70%–75%) | MOD (25%–30%) |
| HIGH (40%) | HIGH (90%) | V. GOOD (93%–94%) | LOW (6%–7%) |

Interpretation of negative results should take into account the clinical characteristics of the case-patient. If an important clinical decision is affected by the test result, the rapid test result should be confirmed by another test, such as viral culture or PCR.

C. Selecting tests

Selection of a test should take into consideration several factors, such as the types of specimens that are considered optimal for that test. Also, tests with high sensitivity and specificity will provide better positive and negative predictive values. Information about test characteristics is provided in product inserts and scientific articles and by the manufacturer.

D. Changes in recommended procedures can affect test results

Modification by the user can affect test performances and increase false-positive and/or false-negative rates. Such modifications include using specimens for which the test is not optimized or using swabs that did not come with the rapid test kit (unless recommended).

DRAFT

Appendix 2- J cont. Rapid Diagnostic Testing for Influenza

E. When are rapid diagnostic tests beneficial?

Use of rapid diagnostic tests are beneficial in these situations:

- To test cases during an outbreak of acute respiratory disease to determine if influenza is the cause, *or*
- To test selected patients during the influenza season, *or*
- In the fall or winter, to test selected patients presenting with respiratory illnesses compatible with influenza to help establish whether influenza is present in a specific population and to guide healthcare providers in diagnosing and treating respiratory illnesses.

In general, the exclusive use of rapid tests does not address the public health need for obtaining viral isolates so that influenza virus strain subtyping and characterization can be conducted to monitor antigenic and genetic changes. During an influenza pandemic, some rapid diagnostic tests may be able to detect the pandemic strain with adequate sensitivity and specificity. Rapid tests can be used by physicians to supplement clinical diagnoses of pandemic influenza. Physicians should be reminded that a negative test result might not rule out influenza and should not affect patient management or infection control decisions.

F. For further information

Information on influenza diagnostics is provided on the CDC website at:
<http://www.cdc.gov/flu/professionals/labdiagnosis.htm>.

3. Healthcare Planning

- I. Overview**
- II. Hospital Planning during the Interpandemic and Pandemic Alert Periods**
 - A. Communication**
 - B. Education and Training**
 - C. Occupational Health**
 - D. Use and Administration of Vaccines and Antiviral Drugs**
 - E. Facility Access and Security**
 - F. Hospital Triage and Clinical Evaluation**
 - G. Hospital Surge Capacity**
 - H. Mortuary Issues**
- III. Non-Hospital Healthcare Planning during the Interpandemic and Pandemic Alert Periods**
- IV. Activities by Pandemic Period**

Appendices:

- 3-A. Mass Fatality**
- 3-B. Volunteer Protocol**

I. Overview

Pandemic influenza differs from many biological threats in its potential magnitude and duration, including the likelihood of second and later waves of disease.

Several features set pandemic influenza apart from other public health emergencies or community disasters:

- Outbreaks can be expected to occur simultaneously throughout much of the U.S., precluding the sharing of human and material resources that usually occur in the response to other disasters. Localities should be prepared to rely on their own resources to respond as much as possible. The effect of pandemic influenza on individual communities will be relatively prolonged (weeks to months) in comparison to disasters of shorter duration.
- Because of widespread susceptibility to a pandemic influenza strain, the number of persons sickened will be high (approximately 30%).

DRAFT

3. Healthcare Planning cont.

- Health care workers and other first responders will be at higher risk of exposure and illness than the general population, further straining the health care system.
- Effective preventive and therapeutic measures, including vaccine and antiviral agents, are likely to be delayed and in short supply.
- Widespread illness in the community could result in sudden and potentially significant shortages of personnel in other sectors that provide critical public safety services.

A pandemic will overwhelm the current healthcare system. The increase in patients requiring hospitalization and critical care will result in shortages of multiple resources including personnel and equipment. This will in turn create a situation where nursing homes and homecare agencies may face more clinically complex hospital discharges and will have to care for patients they would normally discharge to the hospital. Community Health Centers and other primary care providers will need to expand their triage and outpatient treatment capacity to relieve pressure from hospital emergency departments. All facilities will need to supplement their highly trained professional staff with volunteers and lesser trained staff. Standards of care and the current regulatory approach will, by necessity, need to be changed.

During the Interpandemic and Pandemic Alert Periods, emphasis will be centered upon developing institutional plans, protocols and drills for responding to influenza pandemic. Health care facilities included in the planning will be hospitals, primary care centers, emergency medical services, home health agencies and long term care facilities.

II. Hospital Planning during the Interpandemic and Pandemic Alert Periods

Each hospital must develop a plan for response to an influenza pandemic. This plan should be developed by an interdisciplinary team and it should be well integrated and coordinated with the facility's plan to address smallpox and other communicable diseases. The elements of a hospital influenza plan are listed in the Hospital Preparedness checklist provided at www.PandemicFlu.gov.

A. Communications

A well-conceived internal and external communication plan is extremely important during a pandemic. The infrastructure for communication should follow the Incident Command System.

3. Healthcare Planning cont.

B. Education and Training

Each hospital should develop an education and training plan that addresses the needs of staff, patients, family members, and visitors. Hospitals should assign responsibility for coordination of the pandemic influenza education and training program and identify training materials—in different languages and at different reading levels, as needed—from HHS agencies, state and local health departments, and professional associations.

C. Occupational Health

Maintaining an adequate level of competent healthcare staff will be a major challenge during a pandemic. The healthcare workforce will be stressed physically and psychologically. Like others in the community, many healthcare workers will become ill. Healthcare facilities must be prepared to: 1) protect healthy workers from exposures in the healthcare setting through the use of recommended infection control measures; 2) evaluate and manage symptomatic and ill healthcare personnel; 3) distribute and administer antiviral drugs and/or vaccines to healthcare personnel, as recommended by HHS and DHMH; and 4) provide psychosocial services to health care workers and their families to help sustain the workforce.

To achieve these ends, healthcare facilities must establish systems to effectively screen workers for respiratory symptoms; reinforce proper use of PPE (section 4: Infection Control), hand hygiene and other infection control measures; review time-off policies and have a plan for reassignment of high-risk personnel (e.g., pregnant women, immuno-compromised staff) to low risk duties; promote annual influenza vaccination; and develop a plan to rapidly administer vaccine and antivirals should they become available.

The provision of mental health/psycho-social support to workers is especially important during a pandemic. Healthcare workers will be under constant stress due to their increased risk of contracting influenza, the likely inordinate increase in the number of patient deaths, and the possible alteration of standards of patient care necessitated by the pandemic. In addition, staff may experience the stress of ill persons at home or recent death of a family member and/ or friend. The necessity of working while wearing PPE and the possibility of quarantine also can take a toll.

Healthcare facilities must ensure that plans are made to meet workers' physical needs at work (e.g., food and housing, rest and recuperation including breaks from PPE and patient care) and provide emotional support and counseling.

DRAFT

3. Healthcare Planning cont.

Hospitals should have a system in place for documenting influenza vaccination of healthcare personnel.

D. Use and Administration of Vaccines and Antiviral Drugs Pandemic influenza vaccine and “pre-pandemic” influenza vaccine

Once the characteristics of a new pandemic influenza virus are identified, the development of a pandemic vaccine will begin. Recognizing that there may be benefits to immunization with a vaccine prepared before the pandemic against an influenza virus of the same subtype, efforts are underway to stockpile vaccines for subtypes with pandemic potential. As supplies of these vaccines become available, it is possible that some healthcare personnel and other persons critical to a pandemic response will be recommended for vaccination to provide partial protection or immunological priming for a pandemic strain.

Antiviral medications may be effective for a particular virus in a pandemic. Hospitals and practitioners should keep abreast of recommendations from CDC and DHMH on use for treatment vs. prophylaxis (see Section 7: Antiviral Medication Procurement, Distribution, and Use).

E. Facility Access and Security

Hospitals should determine in advance what criteria and procedures they will use to limit non-patient access to the facility if pandemic influenza spreads through the community. Any variation from normal hospital access should be communicated to patients, staff and visitors.

Hospitals should develop criteria or thresholds for temporary closure of the hospital to new admissions and transfers. The criteria should consider staffing ratios, isolation capacity, and risks to non-influenza patients. As part of this effort, hospital administrators should determine who in the hospital will make the request for temporary closings.

Hospitals should have a plan for security including:

- Assessment of building for security/access risks.
- A defined method of identification of staff and visitors.
- A plan for enforcement of hospital access by hospital security services. Local law enforcement should be informed of the plan, however; they might be overburdened during a pandemic and therefore will have limited ability to assist healthcare facilities with security services.

DRAFT

3. Healthcare Planning cont.

- Healthcare facilities should plan for additional security. This may be required given the increased demand for services, the possibility of long wait times for care and because triage or treatment decisions may not be in agreement with patient or family expectations.

F. Hospital Triage and Clinical Evaluation

During a pandemic, hospital emergency departments and outpatient departments may be overwhelmed with patients seeking care. Therefore, hospitals must review current procedures for clinical evaluation and admission in order to make them as efficient as possible, thereby reducing the number of patient encounters.

They must develop efficient systems to: 1) identify patients with pandemic influenza versus the worried well; 2) physically separate suspect influenza patients from other patients during waiting and triage to reduce risk of disease transmission; and 3) determine whether hospitalization is required. Hospitals should plan to assign a triage coordinator to manage patient flow.

The adherence to proper infection control standards must be reinforced as well. Hospitals should also develop plans to enhance their capacity to triage. A hospital may choose to surge their triage capacity by using on-campus sites (e.g., additional outpatient clinics, temporary shelters) or off-campus at extension clinic sites.

The success of a hospital's efforts to divert triage away from its Emergency Department to other sites will be dependant upon the effective use of public service announcements that explain the rationale to the community.

G. Hospital Surge Capacity

Pandemic influenza will create demands for healthcare resources that greatly exceed normal capacity. Healthcare facilities must plan ahead to address emergency staffing needs and increased demand for isolation, ICUs, assisted ventilation services and consumable and durable medical supplies. Hospital planners can use FluSurge software (<http://www.cdc.gov/flu/flusurge.htm>) to estimate the potential impact of a pandemic on resources such as staffed beds (both overall and ICU) and ventilators and then develop strategies to allocate these resources.

In the event of a massive pandemic where there are not enough human or material assets (e.g., nursing, ventilators, nutrition, hydration) available to meet patient needs, decisions to alter the standard of care will need to be made in an effort to provide the best possible outcome to the greatest number of patients.

DRAFT

3. Healthcare Planning cont.

Staffing

A major concern during an influenza pandemic is will be the shortage of nurses and other healthcare personnel. This lack of healthcare personnel will limit the ability of a hospital to handle increased surge capacity.

Identification of sources of back-up personnel is of paramount importance given the likelihood of increased demands on the system posed by the pandemic, coupled with concurrent reduction in the work force due to illness, absenteeism, and exhaustion. Healthcare facilities should take the following steps to attempt to address projected staffing shortages:

- Assign responsibility for the assessment and coordination of staffing during an emergency and ensure call-down lists (phone tree) are updated and procedures are current.
- Estimate the minimum number and categories of personnel needed to care for a cohort of influenza patients per day/shift and use to project staffing needs;
- Develop strategies to enhance staffing to required levels including:
 - o reassign non-clinical staff to clinical and clinical support functions;
 - o recruit retired healthcare personnel;
 - o utilize healthcare students (e.g., medical and nursing students) and family members of patients where feasible; and
 - o develop Mutual Aid Agreements or Memoranda of Understanding/Agreement with other healthcare facilities.
- Increase cross-training of personnel to provide support for essential patient-care areas at times of severe staffing shortages (e.g. in emergency departments, ICUs, or medical units).
- Create a list of essential-support personnel titles (e.g. environmental and engineering services, nutrition and food services, administrative, clerical, medical records, information technology, laboratory) that are needed to maintain hospital operations.
- Create a list of non-essential positions that can be re-assigned to support critical hospital services or placed on administrative leave to limit the number of persons in the hospital.

DRAFT

3. Healthcare Planning cont.

- Identify the credentialing requirements and insurance and liability concerns related to using non-facility staff.
- Consult with the state health department on plans for rapidly credentialing healthcare professionals during a pandemic. This might include defining when an “emergency staffing crisis” can be declared and identifying emergency laws that allow employment of healthcare personnel with out-of-state licenses.

Bed capacity

The following actions should be taken:

- Review and revise admissions and discharge criteria for times when bed capacity is critically short.
- Work with home healthcare agencies to arrange at-home follow-up care for patients who have been discharged early and for those whose admission was deferred because of limited bed space.
- Hospitals in a region should plan and work together to provide support and back-up and to transfer patients when either capacity or capability of a facility is exceeded.
- Review and refine the criteria hospitals currently use for temporarily canceling elective surgical procedures during surge periods. Plans should also be made for determining what and where emergency procedures will be performed during a pandemic.
- Develop policies and procedures for moving patients (e.g., cohorting) between nursing units in order to obtain optimal utilization of resources (staff).
- Develop policies and procedures for expediting the discharge of patients who do not require ongoing inpatient care (e.g., develop plans and policies for transporting discharged patients home or to other facilities; create a patient discharge holding area or discharge lounge to free up bed space).
- Discuss with local and state health departments how bed availability, including available ICU beds and ventilators, will be tracked during a pandemic.

DRAFT

3. Healthcare Planning cont.

- Identify permanent and temporary beds in controlled environments. Identify locations for infectious patients that will prevent exposure of other, non-infectious patients.
- Consult with hospital licensing agencies on plans and processes to expand bed capacity during times of crisis. These efforts should take into account the need to provide staff and medical equipment and supplies to care for the occupant of each additional hospital bed.

Consumable and durable supplies

- Inventory existing supplies and estimate resources required to address patient needs during pandemic. For additional details see: (<http://www.cdc.gov/flu/flusurge.htm>).
- Consider stockpiling enough consumable resources such as masks for the duration of a pandemic wave (6-8 weeks).
- The existing system for tracking available medical supplies in the hospital should be evaluated as to whether it is capable of detecting rapid consumption, including PPE. Improve the system as needed to respond to growing demands for resources during an influenza pandemic.
- Assess anticipated needs for consumable and durable resources, and determine a trigger point for ordering extra resources. Estimate the need for respiratory care equipment (including mechanical ventilators), and develop a strategy for acquiring additional equipment if needed.
- Consider adopting strategies for using all available resources; triaging the use of critical resources, like ventilators; and establishing a criteria system with triggers for allocating scarce resources.
- Anticipate needs for antibiotics, as well as other medications to treat complications of influenza and determine how supplies can be maintained during a pandemic.

Continuation of essential medical services

Address how essential medical services will be maintained for persons with chronic medical problems served by the hospital (e.g., hemodialysis patients, drug infusion therapy).

DRAFT

3. Healthcare Planning cont.

H. Mortuary Issues

DHMH, Local Health Departments, and hospitals must prepare for the possibility that mass mortalities may result from pandemic influenza. In Maryland, the OCME is responsible for investigating death while the State Anatomy Board is responsible for caring for the State's dead. There are no coroners in Maryland and no local offices of medical examiners but rather a statewide system.

The following steps should be included in pandemic influenza plans:

- Assessment of current capacity for refrigeration of deceased persons
- Mass fatality plans including temporary sites to accommodate morgue surge
- Consult with the Office of the Chief Medical Examiner to project the supply and equipment needs to handle an increased number of deceased persons. Use of FluSurge software will assist in identifying potential needs (<http://www.cdc.gov/flu/flusurge.htm>)

III. Planning for provision of care in non-hospital settings

Planning and effective delivery of care in outpatient settings is critical. Appropriate management of outpatient influenza cases will reduce progression to severe disease and thereby reduce demand for inpatient care. A system of effective outpatient management will have several components. To decrease the burden on providers and to lessen exposure of the "worried well" to persons with influenza, telephone hotlines should be established to provide advice on whether to stay home or to seek care. Most persons who seek care can be managed appropriately by outpatient providers. Health care networks may designate specific providers, offices, or clinics for patients with influenza-like illness. Nevertheless, some persons with influenza will likely present to all medical offices and clinics so that planning and preparedness is important at every outpatient care site. In underserved areas, health departments may establish influenza clinics to facilitate access. Hospitals should develop a strategy for triage of potential influenza patients, which may include establishing a site outside the Emergency Department where persons can be seen initially and identified as needing emergency care or may be referred to an outpatient care site for diagnosis and management. Finally, home health care providers and organizations can provide follow-up for those managed at home, decreasing potential exposure of the public to persons who are ill and may transmit infection.

DRAFT

3. Healthcare Planning cont.

Effective management of outpatient care in communities will require that health departments, healthcare organizations, and providers communicate and plan together. Issues to address include:

- Plan to establish and staff telephone hotlines for providing the public with information about seeking care during a pandemic.
- Develop training modules, protocols and algorithms for hotline staff
- Within health care networks, develop plans on the organization of care for influenza patients and develop materials and strategies to inform patients on care-seeking during a pandemic.
- For clinics and offices, develop plans that include education, staffing, triage, infection control in waiting rooms and other areas, and communication with healthcare partners and public health authorities.

Non-hospital healthcare facilities

The hospital planning recommendations can serve as a model for planning in other healthcare settings, including nursing homes and other residential care facilities, and primary care health centers. All healthcare facilities should do the following:

- Create a planning team and develop a written plan that builds on the emergency response plan.
- Establish a decision-making communications and coordinating structure that can be tested during the Interpandemic Period and will be activated during an influenza pandemic.
- Determine how to conduct surveillance for pandemic influenza in healthcare personnel and, for nursing homes and homecare, in the population served.
- Develop policies and procedures for managing pandemic influenza in patients and staff including proper infection control practices.
- Educate and train healthcare personnel on pandemic influenza and the healthcare facility's response plan; reinforce infection control practices.
- Develop an educational package directed toward staff and families focusing on the disease, its transmission and proper infection control procedures, and family preparedness plans in the event of a pandemic.

DRAFT

3. Healthcare Planning cont.

- Develop written material for visitors and others entering the facility focusing on the disease, its transmission and proper infection control procedures.
- Understand the local and state Incident Command System (ICS) structures and methods of communication and coordination with healthcare and public health partners.
- Determine how the facility will communicate with patients, residents, and responsible parties and help educate the public regarding prevention and control measures.
- Develop a plan for procuring the supplies (e.g., PPE) needed to manage influenza patients.
- Develop a plan for maintaining/expanding operations during the pandemic period by working with healthcare partners and LHD to recruit volunteers.
- Determine how the facility will participate in the community plan for distributing either vaccine or antiviral drugs, including possibly serving as a point of dispensing and providing staff for alternative community points of distribution.

IV. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State Health Department:

- Guide and assist healthcare facilities in planning for a pandemic.
- Provide for the maintenance of mental health services for health care employees.
- Recruit volunteers for increased staffing capacity during a pandemic.
- Educate healthcare providers on potential changes in the healthcare system (protocols, procedures and standards) in a pandemic.
- Provide consultation to LHDs and healthcare providers, as needed, on suspect novel influenza cases or influenza outbreaks.

DRAFT

3. Healthcare Planning cont.

- Work with healthcare providers on securing volunteers to be used to expand the capacity of traditional triage to alternate areas of existing buildings.
- Provide ongoing information to healthcare facilities and LHDs on the progression of influenza that will inform their decisions on triage procedures.
- Assess capacity and capability of health care and emergency response systems to meet needs in a pandemic.
- Issue routine influenza advisories to health care providers encouraging vaccination.
- Provide technical assistance and guidance as well as disseminate up-to-date pertinent information and advisory alerts.
- Promote enrollment in Maryland's Health Care Volunteer Corps and Medical Reserve Corps.
- Promote infection control education and training of EMS personnel. Promote routine annual influenza vaccination of EMS personnel throughout Maryland.
- Request cemeteries to identify their surge capacity and assess their labor availability and/or labor issues.
- Request the Office of the Chief Medical Examiner develop an emergency staffing plan to address the anticipated surge in volume and absenteeism associated with a pandemic
- Review pertinent legal authorities including medical volunteer licensure, liability, and compensation laws for in-state, out of state, and returning retired and non-medical volunteers.
- Collaborate with partners to establish criteria for alternate standards of care.
- Link with local emergency management office for activation of Medical Reserve Corps (MRC).
- Maintain Maryland Health Care Volunteer Database.

DRAFT

3. Healthcare Planning cont.

- Maintain a state-based ESAR-VHP program to provide advanced registration and credentialing of health professionals who would augment a hospital or medical facility's staff during a declared emergency.
- Work with health care provider organizations to provide technical and planning assistance.
- Identify contacts (names/titles) at each health care facility/agency that may have a role in responding to a pandemic. Multiple means of communication (phone, beeper, cell phone, e-mail, etc.) for contacting each person should be listed.
- Increase enrollment in and utilization of the health provider network (HPN) and assist facilities/agencies in their use of the HPN.
- Conduct periodic meetings or teleconferences with provider associations to provide planning updates and discuss issues.

Local Health Departments:

- Guide and assist hospitals in planning for a pandemic.
- Provide for the maintenance of mental health services for health care employees.
- Recruit volunteers for increased staffing capacity for activities such as epidemiological investigation and other functions during a pandemic.
- Educate healthcare providers on potential changes in the healthcare system (protocols, procedures and standards) in a pandemic.
- Identify facilities in the community that could be used as alternate care sites in the event that hospitals and health care facilities are overwhelmed.
- In consultation with DHMH, develop a plan to immunize direct care providers and essential ancillary staff in a short period of time, should a vaccine be made available for a novel influenza virus causing a pandemic.
- In consultation with DHMH, develop a plan to provide antiviral medications for prophylaxis and/or treatment of direct care providers and essential ancillary staff should antivirals be made available for a novel influenza virus causing a pandemic.

DRAFT

3. Healthcare Planning cont.

- Work with DHMH to offer and coordinate infection control education and training of EMS personnel.
- Coordinate and collaborate with the County Emergency Manager and EMS coordinator to identify alternate means for transporting non-critically ill patients to and between medical facilities.
- Identify a liaison to the County Emergency Medical Services Coordinator.
- Provide infection control guidelines during mass fatalities for funeral homes. The Mass Fatality Plan from the Office of the Chief Medical Examiner, State of Maryland, has specific guidance regarding procedures and resources. (see Appendix 3-A)
- Conduct a meeting at the county level with active funeral directors, firm managers and the Office of the Chief Medical Examiner to discuss infection control guidelines for handling the event. Guidelines should include:
 - Infection control precautions
 - Personal protective equipment
 - Environmental disinfection
- Work with the Office of the Chief Medical Examiner to:
 - Identify the surge capacity of funeral firms in the county,
 - Identify the surge capacity, if any, at the Office of the Chief Medical Examiner,
 - Identify a threshold for the number of deaths within the county that will be used to determine when different aspects of the plan will be implemented.
- Continue ongoing communication with the Office of the Chief Medical Examiner and funeral directors.
- Review pertinent legal authorities including medical volunteer licensure, liability, and compensation laws for in-state, out of state, and returning retired and non-medical volunteers.
- Continue volunteer recruitment programs.
- Provide adequate training to volunteers to maintain level of competency and preparedness.
- Ensure volunteers practice by demonstrating capabilities in drill training exercises.

DRAFT

3. Healthcare Planning cont.

Pandemic Period

State Health Department:

- Update LHDs and providers regularly as the influenza pandemic unfolds.
- Work with LHDs to assist facilities in alerting and deploying volunteers.
- Work with LHDs to disseminate clear messages to providers to encourage expanding triage capacity/hours of operation and to inform public of triage options.
- Expedite any necessary approvals for hospitals to temporarily exceed bed capacity and/or establish extension sites to address surge issues.
- Assist LHDs in identifying healthcare facilities that are projecting shortages or have shortages of food, supplies, pharmaceuticals, equipment and assists with acquisitions as possible.
- Assist LHDs in identifying healthcare facilities that could accept additional ventilator residents/patients and identify needed supplies, equipment and staff for these facilities.
- Work with nursing homes capable of surging capacity to provide temporary emergency approval for increased capacity.
- Issue guidance to providers on decisions made on altered standards of care.
- Communicate with the SEOC to determine the status of needed volunteers.
- Activate and deploy volunteers as demand for volunteers at the local level exceeds local resources in accordance with ICS.
- Employ “FRED” (Facilities Resources Emergency Database), which is an Internet-based application that assists hospitals, health care facilities, and emergency medical providers, to gather and disseminate critical information during major health incidents or mass casualty events.

DRAFT

3. Healthcare Planning cont.

- Collaborate with and provide regular updates to State and County EMS Coordinator and EMS agencies regularly as the influenza pandemic unfolds.
- Monitor status of EMS resources through County EMS Coordinators.
- Assist in mobilization and allocation of requested resources through SEOC.
- Advise the Secretary of Health and SEOC on health facility/agency issues.
- Continue to provide information on the evolving pandemic situation through alerts, teleconferences and/or meetings.
- Partner with LHDs to review, analyze and evaluate data and make recommendations on resource allocation through the SEOC.
- Work with Centers for Medicare and Medicaid Services (CMS) to provide regulatory relief where indicated.
- Keep facilities/agencies apprised of any determinations made regarding altered standards of care (each change in standard of care will be the result of the evolving pandemic and will be a measured/proportionate response).
- Provide technical assistance to facilities and agencies.

Local Health Departments:

- Work with DHMH to disseminate clear messages to providers to encourage expanding triage capacity/hours of operation and to inform public of triage options.
- Establish auxiliary care sites, as necessary.
- Work with DHMH to regularly update providers as the influenza pandemic unfolds.
- Use volunteers to assist in public health efforts (e.g., public health home care visits, isolation/quarantine visits).

DRAFT

3. Healthcare Planning cont.

- Monitor for indications that enhanced triage capacity may be needed, including reports from sentinel physician or walk-in clinics that they cannot accommodate all of the patients requesting appointments for influenza-like illness.
- Vaccinate direct care providers and essential ancillary staff, at direction of DHMH, if vaccine available.
- Provide antiviral medications for prophylaxis and/or treatment of direct care providers and essential ancillary staff, at direction of DHMH.
- Continue ongoing communication with the Office of the Chief Medical Examiner and funeral directors.
- Assess refrigeration storage needs as appropriate.
- Communicate with the local funeral firms and cemeteries to assess the status of their current capacity.
- Collaborate with DHMH and Emergency Management regarding surge capacity and mass disposition.

DRAFT

Appendix 3-A Mass Fatality

The following are excerpts from the Maryland Office of the Chief Medical Examiner (OCME) Mass Fatality Plan.

In the event that a hospital or jurisdiction anticipates exceeding or has exceeded their mass fatality surge capacity, they must receive approval from the OCME to establish a temporary morgue. During the interpandemic and pandemic alert phases, LHDs should identify mass fatality surge capacity capabilities and shortfalls.

PRESERVATION OF BODIES

Refrigeration

Where the numbers of human remains are in excess of the OCME capacity to maintain bodies under refrigeration, alternate means will be used including rental of refrigerated trucks.

Embalming

Embalming may be considered as a means of preservation of human remains in instances where extended storage time is deemed necessary.

Temporary burial

This will only be used where the numbers of bodies exceed the above two capacities, or in cases where the bodies may pose a public health risk due to contamination by a chemical, biological or radiological substance.

RELEASE OF BODIES

BEFORE RELEASE, VERIFICATION OF CASE COMPLETION SHOULD BE MADE ON MFI RECORD BOARD.

- Chief Medical Examiner or Medical Examiner alternate will only release remains after review.
- Bodies of local residents will be released to funeral homes of the family's choice.
- Bodies of out of area residents will be released to funeral homes of family choice or in accordance with Mutual Aid Agreement with the local or state Funeral Directors Association. In the absence of written mutual aid agreements with the local or state agencies the Medical Examiner will

DRAFT

Appendix 3-A cont. Mass Fatality

detetermine the method of release and distribution of remains for disposition.

PROPERTY/EVIDENCE TRANSFER AND STORAGE

In the event property/evidence is processed somewhere other than the Medical Examiner facility, a secured area such as a room, van, or truck will be used to store and/or transfer property/evidence. This area will be under the control of law enforcement.

TEMPORARY MORGUE

Depending upon the nature and number of fatalities involved, a decision may be made to establish a temporary morgue. The temporary morgue may be used to store bodies prior to transport, serve as a facility for visual identification or serve as a substitute location for the routine processing, autopsy and related activities which normally would occur at the OCME's facility. A temporary morgue may serve all or a combination of these functions.

Establishing a temporary morgue and what functions it will serve is a decision of the Chief Medical Examiner.

LOCATIONS

Location of a temporary morgue will be incident dependent, with priority given to existing structures. If the OCME building becomes inoperable Springfield Hospital Center would be the alternate location for operations. Additionally, Springfield may be used to process remains from any major incident and the existing building would continue to manage the daily caseload not related to the incident. The Maryland State Anatomy Board in Baltimore may also be utilized. Should these sites become unusable, the Chief Medical Examiner will determine the location of the temporary morgue facility. Maryland State Police Waterloo Barracks in Jessup, Maryland is designated as the alternate administrative meeting site. The OCME mobile MFI Trailer will be utilized at the scene of the incident. This trailer is stored at the Maryland State Police Waterloo Barracks.

COMMUNICATION

Dependent upon the location chosen for a temporary morgue a decision will be made to establish or augment telephone communication by the I.T. specialist in conjunction with the Chief Medical Examiner and Incident Commander.

DRAFT

Appendix 3-A cont. Mass Fatality

SECURITY

A secure perimeter must be established around the temporary morgue facility. Ordinarily, this is maintained by the investigating police agency of the jurisdiction in which the incident occurred. A decision to utilizing staff other than those previously mentioned is made by the Chief Medical Examiner and the Investigating agency.

EQUIPPING A TEMPORARY MORGUE (as needed)

The temporary morgue site must include the basics utilities:

- Electricity Plumbing
- Temporary Morgue Assets for Processing and Performance of Autopsies:
 - o Autopsy tables, drains
 - o Instruments Supplies
 - o Portable x-ray machine
 - o NOTE: Arrangements will have to be made with local institutions for developing of x-rays
 - o Staff
 - o Sanitation and Disposal of Waste
 - o Solid waste will be double bagged in red plastic bags. Provisions will be made for deposit of bags into a dumpster or sanitation truck.
 - o Portable refrigeration
- Temporary Morgue for Preservation and Preparation of Bodies for Disposition

It may be determined that embalming, casketing and preparation for transport of bodies is performed at the temporary morgue location. Mutual aid agreements with the State Funeral Directors Association will be activated for equipment and necessary staffing.

Portable refrigeration: Penske truck rental 1-800-222 0277
Ryder 1-800-297-9337

Truck rentals as above

DRAFT

Appendix 3-B cont. DHMH HEALTH CARE VOLUNTEER CORPS PROTOCOL

REQUEST FOR HEALTH CARE VOLUNTEERS (Boards and LHD)

An incident occurs:

DHMH:

- a. LHD contact DHMH Desk at MEMA (Emergency Coordinator)
- b. Emergency Coordinator contacts Deputy Secretary Public Health Services plus internal and external partners to discuss and evaluate needs
- c. If approved by the Governor/Secretary or designee the Emergency Coordinator notifies LHDs to send their requests to Volunteer Manager at:
e-mail: MPVC@dhmh.state.md.us
- d. DHMH Desk at MEMA (Emergency Coordinator) notify the Volunteer Coordinator via email, phone or Blackberry
- e. Volunteer Manager ALERT (via E-mail, Arch Wireless, Blackberry, or phone) for possible activation of volunteers
- f. Volunteer Manager provide to the Boards as much information as applicable
- g. The Boards may be asked to participate in one of the following:
 - i. conference call with *LHD/MEMA/DHMH etc.* at a designated time, or
 - ii. Instructions/information to activate volunteers immediately.
- h. LHDs Emergency Operations Center (EOC) e-mail Request Checklist for Volunteers to: MPVC@dhmh.state.md.us
- i. Volunteer Manager review request (make adjustments if applicable – ***using patient to health care volunteers model – to be developed***)
Volunteer Coordinator email request to Boards (pharmacy, physicians, nursing, MHA, etc) for activation and deployment of volunteers.

Review requests for the following:

- Type of event (i.e. *Biological, Chemical, Nuclear, Natural Disasters*)
- Volunteers to number of people infected (affected)
- Specialist areas

DRAFT

- Expectations and/or anticipated duties
- Special precautions to be taken at the site
- Logistics for Volunteers:
 - I D Badge, current license (*where applicable*), photo I D, etc.
 - Meeting location
 - Alternative site
 - Identify county(s) and zip code(s) of infected area(s)
 - Map, directions, road closures
 - Number of volunteers per shift required
 - Response time (i.e. immediately, 24-hr)
 - Lodging, Parking, Transportation
 - LHD Requestors contact information
 - Report to LHD Volunteer Center on arrival

Board Activates:

- Board begin activating volunteers
- Board(s) will notify Volunteer Manager via email MPVC@dhhm.state.md.us number of volunteers to expect per site, time and shift (i.e. *pharmacists, physicians, nurses, social workers, psychologists, dentists, professional counselors*)
- Volunteer Coordinator e-mail information to the local health department(s) and update DHMH Desk at MEMA (Emergency Coordinator)
- LHD will contact the Board(s) for no-show volunteers
- Boards will track volunteers activated

LHD

LHD Volunteer Reception Center: (arrival, departure, scheduling and emergency)

- Check-in/track volunteers on arrival (I D Badge, photo I D)
- LHD will have the ability to review and update volunteers on Web EOC (*in development with MEMA*)

DRAFT

- Local Health Volunteer Coordinator will notify DHMH Volunteer Coordinator if number of volunteers did not turn up for their shift
- DHMH Volunteer Manager will notify Board(s) need for additional or non-show volunteers
- LHD will brief volunteers on incident, number of cases, precautions, command structure, shifts, roles and responsibilities, accommodations, meals, stress and psychological concerns---*what to expect in terms of normal stress reactions during emergency response*
- Request volunteers to fill out form with contact information for a family member or person to contact in an emergency.
- Inform volunteers they must check out with the Volunteer Reception Desk before leaving
- LHD will request volunteers for additional shifts (at least a week out).

CONSIDERATIONS: (Board unable to activate volunteers)

- Lack of resources (*volunteer activators*)
 - Request for volunteers exceeds Board activation resources (i.e. 100+)
 - Facilities inaccessible
 - Utilities out of service

ACTION:

- Board(s) communicate considerations to Volunteer Manager- email: MPVC@dhmh.state.md.us or via Blackberry
- Volunteer Manager, notify Center Commander
- ICS decision is made to activate mass media (TV, Radio etc.)
- DHMH Public Relations (*approval from ICS Executive Team*) utilizes mass media activation
- DHMH Public Relations access Board(s) activation press release (*specific Board*)
- DHMH Public Relations communicates with Volunteer Coordinator - for information (*i.e. message, zip codes, meeting locations etc.*)

OR

- DHMH activates volunteers using activation system

DRAFT

NOTE

G.E.D.A.P.E.R.:

- **G**ather information (*gather as much information about the incident as possible*).
- **E**stimating course and harm (*estimating the course of an incident involves using the information you have gathered to make a series of predictions*).
- **D**etermining strategic goals (*strategic goals are broad, general statements of intent i.e. protection of critical systems, community*).
- **A**ssessing tactical options and resources (*resources including personnel and equipment*).
- **P**lanning and implementing actions (*operational actions to be taken by various personnel*).
- **E**valuating (*identify errors and allow corrections, determine whether the plan of actions is working, if not create an alternate plan of action that can be implemented quickly, depending on resources*).
- **R**eviewing (*revisiting and confirming the process, modify where necessary to reflect appropriate change*).

The actions you take and the decisions you make early in the incident will have a dramatic effect on the outcome of the event:

1. *Your safety and that of your fellow personnel is paramount.*
2. *The initial steps of gaining control will greatly affect incident management.*
3. *Be proactive, not reactive. In other words, try to stay a few steps ahead of the current situation to be better prepared for what may occur next.*
4. *Remember also that you are only human and that you can do only a limited number of tasks simultaneously.*
5. *Plan to be a part of the solution, not part of the problem.*
6. *Do not hesitate to seek additional assistance.*

DRAFT

DHMH Volunteer Corps Request Checklist

Type of Event E-mail: mpvc@dhhm.state.md.us

| | | |
|---|---|---|
| <input type="checkbox"/> A drill | <input type="checkbox"/> An Alert | <input type="checkbox"/> EMERGENCY |
| <input type="checkbox"/> Table Top | <input type="checkbox"/> On Location | <input type="checkbox"/> Other |

Request is from: _____ **City/County**

Date _____ Time _____ Description of Event _____

Requestor:

| | |
|---------------------|--|
| Agency/jurisdiction | |
| Contact # | |
| Alternate # | |
| Fax | |
| E-mail | |
| Contact Person | |

Volunteers needed:

| Resource Typing | # Vol. per shift | Shift times | # Days | # of Vols. currently Onsite | Duties |
|------------------------|------------------|-------------|--------|-----------------------------|--------|
| Physicians PA | | 1 2 3 | | | |
| Pharmacist Ph Techs | | 1 2 3 | | | |
| Nurses | | 1 2 3 | | | |
| Mental Health | | 1 2 3 | | | |

DRAFT

| | | | | | |
|-------------------------|--|-------------|--|--|--|
| Veterinary | | 1 2 3 | | | |
| Special needs/ Other | | 1 2 3 | | | |

Volunteer Point of contact at LHD Site

| | |
|--------------------------------|--|
| Agency/Jurisdiction | |
| Contact Person(s) and title(s) | |
| Contact # | |
| Alternate # | |
| Fax | |
| E-mail | |

patients impacted _____

Special precautions needed (possible agents, person-person contamination) or special equipment or clothing that volunteers will need? _____

Volunteer to report to LHD Volunteer Reception Center (address if different from meeting or treatment center:

Logistics:

Report To: (circle one) Health Department Clinic Staging area
Reception Site Other

Address &
Phone _____

If volunteers are to report to multiple sites provide information of locations

DRAFT

Directions to meeting/treatment center: Location(s):

Response time needed for first shift (immediate? X hours?) _____

Is Lodging available? _____ Meals _____ Parking (where reporting) _____

Additional Information

DRAFT

VOLUNTEER REPORTING FORM TO LHD
of Volunteers to be deployed

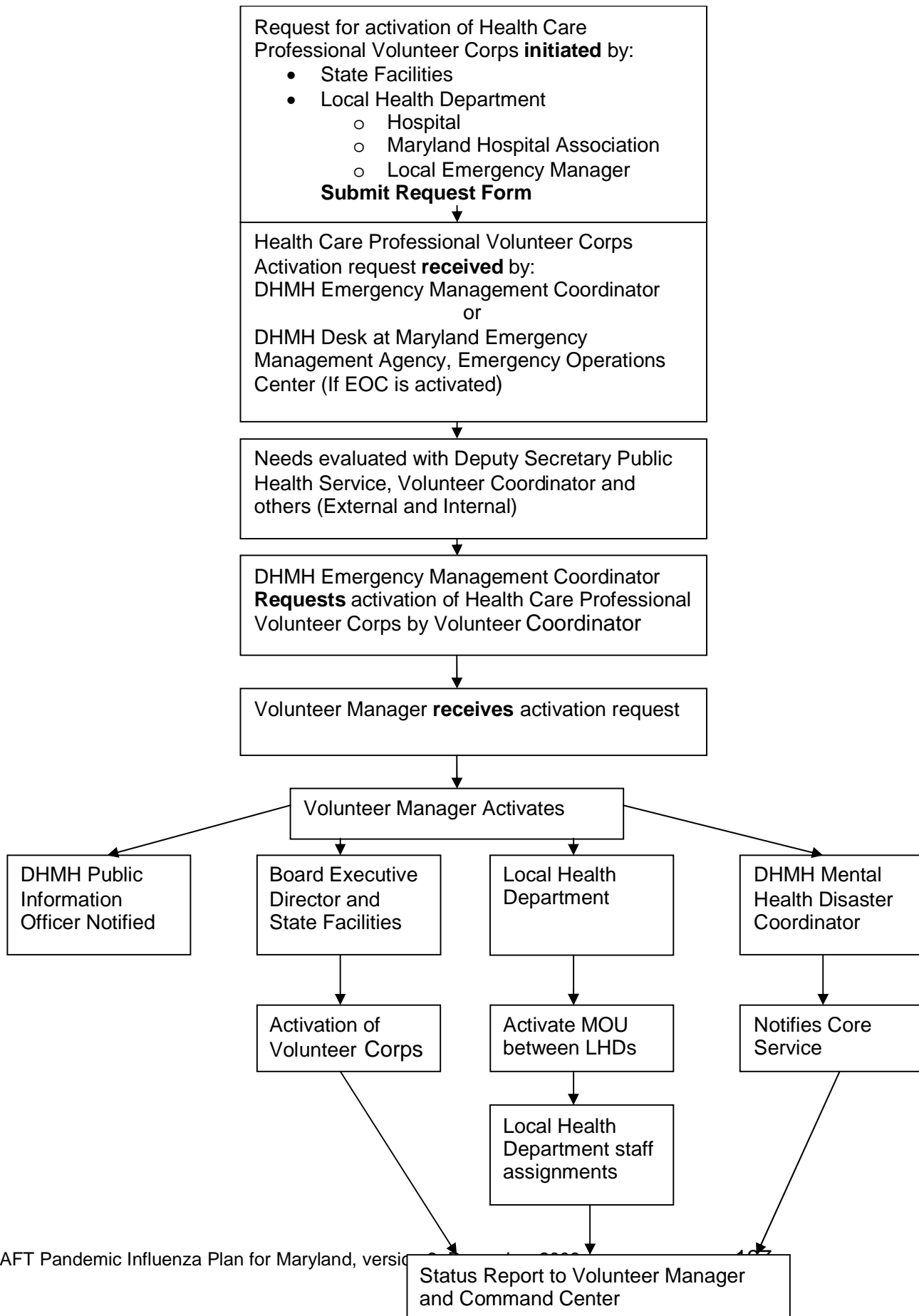
Attention: DHMH Command Center
 MPVC@dhhm.state.md.us

E-mail:

| COUNTY | TOTAL VOLUNTEERS REQUESTED | TOTAL VOLUNTEER SENT | NUMBER OF SHIFT(S) | # OF VOLUNTEER P/SHIFT |
|----------------|----------------------------|----------------------|--------------------|------------------------|
| ALLEGANY | | | | |
| ANNE ARUNDEL | | | | |
| BALTIMORE CITY | | | | |
| BALTIMORE | | | | |
| CALVERT | | | | |
| CAROLINE | | | | |
| CARROLL | | | | |
| CECIL | | | | |
| CHARLES | | | | |
| DORCHESTER | | | | |
| FREDERICK | | | | |
| GARRETT | | | | |
| HARFORD | | | | |
| HOWARD | | | | |
| KENT | | | | |
| MONTGOMERY | | | | |
| PRINCE GEORGES | | | | |
| QUEEN ANNES | | | | |
| SOMERSET | | | | |
| ST. MARY | | | | |
| TALBOT | | | | |
| WASHINGTON | | | | |
| WICOMICO | | | | |
| WORCESTER | | | | |

Questions Call: Volunteer Coordinator at: E-mail: MPVC@dhhm.state.md.us
 or Blackberry Tel: 443-865-7833

DHMH Health Care Professional Volunteer Corps Activation Flow Chart



DRAFT

4. Infection Control

- I. Overview**
- II. Background**
- III. Recommendations for Infection Control in Healthcare Settings**
 - A. Basic infection control principles for preventing the spread of pandemic influenza**
 - B. Management of infectious patients**
 - C. Infection Control Practices for Healthcare Personnel**
 - D. Occupational Health issues**
 - E. Reduce Exposure of Personnel at High Risk for Complications of Influenza**
 - F. Healthcare Setting Specific Guidelines**
- IV. Care of Pandemic Influenza Patients in the Home**
- V. Care of Pandemic Influenza Patients at Alternative Sites**
- VI. Recommendations for Infection Control for Schools and Workplaces**
- VII. Recommendations for Infection Control in Community Settings**

Appendices:

- 4-A. Summary of Infection Control Recommendations for the Care of Patients with Pandemic Influenza**
- 4-B. Respiratory Hygiene/Cough Etiquette**

I. Overview

The intention of this document is to assist healthcare settings in the planning for pandemic influenza and to enhance infection control precautions according to the current global and local epidemiology of influenza. Covered in this section are basic infection control principles, infection control management of infectious patients, occupational health guidance, and setting specific guidance. Users of this document should also refer to the vaccine and antiviral, healthcare planning, and clinical guidelines sections of the Maryland Pandemic Influenza Plan.

DRAFT

4. Infection Control cont.

This section provides basic infection control principles and guidance in planning for pandemic influenza.

II. Background

Influenza is primarily transmitted by large infectious respiratory droplets that are deposited on the oral, nasal or conjunctival mucosa of a susceptible host.

Transmission via large-particle droplets requires close contact between the infectious host and susceptible persons, as large-particle droplets do not remain suspended in the air and generally travel only short distances (about three feet) through the air.

The incubation period for routine seasonal influenza is 1 – 4 days, with an average of 2 days. The incubation period for novel types of influenza is currently unknown and may be longer. Therefore, the maximum interval between potential exposure and symptom onset for pandemic influenza is set conservatively at 10 days.

Influenza is contagious during the 24 hours before the onset of symptoms and during most of the symptomatic period. Children and persons with compromised immune systems may shed the virus in the respiratory tract for a prolonged period (i.e., weeks to months).

Clinically, influenza-like illness (ILI) is described as acute onset of constitutional and respiratory signs and symptoms (e.g., fever of > 100° F, myalgia, headache, malaise, cough, sore throat, and rhinitis). Among children, otitis media, nausea, and vomiting may also be present. The classic symptoms of ILI (e.g., fever) may not always be present in the elderly, children, and persons with altered immune status. The duration of illness typically is a few days, although cough and malaise may persist for weeks. Complications and hospitalizations from seasonal influenza are increased for children aged 0-23 months, adults > 65 years, and persons with pre-existing medical conditions (e.g., cardiac or pulmonary disease) and include secondary bacterial pneumonia, or primary influenza viral pneumonia. See Section 5: Clinical Guidelines for additional information on the clinical presentation of influenza.

Because vaccine for influenza is developed using strain characterization from the previous influenza season, it can be assumed that vaccine will provide little if any protection from developing infection during a pandemic influenza outbreak. Given this, adherence to infection control principles to prevent transmission of influenza and initiation of antiviral medication for treatment and prophylaxis will be paramount to control the spread and reduce morbidity and mortality during an influenza pandemic.

DRAFT

4. Infection Control cont.

The specific characteristics of a new pandemic influenza virus, including virulence, transmissibility, incubation period, period of communicability, and drug susceptibility, will remain unknown until the pandemic gets under way. The DHMH will continue to work with CDC and WHO to assess differences in any of these aspects and to revise infection control guidance as appropriate.

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, out-patient facilities, residential care facilities, homes). Details of how these principles may be applied in each healthcare setting follow.

- Limit contact between infected and non-infected persons (2)
- 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.

² During the early stages of a pandemic, laboratory-confirmation of influenza infection is recommended when possible.

DRAFT

4. Infection Control cont.

Persons who must be in contact should:

- Wear a surgical or procedure mask (3) for close contact with infectious patients.
- Use contact and airborne precautions, including the use of N95 respirators, when appropriate.
- Wear gloves (gown if necessary) for contact with respiratory secretions.
- Perform hand hygiene after contact with infectious patients.
- Contain infectious respiratory secretions:
- Instruct persons who have “flu-like” symptoms (see below) to use respiratory hygiene/cough etiquette.
- Promote use of masks 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 fever, headache, myalgia, prostration, coryza, sore throat, and 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.

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

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

DRAFT

4. Infection Control cont.

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 hygiene. 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
- Source control measures (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)
- Hand hygiene after contact with respiratory secretions, and
- Spatial separation, ideally >3 feet, of persons with respiratory infections 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 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. 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

DRAFT

4. Infection Control cont.

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.

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. 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 www.cdc.gov/ncidod/hip/isolat/isolat.htm/.

Masks (surgical or procedure)

- Wear a mask when entering a patient's room. A mask should be worn once and then discarded. If pandemic influenza patients are cohorted in a common area or in several rooms on a nursing unit, and multiple patients must be visited over a short time, it may be practical to wear one mask for the duration of the activity; however, other PPE (e.g., gloves, gown) must be removed between patients and hand hygiene 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.

DRAFT

4. Infection Control cont.

- 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 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 area 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, and therefore should be avoided. 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

In general, 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, goggles or a face shield should be worn as recommended for standard precautions. Additional information related to the use of eye protection for

DRAFT

4. Infection Control cont.

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 a N95 respirator or other appropriate particulate respirator. Respirators should be used within the context of a respiratory protection program that includes fit-testing, medical clearance, and training. 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.

Enhanced infection control principles for preventing the spread of pandemic influenza in healthcare settings

(excerpted from Interim Recommendations for Infection Control in Health-Care Facilities Caring for Patients with Known or Suspected Avian Influenza, <http://www.cdc.gov/flu/avian/professional/infect-control.htm>, May 21, 2004)

Note: CDC is revising its interim guidance for infection control precautions for avian influenza. The revised recommendations will be posted on the CDC website as soon as they are finalized.

DRAFT

4. Infection Control cont.

2. Rationale for Enhanced Precautions

Human influenza is thought to transmit primarily via large respiratory droplets. Standard Precautions plus Droplet Precautions are recommended for the care of patients infected with human influenza. However, given the uncertainty about the exact modes by which avian influenza may first transmit between humans additional precautions for healthcare workers involved in the care of patients with documented or suspected avian influenza may be prudent.

Patients with a history of travel within 10 days to a country with avian influenza activity and are hospitalized with a severe febrile respiratory illness, or are otherwise under evaluation for avian influenza, should be managed using isolation precautions identical to those recommended for patients with known Severe Acute Respiratory Syndrome (SARS). These include:

- Standard Precautions
 - Pay careful attention to hand hygiene before and after all patient contact or contact with items potentially contaminated with respiratory secretions.
- Contact Precautions
 - Use gloves and gown for all patient contact.
 - Use dedicated equipment such as stethoscopes, disposable blood pressure cuffs, disposable thermometers, etc.
- Eye protection (i.e., goggles or face shields)
 - Wear when within 3 feet of the patient.
- Airborne Precautions
 - Place the patient in an airborne isolation room (AIR). Such rooms should have monitored negative air pressure in relation to corridor, with 6 to 12 air changes per hour (ACH), and exhaust air directly outside or have recirculated air filtered by a high efficiency particulate air (HEPA) filter.
 - Use a fit-tested respirator, at least as protective as a National Institute of Occupational Safety and Health (NIOSH)-approved N-95 filtering facepiece (i.e., disposable) respirator.

These precautions should be continued for 14 days after onset of symptoms or until either an alternative diagnosis is established or diagnostic test results indicate that the patient is not infected with influenza A virus.

DRAFT

4. Infection Control cont.

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 also: <http://www.cdc.gov/ncidod/hip/ppe/default.htm>.)
- Contaminating environmental surfaces that are not directly related to patient.

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

- Contain and dispose of contaminated medical waste in accordance with facility-specific procedures and/or local or state regulations for handling and disposal of 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.

3. Hand hygiene

Hand hygiene has frequently been cited as the single most important practice to reduce the transmission of infectious agents in healthcare settings (see <http://www.cdc.gov/handhygiene/pressrelease.htm>) and is an essential element of standard precautions. The term “hand hygiene” includes both handwashing with either plain or antimicrobial soap and water and 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 antimicrobial or plain soap 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.

DRAFT

4. Infection Control cont.

- 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/>.

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 (www.cdc.gov/ncidod/hip/enviro/guide.htm).

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 (www.cdc.gov/ncidod/hip/enviro/guide.htm).
- Disposable dishes and utensils (e.g., used in an auxiliary 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.

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.

DRAFT

4. Infection Control cont.

- 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: www.cdc.gov/ncidod/hip/enviro/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.
- 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 (www.cdc.gov/ncidod/hip/ISOLAT/Isolat.htm).

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.

DRAFT

4. Infection Control cont.

- 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.

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, and 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, postpone nonessential medical care).

DRAFT

4. Infection Control cont.

F. Healthcare setting-specific guidance

The following guidance is intended to address setting-specific infection control issues.

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 (see www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm).

Sample visual alerts are available on CDC's SARS website:
<http://www.cdc.gov/ncidod/hip/INFECT/RespiratoryPoster.pdf>

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.

DRAFT

4. Infection Control cont.

b) “Source control” measures to limit dissemination of influenza virus from respiratory secretions

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 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 on CDC’s SARS website:
<http://www.cdc.gov/ncidod/hip/INFECT/RespiratoryPoster.pdf>

- 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.

DRAFT

4. Infection Control cont.

Cohorting

- Designated units or areas of a facility should be used for cohorting patients with pandemic influenza.⁽⁴⁾ 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. 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.

⁴ During the early stages of a pandemic, laboratory-confirmation of influenza infection is recommended when possible before cohorting patients.

DRAFT

4. Infection Control cont.

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.

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

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 through 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.

DRAFT

4. Infection Control cont.

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 exposed cohorts.

- 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).

DRAFT

4. Infection Control cont.

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.

DRAFT

4. Infection Control cont.

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.

5. Outpatient medical offices

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.

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 website:
<http://www.cdc.gov/ncidod/hip/INFECT/RespiratoryPoster.pdf>

- Triage patients calling for medical appointments for influenza symptoms:
- Discourage unnecessary visits to medical facilities.

DRAFT

4. Infection Control cont.

- Instruct symptomatic patients on infection control measures to limit transmission in the home and when traveling to necessary medical appointments.

b) “Source control” measures

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

DRAFT

4. Infection Control cont.

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 nonemergency services when there is pandemic influenza in the community.

IV. 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.

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.

DRAFT

4. Infection Control cont.

- 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 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.

V. Care of pandemic influenza patients at auxiliary 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 auxiliary 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.

4. Infection Control cont.

VI. 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. (CDC will develop educational materials appropriate to various audiences.)

VII. Recommendations for Infection Control in Community Settings.

Infection control in the community should focus on “social distancing” and promoting respiratory hygiene/cough etiquette and hand hygiene to decrease exposure to others. 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.

DRAFT

**Appendix 4-A
Summary of Infection Control Recommendations for Care of
Patients with Pandemic Influenza**

| COMPONENT | RECOMMENDATIONS |
|--|---|
| STANDARD PRECAUTIONS | See www.cdc.gov/ncidod/hip/ISOLAT/std_prec_excerpt.htm |
| 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 either plain or antimicrobial soap and water or use of alcohol-based products (gels, rinses, foams) that contain an emollient and do not require the use of water. If hands are visibly soiled or contaminated with respirator 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 antimicrobial or plain soap and water because of their superior microbicidal activity, reduced drying of the skin, and convenience. |
| Personal protective equipment (PPE) | |
| ▪ Gloves | For touching blood, body fluids, secretions, excretions, and contaminated items; for touching mucous membranes and nonintact skin |
| ▪ Gown | During procedures and patient-care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated |
| ▪ Face/eye protection (e.g., surgical or procedure mask and goggles or a face shield) | During procedures and patient care activities likely to generate splash or spray of blood, body fluids, secretions, excretions |
| 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). |

DRAFT

| Appendix 4-A cont. Summary of Infection Control Recommendations for Care of Patients with Pandemic Influenza | |
|---|---|
| COMPONENT | RECOMMENDATIONS |
| 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, others, 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. |
| 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 (medical and non-medical) in accordance with facility procedures and/or local or state regulations; wear gloves when handling waste; wear gloves when handling waste containers; perform hand hygiene. |
| Respiratory hygiene/cough etiquette Source control measures for persons with symptoms of a respiratory infection; implement at first point of encounter (triage/reception) 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 not ill. |

DRAFT

| Appendix 4-A cont. Summary of Infection Control Recommendations for Care of Patients with Pandemic Influenza | |
|---|---|
| DROPLET PRECAUTIONS | www.cdc.gov/ncidod/hip/ISOLAT/droplet_prec_excerpt.htm |
| 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 and laundry and 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 a fit-tested N95 respirator or other appropriate particulate respirator. |

DRAFT

Appendix 4-B: 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.

DRAFT

5. Clinical Guidelines

- I. Overview**
- II. Clinical Guidelines for the Interpandemic and Pandemic Alert Periods**
- III. Clinical Guidelines for the Pandemic Period**
- IV. Activities by Pandemic Period**

Appendices:

- 5-A. Risk of Novel Influenza in Persons with Severe Respiratory Disease or Influenza-Like Illness during the Interpandemic and Pandemic Alert Periods**
- 5-B. Clinical Evaluation of Patients with Influenza-Like Illness during the Interpandemic and Pandemic Alert Periods**
- 5-C. Special Situations and Exceptions to the Clinical Criteria**
- 5-D. Home Care Infection Control Guidance for Pandemic Influenza Patients and Household Members**
- 5-E. Case Detection and Clinical Management during the Interpandemic and Pandemic Alert Periods**
- 5-F. Case Detection and Clinical Management during the Pandemic Period**
- 5-G. Management of Community-Acquired Pneumonia during an Influenza Pandemic: Adults**
- 5-H. Management of Community-Acquired Pneumonia during an Influenza Pandemic: Children**
- 5-I. Pandemic Influenza Infection Control Guidance for Healthcare Providers**
- 5-J. Clinical Presentation and Complications of Seasonal Influenza**
- 5-K. Clinical Presentation and Complications of Illnesses Associated with Avian Influenza A (H5N1) and Previous Pandemic Influenza Viruses**
- 5-L. Guidelines for Management of Community-Acquired Pneumonia, Including Post-Influenza Community-Acquired Pneumonia**

DRAFT

5. Clinical Guidelines

I. Overview

This section provides clinical procedures for the initial screening, assessment, and management of patients with suspected novel influenza during the Interpandemic and Pandemic Alert Periods, and for patients with suspected pandemic influenza during the Pandemic Period.

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

II. Clinical Guidelines for the Interpandemic and Pandemic Alert Periods

During the Interpandemic and Pandemic Alert Periods, the primary goal of rapid detection is to quickly identify and contain cases of novel influenza. To limit the need to evaluate an overwhelming number of patients, the screening criteria should be specific, relying on a combination of clinical and epidemiologic features. Although febrile respiratory illnesses are one of the most common indications for medical evaluation, particularly during the winter, during the interpandemic and pandemic alert period, human cases of novel influenza are expected to be quite rare; laboratory diagnosis will most likely be sought for those with severe respiratory illness, such as pneumonia. The main features of detection and clinical management during the Interpandemic and Pandemic Alert Periods are outlined in Appendix 5-B, 5-C, and 5-E.

A. Criteria for evaluation of patients with possible novel influenza

The following criteria are based on the features of recent avian influenza A (H5N1) cases but are intended for use in evaluating suspected cases of infection with any novel influenza A virus strain. During the Pandemic Alert Period, human infections with novel influenza A viruses will be an uncommon cause of influenza-like illness (temperature of $>38^{\circ}\text{C}$ plus either sore throat, or cough with dyspnea as an additional criteria); therefore, **both clinical and epidemiologic criteria should be met**. The criteria will be updated when needed as more data are collected.

DRAFT

5. Clinical Guidelines cont.

1. Clinical criteria

Any suspected cases of human infection with a novel influenza virus must first meet the clinical criteria:

- Severe illness: hospitalized with severe ILI, including pneumonia or ARDS
- Mild to moderate illness:
 - Fever (temperature >38 ° C or 100.4 ° F) and
 - Either sore throat, cough, or dyspnea

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: travel and occupational.

a.) Travel risks

Persons have a travel risk if they have:

- 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,
- Had direct contact with poultry (see definition below), or
- 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:

- Touching birds (well-appearing, sick, or dead), or
- Touching poultry feces or surfaces contaminated with feces, or
- 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

DRAFT

5. Clinical Guidelines cont.

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.

b.) Occupational risks

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

- Persons who work on farms or live poultry markets or who process or handle poultry infected with known or suspected avian influenza viruses,
- Workers in laboratories that contain live animal or novel influenza viruses, and
- Healthcare workers in direct contact with a suspected or confirmed novel influenza case.

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

During the Interpandemic and Pandemic Alert Periods (Phases 1-4), 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—for any reason—requires 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 Appendix 5-A). 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.

Given the large number of influenza-like illnesses defined as temperature of $>38^{\circ}\text{C}$ plus either sore throat, cough, or dyspnea that clinicians encounter during a typical flu season, **laboratory evaluation for novel influenza A viruses during the Interpandemic and Pandemic Alert Periods is recommended only for:**

DRAFT

5. Clinical Guidelines cont.

1. Hospitalized patients with severe ILI, including pneumonia or ARDS, who meet the epidemiologic criteria of travel within 10 days of onset to an affected country even if no history of direct contact with poultry or confirmed human case.

2. Mild to moderate illness: 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 or occupational exposure).

3. Recommendations for the evaluation of patients with respiratory illnesses are provided in Appendix 5-B. Exceptions to the current clinical criteria are provided in Appendix 5-C.

Although recent infections with novel influenza viruses have resulted in severe respiratory illness, the next pandemic influenza virus strain might present with a different clinical syndrome (see Appendix 5-J and Appendix 5-K). In such a situation, the clinical criteria will be modified accordingly.

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) **Notify the local health department (LHD).** Report each patient who meets the clinical and epidemiologic criteria for a suspected case of novel influenza to the LHD as quickly as possible to facilitate initiation of public health measures. Designate one person as a point of contact to update public health authorities on the patient's clinical status.

2) **Implement infection control precautions for novel influenza, including Respiratory Hygiene/Cough Etiquette.** Patients should be placed on Droplet Precautions for a minimum of 14 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, as well as gloves and gowns, when indicated for Standard Precautions (Appendix 5-I). 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 Section 4: Infection Control).

DRAFT

5. Clinical Guidelines cont.

3) **Obtain clinical specimens for novel influenza A virus testing after consulting with the LHD to arrange testing.** Testing will be directed by public health authorities and current guidelines are provided in Section 2: Surveillance and Laboratory Testing, and Appendix 2-C: Diagnostic Laboratory for Pandemic Influenza.

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. Patients cared for at home should be separated from other household members as much as possible. Consult with LHD for guidance (see Section 2: Surveillance and Laboratory Testing). 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 (Appendix 5-D).

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 Section 7).

7) **Assist public health officials** with the identification of potentially exposed contacts. After consulting with state and 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 (see Section 2: Surveillance and Laboratory Testing).

DRAFT

5. Clinical Guidelines cont.

C. Management of patients who test positive for novel influenza

If a patient is confirmed to have an infection with a novel influenza virus, healthcare personnel should continue antiviral treatment and all isolation and infection control precautions, and 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 suspected novel influenza cases may be found to have seasonal human influenza, particularly during the winter season. It should be recognized that human influenza viruses circulate among people worldwide, including in affected areas with poultry outbreaks of avian influenza A viruses during non-seasonal influenza activity in the United States. For patients with confirmed seasonal influenza, maintain Standard and Droplet Precautions, and continue antiviral treatment for a full treatment course (e.g., 5 days).

E. Management of patients who test negative for novel influenza

- 1) The sensitivity of the currently available tests for detecting novel influenza viruses in clinical specimens has not been thoroughly evaluated with a full range of specimen types. Consequently, false-negative test results may occur. Therefore, if test results are negative but the clinical and epidemiologic suspicion remains high, continuing antiviral treatment and isolation procedures should be considered.
- 2) 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 LHD or state.
- 3) 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.
- 4) 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, particularly in the absence of a strong epidemiologic link, if the alternative diagnosis is made using a test with a high positive-predictive value, and if the clinical manifestations are explained by the alternative diagnosis.

DRAFT

5. Clinical Guidelines cont.

III. 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 Appendix 5-F.

A. Criteria for evaluation of patients with possible pandemic influenza

1. Clinical criteria

Suspected cases of pandemic influenza virus infection should meet the criteria of: **fever (temperature of >38°C) plus one or more 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 5-J and Appendix 5-K). During a pandemic, updates on other clinical presentations will be provided at: <https://commerce.health.state.ny.us/hpn/>, www.pandemicflu.gov, and www.cdc.gov/flu/.

Recommendations for general evaluation of patients with influenza-like illness are provided in Appendix 5-B. Exceptions to the clinical criteria are provided in Appendix 5-C.

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.**

DRAFT

5. Clinical Guidelines cont.

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) **Follow local and state health department recommendations on reporting** for patients who meet the criteria for pandemic influenza (see Section 2: Surveillance and Laboratory Testing).
- 2) **If the patient is hospitalized, implement infection control precautions for pandemic influenza**, including Respiratory Hygiene/Cough Etiquette (see Section 4: Infection Control). Place the patient on Droplet Precautions for a minimum of 5 days from the onset of symptoms. Healthcare personnel should wear surgical or procedure masks on entering a patient's room, as per Droplet Precautions, as well as gloves and gowns when indicated, as per Standard Precautions (Appendix 5-I). Once a pandemic is underway, hospital admission of patients should be limited to those with severe complications who cannot be cared for outside the hospital setting. Patients should be admitted to either a single-patient room or an area designated for cohorting of patients with influenza. Patient movement and transport outside the isolation area should be limited to medically necessary purposes (see Appendix 5-I and Section 4: Infection Control).
- 3) **Obtain clinical specimens for general evaluation, as clinically indicated** (see Appendix 5-B). Once pandemic influenza has arrived in a community, influenza testing will likely not be needed for most patients. Laboratory testing in conjunction with health departments will likely be performed in a subset of pandemic influenza cases, however, as part of ongoing virologic surveillance to monitor the antigenic evolution of the strains for vaccine strain selection purposes (see Section 2: Surveillance and Laboratory Testing). At the beginning or end of a pandemic outbreak in a community, diagnostic testing might aid cohorting decisions, but may be optional in the setting of high local prevalence. Influenza diagnostic testing should be considered before initiating treatment with antivirals. Guidelines for pandemic influenza virus testing are provided in Section 2: Surveillance and Laboratory Testing.

As with seasonal influenza, RT-PCR and virus isolation from tissue culture will be the most accurate methods for diagnosing pandemic influenza. Generally, specimens should include combined nasopharyngeal aspirates or nasal swabs, and throat swabs, stored at 4°C in viral transport media. During the Pandemic Period, BSL-2 conditions should be sufficient for viral culture of clinical specimens from suspected pandemic influenza patients.

5. Clinical Guidelines cont.

Rapid diagnostic tests for influenza and immunofluorescence may be helpful for initial clinical management, including cohorting and treatment (see above). However, rapid influenza tests have relatively low sensitivity for detecting seasonal influenza, and their ability to detect pandemic influenza viruses is unknown. 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. Because during a pandemic a negative rapid test may be a false negative, 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. The risk of a false-negative test also must be taken into account in making cohorting decisions. Rapid diagnostic testing should not preclude more reliable testing, if available. Further information on rapid diagnostic testing can be found in Section 2: Surveillance and Laboratory Testing.

4) **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 Section 4: Infection Control. An unstable patient will be considered a high priority for admission, but patients with high-risk conditions (see Appendix 5-J) might also warrant special attention, such as observation or close follow-up, even if disease is mild. On the other hand, home management with follow-up might be appropriate for well-appearing young children with fever alone.

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 with other household waste (Appendix 5-D). 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 of benefit. 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 (Appendix 5-D).

DRAFT

5. Clinical Guidelines cont.

C. Clinical management of pandemic influenza patients

See Section 7 for current antiviral information and treatment strategies. In addition to use of antivirals, clinical management of severe influenza should address supportive care and the rapid identification and treatment of secondary complications. During the Pandemic Period, DHMH may request virus isolates from persons who fail treatment or antiviral prophylaxis, as these strains may more likely be drug resistant. In addition, randomly collected isolates will be tested for resistance to establish nationwide rates.

Children aged <18 years with suspected or confirmed pandemic influenza should not be treated with aspirin or other salicylate-containing products because of an increased risk of Reye syndrome (characterized by acute encephalopathy and liver failure) in this age group.

The major clinical presentations and 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 5-J. Limited data are available on risk factors and complications related to infection with novel influenza viruses, and these may change as individual strains evolve. A summary of the clinical presentations and complications associated with recent influenza A (H5N1) viruses is included in Appendix 5-K. In particular, post-influenza community-acquired pneumonia will likely be a commonly encountered complication, and clinicians will need to be aware of recommended methods for diagnosis and treatment. Guidance on the management of influenza-related pneumonia is presented in Appendix 5-L.

IV. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State Health Department:

- Develop materials and help educate healthcare providers about novel and pandemic influenza.
- Disseminate clinical guidelines to LHDs.
- Provide consultation to LHDs and healthcare providers as needed, on suspect novel influenza cases.
- Provide updated information and materials to LHDs.

DRAFT

5. Clinical Guidelines cont.

- Develop a state stockpile of antiviral drugs.
- Work with LHDs to coordinate testing.

Local Health Departments:

- Help educate healthcare providers about novel and pandemic influenza.
- Provide consultation and investigation of suspected novel influenza cases to healthcare providers in conjunction with the state health department.
- Consult on collection of specimens of suspected novel influenza testing.
- Facilitate the transfer of specimens to the DHMH State Laboratory.
- Conduct follow-up of suspected novel influenza cases.
- Conduct contact investigations.
- Disseminate clinical guidelines to local healthcare providers.

Pandemic Period

State Health Department:

- Update LHDs and providers regularly as the influenza pandemic unfolds.
- Work with LHDs and DHMH State Laboratory to coordinate testing.
- Work with LHDs to investigate and report special pandemic situations.

Local Health Departments:

- Update providers regularly as the influenza pandemic unfolds.
- Provide or facilitate testing and investigation of pandemic influenza cases.
- Work with DHMH to investigate and report special pandemic situations.

DRAFT

Appendix 5-A 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.**

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-B 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:
 - Travel to an area affected by avian influenza A virus outbreaks in poultry,
 - Direct contact with poultry,
 - Close contact with persons with suspected or confirmed novel influenza, or
 - 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.**
- Immediately contact the local and state health departments to report the suspected case and to arrange laboratory testing.
- 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. See Section 2.
 - RT-PCR testing is not available in hospital laboratories and must be performed at a qualified laboratory such as the Wadsworth Center laboratory or the CDC Influenza Laboratory. Viral culture should be performed only at biosafety level 3 [BSL-3] with enhancements.
- 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)

DRAFT

Appendix 5-B cont.

Clinical Evaluation of Patients with Influenza-Like Illness during the Interpandemic and Pandemic Alert Periods

- o 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
- o In adults with radiographic evidence of pneumonia, Legionella and pneumococcal urinary antigen testing
- o 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
- o 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 Appendix 5-C).

** 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)

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-C

Special Situations and Exceptions to the Clinical Criteria

- 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.
- 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 websites of the OIE (http://www.oie.int/eng/en_index.htm), WHO (www.who.int/en/), and CDC (www.cdc.gov/flu/).

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-D 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.

DRAFT

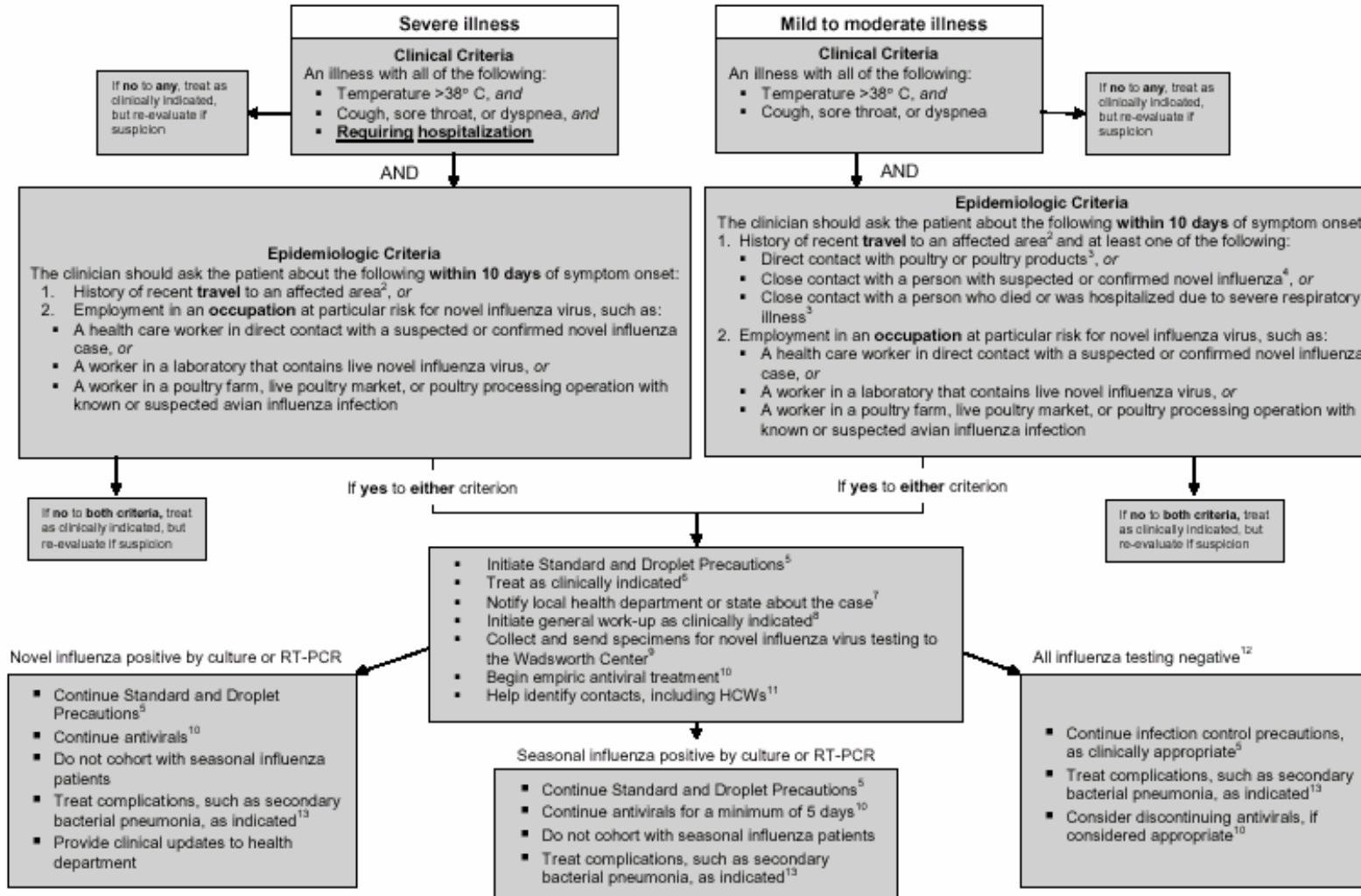
Appendix 5-D cont. Home Care Infection Control Guidance for Pandemic Influenza Patients and Household Members

- 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 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.

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

Case Detection and Clinical Management during the Interpandemic and Pandemic Alert Periods

Situation: No human cases of novel influenza are present in the community. Human cases might be present in another country or another region of the United States.



DRAFT

Footnotes to Appendix 5-E: Case Detection and Clinical Management during the Interpandemic and Pandemic Alerts Periods

1. Further evaluation and diagnostic testing should also be considered for outpatients with strong epidemiologic risk factors and mild or moderate illness. (See Appendix 5-B).
2. Updated information on areas where novel influenza virus transmission is suspected or documented is available on the CDC website at www.cdc.gov/travel/other/avian_flu_ah5n1_031605.htm and on the WHO website 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 fecally contaminated surfaces 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 (Appendix 5-I and Section 4, Infection Control). 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 (Appendix 5-C). 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 Surveillance and Laboratory Testing.
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

DRAFT

Footnotes to Appendix 5-E cont. Case Detection and Clinical Management during the Interpandemic and Pandemic Alerts Periods

- 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

9. Guidelines for novel influenza virus testing can be found in Section 2. 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 Section 3.

11. Guidelines for the management of contacts in a healthcare setting are provided in Section 4.

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:

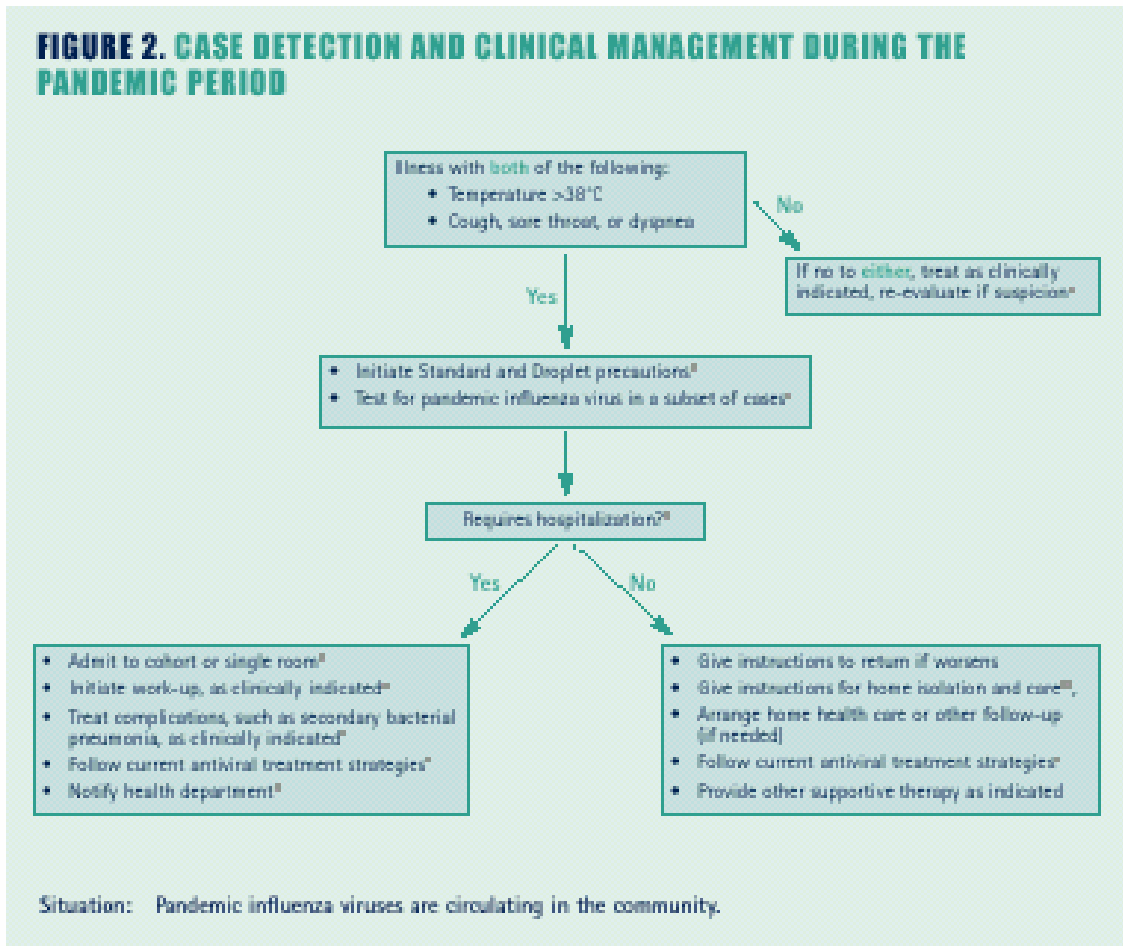
- Absence of strong epidemiologic link to known cases of novel influenza
- Alternative diagnosis confirmed using a test with a high positive-predictive value
- Clinical manifestations explained by the alternative diagnosis

13. Guidance on the evaluation and treatment of suspected post-influenza community-associated pneumonia is provided in Appendix L of HHS Pandemic Plan.

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-F:
Case Detection and Clinical Management During the Pandemic Period



Source: U. S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Footnotes to Appendix 5-F: Case Detection and Clinical Management during the Pandemic Period

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 (Appendix 5-I and Section 4, Infection Control). 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 Section 2, Surveillance and Laboratory Testing. 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 Section 4, Infection Control. 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

DRAFT

Footnotes to Appendix 5-F cont.

Case Detection and Clinical Management during the Pandemic Period

- 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

7. Guidance on the evaluation and treatment of community acquired pneumonia and suspected post- influenza community-acquired bacterial pneumonia are provided in Appendix 5-L.

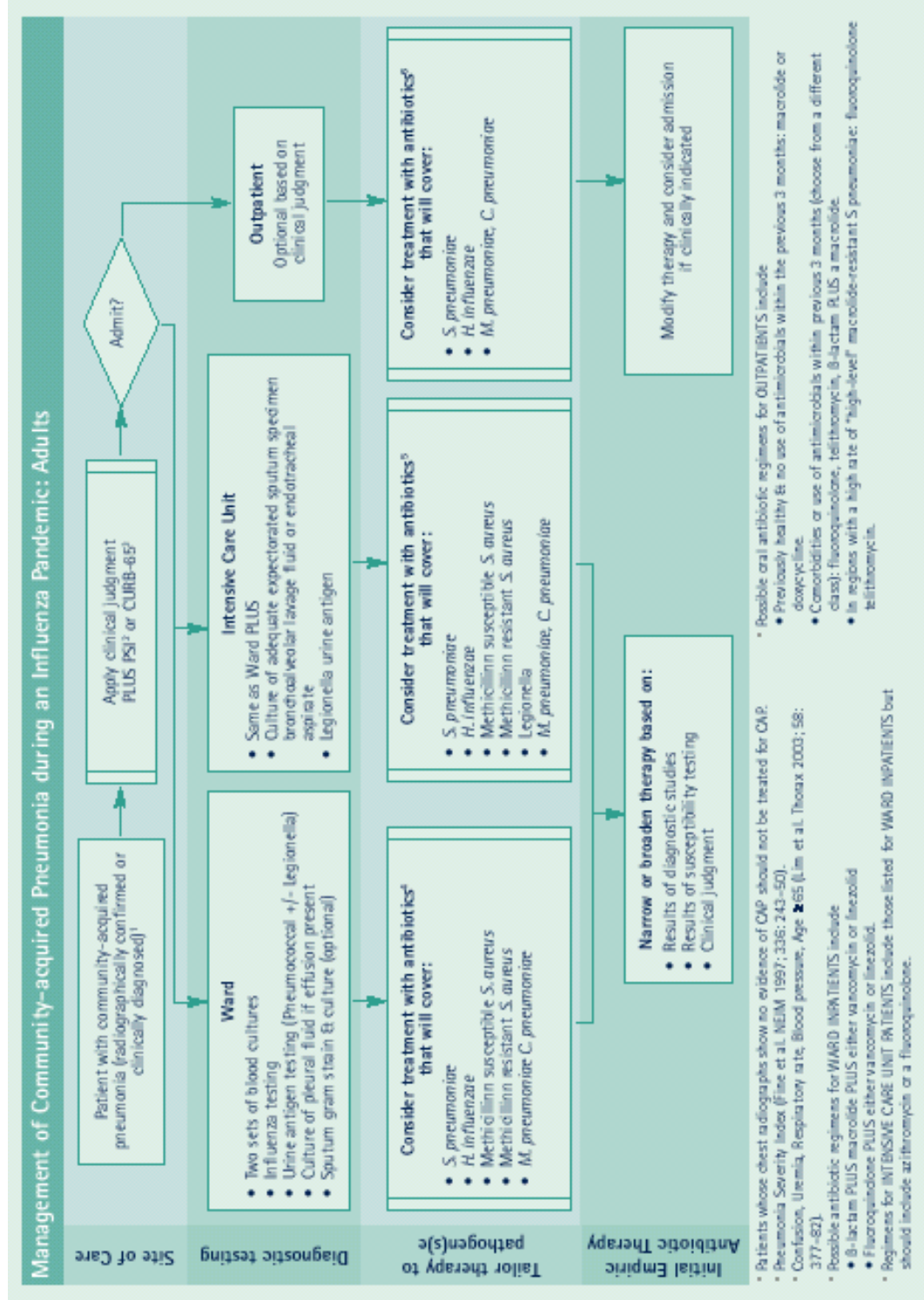
8. Strategies for the use of antiviral drugs are provided in Section 7, Antiviral Medication Procurement, Distribution, and Use.

9. Guidance on the reporting of pandemic influenza cases is provided in Section 2, Surveillance and Laboratory Testing.

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 (Appendix 5-D). Patients care 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 Section 8, Travel-Related Disease Control and Community Containment.

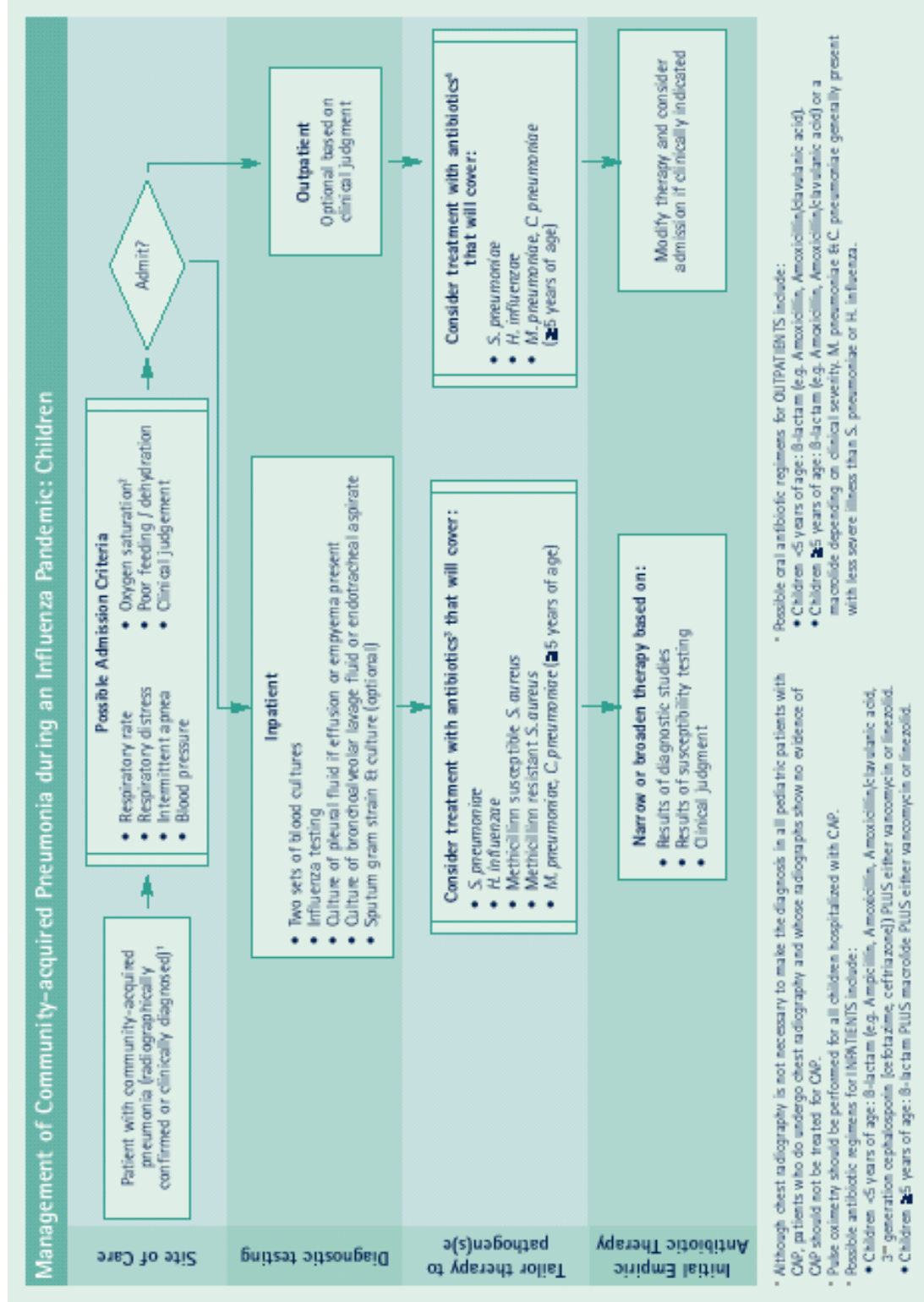
Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

Appendix 5- G: Management of Community Acquired Pneumonia: Adults



Source: U. S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

Appendix 5- H: Management of Community Acquired Pneumonia: Children



Source: U. S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

Appendix 5- I: Pandemic Influenza Infection Control Guidance for Healthcare Providers

| TABLE 1. PANDEMIC INFLUENZA INFECTION CONTROL GUIDANCE FOR HEALTHCARE PROVIDERS | |
|--|---|
| COMPONENT | RECOMMENDATIONS |
| STANDARD PRECAUTIONS | See www.cdc.gov/ncidod/hip/ISOLAT/std_prec_excerpt.htm |
| Hand hygiene | Perform hand hygiene after touching blood, body fluids, secretions, excretions, and contaminated items; after removing gloves; between patient contacts. Hand hygiene includes both handwashing with either plain or antimicrobial soap and water and use of alcohol-based products (gels, rinses, 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 antimicrobial or plain soap 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"> • For touching blood, body fluids, secretions, excretions, and contaminated items; for touching mucous membranes and nonintact skin • During procedures and patient-care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated • Face/eye protection (e.g., surgical or procedure mask and goggles or a face shield) |
| Safe work practices | <ul style="list-style-type: none"> • During procedures and patient care activities likely to generate splash or spray of blood, body fluids, secretions, excretions |
| 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, 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, others and to 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. |

**Appendix 5- I cont.
Pandemic Influenza Infection Control Guidance for Healthcare Providers**

| TABLE 1. PANDEMIC INFLUENZA INFECTION CONTROL GUIDANCE FOR HEALTHCARE PROVIDERS (CONT.) | |
|---|---|
| COMPONENT | RECOMMENDATIONS |
| STANDARD PRECAUTIONS (cont.) | |
| 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 (medical and non-medical) in accordance with facility procedures and/or local or state regulations; wear gloves when handling waste; wear gloves when handling waste containers and perform hand hygiene |
| Respiratory hygiene/cough etiquette 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. | Have the patient cover the mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacle; 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) away from persons who are not ill |
| DROPLET PRECAUTIONS | www.cdc.gov/ncidod/dhqp/H1N1/droplet_prec_excerpt.htm |
| 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 and laundry and dishes and eating utensils, and for cleaning/disinfection of environmental surfaces and patient care equipment, disposal of solid waste, and post-mortem care. |

Appendix 5- I cont.
 Pandemic Influenza Infection Control Guidance for Healthcare Providers

| TABLE 1. PANDEMIC INFLUENZA INFECTION CONTROL GUIDANCE FOR HEALTHCARE PROVIDERS (CONT.) | |
|--|---|
| COMPONENT | |
| 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 a fit-tested N-95 respirator or other appropriate particulate respirator. |
| | <p>Standard Precautions for home health care Healthcare providers who enter homes where there is a person with an influenza-like illness should follow the recommendations for Standard and Droplet Precautions. Standard Precautions include performing hand hygiene and respiratory hygiene/cough etiquette, wearing gloves and gowns, using face/eye protection when needed; and following safe work practices.</p> <p>Droplet Precautions for home health care Healthcare providers who enter homes where there is a person with an influenza-like illness should follow the recommendations for Standard and Droplet Precautions. Droplet Precautions include all Standard Precautions plus separating the patient from others in the household as much as possible and wearing a surgical or procedure mask for patient interactions. Professional judgment should be used in determining whether to don a mask upon entry into the home or only on entering the patient's room. Factors to consider in this decision include the possibility that others in the household may be infectious and the extent to which the patient is ambulating within the home.</p> |

Source: U. S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-J 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. Appendix K includes a brief clinical summary of illnesses associated with previous influenza pandemics and with avian influenza A (H5N1) virus in humans.

Presentation

- 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, diarrhea) occur more frequently in children. Fever or apnea without other respiratory symptoms might be the only manifestations in young children, particularly in neonates.

DRAFT

Appendix 5-J cont.

Clinical Presentation and Complications of Seasonal Influenza

Influenza is 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

No routine laboratory test results are specific for influenza. Leukocyte counts are variable, although thrombocytopenia and severe leukopenia 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 below).

Differential diagnosis

The fever and respiratory manifestations of seasonal influenza are not specific and can occur with several other pathogens, including respiratory syncytial virus (RSV), parainfluenza viruses, adenoviruses, human metapneumovirus, rhinoviruses, coronaviruses, and *Mycoplasma pneumoniae*. In contrast to influenza viruses, most of these pathogens do not usually cause severe disease, particularly in previously healthy adults. RSV and parainfluenza viruses can, however, 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.

The tendency for influenza to occur in community epidemics and to affect persons of all ages can sometimes allow the clinician to diagnose seasonal influenza with reasonable certainty in the absence of laboratory testing. Nevertheless, a definitive diagnosis requires laboratory testing. Rapid influenza diagnostic tests and immunofluorescence testing using a panel of respiratory pathogens have become increasingly available for aiding 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>.

DRAFT

Appendix 5-J cont. Clinical Presentation and Complications of Seasonal Influenza

Complications

Groups at risk for complications of influenza

The following groups are currently recognized by the Advisory Committee on Immunization Practices (ACIP) to be at higher risk for complications of seasonal influenza (e.g., hospitalization; death) compared to healthy older children and younger adults:

- Persons aged 65 years
- 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

Exacerbations 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.

Secondary bacterial pneumonia, another 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*.

DRAFT

Appendix 5-J cont.

Clinical Presentation and Complications of Seasonal Influenza

Influenza virus infection can also result in a primary 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. Mixed viral-bacterial pneumonia 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.

Bronchiolitis due to influenza is more common in children, with a clinical picture similar to that of RSV or parainfluenza virus infections. Influenza is a cause of croup (laryngotracheobronchitis) in children, and, although influenza viruses are a less common etiology than other respiratory viruses, the illness can be more severe. 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.

Seasonal influenza can cause a range of cardiovascular complications, 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.

Gastrointestinal involvement is uncommon with seasonal influenza, although more commonly reported in children. Manifestations can include vomiting and diarrhea, sometimes leading to significant dehydration. Transient hepatic inflammation can occur in rare circumstances.

DRAFT

Appendix 5-J cont. Clinical Presentation and Complications of Seasonal Influenza

Myositis related to influenza is another complication more commonly found in children, although more frequently associated with influenza B. Involvement may be limited to pain and weakness of the lower extremities but can progress to rhabdomyolysis and renal failure in some cases.

Among the neurologic complications associated with seasonal influenza, uncomplicated self-limited febrile seizures are the most common, usually occurring in younger children with high fever. 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. Guillain-Barre syndrome and transverse myelitis have been reported to occur in very rare instances after influenza, but no definite etiologic relationship has been established.

Reye syndrome is another serious neurologic complication associated with influenza. It 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. Seasonal influenza can be associated with systemic complications, 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* has been reported. Toxic shock syndrome without bacterial co-infection has also been reported.

(2) Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005;54:1-40
www.cdc.gov/mmwr/pdf/rr/rr54e713.pdf.

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-K 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.

DRAFT

Appendix 5-K cont.

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

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,³ 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,⁴ 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.^{5,6,7} 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/.

DRAFT

Appendix 5-K cont.

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

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, 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.

DRAFT

Appendix 5-K cont.

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

3 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.

4 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

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.

6 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.

7 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.

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-L 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.⁸

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.

DRAFT

Appendix 5-L cont. Guidelines for Management of Community-Acquired Pneumonia, Including Post-Influenza Community-Acquired Pneumonia

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. 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) and the American Thoracic Society (ATS).^{9,10} For children, the guidance incorporates recommendations from the British Thoracic Society (BTS),¹¹ a published review,¹² and expert opinion.

Prevention

Efforts to maximize vaccination coverage against *Streptococcus pneumoniae* is an important component of post-influenza bacterial community-acquired pneumonia prevention during the Interpandemic, Pandemic Alert, and Pandemic Periods. Current guidelines on the use of the 23-valent pneumococcal polysaccharide vaccine among adults and the 7-valent pneumococcal conjugate vaccine among children are available.^{13,14}

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,^{15,16} 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 to supplement rather than 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.

DRAFT

Appendix 5-L cont.

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

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 patient will be considered a high priority for admission, patients with certain high-risk conditions (see Appendix 5-J) 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.

- Draft IDSA-ATS guidelines recommend obtaining appropriate specimens for etiologic diagnosis whenever such an etiology would alter clinical care. Given that 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.
- For hospitalized patients, blood cultures, pneumococcal urine antigen testing, and pleural fluid aspiration with Gram stain and culture should be considered.
- Because the diagnostic utility of sputum Gram stain and culture is highly dependent on patient and technical conditions, these are considered optional for hospitalized but non-severe patients.
- For patients admitted to an ICU, aspiration and Gram stain and bacterial culture of endotracheal secretions might also be useful.

Children

- Diagnostic studies for identifying bacterial pneumonia in young children are severely limited.
- Blood cultures should be obtained from all children suspected of having post-influenza bacterial community-acquired pneumonia.
- Sputum samples are rarely useful in children, but tracheal or pleural fluid aspirates—if available—should be submitted for Gram stain and bacterial culture.
- If pleural effusions are present, they should be aspirated and submitted for Gram stain and culture.

DRAFT

Appendix 5-L cont. Guidelines for Management of Community-Acquired Pneumonia, Including Post-Influenza Community-Acquired Pneumonia

- When feasible, antibiotic susceptibility testing of any bacterial isolates is encouraged to direct treatment.

Antibiotic Treatment

Adults and children

Antibiotics, particularly those needed to treat CAP, will likely be in short supply during the Pandemic Period. Therefore, use of empiric therapy for all persons with post-influenza bacterial community-acquired pneumonia will likely not be feasible. Antimicrobial therapy will have to be driven by culture and susceptibility testing of appropriate clinical specimens and by awareness of local antibiotic susceptibility patterns. (See Appendix 5-E and 5-F)

- A history of preceding influenza-like illness, especially when pandemic influenza is circulating in the community, might help to screen patients.
- Empiric therapy in adults should be directed toward the most likely etiologies of post-influenza bacterial community-acquired pneumonia.
- Concurrent antiviral treatment might also be beneficial, depending on the timing and presentation of illness (see Section 6).

DRAFT

Appendix 5-L cont. Guidelines for Management of Community-Acquired Pneumonia, Including Post-Influenza Community-Acquired Pneumonia

Table 1 Pneumonia Port Severity Index (PSI) Calculation

| Patient Characteristic | Points Assigned |
|--|--------------------|
| Demographic Factor | |
| Age | |
| Male | Number of years |
| Female | 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 |
| Hypoxemia | +10 |
| <90% by pulse oximetry OR | |
| <60mm Hg by arterial blood gas | |
| Pleural effusion on baseline radiograph | +10 |

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-L cont. Guidelines for Management of Community-Acquired Pneumonia, Including Post-Influenza Community-Acquired Pneumonia

Table 2. 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 |

Table 3. 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.

Table 4. 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 |

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

Appendix 5-L cont.

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

FOOTNOTES

8. 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.
9. 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.
10. 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.
11. 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.
12. McIntosh, K. Community-acquired pneumonia in children. *N Engl J Med*. 2002;346:429-37.
13. 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).
14. CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 1997;46(RR-8).
15. Fine MJ, Auble TE, Yealy DM, Hanusa BH, Weissfeld LA, Singer DE, et al. A prediction rule to identify low-risk patients with community-acquired pneumonia. *N Engl J Med*. 1997;336(4):243-50.
16. Lim WS, van der Eerden MM, Laing R, Boersma WG, Karalus N, Town GI, et al. Defining community acquired pneumonia severity on presentation to hospital: an international derivation and validation study. *Thorax*. 2003;58(5):377-82.

Source: U.S. Department of Health and Human Services. HHS Pandemic Plan. November 2005

DRAFT

6. Vaccine Distribution Procurement, Distribution and Use

- I. Overview**
- II. Vaccine Procurement and Distribution**
- III. VAERS: Vaccine Adverse Event Reporting System**
- IV. References**
- V. Activities by Pandemic Period**

Appendices:

- 6-A: Vaccine Priority Group Recommendations**
- 6-B: Vaccine and Antiviral Medication Supply Management**

I. Overview

Once available, a vaccine against the circulating pandemic virus strain will be a major focus of pandemic response efforts. Ensuring rapid, efficient, and equitable distribution of vaccine is central to pandemic planning. Vaccine will be key to reducing the morbidity and mortality resulting from the pandemic, and to minimizing social disruption by maintaining essential services. It is not known how quickly the pandemic vaccine will become available, and supply is likely to be limited during the early stage of the pandemic. Furthermore, it is likely that two doses of vaccine will be required to achieve a protective response in the vaccinee.

A limited amount of avian influenza A (H5N1) vaccine is being stockpiled and will be considered for early use in the event of an H5N1 pandemic. Development of vaccines against other strains with pandemic potential is also being considered. A monovalent vaccine directed against the circulating pandemic virus strain of influenza should begin to be available within 4-6 months after identification of the new pandemic virus strain. The number of persons who may be protected by vaccination depends on the manufacturing capacity, the amount of antigen per dose needed for a protective immune response, and the number of doses required.

The Department of Health and Human Services (DHHS) and the National Vaccine Advisory Committee (NVAC), in cooperation with the CDC and the Advisory Committee on Vaccine Practices (ACIP), have begun work to provide

DRAFT

6. Vaccine Distribution Procurement, Distribution and Use cont.

guidance on prioritization during a pandemic. The categories that have been specified are included in this plan (Appendix 6-A). The discussion of priority groups is ongoing and will be modified as needed. In particular, priority groups will be modified according to the epidemiology of the pandemic. In addition, continuity of essential societal functions must also be considered. Any priority groups established during the interpandemic period will have to be reassessed, and likely altered, as epidemiologic data on the specific pandemic virus becomes available.

II. Vaccine Procurement and Distribution

The administration of vaccine will be central to a response to an influenza pandemic, although there may be significant morbidity and mortality in the period during which an effective vaccine is being developed and produced in sufficient quantities. The Federal government continues to work closely with vaccine manufacturers in the creation of vaccines that may be beneficial in combating likely pandemic strains of influenza. However, because of the uncertainties associated with predicting which strain will be the cause of a pandemic, and the time needed to produce vaccine in amounts great enough to have an impact, it is anticipated that there will be a period of several months before vaccine is available for administration.

It is assumed that the Federal government will control the supply of vaccine in the United States and that the states will be responsible for distribution of vaccine within their respective jurisdictions. In Maryland, the Department of Health and Mental Hygiene will take the lead in determining the distribution of vaccine to local health departments and providers for administration to the public.

III. Vaccine Adverse Event Monitoring and Reporting

In the U.S., national surveillance for adverse events following immunization is routinely conducted through the Vaccine Adverse Event Reporting System (VAERS), which is managed jointly by the CDC and FDA. Events that may be associated with vaccination can be reported on paper forms, by telephone, or electronically by health care providers, patients, health departments, or vaccine manufacturers. Reports of serious adverse events are followed up to collect additional information for analysis to determine whether such events are reported more frequently than expected. During a pandemic, VAERS would remain the major reporting mechanism.

DRAFT

6. Vaccine Distribution Procurement, Distribution and Use cont.

IV. References and Resources for Mass Vaccination or Antiviral Dispensing

- Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)
<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>
- General Guidelines for Smallpox Vaccination Clinics:
www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-2.pdf
- Guidelines for Large Scale Vaccination Clinics:
www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-3.pdf
- Pandemic Influenza Response and Preparedness Plan:
www.pandemicflu.gov
- Guidelines for Large-Scale Influenza Vaccination Clinic Planning:
<http://www.cdc.gov/flu/professionals/vaccination/pdf/vaxclinicplanning0405.pdf>

V. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State Health Department:

- Continue to promote use of annual influenza vaccine.
- Continue to promote the use of pneumococcal vaccine.
- Identify a process for reviewing national recommendations for pandemic influenza vaccination and developing state specific modifications or refinements in priority groups.
- Develop specific definitions for priority groups identifying occupational categories and sub-categories.
- Develop a plan on how persons in priority groups would be identified at vaccination clinics and how vaccine would be most efficiently provided to those groups.
- Develop a plan to vaccinate the remainder of the population after priority groups have been vaccinated.
- Educate stakeholders about the need for priority groups and the rationale for the groups recommended.
- Plan for the use and training of non-licensed persons to administer vaccine.

DRAFT

6. Vaccine Distribution Procurement, Distribution and Use cont.

- Continue public health preparedness activities in regard to mass distribution of vaccines.
- Identify or develop a statewide data collection system that can collect all required vaccine data elements.
- Ensure that the system can be used to supply required elements to CDC and calculate vaccine coverage and efficacy rates.
- Provide information on vaccine data collection to LHDs.

Local Health Departments:

- Continue to promote the use of annual influenza vaccine.
- Continue to promote the use of pneumococcal vaccine.
- Develop a plan on how individuals in priority groups would be reached and vaccinated.
- Develop a plan on how to identify priority groups at vaccination clinics.
- Educate providers and other stakeholders about local health department plans for vaccination.
- Plan for the use and training of non-licensed persons to administer vaccine.
- Continue public health preparedness activities especially in regard to mass distribution of vaccines.
- Participate in the development of the vaccine data management system.
- Consider including the following personnel in your dispensing operations: mental health professionals, interpreters, and special needs specialists.

Pandemic Period

State Health Department:

- Work with LHDs and health care partners to distribute, deliver, administer, and track pandemic vaccine to priority groups.

DRAFT

6. Vaccine Distribution Procurement, Distribution and Use cont.

- Continue to review and revise priority groups, and communicate changes and their rationale to LHDs and health care partners.
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated.
- Collect vaccine adverse event data from LHDs and providers.
- Consult with CDC on adverse events as needed.
- Report all adverse events to VAERS.
- Update LHDs and providers on any new adverse events identified or any updates on the vaccine adverse event profile.
- Conduct active surveillance for adverse events as needed.
- Provided guidance to LHDs for case investigation of adverse events.
- Provide technical assistance to LHDs.
- Collect data from LHDs on vaccine efficacy and coverage and transmit to CDC at regular intervals as required.
- Calculate efficacy in and coverage of priority groups.

Local Health Departments:

- Work with DHMH and health care partners to distribute, deliver, administer, and track pandemic vaccine to priority groups.
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated.
- Collect reports on adverse events from providers and patients, and provide the information to DHMH.
- Conduct adverse event case investigations.
- Update health care partners on new adverse events or updates on the vaccine adverse event profile.
- Participate in active surveillance of pandemic influenza cases as needed.

DRAFT

Appendix 6-A: Vaccine Priority Group Recommendations

| Tier | Subtier | Population | Rationale |
|----------|----------|---|---|
| 1 | A | <ul style="list-style-type: none"> ▪ Vaccine and antiviral manufacturers and others essential to manufacturing and critical support (~40,000) ▪ Medical workers and public health workers who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators (8-9 million) | <ul style="list-style-type: none"> ▪ Need to assure maximum production of vaccine and antiviral drugs ▪ 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 |
| | B | <ul style="list-style-type: none"> ▪ Persons > 65 years with 1 or more influenza high-risk conditions, not including essential hypertension (approximately 18.2 million) ▪ Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertension (approximately 6.9 million) ▪ Persons 6 months or older with a history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year (74,000) | <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. |
| | C | <ul style="list-style-type: none"> ▪ Pregnant women (approximately 3 million) ▪ Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine (1.95 million with transplants, AIDS, and incident cancer x 1.4 household contacts per person = 2.7 million persons) ▪ Household contacts of children < 6 months old (5 million) | <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 the 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 |
| | D | <ul style="list-style-type: none"> ▪ Public health emergency workers critical to pandemic response (assumed one-third of estimated public health workforce = 150,000) ▪ 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 |
| 2 | A | <ul style="list-style-type: none"> ▪ Health 65 years and older (17.7 million) ▪ 6 months to 64 years with 1 high risk condition (35.8 million) ▪ 6-23 months old, healthy (5.6 million) | <ul style="list-style-type: none"> ▪ Groups that are also at increased risk but not as high risk as population in Tier 1B |

DRAFT

Appendix 6-A cont. Vaccine Priority Group Recommendations

| Tier | Subtier | Population | Rationale |
|----------|----------|---|--|
| 2 | B | <ul style="list-style-type: none"> ▪ Other public health emergency responders (300,000 = remaining two-thirds of public health work force) ▪ Public safety workers including police, fire, 911 dispatchers, and correctional facility staff (2.99 million) ▪ Utility workers essential for maintenance of power, water, and sewage system functioning (364,000) ▪ Transportation workers transporting fuel, water, food, and medical supplies as well as public ground public transportation (3.8 million) ▪ Telecommunications/IT for essential network operations and maintenance (1.08 million) | <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 |
| 3 | | <ul style="list-style-type: none"> ▪ Other key government health decision-makers (estimated number not yet determined) ▪ Funeral directors/embalmers (62,000) | <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 (179.3 million) | <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 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.

Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 6

DRAFT

Appendix 6-B Vaccine and Antiviral Medication Supply Management

It should be recognized that supplies of both vaccine and antivirals may be limited during a pandemic. In all cases, the disposition of these items must be carefully tracked to ensure their appropriate use and efficacy.

I. Levels of Supply

A public health crisis involving pandemic influenza necessitating the need for distributing vaccine/antiviral medications may be similar to most events that may require activation of the Maryland SNS plan. Vaccine/antiviral availability will change during the course of a pandemic. Pandemic response strategies will vary with vaccine/antiviral supply. Four vaccine/antiviral supply levels can be defined.

Stage 1: No Vaccine/Antiviral Supply

At the beginning of a pandemic, it is possible that no vaccine will be available. Depending on the particular viral strains that make up the pandemic, there may or may not be a supply of effective antiviral medications available for distribution and use.

Stage 2: Limited Vaccine/Antiviral Supply

When first available, the vaccine/antiviral supply may be less than that required to protect the susceptible population. Priority groups for vaccine/antivirals will need to be identified. Plans for distribution of vaccine/antivirals will need to be formulated. Approaches to inform priority groups about the availability of vaccine/antivirals and where to receive it; and to educate the public regarding vaccine/antiviral priorities and their rationale will be needed. Allocation plans for counties that are to receive vaccine/antivirals need to be developed, based on priority populations.

Stage 3: Adequate Vaccine/Antiviral Supply

Vaccine/antiviral supply will match the need and ability to distribute vaccine/antivirals. This will allow a shift from priority groups to the wider population. Strategies will need to be developed to assure equitable distribution to special needs populations. The State SNS Plan may be activated to facilitate distribution of the vaccine/antivirals.

Stage 4: Excess Vaccine/Antiviral Supply

Vaccine/antiviral supplies exceed that needed to protect the Maryland population. The State SNS Plan may be activated to facilitate distribution of the vaccine/antivirals. With less demand and abundant supply vaccine/antiviral distribution may return to normal pre-pandemic supply strategies that include the use of private distribution and/or private providers.

DRAFT

Appendix 6-B

Vaccine and Antiviral Medication Supply Management cont.

II. Operational Assumptions

- All SNS vaccine/antiviral materiel will be procured by CDC and arrive at a State Receipt, Storage, and Staging (RSS) site after CDC's decision to deploy the vaccine/antivirals.
- Maryland will activate its SNS Plan to facilitate the widespread distribution of vaccines/antivirals.
- Influenza vaccine will be distributed rapidly to the public sector in partnership with LHDs.
- Multiple shipments of vaccine/antivirals may be requested and deployed.
- Upon receipt of the vaccine/antivirals from the CDC, Maryland will assume responsibility for the vaccine/antivirals until they are delivered to the affected locality.
- State agency resources and personnel may be needed to support local distribution and dispensing efforts.
- The affected locality will be responsible for vaccine/antivirals delivered to it and will have identified suitable locations for storage and distribution.
- If vaccines with applicable influenza strains are not immediately present during initial stages of the pandemic, it will take 4 to 6 months before vaccine availability.
- Only a percentage of the total vaccine needs for Maryland will be available to immunize the population on a monthly basis.

III. Vaccine and Antiviral Deployment

The goal of deployment is to quickly and orderly deliver needed supplies to local agencies to allow them to immunize, treat or prophylax members of their communities. When appropriate, distribution will be via the State's SNS plan.

DRAFT

7. Antiviral Medication Procurement, Distribution, and Use

- I. Overview**
- II. Antiviral Medication Adverse Event Monitoring and Reporting**
- III. Activities by Pandemic Period**

Appendices:

- 7-A. Characteristics of Anti-Influenza Antiviral Medications**
- 7-B. Recommended Daily Dosage of Antiviral Medications for Treatment and Prophylaxis**
- 7-C. Antiviral Medication Priority Group Recommendations**
- 7-D. Pediatric Use of Antiviral Medications**

I. Overview

The targeted use of antiviral agents could, as part of a response strategy to susceptible strains, decrease the health impact of an influenza pandemic. Use of antiviral prophylaxis has been up to 70% to 90% effective in preventing symptomatic influenza infection caused by susceptible strains, if prophylaxis is begun before exposure to influenza. Also, treatment with one class of agents, neuraminidase inhibitors, has been shown to decrease severe complications such as pneumonia and bronchitis and to reduce hospitalizations. These interventions may be particularly important before vaccine is available and for those in whom vaccination may be medically contraindicated. Protection afforded by antiviral medications is virtually immediate and does not interfere with the response to inactivated influenza vaccines. It is important to avoid inappropriate use of antiviral medications that may lead to viral resistance.

Drugs with activity against influenza viruses (antivirals) include the adamantanes, amantadine and rimantadine, and the neuraminidase inhibitors, oseltamivir and zanamivir. 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.

The Department of Health and Human Services (DHHS) and the National Vaccine Advisory Committee (NVAC), in cooperation with the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP), have provided guidance on prioritization of

DRAFT

7. Antiviral Medication Procurement, Distribution, and Use cont.

persons to be given antivirals during a pandemic. The discussion of priority groups is ongoing and will be modified as needed. In particular, priority groups will be modified according to the epidemiology of the pandemic. In addition, continuity of essential societal functions must also be considered. Any priority groups established during the interpandemic period will have to be reassessed, and likely altered, as epidemiologic data on the specific pandemic virus becomes available.

II. Antiviral Medication Adverse Event Monitoring and Reporting

Adverse events associated with antiviral drug use inevitably will occur. Adverse events are currently monitored nationally by FDA's MedWatch system. During a pandemic, those who have received antiviral prophylaxis and have concerns about a potential adverse event, will be referred to their own health care provider or the local emergency department for medical evaluation.

Serious adverse events associated with the use of antiviral influenza drugs should be reported to the FDA, using the Med Watch monitoring program. MedWatch forms are available at <http://www.fda.gov/medwatch/>. Adverse events reported to Med Watch are collated and analyzed by the FDA's Adverse Events Reporting System (AERS).

Antiviral Drug Resistance

CDC will work with state and local partners to monitor the development of resistance to antivirals. Because resistance to adamantanes (amantadine and rimantadine) may involve a single base pair change, resistance may develop rapidly if these drugs are used widely. Information about antiviral resistance to can be found in the July 2005 recommendations of the ACIP at <http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>. Surveillance for antiviral resistance may be particularly important during the later stages of the pandemic, especially if adamantanes have been widely used. Under these circumstances, the detection of widespread adamantane resistance might require a re-evaluation of priorities for prophylaxis and treatment.

CDC will test the drug susceptibilities of viruses isolated from different age groups and geographic areas over the course of the pandemic. DHMH will encourage LHDs and clinicians to obtain specimens from patients who develop severe disease while receiving treatment or prophylaxis.

DRAFT

7. Antiviral Medication Procurement, Distribution, and Use cont.

III. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State Health Department:

- Identify a process for reviewing national recommendations for pandemic influenza antiviral use and developing state specific modifications or refinements in priority groups.
- Identify, define, and quantify priority groups for antiviral use.
- Plan for mass distribution of antivirals to priority groups if needed.
- Provide information to health professionals and the public on issues related to availability and use of antiviral drugs during an influenza pandemic.

Local Health Departments:

- Continue the use of antivirals to control outbreaks in hospitals and long-term care facilities.
- Determine the size of priority groups in local jurisdiction.
- Identify, define, and quantify priority groups in local jurisdictions that are prioritized for antiviral use.
- Plan for mass administration of antivirals to priority groups if needed.
- Plan for reporting of antiviral adverse events.

Pandemic Period

State Health Department:

- Work with LHDs to disseminate public health guidance that encourages antiviral drug-use practices that help minimize the development of drug resistance.
- Review modifications, if any, to interim recommendations on antiviral use in selected groups.

DRAFT

7. Antiviral Medication Procurement, Distribution, and Use cont.

- Revise the strategies for the use of antivirals as the pandemic progresses, depending on supplies, on what is learned about the pandemic strain, susceptibility of the pandemic strain, and on when a vaccine becomes available.
- In conjunction with CDC authorize the use of antivirals to treat and control the spread of disease from individuals, if cases of novel influenza should occur in the US.
- In conjunction with CDC authorize the tracing of and use of antivirals to prophylax close contacts of persons with novel influenza. (As the pandemic becomes more widespread it will no longer be practical or useful to prophylax against outbreaks.)
- Distribute information about changes in the prioritization guidelines, viral susceptibility, resistance, or supply as available.
- Distribute and deliver stockpiled supplies of antiviral, as appropriate to delivery sites that will administer them to priority groups.
- Communicate updates in the guidelines for appropriate use of antivirals as the pandemic continues.
- Continue to work with health care providers to ensure appropriate use of antivirals in the medical management of early cases and contacts.
- Report adverse events to the FDA using the MedWatch monitoring program.
- Educate health care workers and LHD staff about the recognition and reporting of adverse events.
- Distribute MedWatch forms to each end-user that receives antivirals.
- Work with CDC to monitor the development of antiviral resistance.
- Encourage clinicians to obtain specimens from patients who develop severe disease while receiving antiviral treatment or prophylaxis.
- Track antiviral agent supply in the state and redistribute as needed.
- Collect data on adverse events following administration of antiviral drugs.
- Participate in federal efforts to collect data on the effectiveness of treatment and prophylaxis, as requested.

DRAFT

7. Antiviral Medication Procurement, Distribution, and Use cont.

- Participate in federal efforts to collect data on the development of drug resistance, as requested.

Local Health Departments:

- Work with health care providers to disseminate public health guidance that encourages drug-use practices that help minimize the development of drug resistance.
- Administer antivirals to control the spread of disease in small cluster outbreaks or outbreaks in contained settings, if indicated by DHMH.
- Trace and prophylax close contacts of confirmed cases if indicated by DHMH.
- Distribute information about changes in the prioritization guidelines, viral susceptibility, resistance, or supply as available.
- Activate plans for distributing and administering antivirals to persons in priority groups.
- Communicate updates in the guidelines for appropriate use of antivirals as the pandemic continues.
- Continue to work with health care providers to ensure appropriate use of antivirals in the medical management of early cases and contacts.
- Report antiviral adverse events.
- Distribute MedWatch forms to providers and patients as needed.
- Encourage clinicians to obtain specimens from patients who develop severe disease while receiving treatment of prophylaxis.
- Track antiviral supply in the local jurisdiction and redistribute as needed.

DRAFT

Appendix 7-A Characteristics of Anti-Influenza Antiviral Medications

Characteristics of Anti-Influenza Antiviral Medications

| | Inhibits | Acts On | Administration | Common Side Effects |
|--------------------|----------------|-------------------|----------------|--------------------------------------|
| Amantadine | M2 ion channel | Influenza A | Oral | CNS, GI |
| Rimantadine | M2 ion channel | Influenza A | Oral | CNS, GI (less often than Amantadine) |
| Oseltamivir | Neuraminidase | Influenza A and B | Oral | GI |
| Zanamivir | Neuraminidase | Influenza A and B | Inhaler | Bronchospasm |

These agents differ in mechanisms of action, pharmacokinetics, FDA-approved indications, dosages, cost, and potential for emergence of drug resistance (see July 2005 recommendations of the AHIC: <http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>.)

The neuraminidase inhibitors and rimantadine are superior with regard to the frequency of side effects.

The use of M2 inhibitors, particularly for treatment, is likely to lead to the emergency and spread of drug-resistant influenza viruses.

Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7

DRAFT

**Appendix 7-B
Recommended Daily Dosage of Antivirals**

Recommended Daily Dosage of Antivirals for Treatment and Prophylaxis
(Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7)

| Antiviral Agent | Age Groups (years) | | | | |
|---|---|---|-----------------------------------|---------------------------|----------------------|
| | 1-6 | 7-9 | 10-12 | 13-64 | >65 |
| Amantadine (a) | | | | | |
| Treatment, influenza A | 5 mg/kg body weight/day up to 150 mg in two divided doses (b) | 5 mg/kg body weight/day up to 150 mg in two divided doses (b) | 100 mg twice daily (c) | 100 mg twice daily (c) | < 100 mg twice daily |
| Prophylaxis, influenza A | 5 mg/kg body weight/day up to 150 mg in two divided doses (b) | 5 mg/kg body weight/day up to 150 mg in two divided doses (b) | 100 mg twice daily (c) | 100 mg twice daily (c) | < 100 mg twice daily |
| Rimantadine (d) | | | | | |
| Treatment, (e) influenza A | NA (f) | NA | NA | 100 mg twice daily (c, g) | 100 mg/day |
| Prophylaxis, influenza A | 5 mg/kg body weight/day up to 150 mg in two divided doses (b) | 5 mg/kg body weight/day up to 150 mg in two divided doses (b) | 100 mg twice daily (c) | 100 mg twice daily (c) | 100 mg/day (h) |
| Zanamivir (l,j) | | | | | |
| Treatment, influenza A and B | NA | 10 mg twice daily | 10 mg twice daily | 10 mg twice daily | 10 mg twice daily |
| Oseltamivir | | | | | |
| Treatment, (k) influenza A and B | dose varies by child's weight (l) | dose varies by child's weight (l) | dose varies by child's weight (l) | 75 mg twice daily | 75 mg twice daily |
| Prophylaxis, influenza A and B | NA | NA | NA | 75 mg/day | 75 mg/day |

DRAFT

Footnotes to Appendix 7-B Recommended Daily Dosage of Antivirals

NOTE: Amantadine manufacturers include Endo Pharmaceuticals (Symmetrel (R)–tablet and syrup) and Geneva Pharms Tech (Amantadine HCL–capsule); USL Pharma (Amantadine HCL–capsule and tablet); and Alpharma, Carolina Medical, Copley Pharmaceutical, HiTech Pharma, Mikart, Morton Grove, and Pharmaceutical Associates (Amantadine HCL–syrup), and Sandoz. Rimantadine is manufactured by Forest Laboratories (Flumadine (R)–tablet and syrup); Corepharma , Impax Labs (Rimantadine HCL–tablet), and Amide Pharmaceuticals (Rimantadine HCL–tablet). Zanamivir is manufactured by GlaxoSmithKline (Relenza (R)–inhaled powder). Oseltamivir is manufactured by Roche Pharmaceuticals (Tamiflu (R)–tablet). Information based on data published by the U.S. Food and Drug Administration at www.fda.gov, accessed 3/30/2005

a The drug package insert should be consulted for dosage recommendations for administering amantadine to persons with creatinine clearance <50 l/min/1.73m²

b 5 mg/kg body weight of amantadine or rimantadine syrup = 1 tsp/2.2 lbs.

c Children aged >10 years who weigh <40 kg should be administered amantadine or rimantadine at a dosage of 5 mg/kg body weight /day.

d A reduction in dosage to 100 mg/day of rimantadine is recommended for persons who have severe hepatic dysfunction or those with creatinine clearance <10 mL/min. Other persons with less severe hepatic or renal dysfunction taking 100 mg/day of rimantadine should be observed closely, and the dosage should be reduced or the drug discontinued, if necessary.

e Approved by FDA only for treatment among adults.

f Not applicable.

g Rimantadine is approved by FDA for treatment among adults. However, certain experts in the management of influenza consider it appropriate for treatment among children. (See American Academy of Pediatrics, 2003 Red Book.)

h Older nursing-home residents should be administered only 100 mg/day of rimantadine. A reduction in dosage to 100 mg/day should be considered for all persons aged >65 years if they experience possible side effects when taking 200 mg/day.

DRAFT

Footnotes to Appendix 7-B cont. Recommended Daily Dosage of Antivirals

i Zanamivir administered via inhalation using a plastic device included in the medication package. Patients will benefit from instruction and demonstration of the correct use of the device.

j Zanamivir is not approved for prophylaxis.

k A reduction in the dose of oseltamivir is recommended for persons with creatinine clearance <30 ml/min.

l The dose recommendation for children who weigh <15 kg is 30 mg twice a day. For children who weigh >15 to 23 kg, the dose is 45 mg twice a day. For children who weigh >23 to 40 kg, the dose is 60 mg twice a day. And for children who weigh >40 kg, the dose is 75 mg twice a day.

DRAFT

**Appendix 7-C
Antiviral Medication Priority Group Recommendations**

Antiviral Medication Priority Group Recommendations

| | Group | Estimated population (millions) | Strategy | # Courses (millions) | | Rationale |
|---|---|---------------------------------|----------|----------------------|------------|--|
| | | | | For target group | Cumulative | |
| 1 | Patients admitted to hospital *** | 10 | T | 7.5 | 7.5 | Consistent with medical practice and ethics to treat those with serious illness who are most likely to die. |
| 2 | Health care workers (HCW) with direct patient contact and emergency medical (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 >65 yrs old, and persons with underlying medical conditions | 85.5 | T | 2.0 | 35.9 | Groups are at high risk for hospitalization and death. |
| 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. |

DRAFT

| | | | | | | |
|-----------|---|------|---|------|-------|--|
| 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 | 100.7 | Prevents illness in the highest risk groups for hospitalization and death. |
| 11 | Other HCWs with direct patient contact | 8.0 | P | 32 | 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) requires a total of 10 capsules and is defined as 1 course. Post-exposure prophylaxis (PEP) also requires a single course. Prophylaxis (P) 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.

Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7

Appendix 7-D Pediatric Use of Antiviral Medications

Pediatric Use of Antiviral Medications

None of the available influenza antivirals are currently FDA approved for use among children aged <1 year. In particular, the safety and efficacy of oseltamivir have not been studied in children aged <1 year for either treatment or prophylaxis of influenza (see oseltamivir package insert). The decision by an individual physician to treat children aged <1 year in an emergency setting on a off-label basis with an antiviral must be made on case-by-base basis with full consideration of the potential risks and benefits. Additional human data on the safety of these agents in the treatment of influenza in young children are needed.

Osteltamivir is available as an oral suspension for use in children. This formulation of oseltamivir may not be available in sufficient supply during a pandemic to treat all pediatric patients. If physicians consider opening 75 mg oseltamivir capsules and using the contents in an attempt to deliver a partial, pediatric dose to children, it must be recognized that there are insufficient data on palatability, stability, and dosing consistency to predict the safety or effectiveness of such unapproved use. Additional study of these issues is needed.

Source: HHS Pandemic Influenza Plan, Part 2-Public Health Guidance Supplements, Supplement 7

DRAFT

8. Travel-Related Disease Control and Community Prevention

- I. Overview**
- II. Travel-Related Disease Control**
- III. Community Prevention**
- IV. Activities by Pandemic Period**

Appendices:

8-A. Definitions: Interventions for Community Containment

I. Overview

The initial response to a novel strain of influenza will aim at containing the virus at its source. Thorough case isolation and quarantine of contacts in the area where the novel strain emerges may slow the spread of a pandemic. Travel restrictions to and from areas of viral transmission may help slow viral spread to other parts of the world. When the virus moves beyond its initial range and is introduced into the United States, early efforts will likely include isolation and quarantine of newly arrived cases and their contacts. But as transmission becomes more widespread in the United States, quarantine becomes less effective and practical and will likely not be used as a primary public health intervention. Slowing initial viral spread will allow greater time to manufacture and distribute influenza antiviral medications and to develop, manufacture, distribute, and administer influenza vaccine. Epidemiologic investigation of early influenza cases may reveal features of the novel strain that will be relevant to what efforts have the greatest potential in slowing viral spread.

The goal of Community Control Measures is to slow the initial spread of pandemic influenza. This section describes steps that individuals can take (to reduce their risk of becoming infected and their risk of spreading infection to others) and steps that the community as a whole can take.

II. Travel-Related Disease Control

The overall travel-related strategy aims at protecting travelers and decreasing entry of pandemic influenza into Maryland. International health and travel organizations will be expected to implement exit screening for ill persons and to

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

identify persons with influenza-like illness during transit and implementing protocols to limit potential transmission to other passengers.

In-state activity will include:

- Promoting awareness of CDC and WHO travel advisories and information on how travelers can reduce their risk of acquiring pandemic influenza when traveling outside Maryland;
- Implementing point-of-entry interventions to rapidly identify persons who may have or have been exposed to pandemic influenza;
- Isolating persons and identifying and quarantining contacts, at home or in isolation and quarantine facilities.

Travelers can learn where a novel influenza strain is present from CDC's Travel Health Precautions and Warnings web site (<http://www.cdc.gov/travel>) and WHO's Disease Outbreak News web site (<http://www.who.int/csr/don/en/>).

Effective management of travelers will require public health resources at entry points. Persons traveling from an affected area who become ill in transit should be separated from fellow travelers (if possible) on board. Illness among travelers should be reported to health authorities in the countries of embarkation, destination, and transit (if any). Upon arrival, newly ill persons should be referred for medical care and influenza testing. Ill travelers arriving in an area where influenza has not begun to circulate should be isolated for a minimum of 5 days, and contacts to the ill traveler should be quarantined for 10 days. Isolation and quarantine facilities for non-resident travelers should be identified in advance and will be needed during the late pandemic alert period and early in the pandemic phase. Local and state health department personnel may be needed to support federal quarantine station personnel at ports of entry.

III. Community Prevention

Containment strategies aimed at controlling and slowing the spread of a novel virus include measures that affect:

- Individuals or groups of exposed persons (e.g., isolation of patients and quarantining of their contacts), and
- Entire communities (e.g., cancellation of public gatherings; implementation of community-wide snow days).

Guided by epidemiologic data, state and local authorities will implement the most appropriate measures to maximize impact on disease transmission and minimize impact on individual freedom of movement.

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

These measures include:

- Case isolation at home or in a special isolation facility;
- Quarantine of groups of exposed persons, including:
 - Persons exposed to an influenza case via family members, at a public gathering, on an airplane or cruise ship or other closed conveyance, at their school or workplace, or
 - Healthcare providers who work at a facility where influenza cases receive care.

A. The Decision to Launch a Containment Operation

Any attempt to contain an emerging pandemic virus at its source will be a demanding and resource-intensive operation. Moreover, supplies of antiviral drugs reserved for use to support such an operation are finite and not easily replenished, and must therefore be used judiciously.

For these reasons, the decision to initiate activities aimed at rapid containment should be triggered by compelling evidence that the situation represents a transition in the behaviour of the virus towards more efficient human-to-human transmission. Such evidence will be drawn from a combination of clinical, epidemiological, and virological findings as guided by the following criteria:

1. Clustering of cases of moderate-to-severe respiratory illness (or deaths) with two generations of transmission in a health care facility, and laboratory confirmation of H5N1 or another novel influenza A virus infection in at least one of them. The cases could be three or more health care workers who have no known exposure other than contact with ill patients, or just one health care worker and additional patients with evidence of nosocomial transmissions.
2. Moderate-to-severe respiratory illness (or deaths) in 5 to 10 persons with evidence of human-to-human transmission in at least some as determined by temporal sequencing of onset dates of cases and opportunity among cases for exposures to one another consistent with respective infectiousness and incubation period. At least 2 of these persons should have a laboratory-confirmed H5N1 or another novel influenza A virus infection.
3. Isolation of a novel virus combining avian and human genetic material or a virus with an increased number of mutations not seen in avian isolates from one or more persons with moderate-to-severe respiratory illness (acute onset), supported by epidemiological evidence that transmission patterns have changed.

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

Rapid containment measures should not be attempted in the following circumstances:

1. Laboratory studies fail to confirm H5N1 or another novel influenza A virus.
2. The number or geographical distribution of affected persons is so large at the time of detection that it renders containment impracticable for logistical reasons.
 - The number of persons requiring prophylactic administration of antiviral drugs exceeds available supplies
 - The size of the affected community makes it impossible to ensure adequate supplies of food and shelter, and the provision of medical care and emergency services during a containment operation

The feasibility of rapid containment will depend further on the number of contacts of the initial cases and the ability of government authorities and international teams to ensure basic infrastructure and essential services to the affected population. Such services include shelter, water, sanitation, food, security, and communications with the outside world.

B. A two-phased containment response

The rapid containment strategy is implemented in two phases:

1. Immediate implementation of standard measures aimed at reducing further transmission. In this phase, isolation of cases, active case finding and contact tracing are undertaken and antiviral drugs are administered, in a targeted way, to persons identified during these activities.
2. Implementation of exceptional measures, including wider prophylactic administration of antiviral drugs, quarantine, and (possibly) the introduction of social distancing measures.

During both phases, surveillance activities should be intensified in the outbreak zone and the surrounding areas to guide the continued implementation of public health measures and monitor their impact. Geographically surrounding countries, or those that are linked through communication routes, may need to be on the alert for possible introduction of potential cases.

Source: WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment, Updated Draft 30 May 2006

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

The purpose of isolation and quarantine is to reduce influenza transmission by separating infected persons from uninfected persons, exposed persons from non-exposed persons, and monitoring exposed persons for symptoms and providing medical care and infection control precautions as soon as symptoms are detected. Case isolation and quarantine and monitoring of exposed persons may be accomplished by various arrangements (e.g., home isolation or quarantine, isolation or quarantine in a designated facility, etc.).

Case isolation will be valuable during all phases of pandemic influenza. Guidance for the care of an ill person who does not require hospitalization and is isolated at home, including infection control, can be found in the Infection Control and Clinical Guidelines section. Isolation conducted in healthcare settings is discussed in these same sections. Home-based and alternate facility-based isolation and quarantine is discussed below.

The home is generally the preferred setting for isolation and quarantine, but alternative sites for isolation and quarantine may be necessary in certain situations. For example, persons who do not have a home suitable for this purpose or those who require isolation or quarantine away from home (e.g., during travel or homeless) will need to be housed in an alternative location. Special isolation facilities and staffing should be identified in advance and be available to operate beginning in the late pandemic alert period and throughout the pandemic phase. Quarantine facilities and staffing should be identified in advance and will be needed during the late pandemic alert period and early in the pandemic phase.

Monitoring of cases isolated at home or in a special facility and monitoring of contacts quarantined at home or in a special facility will be needed during the late pandemic alert period and early in the pandemic phase. When the pandemic becomes widespread, public health monitoring of cases and quarantined persons will be impractical. Quarantine should be coupled with monitoring of exposed persons for symptoms and provision of medical care and infection control precautions as soon as symptoms are detected. Plans should be developed for instances requiring the enforcement of isolation and quarantine measures.

Contacts of influenza patients can be managed by various interventions designed to facilitate early recognition of illness in persons at greatest risk of becoming infected and thereby prevent transmission to others. Measures applied to individuals may not be feasible or effective during the Pandemic Period, when tracing and quarantining of close contacts may not be possible. The range of interventions is more fully described later in this document. Pandemic influenza may involve a second and third wave of infection. It may be appropriate to

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

resume case and contact tracing and quarantining of contacts at the beginning of new waves of infection.

C. Measures that affect entire communities

Later in a pandemic, when disease transmission is occurring in communities throughout Maryland, efforts directed at individuals and groups of exposed persons are much less likely to slow viral spread and many would not be feasible to implement because of the large number of ill persons and their contacts. Community-based containment measures directed at the entire community that decrease social contact (e.g., self-shielding, closing schools, restricting/cancellation of public buildings/events/gatherings, snow days) and emphasize what individuals can do to reduce their risk of infection (e.g., hand hygiene and cough etiquette) may be more effective disease control tools.

Possible measures include:

- Promotion of community-wide infection control measures including respiratory hygiene/cough etiquette, hand hygiene, and avoiding public gatherings (e.g., movies, religious services, public meetings). Persons at high risk for complications of influenza may wish to avoid going to public areas (e.g., food stores, pharmacies); the use of other persons for shopping or home delivery service is encouraged.
- The benefit of wearing masks by well persons in public settings has not been established and is not recommended as a public health control measure at this time. Nevertheless, persons may choose to wear a mask as part of an individual protection strategy that includes cough etiquette, hand hygiene, and avoiding public gatherings. Mask use is not a substitute for social distance or other personal protection measures. Supply issues should be considered so that mask use in communities does not limit availability for healthcare settings where the importance and effectiveness of mask use has been documented.
- Snow days and self-shielding - Implementation of “snow days” - asking everyone to stay home - involves the entire community. Snow days may be instituted for an initial 10-day period, with a final decision on duration based on an epidemiologic and social assessment of the situation. Recommendations should be made available to the public to acquire and store necessary provisions and supplies needed during snow days. Snow days can effectively reduce transmission without explicit activity restrictions (i.e., quarantine). Exceptions

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

must be made for personnel who maintain primary functions in the community (e.g., law enforcement personnel, transportation workers, utility workers involved with electricity, water, gas, telephone, and sanitation). Voluntary “self-shielding” behavior may precede an official snow day declaration (i.e., many people may elect to stay home or limit their activity even in the absence of an official snow day).

- Closure of office buildings, shopping malls, schools, and public transportation are potential community containment measures during a pandemic. Each of these will have a significant impact on the community and workforce, and careful consideration should be focused on their potential to slow person-to-person spread of influenza. Broad community involvement will be needed for effective implementation, while at the same time maintaining essential community services. For example, when public transportation is cancelled, other modes of transportation must be provided for persons needing medical evaluation.

Anecdotal reports suggest that community influenza outbreaks may be limited by closing schools, especially when schools are closed early in the outbreak. In addition, the risk of infection and illness among children is likely to be decreased, which would be particularly important if the novel strain causes significant morbidity and mortality among children. Children are known to be efficient transmitters of seasonal influenza and other respiratory illnesses. During a Pandemic Period, parents should be encouraged to consider child care arrangements that do not result in large gatherings of children outside the school setting.

The decision to discontinue community-level measures must balance the need to lift individual movement restrictions against community health and safety. Premature removal of containment strategies can increase the risk of additional transmission. A general recommendation is to withdraw the most stringent or disruptive measures first.

School systems, businesses, community infrastructure providers, and other employers should develop plans for continuity of essential operations and modified operation during “snow days.” These plans should include procedures for issues related to employment compensation and job security. Employers should anticipate that approximately 30% of persons will become ill during a 6 to 8 week outbreak, although a lower percentage of working-aged adults will themselves be ill. In addition, about 10% of the workforce will be absent due to illness of a family member. Others may stay home due to a fear of becoming

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

infected. Workplace closure may result in loss of income for affected workers. Such workers will be referred for available public and private assistance.

To assist planning efforts, the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) have developed checklists to assist a variety of entities. These checklists can be found at <http://www.pandemicflu.gov/plan/checklists.html> and include:

- State & Local Government
- Business
- Individuals & Families
- Schools
- Health Care
- Community Organizations

D. Community Support and Special Populations

Community support for provision of food, medical supplies (including delivery of prescription medications), mental health services, and other essentials may be required by ill persons who are isolated or quarantined at home or in special isolation and quarantine facilities. Providing a range of services will be especially important if isolation and quarantine are implemented as strategies to decrease the transmission of infection. Local community resources must be identified to support persons caring for themselves and family members at home, and for those in a specialized isolation and/or quarantine facility. Plans should be developed at the local level by public health and emergency managers along with groups that can provide community support services. Community support strategies may already have been developed as part of preparedness planning for other public health emergencies – either natural or as a result of a bioterrorist attack. Local communities are encouraged to identify civic organizations and other volunteers to meet these needs (e.g., American Red Cross). Local agencies already engaged in providing services to the homebound (e.g., Meals-on-Wheels) may become the nucleus for voluntary efforts to provide services to people confined to their homes or specialized facilities. Additional volunteers may be needed to assist with community support activities.

Certain groups will be hard to reach, including people whose primary language is not English, people who are homeless, and people who are hearing and visually impaired. Services may be especially important for older adults who are likely to

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

be most impacted by pandemic influenza. Service providers must be identified who can ensure that information and services are accessible to these hard to reach/special needs groups.

E. Additional Considerations

1. Public Information and Understanding of Disease Containment Measures

The success of travel-related disease control and community prevention activities described above relies on a coordinated public information campaign targeted at improving public understanding of pandemic influenza and the benefits of individual and community wide disease control practices, including social-distancing measures that reduce disease transmission and prevent illness and death. The success of disease control will be facilitated by clear communication of the rationale for and duration of containment measures. The public information campaign may include information hotlines and community triage resources.

2. Legal Implications

A general guide to Maryland laws governing public health emergency preparedness and response (including reference to isolation and quarantine) is included in section 2.2 of this Plan. A review of pertinent legal authorities, laws and procedures for isolation and quarantine, closing businesses or schools, and suspending public meetings during a declared state of emergency is necessary.

IV. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State Health Department:

- Address legal, logistic, and social challenges associated with individual and community-based containment measures.
- Advise LHDs when to implement isolation of ill persons and quarantine of contacts arriving from an area where pandemic influenza has emerged.

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

- Review pertinent legal authorities and how they apply in a public health emergency, in particular, laws and procedures for closing businesses or schools and suspending public meetings during a declared state of emergency.
- Improve readiness to implement travel-related disease containment measures.
- Promote awareness of CDC and WHO travel advisories.
- Finalize and distribute: Maryland Draft Isolation and Quarantine Guidelines, Draft version 2 March 1, 2006.

Local Health Departments:

- Investigate illness among travelers returning from areas affected with a novel influenza virus and implement isolation and quarantine, as needed.
- Develop plans for isolating ill persons and quarantining of contacts at home and at special isolation and quarantine facilities.
- Develop plans to provide community support services for the provision of food, water, medicine and medical consultation, transportation to medical treatment, if required, and other essential supplies/services (e.g., day care or elder care) to those confined at home, hard to reach/special needs groups, children, and persons with disabilities. Conduct training.
- Promote awareness of CDC and WHO travel advisories.
- Implement individual-level containment measures (e.g., patient isolation and identification, monitoring, and quarantine of contacts).

Pandemic Period

State Health Department:

- Support federal quarantine station personnel.
- In conjunction with CDC, make recommendations regarding individual and community containment measures.

DRAFT

8. Travel-Related Disease Control and Community Prevention cont.

Local Health Departments:

- Isolate ill persons and quarantine contacts as warranted.
- Coordinate the monitoring of individuals in isolation and quarantine as warranted.
- Coordinate operation of specialized isolation facilities, as needed.
- Coordinate community-level containment measures that decrease social contact within groups or whole communities (e.g., quarantine of groups of exposed persons, cancellation of public events, closing recreational facilities, public buildings, snow days, and self-shielding).
- Support federal quarantine station personnel at ports of entry.
- Activate local plans to coordinate community support services.

DRAFT

Appendix 8-A: Definitions: Interventions for Community Containment

Source: Adapted from the November 2005 HHS Pandemic Influenza Plan, Supplement 8, Appendix 1

The ultimate goal of isolation and quarantine is to separate and restrict the movement or activities of persons who are ill, suspected of being ill, or who have been exposed to infection, for the purpose of preventing transmission of diseases.

Isolation

Restriction of movement or separation from other persons, in such places, under such conditions, and for such time, as will prevent transmission of the infectious agent, of persons known to be ill or suspected of being infected with contagious disease.

- Isolation allows for the focused delivery of specialized health care to persons who are ill, and it protects healthy persons from becoming ill.
- Ill persons are usually isolated in a hospital, but they may also be isolated at home or in a designated community-based facility, depending on their medical needs.

“Isolation” is typically used to refer to actions performed at the level of the individual patient. This may be modified if an alternative diagnosis is made or diagnostic test results indicate that the patient is not infected with H5N1 or another novel influenza virus.

Note: CDC is revising this interim guidance for infection control precautions for avian influenza. The revised recommendations will be posted on the CDC website as soon as they are finalized.

Quarantine

Restriction of movement and activities or separation of well person(s) believed to have been exposed to a contagious disease (household contacts and/or incidental contacts) to premises designated by the health officer.

- Persons are usually quarantined in their homes, but they may also be quarantined in community-based facilities.
- Quarantine can be applied to an individual or to a group of persons who are exposed at a large public gathering or to persons believed exposed on a conveyance during to international travel.
- Quarantine can also be applied on a wider population- or geographic-level basis. Examples of this application include the closing of local or community

DRAFT

Appendix 8-A cont.

Definitions: Interventions for Community Containment

borders or erection of a barrier around a geographic area with strict enforcement to prohibit movement into and out of the area.

Contacts of pandemic influenza patients can be managed by use of a range of interventions, all of which are designed to facilitate early recognition of illness in persons at greatest risk of becoming infected and thereby prevent transmission to others. Whereas many of these interventions are applied individually to persons identified as contacts of a person with possible or known influenza disease, others are applied to larger groups of persons, or communities, which share a similar risk of exposure. Measures applied to individuals may not be feasible during the Pandemic Period, when quarantining individuals and tracing close contacts may not be possible. The range of interventions includes the following:

Passive Monitoring

- *Definition:* The contact is asked to perform self-assessment at least twice daily and to contact authorities immediately if respiratory symptoms and/or fever occur.
- *Application:* Situations in which 1) the risk of exposure and subsequent development of disease is low, and 2) the risk to others if recognition of disease is delayed is also low.
- *Benefits:* Requires minimal resources. Places few constraints on individual movement.
- *Challenges:* Relies on self-reporting. Affected persons may not perform an adequate self-assessment.
- *Resources Required:* Supplies (thermometer; symptom log; written instructions). Hotline to notify authorities about symptoms or needs. Staff to receive telephone reports and provide in-person evaluation and care. Plans and procedures for rapid isolation of persons who develop symptoms.
- *Partners:* Household members.
- *Forms/Templates:* Symptom logs. Instructions for patients and healthcare workers.

Active Monitoring without Explicit Activity Restrictions

- *Definition:* A healthcare or public health worker evaluates the contact on a regular (at least daily) basis by phone and/or in person for signs and symptoms suggestive of influenza.

DRAFT

Appendix 8-A cont.

Definitions: Interventions for Community Containment

- *Application:* Situations in which 1) the risk of exposure to and subsequent development of disease is moderate to high, 2) resources permit close observation of individuals, and 3) the risk of delayed recognition of symptoms is low to moderate.
- *Benefits:* Places few constraints on individual liberties.
- *Challenges:* Requires adequate staffing. Requires a system to track information and to verify monitoring and appropriate actions based on findings.
- *Resources Required:* Trained staff to provide in-person and/or telephone evaluations. Plans and procedures for rapid isolation of persons who develop symptoms. Contingency plans for managing noncompliant persons. Hotline to notify authorities about symptoms or needs.
- *Partners:* Professional and lay healthcare workers to perform evaluations on behalf of the health department. Possible need for law enforcement to assist with management of noncompliant persons
- *Forms/Templates:* Checklist for assessment of active monitoring. Template for recording results of clinical evaluation.

Active Monitoring with Activity Restrictions (Quarantine)

- *Definition:* The contact remains separated from others for a specified period (up to 10 days after potential exposure), during which s/he is assessed on a regular basis (in person at least once daily) for signs and symptoms of influenza disease.
- Persons with fever, respiratory, or other early influenza symptoms require immediate evaluation by a trained healthcare provider. Restrictions may be voluntary or legally mandated; confinement may be at home or in an appropriate facility. No specific precautions are required for those sharing the household with a person in quarantine as long as the person remains asymptomatic. Because onset of symptoms may be insidious, it may be prudent to minimize interactions with household members during the period of quarantine, if feasible.
- *Application:* Situations in which the risk of exposure and subsequent development of disease is high and the risk of delayed recognition of symptoms is moderate.
- *Benefits:* Reduces risk of spread from persons with subacute or subclinical presentations or from delayed recognition of symptoms.
- *Challenges:* May infringe on personal movement. May lead to a feeling of isolation from family and friends. May lead to loss of income or employment.

DRAFT

Appendix 8-A cont.

Definitions: Interventions for Community Containment

- Requires plans/protocols for provision of essential services. Requires plan for provision of mental health support. Risk of noncompliance, particularly as duration increases. May require enforcement for noncompliance.
- *Resources Required:* Staff for monitoring and evaluation. Appropriate facility if home setting is unavailable or inadequate. Staff, funding, and goods for provision of essential services. Hotline for notification of symptoms or personal needs. Mechanisms to communicate with family members outside the household or facility. Mental health and social support services. Delivery systems for food and other essential supplies.
- *Partners:* Professional and lay healthcare workers to perform assessments on behalf of the health department. Community volunteers/workers to assist with provision of essential services. Potential need for law enforcement to assist with noncompliant persons.
- *Forms/Templates:* Checklist for active monitoring. Template for recording results of clinical evaluation. Checklist and guidelines for evaluation of homes for quarantine. Checklist and guidelines for evaluation of community-based sites for quarantine. Guidelines for monitoring compliance with home quarantine. Guidelines for monitoring compliance with quarantine in community-based facilities. Forms for recording compliance with quarantine.
- *Examples:* Home quarantine (voluntary or mandatory). Facility quarantine (voluntary or mandatory).

Working Quarantine

- *Definition:* Employees exposed to pandemic influenza but not yet ill are permitted to work but must observe activity restrictions while both on and off duty. Monitoring for influenza-like illness before reporting for work is usually required. This may change based on the clinical presentation of the novel strain. Use of appropriate PPE, including a surgical or procedure mask while at work, is required.
- *Application:* Persons for whom activity restrictions (home or facility quarantine) are indicated but who provide essential services (e.g., healthcare workers).
- *Benefits:* Reduces risk of community spread from high-risk contacts while minimizing adverse impact of activity restrictions on provision of essential services. Clinical monitoring at work reduces the staff required for active monitoring at the quarantine site.

DRAFT

Appendix 8-A cont.

Definitions: Interventions for Community Containment

- *Challenges:* Need for close and consistent pre-shift monitoring at the work site to prevent inadvertent exposures. May require means of transporting persons to and from work site to minimize interactions; persons in working quarantine should wear appropriate PPE during transport. Must maintain close cooperation and communication between work site and local health authorities. Need to provide mental health services to address concerns about isolation from family and friends.
- *Resources Required:* Appropriate facility for off-duty quarantine if home is unavailable or inadequate. Staff, funding, and goods for provision of essential services. Personal protective equipment. Hotline for notification of symptoms and personal needs. System to track results of work-site monitoring and location(s) of off-duty quarantine. Mental health, psychological, and behavioral support services, especially if work includes care of influenza patients.
- *Partners:* Work-site administrators and infection control personnel. Community volunteers/workers. Staff/volunteers to assist with transportation to and from work. Mental health professionals. Potential need for law enforcement to assist with noncompliant persons.
- *Forms/Templates:* Guidelines and instructions for persons in working quarantine. Instructions for supervisors of persons in working quarantine. Checklist to evaluate homes for quarantine. Guidelines for monitoring compliance. Checklist for active monitoring at work site. Template for recording results of clinical evaluation. Forms for recording compliance.

Focused Measures to Increase Social Distance

- *Definition:* Intervention applied to specific groups, designed to reduce interactions and thereby transmission risk within the group. When focused, the intervention is applied to groups or persons identified in specific sites or buildings, most but not necessarily all of whom are at risk of exposure to influenza.
- *Examples:* Quarantine of groups of exposed persons. Cancellation of public events. Closure of office buildings, schools, and/or shopping malls; closure of public transportation such as subways or bus lines.
- *Application:* Groups or settings where transmission is believed to have occurred, where the linkages between cases is unclear at the time of evaluation, and where restrictions placed only on persons known to have been exposed is considered insufficient to prevent further transmission.

DRAFT

Appendix 8-A cont.

Definitions: Interventions for Community Containment

- *Benefits:* Applied broadly, reduces the requirement for urgent evaluation of large numbers of potential contacts to determine indications for activity restrictions. May enable reductions in transmission among groups of persons without explicit activity restrictions (quarantine).
- *Challenges:* May be difficult to solicit cooperation, particularly if popular buildings are closed or popular events are cancelled. Requires excellent communication mechanisms to notify affected persons of details and rationale. May need to provide replacement for affected activities (e.g., school, essential services). Generally relies on passive monitoring.
- *Resources Required:* Systems to communicate relevant messages. May require enforcement, particularly if closure of buildings or gathering places is necessary.
- Requires resources for passive monitoring. Hotlines to report symptoms and obtain follow-up instructions. Transportation for medical evaluation, with appropriate infection control precautions.
- *Partners:* News media and communication outlets. Law enforcement. Community groups.
- *Forms/Templates:* Messages for affected persons. Messages for employers of affected persons. Messages for persons supplying essential services.

Community-Wide Measures to Increase Social Distance

- *Definition:* Intervention applied to an entire community or region, designed to reduce personal interactions and thereby transmission risk. The prototypical example is implementation of a “snow day,” in which offices, schools, and transportation systems are cancelled as for a major snowstorm.
- *Examples:* Snow days.
- *Application:* All members of a community in which 1) extensive transmission of influenza is occurring, 2) a significant number of cases lack clearly identifiable epidemiologic links at the time of evaluation, and 3) restrictions on persons known to have been exposed are considered insufficient to prevent further spread.
- *Benefits:* Reduces need for urgent evaluation of large numbers of potential contacts to determine indications for activity restrictions. May enable reductions in transmission among groups without explicit activity restrictions (quarantine). “Snow days” are familiar concepts and thus are easy to implement on short notice.
- *Challenges:* May be difficult to solicit cooperation. Requires excellent communication mechanisms to notify affected persons of details and rationale. May need to provide replacement for affected activities (e.g., school, essential services). May need to address mental health and financial support issues. When an entire community is involved, requires cooperation with neighboring jurisdictions that may not be using a similar intervention,

DRAFT

Appendix 8-A cont.

Definitions: Interventions for Community Containment

particularly in situations where persons live in one city and work in another and only one locale is affected by the intervention. Generally relies on passive monitoring. Social and economic impact of public transportation closures.

- *Resources Required:* Communication outlets. Enforcement. Resources for passive monitoring. Hotlines and other communication systems to report symptoms and obtain follow-up instructions.
- *Partners:* News media and other communication outlets. Law enforcement and transportation officials to enforce restrictions (e.g., closure of bridges, roads, or mass transit systems) and plan for provision of critical supplies and infrastructure.
- *Forms/Templates:* Messages for affected persons. Messages for employers of affected persons. Messages for persons supplying essential services.

Widespread Community Quarantine, Including *Cordon Sanitaire*

- *Definition:* Legally enforceable action that restricts movement into or out of the area of quarantine of a large group of people or community; designed to reduce the likelihood of transmission of influenza among persons in and to persons outside the affected area. When applied to all inhabitants of an area (typically a community or neighborhood), the intervention is referred to as *cordon sanitaire* (sanitary barrier).
- *Application:* All members of a group in which 1) extensive transmission is occurring, 2) a significant number of cases lack identifiable epidemiologic links at the time of evaluation, and 3) restrictions placed on persons known to have been exposed are considered insufficient to prevent further spread. Widespread quarantine is unlikely to be necessary because other less restrictive measures (e.g., snow days) may be equally effective.
- *Benefits:* Reduces need for urgent evaluation of large numbers of potential contacts to determine indications for activity restrictions.
- *Challenges:* Controversial because of the degree that individual movement is restricted. Difficult to solicit cooperation for extended periods, particularly if the rationale is not readily apparent or was not clearly explained. Requires excellent communication mechanisms to inform affected persons and to maintain public confidence in the appropriateness of the chosen course of action. Need to ensure continuation of essential services. Need to provide financial support and mental health support services for the affected population. When an entire community is involved, requires cooperation with neighboring jurisdictions that may not be using a similar intervention, particularly in situations where persons live in one city and work in another and only one locality is affected by the intervention. Need to provide mechanisms for isolating symptomatic persons with minimal delay.

DRAFT

Appendix 8-A cont.

Definitions: Interventions for Community Containment

- *Resources Required:* Systems to communicate relevant messages. Enforcement to maintain security at borders. Transportation for persons requiring medical evaluation, with appropriate infection control precautions. Staff and supplies to maintain access to and availability of essential services and goods, including food, water, medicine, medical care, and utilities. Psychological support staff. Plan to divert flow of critical infrastructure supplies and materials that normally transit through quarantined area.
- *Partners:* News media and other mass communication outlets. Public and private groups, industries, and officials to coordinate supply and provision of essential services to affected area. Law enforcement to maintain security at borders and to enforce movement restrictions. Transportation industry.
- *Forms/Templates:* Messages for affected persons. Messages for employers of affected persons. Messages for persons supplying essential services.
- *Examples:* Quarantine (*cordon sanitaire*) of a city or town. Quarantine of occupants of a housing complex or office building.

DRAFT

9. Communications

- I. Overview**
- II. Spokespersons and Subject Matter Experts**
- III. Information Release and Joint Information Center**
- IV. Activities by Pandemic Period**

Appendices:

9-A. Draft Message Maps

I. Overview

Effective communication of key messages to all audiences will be critical to successful implementation of a public health response to pandemic influenza. Communication should be timely accurate and useful. The public will want information and a recommendation for action steps to reduce their risk. Public concerns should be treated as legitimate and recognized for their ability to influence effectiveness of a pandemic response. Also, in a severe pandemic, actions of individuals, businesses and community organizations, as much as those of government, will greatly determine the outcome.

Risk communication research suggests that worried people respond better if they are provided with up-to-date factual information, coupled with action steps that permit them some measure of control over their own health and safety. Ideally, risk communication should begin when the target audience is attentive to the message, but not so overwhelmed by psychological or physical communication barriers that they cannot or will not receive, understand and/or act on the message. Therefore, it will be necessary to communicate information about human health risks associated with an influenza pandemic well before emergence of any pandemic strains that represent a threat of large scale human-to-human transmission.

The purpose of pre-event communications to the general public is to alert them of the crucial role they will play in pandemic preparedness and response, and to establish a candid and open dialogue about expected limitations on government resources during a severe pandemic.

DRAFT

9. Communications cont.

II. Spokespersons and Subject Matter Experts

The Secretary of DHMH, or his designee, will be the primary spokesperson regarding emergency health issues related to pandemic flu and for issues related to the human health risk of avian influenza.

Subject matter experts representing the Office of Preparedness and Response, Community Health Administration, and Laboratory Administration will support the primary spokesperson(s) and may serve as secondary spokespersons if their specific expertise is required.

III. Information Release and Joint Information Center

During a Pandemic Period, to update public information and provide recommended action steps in a timely manner, DHMH will facilitate expedited review and clearance of communication products, share public messages with key communication partners and participate in a Joint Information Center (JIC). A JIC will be coordinated by MEMA. The purpose of a JIC will be to facilitate a one-voice response; serve as the clearinghouse for accurate, timely information; and enhance the dissemination of health information essential to an effective health emergency response.

The media will be the primary information resource for all target audiences during a Pandemic Period. It must be recognized that the media will play an essential role in creating an informed public. However, inaccurate or exaggerated press reports can fuel public concern far in excess of an actual health risk. Thus, there must be a constant source of timely "official" public information to reduce rumors that otherwise will quickly fill an information vacuum.

A. Risk Communication

It is important during an emergency event to convey complex information clearly and simply. The communication resources on the next page provide information about crisis, emergency, and pandemic flu risk communications. They are available at <http://www.pandemicflu.gov/rcommunication/>.

DRAFT

9. Communications cont.

Resources

- Crisis and Emergency Risk Communication: By Leaders For Leaders (Centers for Disease Control and Prevention)
 - Course Book (PDF) (695KB)
 - Participant's Manual (includes slides) (PDF) (447KB)
- Communicating in a Crisis: Risk Communication Guidelines for Public Officials (Substance Abuse and Mental Health Services Administration)
- Effective Media Communication during Public Health Emergencies (World Health Organization)
- Terrorism and Other Public Health Emergencies: A Reference Guide for the Media (U.S. Department of Health & Human Services)
- Pandemic Influenza Pre-Event Message Maps (PDF) (220KB)
"Message maps" are risk communication tools used to convey complex information, and to make it easier to understand. Each primary message has three supporting messages that can be used to provide context for the subject of the primary message. This file contains message maps for both avian flu and pandemic influenza.
- WHO Handbook for Journalists: Influenza Pandemic (PDF) (738KB)
- WHO Outbreak Communications Guidelines (PDF) (452KB) (World Health Organization)
- Influenza Pandemic Periodicity, Virus Recycling, and the Art of Risk Assessment (Centers for Disease Control and Prevention)

Source: <http://www.pandemicflu.gov/rcommunication/>

IV. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State Health Department:

- Establish and maintain partnerships with public information staff from state, regional and local government agencies; hospitals and hospital industry organizations and others.
- Facilitate risk communication training opportunities for appropriate DHMH key staff.

DRAFT

9. Communications cont.

- Develop and test public information messages, including for special populations such as non-English speakers; low-literacy versions; and unique versions for people with disabilities.
- Promote awareness of activities that will allow people to “shelter in place,” if necessary.
- Update regularly information on Maryland’s public website www.flu.maryland.gov.
- Develop ahead of time, a variety of communications materials for various pandemic phases and potential scenarios (such as draft press releases, Public Service Announcements (PSAs), fact sheets, etc.).
- Maintain capacity for rapid, interactive communication with key partners, including public health information officers across the nation via the National Public Health Information Coalition.

State and Local Health Departments:

- Maintain and update contact information for key public information partners.
- Utilize social marketing to normalize risk reduction behaviors.
- Identify or enhance alternate communication channels that can be used to help reach Special Needs Populations (SNPs), who otherwise may be unwilling to act upon official health directives in a pandemic, e.g., migrant workers, undocumented aliens, rural isolated individuals, homeless individuals. Such alternate channels may include faith community leaders, community based organizations and other trusted sources.
- Provide public information and education on community containment strategies to reduce disease transmission.
- Provide a mechanism to update information on a regular basis.
- Establish and/or maintain capacity for a public “call center” that can be rapidly activated to provide information in the event of an influenza pandemic and ensure that call center operators can provide risk communication along with public information.

DRAFT

9. Communications cont.

- Ensure communications redundancy and interoperability internally and with key response partners.

Pandemic Period

State Health Department:

- Participate in risk communication conference calls, monitor HHS/CDC telebriefings, and share information with other states via the National Public Health Information Coalition.
- Notify the general public of a specific health threat to Maryland.
- Make public announcements regarding an influenza pandemic via the Governor, Secretary of Health or their designated spokespersons.
- Disseminate protective action messages via Emergency Alert System (EAS) channels that will provide basic information about the emergency and refer viewers/listeners to additional sources of information.
- Finalize draft public notices and ensure they are reviewed by the appropriate executive and program staff, and, as necessary, the Governor's press office.
- Notify the news media of health issues related to pandemic influenza. Disseminate information via bulk faxing to news agencies, and post news releases on the Maryland web site www.flu.maryland.gov.
- Hold press conferences, briefings, and interviews; provide press releases and other mechanism to keep the public updated and informed.
- Update information on Maryland's public website www.flu.maryland.gov.
- In the event of a need for mass prophylaxis, utilize EAS channels, the DHMH website and other media channels to announce the availability/locations of vaccination sites or other protective actions being recommended.
- Participate in a JIC, if one is established, and/or schedule regular media briefings and/or telebriefings.

DRAFT

9. Communications cont.

State and Local Health Departments:

- Coordinate risk communication with key partners to enhance message consistency.
- Activate public call centers.
- Reinforce respiratory etiquette and hand hygiene, mask usage and stay at home messages.
- Reinforce community containment messages.
- Communicate travel alerts.
- Disseminate public information targeted to special populations during a Pandemic period in various languages other than English, such as Spanish, Russian, Chinese and Haitian-Creole; low-literacy versions; and unique versions for persons with disabilities.
- Establish and/or maintain capacity for a public “call center” that can be rapidly activated to provide information in the event of an influenza pandemic and ensure that call center operators can provide risk communication along with public information.

APPENDIX 9-A. MESSAGE MAPS

Organizations should coordinate with their Public Information Offices or Officer and develop templates for public information during a pandemic. These can be Message Maps for press conferences, press releases, statements, or fact sheets. The mission of the organization and the intended audience may require multiple means of communication and in more than one language.

Sample message maps can be found at the Department of Health and Human Services website at: www.pandemicflu.gov/rcommunication/pre_event_maps.pdf. Eight message maps developed by the Delmarva Poultry Industries Health Department Joint Task Force are included in this section.

DRAFT



MESSAGE MAP

PUBLIC ~ ANIMAL HEALTH

SCENARIO: NO CASES OF H5N1 HAVE BEEN FOUND LOCALLY, BUT IT REMAINS A GLOBAL CONCERN

STAKEHOLDER: PUBLIC

QUESTION: IS IT SAFE TO EAT CHICKEN?

| KEY MESSAGE 1  | KEY MESSAGE 2  | KEY MESSAGE 3 |
|---|---|--|
| Yes, it is safe to eat chicken. | The U.S. is free of the H5N1 strain of Avian Influenza. | We are constantly monitoring our poultry farms and live bird markets for signs of the disease. |
| ↓ | ↓ | ↓ |
| Support Point 1.1 | Support Point 2.1 | Support Point 3.1 |
| Handling and cooking the chicken according to guidelines ensures the safety of the chicken. | The International Animal Health Reporting Agency has recognized the U.S. as H5N1-free. | Poultry producers are taking strong preventative measures on their farms. |
| Support Point 1.2 | Support Point 2.2 | Support Point 3.2 |
| Poultry processing is closely regulated by federal meat inspectors. | The U.S. prohibits imports from countries with infected poultry. | Any chicken showing signs of illness is tested. |
| Support Point 1.3 | Support Point 2.3 | Support Point 3.3 |
| In Delmarva, flocks are routinely tested for AI before processing. | Store-bought chickens have been through federal inspections. | Four random samples of flocks are taken before processing. |

DRAFT

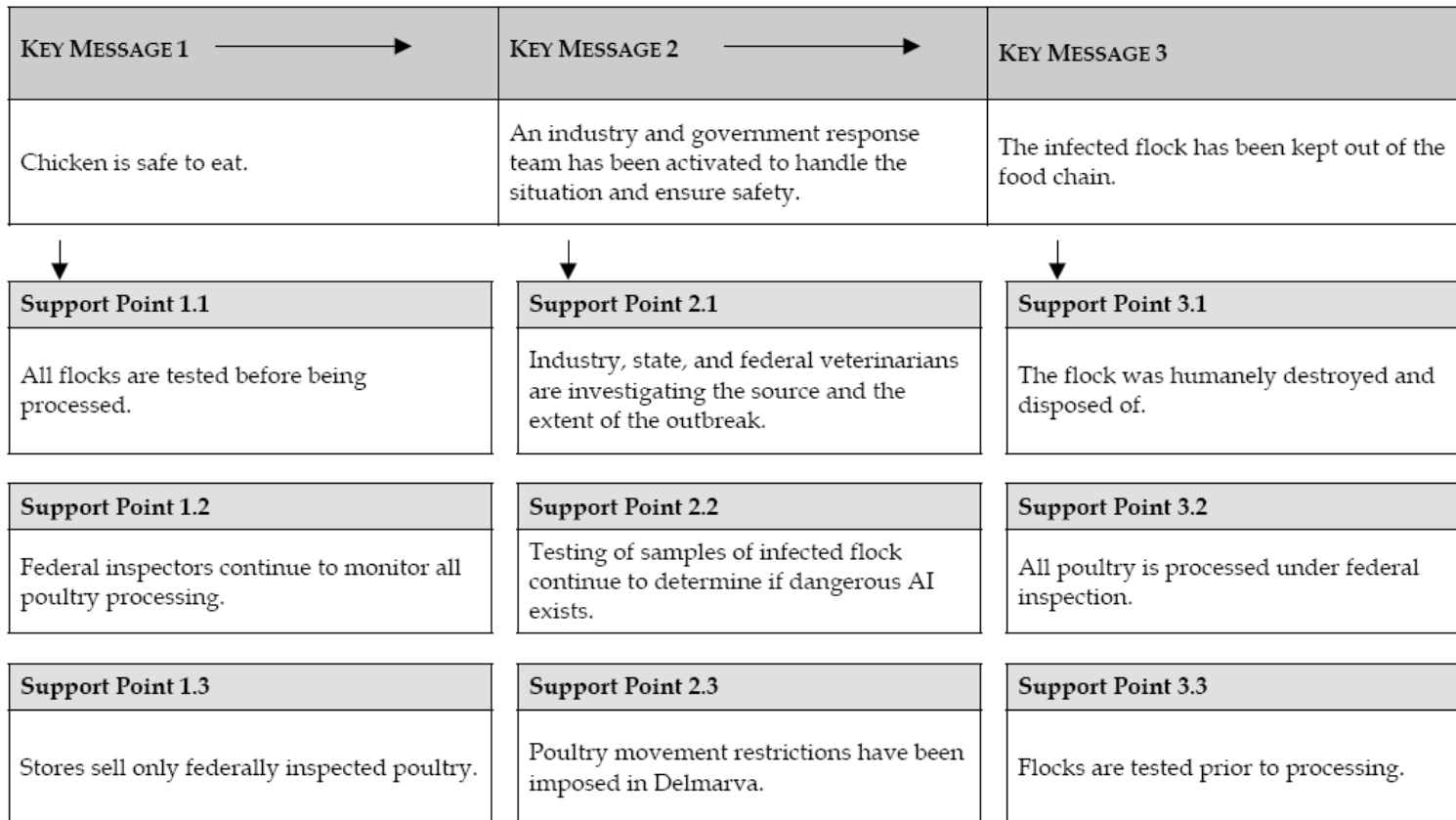
MESSAGE MAP

PUBLIC ~ ANIMAL HEALTH

SCENARIO: A CASE OF H5N? HAS BEEN FOUND IN A DELMARVA FLOCK

STAKEHOLDER: PUBLIC

QUESTION: IS CHICKEN SAFE TO EAT?



DRAFT






MESSAGE MAP

PRODUCERS ~ ANIMAL HEALTH

SCENARIO: NO CASES OF H5N1 HAVE BEEN FOUND LOCALLY, BUT IT REMAINS A GLOBAL CONCERN

STAKEHOLDER: PRODUCER

PREMISE: ADDRESSING CONCERN OF POSSIBILITY OF H5N1 STRAIN OF AVIAN INFLUENZA ENTERING U.S.

| KEY MESSAGE 1  | KEY MESSAGE 2  | KEY MESSAGE 3 |
|---|---|---|
| The risk of finding H5N1 in flocks is low. | Effective and proven poultry protection plans are in place. | U.S. poultry industry practices greatly differ from those overseas. |
|  |  |  |
| Support Point 1.1 | Support Point 2.1 | Support Point 3.1 |
| H5N1 has only appeared outside of the U.S. | We successfully limited last year's avian viral episode. | Our birds live in confined housing. |
| Support Point 1.2 | Support Point 2.2 | Support Point 3.2 |
| We have effective biosecurity measures in place. | The response was decisive and speedy. | We limit bird exposure for both humans and other animals. |
| Support Point 1.3 | Support Point 2.3 | Support Point 3.3 |
| Flocks are contained and controlled. | Delmarva's 2004 response served as a national model. | Our farms practice state-of-the-art health monitoring. |

DRAFT

MESSAGE MAP

PRODUCERS ~ ANIMAL HEALTH

SCENARIO: A CASE OF H5N? HAS BEEN FOUND IN A DELMARVA FLOCK

STAKEHOLDER: PRODUCERS

PREMISE: ADDRESSING CONCERN OVER ECONOMIC LOSS

| | | |
|---|---|---|
| KEY MESSAGE 1 → | KEY MESSAGE 2 → | KEY MESSAGE 3 |
| Every effort is being made to contain the disease. | We are preparing to help you reduce economic hardships. | Everyone's cooperation is required to minimize economic loss. |
| ↓ | ↓ | ↓ |
| Support Point 1.1 | Support Point 2.1 | Support Point 3.1 |
| You are supported by all levels of government, universities and the poultry industry. | The cost to growers with infected flocks will be limited. | Normal activities on Delmarva will be affected. |
| Support Point 1.2 | Support Point 2.2 | Support Point 3.2 |
| Our proven emergency plan is in place and has been activated. | The financial community will work with you through this time. | Restrictions on movement to and from the farm will be in place. |
| Support Point 1.3 | Support Point 2.3 | Support Point 3.3 |
| We are increasing flock surveillance. | Growers will receive compensation/indemnity | |

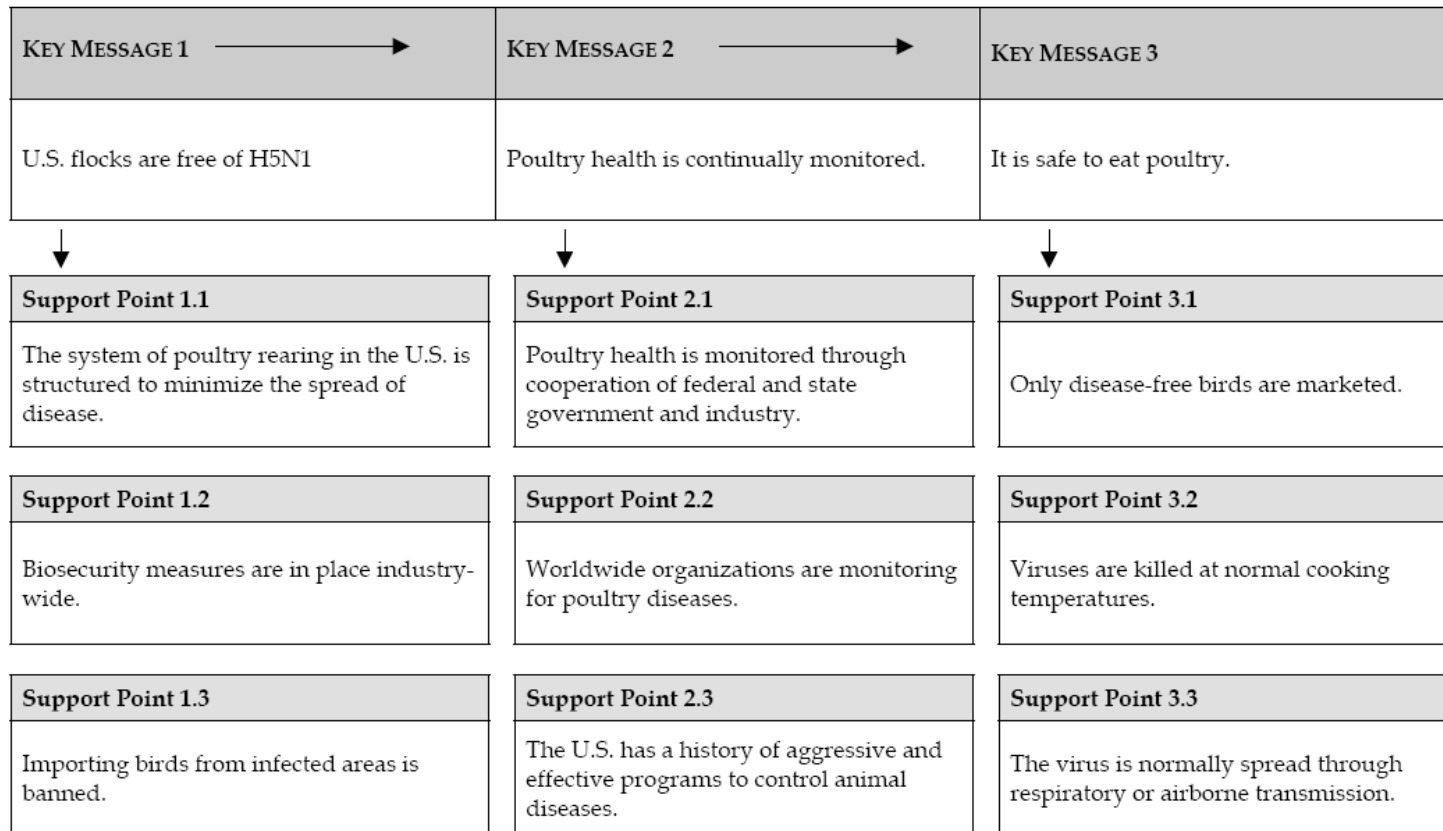
DRAFT

MESSAGE MAP PUBLIC ~ HUMAN HEALTH

SCENARIO: NO CASES OF H5N1 HAVE BEEN FOUND LOCALLY, BUT IT REMAINS A GLOBAL CONCERN

STAKEHOLDER: PUBLIC

QUESTION: WHAT IS MY RISK OF CONTAGION FROM CONTACT WITH LIVE BIRDS AND/OR MEAT FROM BIRDS?



DRAFT

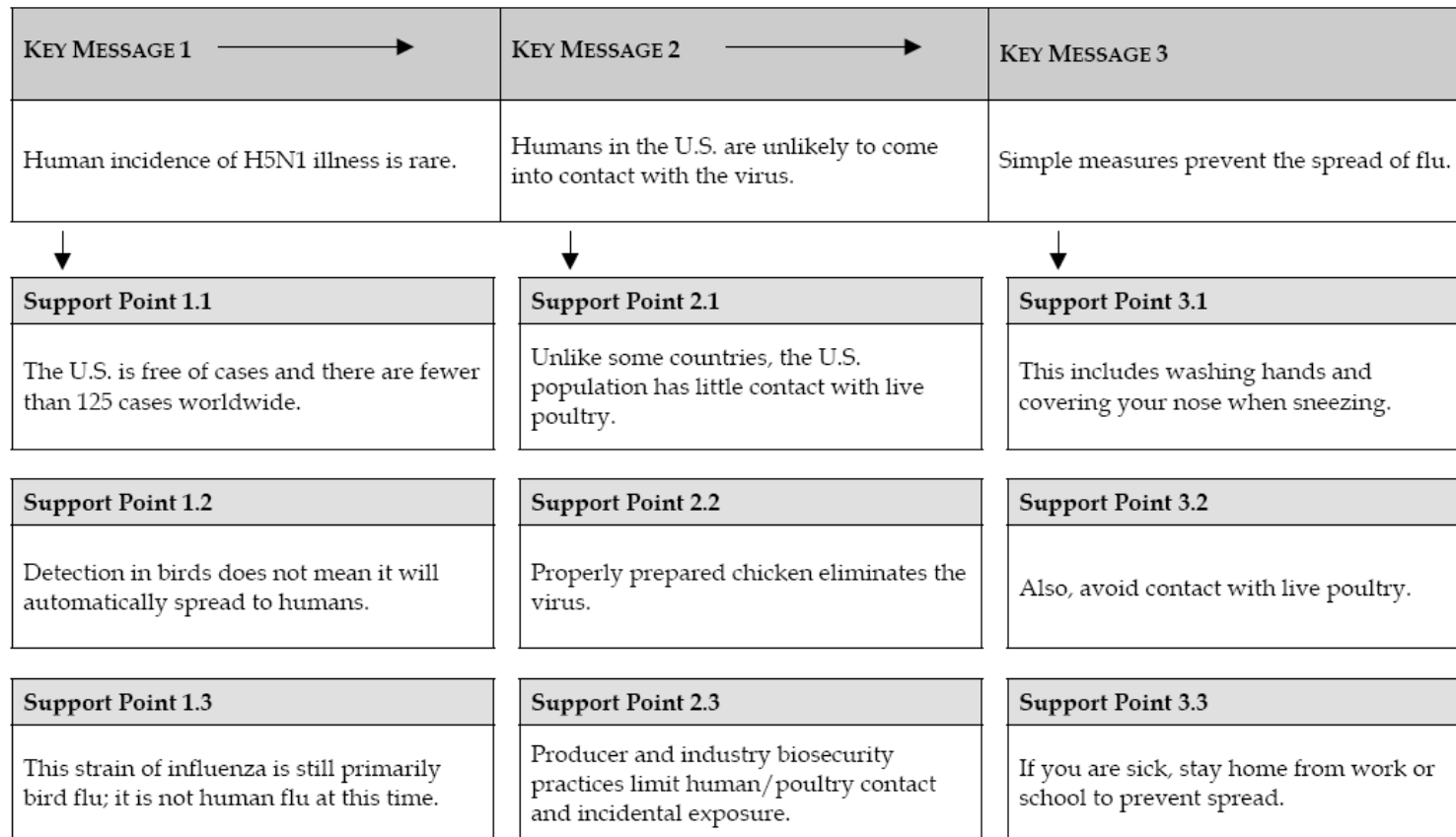
MESSAGE MAP

PUBLIC ~ HUMAN HEALTH

SCENARIO: A CASE OF H5N1 HAS BEEN FOUND IN A DELMARVA FLOCK

STAKEHOLDER: PUBLIC

QUESTION: WHAT IS THE RISK OF HUMAN TO HUMAN SPREAD OF AVIAN INFLUENZA?



DRAFT

MESSAGE MAP

PRODUCERS ~ HUMAN HEALTH

SCENARIO: NO CASES OF H5N1 HAVE BEEN FOUND LOCALLY, BUT IT REMAINS A GLOBAL CONCERN

STAKEHOLDER: PRODUCERS

QUESTION: CAN I CATCH AVIAN INFLUENZA? WILL I GET SICK?

| | | |
|--|---|--|
| KEY MESSAGE 1 → | KEY MESSAGE 2 → | KEY MESSAGE 3 |
| The U.S. is free of and has always been free of the H5N1 strain of Avian Influenza. | Bird to human transmission of Avian Influenza is very rare. | Your best protection is to keep Avian Influenza off of your farm. |
| ↓ | ↓ | ↓ |
| Support Point 1.1 | Support Point 2.1 | Support Point 3.1 |
| The only cases of H5N1 Avian Influenza have been in Asia and Europe. | The vast majority of AI strains only affect poultry or bird species. | Continue to follow vigorous biosecurity practices. |
| Support Point 1.2 | Support Point 2.2 | Support Point 3.2 |
| The U.S. aggressively monitors for AI and tests more than one million birds a year for AI. | Fewer than 200 people have contracted H5N1 worldwide. | Your flock supervisor is available to help you assess your biosecurity practices. |
| Support Point 1.3 | Support Point 2.3 | Support Point 3.3 |
| Very little poultry is imported into the U.S. Live birds are only imported from countries free of Avian Influenza. | H5N1 (HPAI) has not developed the ability to easily transfer from human to human. | Contact your flock supervisor or veterinarian if you see any signs of disease in your flock. |

DRAFT

MESSAGE MAP

PRODUCERS ~ HUMAN HEALTH

SCENARIO: A CASE OF H5N1 HAS BEEN FOUND IN A DELMARVA FLOCK

STAKEHOLDER: PRODUCERS

QUESTION: HOW DO I PROTECT MYSELF AND MY FAMILY?

| | | |
|--|--|--|
| KEY MESSAGE 1 → | KEY MESSAGE 2 → | KEY MESSAGE 3 |
| Risk of contracting Avian Influenza in this situation is very low. | We understand your concern and urge you to take protective measures. | The best protection is to prevent the introduction of AI to your farm. |
| ↓ | ↓ | ↓ |
| Support Point 1.1 | Support Point 2.1 | Support Point 3.1 |
| Aggressive actions are underway to control and eradicate this outbreak. | Information is available at _____. | Information on biosecurity is available from _____. |
| Support Point 1.2 | Support Point 2.2 | Support Point 3.2 |
| Flock will be destroyed promptly. | | |
| Support Point 1.3 | Support Point 2.3 | Support Point 3.3 |
| We urge you to cooperate fully with animal health and public health authorities. | | |

10. Psychosocial Workforce Support Services

I. Overview

II. Activities by Pandemic Period

I. Overview

The response to an influenza pandemic will pose substantial physical, personal, social and emotional challenges to healthcare providers, public health officials, and other emergency responders and essential service workers. Based on experience with disaster relief efforts, enhanced workforce support activities can help responders remain effective during emergencies.

During an influenza pandemic, the occupational stresses experienced by healthcare providers and other responders are likely to differ from those faced by relief workers. Globally and nationally, a pandemic might last for more than a year, while pandemic waves in local communities may last six to eight weeks and recur in two or three waves.

Special planning is needed to ensure that hospitals, public health agencies, first-responder organizations and employers of essential service workers are prepared to help employees maximize personal resilience and professional performance. An essential part of this planning effort involves the creation of alliances with community-based organizations and nongovernmental organizations with expertise in and resources for psychosocial support services or training.

The primary recommendations for workforce support focus on the establishment of psychosocial support services that will assist workers to manage emotional stress during response efforts to an influenza pandemic, and resolve related personal, professional and family issues.

II. Activities by Pandemic Period

Interpandemic and Pandemic Alert Periods

State and Local Health Departments:

- Prepare or obtain workforce support materials on psychosocial issues for distribution to employees during an influenza pandemic. Include materials on:

DRAFT

10. Psychosocial Workforce Support Services cont.

- stressors related to pandemic influenza;
 - signs of distress;
 - traumatic grief;
 - psychosocial aspects related to management of mass fatalities;
 - stress management and coping strategies;
 - strategies for building and sustaining personal resilience;
 - behavioral and psychological support services;
 - strategies for helping children and families in times of crisis;
 - strategies for working with highly agitated patients;
 - developing “family communication plans”;
 - services available during an emergency;
 - measures that persons can take to protect themselves and their families.
- Identify resources that can be made available to employers and their families during and after a pandemic.
 - Develop or identify a workforce resilience program that can help deployed workers prepare for, cope with, and recover from the social and psychological challenges in emergency field work. Components of this program could include:
 - conduct briefings and training on behavioral health, resilience, stress management issues, and coping skills;
 - train supervisors in strategies for maintaining a supportive work environment;
 - deploy several persons as a team;
 - monitor occupational health, safety and psychological well-being of deployed staff;
 - provide access to activities that help reduce stress;
 - refer to behavioral health services upon request;
 - continue to provide outreach to employees’ families to address ongoing psychological and social issues;
 - interview responders and family members to assess lessons learned;
 - provide ongoing access to post-emergency psychosocial support services for responders and their families;
 - conduct an ongoing evaluation of the after-effects of the pandemic on employees’ health, morale and productivity.

DRAFT

10. Psychosocial Workforce Support Services cont.

Pandemic Period

State and Local Health Departments, and Healthcare Partners:

- Provide psychosocial support services to staff that participate in or provide support for the response to a pandemic.
- Facilitate psychosocial support resources to the public, particularly those who require isolation or quarantine (for more information, see: Maryland Draft Isolation and Quarantine Guidelines, Draft version 2 March 1, 2006, Section 9, Addressing Quality of Life During Isolation and Quarantine, and Section 10, Behavioral Health Impact of Isolation and Quarantine).

DRAFT

ADDENDUMS

1. Definition of Terms
2. References and Resources
3. Emergency Points of Contact

DRAFT

ADDENDUM 1 – DEFINITION OF TERMS

| | |
|--------------------------------------|--|
| Adjuvants. | Substances that can be added to a vaccine to increase the effectiveness of the vaccine. |
| Affected country. | An at-risk country experiencing endemic (widespread and recurring) or epidemic (isolated) cases in humans or domestic animals of influenza with human pandemic potential. |
| Antiviral medications. | Medications presumed to be effective against potential pandemic influenza virus strains. These antiviral medications include the neuraminidase inhibitors oseltamivir (Tamiflu®) and zanamivir (Relenza®). |
| Arrival screening. | Medical screening upon arrival to detect individuals who have signs of illness or who are at high risk of developing illness. |
| Asymptomatic. | Asymptomatic means without symptoms of influenza. |
| At-risk country. | An unaffected country with insufficient medical, public health, or veterinary capacity to prevent, detect, or contain influenza with pandemic potential. |
| Colleges. | Educational institutions post-12th grade (post high school). |
| Community-based organization. | A private nonprofit organization, Indian tribe or tribally sanctioned organization, or other type of group that works within a community for the improvement of some aspect of that community. Community-based organizations include non-profit organizations (501 c(3)), faith-based organizations, tribes, and their subsidiaries. |
| Containment. | Contain an outbreak to the affected region(s) and limit of spread of the pandemic through aggressive attempts to contain. |
| Continuity of operations. | Refers to the capability to ensure the performance of essential functions during any emergency or situation that may disrupt normal operations. |
| Cough etiquette. | Covering ones mouth and nose while coughing or sneezing; using tissues and disposing in no-touch receptacles; and washing your hands to avoid spreading an infection to others. |
| Countermeasures. | Refers to pre-pandemic and pandemic influenza vaccine and antiviral medications. |
| Critical infrastructure. | Systems and assets, whether physical or virtual, so vital to the United States or a state that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters. Specifically, it refers to the critical infrastructure sectors and key resources identified in Homeland Security Presidential |

DRAFT

Directive 7 (HSPD-7). As defined by HSPD-7, critical infrastructure includes the following sectors and key resources: agriculture and food; public health and health care; drinking water and water treatment systems; energy (including the production, refining, storage, and distribution of oil and gas, and electric power except for nuclear facilities); banking and finance; national monuments and icons; defense industrial base; information technology; telecommunications; chemical; transportation systems (including mass transit, aviation, maritime, ground/surface, and rail and pipeline systems); emergency services; postal and shipping; dams; government facilities; commercial facilities; and nuclear reactors, material, and waste. Critical infrastructure in this Plan is used to refer to the 17 critical infrastructure and key resources included in the National Infrastructure Protection Plan.

- Delegation of authority.** Identification, by position, the authorities for making policy determinations and decisions at headquarters, field levels, and other organizational locations, as appropriate. Generally, pre-determined delegations of authority will take effect when normal channels of direction are disrupted and terminate when these channels have resumed.
- Departure screening.** Medical screening prior to departure from a high-risk area to identify individuals who have signs of illness (influenza) or who are at high risk of developing illness.
- Devolution.** The capability to transfer and sustain authority and responsibility for essential functions from an organization's primary operating staff and facilities, to other employees and facilities.
- Disaggregation of disease transmission networks.** The disruption of activities and social interactions that facilitate transmission of influenza (e.g., closure of schools, canceling public meetings or large social gatherings, keeping schoolchildren home, and restriction of travel).
- Domestic animals.** Livestock, including poultry, and other farmed birds or mammals; does not include companion animals such as dogs, cats, or pet birds.
- Dose sparing strategies.** Strategies to increase influenza vaccine immunogenicity and minimize the dose of vaccine necessary to confer immunity.
- En route screening.** Surveillance (typically by non-medical personnel) to detect individuals who develop signs of illness (influenza) while en route.
- Epidemic.** A pronounced clustering of cases of disease within a short period of time; more generally, a disease whose frequency of occurrence is in excess of the expected frequency in a population during a given time interval.

DRAFT

| | |
|--|--|
| ESAR-VHP. | Emergency System for Advance Registration of Volunteer Health Professionals. |
| Essential functions. | Functions that are absolutely necessary to keep a business operating during an influenza pandemic, and critical to survival and recovery. |
| Facemask. | Disposable surgical or procedure face mask (see definitions of both below). |
| Faith-based organization. | Any organization that has a faith-inspired interest. |
| Geographic quarantine (cordon sanitaire). | The isolation, by force if necessary, of localities with documented disease transmission from localities still free of infection. |
| Hand hygiene. | Hand washing with either plain soap or antimicrobial soap and water and use of alcohol-based products (gels, rinses, foams) containing an emollient that do not require the use of water. |
| High-throughput rapid diagnostic kit. | Medical technology to accurately and rapidly detect influenza strains. The technology is currently being used to rapidly detect avian influenza employing nucleic acid diagnostic primers (short strands of DNA/RNA). |
| High-risk country. | An at-risk country that is located in proximity to an affected country, or in which a wildlife case of influenza with pandemic potential has been detected. |
| Highly pathogenic avian influenza (HPAI). | An infection of poultry caused by any influenza A virus that meets the World Organization for Animal Health (OIE) definition for high pathogenicity based on the mortality rate of chickens exposed to the virus intravenously or on the amino acid sequence of the cleavage site of the virus' hemagglutinin molecule. |
| Isolation. | Separation of infected individuals from those who are not infected. |
| Key assets. | Subset of key resources that are "individual targets whose destruction could cause large scale injury, death, or destruction of property, and/or profoundly damage our national prestige or confidence." |
| Key resources. | Publicly or privately controlled resources essential to the minimal operations of the economy and government. This refers to the four key resources identified in HSPD-7 and the National Infrastructure Protection Plan. These four key resources include: dams; government facilities; commercial facilities; and nuclear reactors, material, and waste. |
| Laboratory Response Network. | National network of local, State, and Federal public health, food testing, veterinary diagnostic, and environmental testing |

DRAFT

laboratories supported by CDC that provide the laboratory infrastructure and capacity to respond to biological and chemical terrorism, and other public health emergencies.

Layered protective measures.

Rather than focusing on a single measure for mitigation, a layered approach uses an array of measures deployed in tandem, to reduce overall risk. A layered, system-wide, integrated approach to risk reduction includes redundant measures and is designed to avoid a single point of failure. Examples include, implementing pre-departure, en route, and arrival screening measures for international travel.

Live bird marketing system (LBMS).

Live poultry markets in the United States and the poultry distributors and poultry production premises that supply those markets.

Local education agencies (LEAs).

Local (county, city, district) school boards.

Localities.

Refers to local (county, city, municipal) governments and agencies.

National Animal Health Laboratory Network (NAHLN).

Refers to a cooperative effort among the American Association of Veterinary Laboratory Diagnosticians, the USDA Animal and Plant Health Inspection Service, and the USDA Cooperative State Research, Education and Extension Service to coordinate the capabilities of Federal, State, and university veterinary diagnostic laboratories to enhance the response to animal health events.

National Poultry Improvement Plan (NPIP).

Cooperative industry-State-Federal program that establishes standards for the evaluation of poultry with respect to freedom from certain diseases.

National veterinary services.

The national veterinary administration, all the veterinary authorities, and all persons authorized, registered, or licensed by the veterinary statutory body of a country to prevent and/or control animal diseases.

National Veterinary Stockpile (NVS).

Refers to the supply of materiel, including vaccine, that is appropriate for a response to a damaging animal disease and capable of deployment within 24 hours of an outbreak; the stockpile is maintained by USDA's Animal and Plant Health Inspection Service.

Orders of succession.

Refers to the sequential order or ranking of individuals who would assume authority and responsibility if the leadership is incapacitated or unavailable.

DRAFT

| | |
|-----------------------------------|---|
| Outbreak. | An epidemic limited to localized increase in the incidence of disease, e.g., in a village, town, or closed institution; a cluster of cases of an infectious disease. |
| Outbreak containment. | Disruption of epidemic amplification through the use of medical countermeasures and infection control techniques; “containment” also refers more generally to delaying the geospatial spread of an epidemic. |
| Pandemic. | A worldwide epidemic when a new or novel strain of influenza virus emerges in which humans have little or no immunity, and develops the ability to infect and be passed between humans. |
| Pandemic vaccine. | Vaccine for specific influenza virus strain that has evolved the capacity for sustained and efficient human-to-human transmission. This vaccine can only be developed once the pandemic strain emerges. |
| Pathogenicity. | Refers to the condition or quality of being pathogenic, or the ability to cause disease. |
| Post-exposure prophylaxis. | The use of antiviral medications in individuals exposed to others with influenza to prevent disease transmission. |
| Pre-pandemic vaccine. | Vaccine against strains of influenza virus in animals that have caused isolated infections in humans of pandemic potential. This vaccine is prepared prior to the emergence of a pandemic strain and may be a good or poor match (and hence of greater or lesser protection) for the pandemic strain that ultimately emerges. |
| Priority country. | A priority country is a high-risk or affected country that merits special attention because of the severity of the outbreak, its strategic importance, its regional role, or foreign policy priorities. |
| Procedure mask. | Disposable face mask that is either flat or pleated and is affixed to the head with ear loops. |
| Prophylaxis. | Prevention of disease or of a process that can lead to disease. With respect to pandemic influenza this specifically refers to the administration of antiviral medications to healthy individuals for the prevention of influenza. |
| Quarantine. | Separation of individuals who have been exposed to an infection but are not yet ill from others who have not been exposed to the transmissible infection. |
| Rapid diagnostic test. | Medical test for rapidly confirming the presence of infection with a specific influenza strain. |
| Reconstitution. | Refers to the process by which an organization resumes normal operations. |
| Respirator. | Refers to a particulate respirator, commonly known as N-95 respirator, often used in hospitals to protect against infectious agents. Particulate respirators are “air-purifying |

DRAFT

| | |
|-------------------------------|---|
| | respirators” because they clean particles out of the air as one breathes. |
| R 0 . | Represents the basic reproductive rate of a pathogen, i.e., the average number of secondary infections caused by an infected individual within a given social context. An $R_0 = 2$ means that infected individuals, on average, transmit infection to two other people, so that every generation of disease transmission doubles the number of people infected. R_0 will change during an epidemic as public health interventions are applied, the behavior of individuals changes, and as the pool of persons susceptible to the disease is depleted. |
| Schools (K-12). | Refers to schools, both public and private, spanning the grades kindergarten through 12th grade (elementary through high school). |
| Situational awareness. | Situational awareness is the ability to identify, process, and comprehend the critical elements of information about what is happening during an evolving influenza pandemic. |
| Snow days. | Refers to days that the authorities recommend that individuals and families limit social contacts by remaining within their households to reduce community disease transmission of infection. |
| Social distancing. | Infection control strategies that reduce the duration and/or intimacy of social contacts and thereby limit the transmission of influenza. There are two basic categories of intervention: transmission interventions, such as the use of facemasks, may reduce the likelihood of casual social contacts resulting in disease transmission; contact interventions, such as closing schools or canceling large gatherings, eliminate or reduce the likelihood of contact with infected individuals. |
| Standard of care. | The level of care that is reasonably expected under the extant circumstances. |
| Surge capacity. | Refers to the ability to expand provision of services beyond normal capacity to meet transient increases in demand. Surge capacity within a medical context denotes the ability of health care or laboratory facilities to provide care or services above their usual capacity, or to expand manufacturing capacity of essential medical materiel (e.g., vaccine) to meet increased demand. |
| Surgical mask. | Refers to disposable face masks that comes 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 to 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 |

DRAFT

head with a single elastic and has a flexible adjustment for the nose bridge.

Symptomatic.

Symptomatic means with symptoms of influenza.

Targeted passenger travel restrictions.

Travel restrictions to the United States targeting travelers from a high-risk area or from areas unable to meet U.S. criteria for departure and en route screening.

Telecommuting.

Working from home or an alternate site and avoiding coming to the workplace through telecommunication (computer access).

Telework.

Refers to the activity of working away (home) from the workplace through telecommunication (computer access).

T_g.

Generation time of a pathogen, or how long it takes for infected individuals to infect others. Epidemics caused by a pathogen with an $R_0 = 2$ and a $T_g = 2$ days will double in size about every 2 days, epidemics caused by a pathogen with an $R_0 = 3$ and a $T_g = 9$ days will triple in size about every 9 days, etc.

Treatment course (antiviral medications).

The course of antiviral medication prescribed as treatment (not prophylaxis) for a person infected with an agent susceptible to the antiviral medication. For oseltamivir, a treatment course for seasonal influenza is 10 capsules, administered twice daily for 5 days (a prophylaxis course is much greater, typically 42 capsules taken once daily for 42 days).

Treatment course (vaccine).

The course of vaccine (typically two injections) required to induce protective immunity against the target of the vaccine.

Universities.

Refers to educational institutions post 12th grade (post high school).

U.S. travelers from affected areas.

U.S. citizens traveling to the United States from countries or region where an outbreak (influenza pandemic) has occurred.

Virulence.

Virulence refers to the disease-evoking severity of influenza.

Wave.

The period during which an outbreak or epidemic occurs either within a community or aggregated across a larger geographical area. The disease wave includes the time during which disease occurrence increases rapidly, peaks, and declines back toward baseline.

DRAFT

ADDENDUM 2 – RESOURCES AND REFERENCES

STATE

- Pandemic Influenza Preparedness Plan for Maryland, Version 5
- Planning Resolution between Secretary of Health and Human Services Mike Leavitt and Governor Robert Ehrlich Jr. of Maryland, www.pandemicflu.gov/plan/states/planningResolutionMD.html
- Mandatory Registration to Speed Response to Avian Disease, www.americanfarm.com/TopStory4.18.06i.html
- Timeline of Pandemic Influenza Preparedness Activities by DHMH
- Maryland Draft Isolation and Quarantine Guidelines, Draft version 2 March 1, 2006
- Pandemic Influenza and Avian Influenza, Maryland Prepares, Status Report, May 2006
- Maryland Improving Readiness for Possible Pandemic Flu, News Release, May 9, 2006

FEDERAL

- The National Response Plan
- The National Incident Management System
- Emergency Support Function 8
- The National Strategy for Pandemic Influenza
- Implementation Plan for the National Strategy for Pandemic Influenza
- HHS Pandemic Influenza Plan
- HHS Pandemic Influenza Planning Checklists
- DHHS Pandemic Planning Update, March 13, 2006
- Pandemicflu.gov
- Key Facts About Avian Influenza, www.bt.cdc.gov/scripts/emailprint/print.asp
- USGS News Release, March 9, 2006: USGS Testing Wild Birds for Avian Influenza

WORLD HEALTH ORGANIZATION

- WHO Checklist for Influenza Pandemic Preparedness Planning
- WHO Global Influenza Preparedness Plan
- Responding to the Avian Influenza Pandemic Threat: Recommended Strategic Actions

DRAFT

ADDENDUM 2 cont. RESOURCES AND REFERENCES

- Fifty-ninth World Health Assembly, April 24, 2006: Strengthening Pandemic-Influenza Preparedness and Response, Including Application of the International Health Regulations (2005), Report by the Secretariat
- Avian Influenza – Situation in Indonesia –Update 14, May 23, 2006

OTHER

Johns Hopkins Bloomberg School of Public Health Public Health News Center, April 17, 2006: Nearly Half of Public Health Employees Unlikely to Work During Pandemic

New York State Pandemic Influenza Plan, April 2006. This plan was instrumental as a model for DHMH's pandemic influenza planning.

DRAFT

ADDENDUM 3 – EMERGENCY POINTS OF CONTACT

PURPOSE: This checklist is to be used as a reference to ensure that all parties are properly notified in the case of a public health threat or emergency. Please note that this checklist is to be used as a guide only; depending on the event, all or only some of the following parties may need to be contacted.

| <i>Crisis Communications Checklist</i> | Phone | Page/cell | Email |
|--|--------------|--------------------------------|--|
| DHMH | | | |
| <input type="checkbox"/> Physician on Call | | 410.407.6154 / 410.795.7365 | 4104076154@archwireless.net |
| Text Page Notification Group Includes: Emergency Preparedness and Response on call, physician on call | | Notification Group on BT pager | |
| <input type="checkbox"/> Maryland SNS Coordinator | | 800.455.5028 | 8004555028@archwireless.net |
| <input type="checkbox"/> State Epidemiologist | 410.767.6700 | 410.408.3941 | |
| <input type="checkbox"/> Division of Outbreak Investigation | 410.767.6700 | 410.795.7365 | |
| <input type="checkbox"/> Division of Communicable Disease Surveillance | 410.767.6700 | | |
| <input type="checkbox"/> EDCP First On-Call | 410.767.6700 | 410.716.8194 / 410.795.7365 | krickjo@dhmh.state.md.us |

DRAFT

| <i>Crisis Communications Checklist</i> | Phone | Page/cell | Email |
|---|---|------------------------------|-----------------------------|
| <input type="checkbox"/> Infection Control Nurse Consultant | 410.767.6704 | | |
| <input type="checkbox"/> Laboratories Administration | 410.471.0595 | 410.471.0595 | 4104710595@archwireless.net |
| <input type="checkbox"/> Office of Public Relations | 410.767.6490 | 800.349.3885 410.471.0842 | |
| <input type="checkbox"/> Office of Local Health | 410.767.5045 | | |
| <input type="checkbox"/> Office of Primary Care and Rural Health | 410.0767.8447 | 410.408.7380 | |
| State Partners | | | |
| <input type="checkbox"/> MEMA | 410.517.3600 | | |
| <input type="checkbox"/> MIEMSS/EMRC | 410.706.7814 | | |
| <input type="checkbox"/> MCAC | 301.586.4603 800.492.8477 | | |
| <input type="checkbox"/> Department of Agriculture; State Veterinarian | 410.841.5810 443.336.7346 (cell) | | |
| <input type="checkbox"/> Department of Environment | 410.537.3000 800.633.6101 Emergency: 866.633.4686 | | |

DRAFT

| <i>Crisis Communications Checklist</i> | Phone | Page/cell | Email |
|--|--|------------------|--------------|
| <input type="checkbox"/> Department of Natural Resources | 877.620.8367 | | |
| <input type="checkbox"/> OCME | 410.333.3225 | | |
| Regional Partners | | | |
| <input type="checkbox"/> DC Department of Health | Business hours: 202.671.0733 / 202.442.5400 After hours: 202.727.1000 | | |
| <input type="checkbox"/> VA Department of Health | Business Hours: 804.864.8141 After hours: 866.820.9611 | | |
| <input type="checkbox"/> PA Department of Health | 877.724.3258 After hours: 717.737.5349 | | |
| <input type="checkbox"/> DE Department of Health | 302.744.4700 | | |
| <input type="checkbox"/> WV Department of Health | 304.558.0684 After hours: 304.540.5719 | 877.364.5571 | |