

# **Pandemic Influenza: Clinical and Public Health Guidelines for the Military Health System**

**Swine-Origin Influenza A  
(H1N1) Virus in 2009**



May 2009

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## INTRODUCTION

The Military Health System must be prepared to rapidly evaluate and effectively manage patients with suspected or confirmed pandemic influenza throughout the entire range of military operations and health care settings. In addition to providing health care, efforts must limit the spread of disease among Service members, their families, local communities, and the workplace. These guidelines represent a recommended approach for the Military Health System with respect to patient evaluation and management, laboratory planning and diagnostics, occupational safety and health for healthcare and medical research personnel, community disease containment, and patient care/transport during military deployments. Unlike the previous version of this guidance published in October 2008, which addressed the risk of highly pathogenic avian influenza, this publication focuses on the specific threat from swine-origin influenza A (H1N1) virus (S-OIV), in addition to the general threat from any novel influenza virus.

These guidelines are based upon pandemic influenza clinical guidelines published by the Department of Health and Human Services, as well as advice from subject matter experts throughout the Department of Defense and other federal agencies. Target audiences include clinicians, laboratory workers, and other health care personnel; medical planners; public health emergency officers (PHEOs); as well as commanders and senior leaders.

These clinical guidelines use the pandemic influenza staging construct established in the “National Strategy for Pandemic Influenza – Implementation Plan” (May 2006). Other phasing constructs may be used for planning purposes (e.g., Joint Planning and Execution System, World Health Organization, etc), but these were synchronized with the Federal Government Response Stages described in the National Strategy for Pandemic Influenza – Implementation Plan.

This guidance supersedes the Department of Defense Influenza Pandemic Preparation and Response Health Policy Guidance (January 25, 2005), Appendix 1 (Sections IV, V, VI, VII, and VIII), Appendix 2, and Appendix 3, and updates the Department of Defense "Pandemic Influenza: Clinical and Public Health Guidelines for the Military Health System", published in October 2008, and focusing on the threat of Highly Pathogenic Avian Influenza (H5N1). These guidelines are posted on the DoD Pandemic Influenza Watchboard, which is indexed at [http://fhp.osd.mil/aiWatchboard/preparedness\\_and\\_communication.jsp#dodpolicies](http://fhp.osd.mil/aiWatchboard/preparedness_and_communication.jsp#dodpolicies). Updates to the guidelines will be made and posted as necessary to the website, including any change in standards of clinical practice, likely pandemic strain candidate(s) and laboratory diagnostics, case definitions, recommended infection control practices and personal protection equipment, etc.

# **I. Guidelines for Patient Evaluation and Management (E&M)**

## **A. Federal Government Response Stages 0-2 (WHO Phases 1-5)**

### **1. Evaluation of Patients with Influenza-like Illness (ILI)**

Early identification of cases of pandemic influenza (PI) may help slow the spread of influenza within a community, as well as benefit the individual patient. Rapid initiation of treatment resulting from early identification can avert potentially severe complications.

During early stages, human infections with suspected PI will be an uncommon cause of Influenza-Like Illness, or ILI. The US Centers for Disease Control and Prevention defines an "ILI" as "fever (temperature of 100°F [37.8°C] or greater) and a cough and/or a sore throat in the absence of a KNOWN cause other than influenza."

Therefore, both clinical and epidemiologic criteria associated with novel influenza virus infection risk should be met before such a cause is considered or investigated.

In individuals with a high risk of exposure, epidemiologic criteria may be sufficient to initiate further diagnostic measures even if clinical criteria are not fully met.

All suspected, presumptive positive, or confirmed cases of PI shall be reported to the respective military installation/command Public Health Emergency Officer (PHEO). The PHEO will then notify, through established reporting channels, the appropriate chain-of-command, the Centers for Disease Control and Prevention (CDC), State/local government public health agencies, and host nations if OCONUS (subject to Status of Forces Agreement or other international agreements). Emergency health powers, including restriction of movement (e.g., isolation and quarantine) and use of other disease containment strategies (e.g., social distancing to include telecommuting, snow days, mission essential personnel only, shelter-in-place, etc.) may be exercised by the installation/military commander in consultation with the PHEO.

In addition to being responsible for the evaluation, diagnosis, and treatment of suspected/confirmed PI cases, clinicians shall assist PHEOs with the identification of potentially exposed contacts. In general, individuals are considered at risk when they are in close contact with a case at any time beginning 24-48 hours before the onset of illness and up to 5 days after the onset of symptoms in adults and the duration of illness for children and immunocompromised patients. Close contacts might include household and social contacts, family members, workplace or school contacts, fellow travelers, and/or healthcare personnel.

#### **a. Epidemiologic Criteria**

- (1) The maximum interval between possible exposure and symptom onset is set at 10 days.
- (2) Exposure risk (Travel). Individuals have a travel risk if they have:
  - (a) recently visited or lived in a geographic where a human case of novel influenza virus infection has been confirmed. (for a regularly updated listing of affected countries, the World Health Organization (WHO) web site at <http://www.who.int/en/>) and/or

- (b) had close contact with an individual with confirmed or suspected novel influenza virus infection.
- (3) Exposure risk (Occupational). Individuals have an occupational risk if they:
  - (a) work on farms or in live animal markets, or process/handle animals infected with known or suspected pathogenic viruses or in high-risk geographic areas,
  - (b) are involved in culling operations of high-risk animals,
  - (c) work in laboratories that contain live animal or novel influenza viruses,
  - (d) are healthcare personnel or others in direct contact with a suspected or confirmed case of PI, or
- (4) **Direct or close contact with suspect animals** in high-risk geographic areas:
- (5) **Close contact with an individual** from an affected area with confirmed or suspected PI is “within 3-6 feet of that individual during the illness.”
- (6) Human influenza viruses circulate worldwide and year-round, including in countries or areas with outbreaks of influenza viruses among animals, and sustained human-to-human transmission of novel influenza viruses of animal origin, such as the 2009 swine-origin influenza A (H1N1) virus (S-OIV). Human influenza virus infection can be a cause of ILI among returned travelers at any time of the year, including during the summer in the United States. This includes travelers returning from areas affected by outbreaks of novel influenza viruses such as the currently circulating (S-OIV) strain.
- (7) The DoD PI Watchboard at [www.dod.mil/pandemicflu](http://www.dod.mil/pandemicflu) provides updated epidemiological information regarding the above.

**b. Clinical Criteria**

- (1) Clinicians should maintain awareness of the most current CDC case definitions by frequently checking the DoD PI Watchboard at [www.dod.mil/pandemicflu](http://www.dod.mil/pandemicflu).
- (2) Case Definitions for Infection with Swine-origin Influenza A (H1N1) Virus (S-OIV) (as of 30 April 2009):
  - (a) A **confirmed case** of S-OIV infection is defined as a person with an **acute febrile respiratory illness** with laboratory confirmed S-OIV infection at CDC by one or more of the following tests:
    - real-time RT-PCR
    - viral culture
  - (b) A **probable case** of S-OIV infection is defined as a person with an **acute febrile respiratory illness** who is positive for influenza A, but negative for H1 and H3 by influenza RT-PCR
  - (c) A **suspected case** of S-OIV infection is defined as a person with **acute febrile respiratory illness** with onset
    - within 7 days of close contact with a person who is a confirmed case of S-OIV infection, or

- within 7 days of travel to community either within the United States or internationally where there are one or more confirmed cases of S-OIV infection, or
  - resides in a community where there are one or more confirmed cases of S-OIV infection;
- (d) **Acute febrile respiratory illness** consists of temperature of  $> 100^{\circ} \text{F}$  ( $>38^{\circ}\text{C}$ ), plus either nasal congestion or runny nose, sore throat, or cough.
- (3) As infection with a novel influenza virus, such as the S-OIV strain, becomes more widespread in the community, CDC recommends that testing be prioritized for those with severe respiratory illness and those at highest risk of complications (<http://www.cdc.gov/h1n1flu/identifyingpatients.htm>). If disease is not widespread locally, patients recommended for PI-specific laboratory evaluation, including an upper respiratory specimen to test for the 2009 swine-origin influenza A (H1N1) virus during Federal Government Response Stages 0-2 (WHO Phases 1-5), include:
- (a) Hospitalized patients with severe acute febrile respiratory illness or ILI, including pneumonia, who meet the above epidemiologic criteria,
- (b) Non-hospitalized patients with acute febrile respiratory illness or ILI and with strong epidemiologic suspicion of S-OIV virus exposure, such as:
- within 7 days of close contact with a person who is a confirmed case of S-OIV infection, or
  - within 7 days of travel to community either within the United States or internationally where there are one or more confirmed cases of S-OIV infection, or
  - resides in a community where there are one or more confirmed cases of S-OIV infection.
- (c) A patient with mild or atypical disease (hospitalized or ambulatory) who has one of the exposures listed above, or
- (d) A patient with severe or fatal respiratory disease whose epidemiologic information is uncertain, unavailable, or otherwise suspicious but does not meet the epidemiologic criteria above.
- (e) In regions with few or no reported cases of S-OIV, consider the following recommendations for testing of the following persons for S-OIV infection with a nasopharyngeal swab by PCR:
- Patients presenting to providers participating in the US Outpatient Influenza-like Illness Surveillance Network (ILINet) who meet the case definition of influenza-like illness (ILI), or
  - Patients with an ILI who have traveled within 7 days to a community either within the United States or internationally where there are one or more confirmed swine influenza A (H1N1) cases, or

- Patients admitted to the hospital with an acute febrile respiratory illness ILI.

c. **Screening Methods for Patients with Suspected Swine-origin Influenza A**

- (1) If S-OIV flu is suspected but has not spread extensively in the community, a nasopharyngeal swab/aspirate or nasal wash/aspirate should be obtained as soon as possible after onset of symptoms.
- (2) If these specimens cannot be collected, a combined nasal swab with an oropharyngeal swab is acceptable.
- (3) For patients who are intubated, an endotracheal aspirate should also be collected.
- (4) Specimens should be placed into sterile viral transport media (VTM) and immediately placed on ice or cold packs or at 4°C (refrigerator) for transport to the laboratory. See Part II, Guidelines for Laboratory Planning and Diagnostics, for laboratory policies on handling and testing of influenza specimens for H1N1.
- (5) Swabs: Ideally, swab specimens should be collected using swabs with a synthetic tip (e.g. polyester or Dacron®) and an aluminum or plastic shaft. Swabs with cotton tips and wooden shafts are not recommended. Specimens collected with swabs made of calcium alginate are not acceptable. The swab specimen collection vials should contain 1-3ml of viral transport medium.
- (6) Handling and shipping of **Clinical Specimens:** All respiratory specimens should be kept at 4°C until they can be placed at -70°C or below. If a -70°C freezer is not available, specimens should be kept at 4°C, preferably no longer than 48 hours. Clinical specimens should be shipped on dry ice in appropriate packaging. See Part II, Guidelines for Laboratory Planning and Diagnostics.

d. **Interpretation of Laboratory Test Results:**

- (1) Alternative diagnoses should be entertained based only on laboratory tests with high positive predictive. At this time infections identified as a untypable Influenza A virus has over a 95% PPV for S-OIV. If an alternate etiology is identified, the possibility of co-infection with a PI virus may still be considered if there is a strong epidemiologic link to exposure.
- (2) If PI laboratory testing results are negative and no alternate diagnosis is established, but the clinical and epidemiologic suspicion remains high, clinicians should consider continuing PI-directed management as described below
- (3) If PI laboratory testing results are negative and an alternative diagnosis is established using a test with a high positive-predictive value, PI-specific isolation precautions (see I.A.2.b(4) below - Infection Control Practices during the Federal Government Response Stages 0-2 (WHO Phases 1-5)) and antiviral drug therapy may be discontinued. This decision should be based upon the absence of a strong epidemiologic link and an explanation of clinical manifestations by the alternative diagnosis.

## **2. Management of Patients with Suspected Pandemic Influenza**

### **a. Patient Placement and Transport**

- (1) Respiratory Hygiene/Cough Etiquette infection control measures should be implemented at the first point of contact with a potentially infected person. Patients who are confirmed, probable or suspected cases and present for care at a healthcare facility should be placed directly into individual rooms with the door kept closed. Healthcare personnel interacting with the patients should follow the infection control guidance in this document. For the purposes of this guidance, healthcare personnel are defined as persons, including employees, students, contractors, attending clinicians, and volunteers, whose activities involve contact with patients in a healthcare or laboratory setting.
- (2) Procedures that are likely to generate aerosols (e.g., bronchoscopy, elective intubation, suctioning, administering nebulized medications), should be done in a location with negative pressure air handling whenever feasible. An airborne infection isolation room (AIIR) with negative pressure air handling with 6 to 12 air changes per hour can be used. Air can be exhausted directly outside or be recirculated after filtration by a high efficiency particulate air (HEPA) filter. Facilities should monitor and document the proper negative-pressure function of AIIRs, including those in operating rooms, intensive care units, emergency departments, and procedure rooms.
- (3) Procedures for transport of patients in isolation precautions should be followed. Facilities should also ensure that plans are in place to communicate information about suspected cases that are transferred to other departments in the facility (e.g., radiology, laboratory) and other facilities. The ill person should wear a surgical mask to contain secretions when outside of the patient room, and should be encouraged to perform hand hygiene frequently and follow [respiratory hygiene / cough etiquette practices](#).

### **b. Hospitalization (Inpatient).**

- (1) Admission and Referral Criteria during the Federal Government Response Stages 0-2 (WHO Phases 1-5): Although for some novel influenza viruses, patients fulfilling both epidemiological and clinical case criteria above should be admitted for evaluation, treatment, and isolation, in the current situation evolving in 2009, with the less virulent S-OIV strain, clinical judgment and other sections of these guidelines should be followed when making decisions regarding necessity of hospital admission and treatment with antiviral medications. However, patients in non-traditional or congregate settings (e.g., operational settings, barracks, afloat platforms, etc.) who meet either epidemiological or clinical criteria can be considered for admission to prevent potential spread of disease and provide supportive care.
- (2) The decision to hospitalize a patient is based upon clinical and epidemiological criteria and whether adequate precautions can be taken at the place of residence to prevent the potential spread of infection. In addition to the use of antivirals, clinical management of severe influenza should address prevention of complications, supportive care, and the rapid identification and

treatment of secondary complications (see below). To minimize the spread of disease, restrictive visitor policies will be needed.

- (3) Work-up during the Federal Government Response Stages 0–2 (WHO Phases 1-5): PI viruses may cause 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. However, the characteristic clinical features of the next influenza pandemic cannot be predicted. While it is reasonable to assume that most affected individuals will have the typical features of influenza (e.g., fever, respiratory symptoms, myalgia, and malaise), past pandemics have varied considerably with regard to severity and associated complications.
- (a) Fevers are often higher in children and can lead to febrile seizures. Gastrointestinal manifestations (e.g., vomiting, abdominal pain, and diarrhea) occur more frequently in children. Fever or apnea without other respiratory symptoms might be the only manifestations in young children, particularly in neonates.
- (b) The comprehensive work-up for patients who meet both the clinical and epidemiological criteria should include a PI-specific diagnostic assay (e.g., a Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) for H1N1 cleared by the Food and Drug Administration). For influenza H1N1 diagnosis, available data indicate that oropharyngeal swab specimens. Therefore, if testing is indicated, all of the following respiratory specimens should be collected for pandemic virus testing when feasible: nasopharyngeal wash/aspirate (generally preferred) or swab; throat swab, and for intubated patients, endotracheal aspirate. (Viral culture of specimens from suspected cases of infection with a novel influenza virus should be attempted only in laboratories that meet the biocontainment conditions for biosafety level 3 (BSL-3) with enhancements or higher.) See Section II (Guidelines for Laboratory Diagnostics) regarding laboratory diagnostics testing flow and Section III (Guidelines for Collection of Clinical Specimens) regarding collection of specimens.
- (c) Additional work-up should be guided by clinical indications and may include:
- Tests for other common viral respiratory pathogens (e.g., immunofluorescent antibody testing or PCR for Respiratory Syncytial Virus (RSV), Adenovirus, Parainfluenza, etc.), blood cultures, sputum or endotracheal aspirate Gram stain and culture and, in adults with radiographic evidence of pneumonia, *Legionella* DFA or urinary antigen and pneumococcal urinary antigen testing, in order to rule out alternative diagnoses or secondary bacterial infection in patients. (If alternate etiology is identified, the possibility of co-infection with a novel influenza virus may still be

considered if there is a strong epidemiological link to exposure to a novel influenza virus.)

- Pulse oximetry, chest radiograph, complete blood count with differential, and serum chemistries.
- Acute and convalescent sera for future testing. (Note: Confirm the capability of the supporting laboratory to store serum specimens long-term before collection of such specimens is initiated).

(4) Infection Control Practices for S-OIV during the Federal Government Response Stages 0-2 (WHO Phases 1-5)

(a) When transmission of S-OIV is present in the community (based upon information provided by state and local health departments), these infection control recommendations should apply to all patients with **febrile respiratory illness** (see definition in section I.A.1.b. Clinical Criteria). [*These are suspected cases.*] If the patient is presenting in a community without S-OIV transmission, these infection control recommendations should apply to those patients with **febrile respiratory illness** AND:

- close contact with a person who is a confirmed, probable, or suspected case of swine influenza A (H1N1) virus infection, within the past 7 days [*this may be broader than the definition of suspected case*] OR
- travel to a community either within the United States or internationally where there are one or more confirmed swine influenza A (H1N1) cases within 7 days. [*These are suspected cases.*]

(b) As the situation evolves, the ability to use epidemiologic links to identify potentially infectious patients may be lost, and these infection control recommendations may need to be applied to all patients with **febrile respiratory illness**, since they will all become **suspected cases**, based on the case definitions in section I.A.1.b. Clinical Criteria.

(c) The epidemiologic pattern observed for PI is generally consistent with spread through close contact (i.e., exposure to large respiratory droplets, direct contact, or near-range exposure to airborne aerosols)

(d) **Isolation precautions:**

- Isolate infected individuals by confining patients to a defined area as appropriate for the health care setting.
- Nonsterile gloves and gowns along with eye protection should be donned for all patient care activities for patients being evaluated or in isolation for S-OIV (H1N1), including all health care personnel who enter the patient's room. (See <http://www.cdc.gov/ncidod/dhqp/ppe.html>)

- Gloves and hand hygiene. Maintain adherence to hand hygiene by washing with plain or anti-microbial soap and water, or using alcohol-based products (gels, rinses, or foams) immediately after removing gloves and other equipment and after any contact with respiratory secretions. Use alcohol-based products containing an emollient that does not require the use of water only if hands are not visibly soiled.
- Minimal personal protective equipment (PPE) recommended for S-OIV to enter any patient room/area includes:
  - Respiratory protection:
    - i. National Institute for Occupational Safety and Health (NIOSH)-certified disposable or reusable N-95 (or higher) filtering face piece respirators are recommended for health care personnel during direct patient care activities (e.g., examination, bathing, feeding) and for support staff who may have direct contact with PI patients. Fit-testing is required prior to respirator use. Discard respirators when exiting patient room/area.
    - ii. If necessary, a disposable N-95 respirator can be reused by the same individual with the following precautions: (1) a protective covering such as a medical mask or a clear plastic face shield should be worn over the respirator to protect it from surface contamination; (2) the respirator should be carefully stored between uses; and (3) wearer should wash his/her hands before and after handling the respirator and the device used to shield it.
    - iii. If PI patients are cohorted in a common area or in several rooms on a nursing unit or field location, 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 or respirators when they become moist, damaged, contaminated, or if breathing becomes difficult. Do not wear masks or respirators dangling around neck.
    - iv. Note that this recommendation differs from current infection control guidance for seasonal influenza, which recommends that healthcare personnel wear surgical masks for patient care. The rationale for the use of respiratory protection is that a more conservative approach is needed until more is known about the specific transmission characteristics of this new virus. This recommendation is also outlined in the October 2006 “Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Healthcare Settings during an Influenza Pandemic” <http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html>.

- v. If N-95 (or higher) respirators are not available, surgical masks can provide benefit against large droplet exposure and should be worn for all health care activities involving patients with confirmed or suspected PI. Discard masks when exiting patient room/area.
- vi. FDA-cleared surgical N-95 respirator (or higher) with eye protection, or full face-shields with the N-95 disposable respirator, must be worn during the performance of any aerosol-generating procedures (e.g., endotracheal intubations, suctioning, nebulizer treatment, bronchoscopy, etc.) or where there is potential exposure to blood and bodily fluids
- vii. A loose-fitting powered air-purifying respirator may be used if fit-testing is not possible (for example, if the individual has a beard).
  - Eye protection (goggles or face-shield) when within six feet of the patient(s)
  - Fluid resistant gowns if exposure to body fluids anticipated. Procedures such as intubations and activities that involve holding the patient close (e.g., pediatric settings) are examples of when a gown may be needed when caring for PI patients. A disposable gown made of synthetic fiber or a washable cloth gown may be used. Gowns should be worn only once and then placed in a waste or laundry receptacle, as appropriate, and hand hygiene performed.
- Duration of precautions: Isolation precautions should be continued for seven (7) days from symptom onset or until the resolution of symptoms, whichever is longer. Persons with swine influenza A (H1N1) virus infection should be considered potentially contagious from one day before to 7 days following illness onset. Persons who continue to be ill longer than 7 days after illness onset should be considered potentially contagious until symptoms have resolved. Children, especially younger children, might be contagious for longer periods.
- (e) Limit the contact of nonessential health care personnel (as defined by the medical treatment facility (MTF)) and other individuals (e.g., social visitors) with patients who are ill with PI. Establish a group of clinical and non-clinical healthcare staff prepared to take care of PI patients – ensure this group is adequately educated and provided with appropriate prophylaxis.
- (f) Limit visitors to patients in isolation for swine influenza A virus (H1N1) infection to persons who are necessary for the patient's emotional well-being and care. Visitors who have been in contact with the patient before and during hospitalization are a possible source of S-OIV (H1N1). Therefore, schedule and control visits to allow for appropriate screening for acute respiratory illness before entering the hospital and appropriate instruction on use of personal protective equipment and other precautions

- (e.g., hand hygiene, limiting surfaces touched) while in the patient's room. Visitors should be instructed to limit their movement within the facility
- (g) Schedule procedures/appointments of symptomatic patients at end-of-day or in a cohort limited to those with like symptoms.
  - (h) It may be beneficial to maintain spatial separation in all common areas (i.e., sit or stand as far away as possible—at least 3-6 feet—from possibly infectious individuals) to limit contact between symptomatic and non-symptomatic individuals.
  - (i) If feasible, use dedicated equipment such as stethoscopes, disposable blood pressure cuffs, disposable thermometers, etc.
  - (j) Single use patient care items are recommended when possible.
  - (k) Reusable devices should be appropriately cleaned with a hospital-approved disinfectant that is EPA-approved before removing it from the patient room.
  - (l) High-touch surfaces will need to be cleaned more frequently throughout the day to reduce the risk of indirect transmission.
  - (m) There are no special guidelines under PIP for the management of regulated medical waste or trash; soiled linen and laundry; dishes and eating utensils; environmental cleaning and disinfection; or for postmortem care. Follow facility-specific procedures and/or local or State regulations. Begin to plan for shortages of personnel and logistical support during the pandemic period (e.g., inadequate staffing, housekeeping support, overflowing linen/trash, food services, mortuary care, and other services/supplies).
  - (n) Negative pressure isolation is not required for routine patient care of individuals with PI. If possible, airborne infection isolation rooms should be used when performing high-risk aerosol-generating procedures. If work flow, timing, resources, availability, or other factors prevent the use of airborne infection isolation rooms, it is prudent to conduct these activities in a private room (with the door closed) or other enclosed area, if possible, and to limit personnel in the room to the minimum number necessary to perform the procedure properly.
  - (o) Respiratory hygiene/cough etiquette:
    - Enforce use of surgical masks by symptomatic individuals in common areas (e.g., waiting rooms in physician offices or emergency departments) and when being transported (e.g., in emergency vehicles, within Military Treatment Facilities (MTFs))
    - Educate healthcare facility staff, patients, and visitors on the importance of containing respiratory secretions to help prevent the transmission of influenza and other respiratory viruses. 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 individuals in the healthcare facility.

- (p) Monitoring of Health Care Providers: In communities where swine influenza A (H1N1) virus transmission is occurring, healthcare personnel should be monitored daily for signs and symptoms of febrile respiratory illness. Healthcare personnel who develop these symptoms should be instructed not to report to work, or if at work, should cease patient care activities and notify their supervisor and infection control personnel. In communities without H1N1 virus transmission, health care personnel working in areas of a facility where there are patients being assessed or isolated for H1N1 should be monitored daily for signs and symptoms of febrile respiratory infection. This would include personnel exposed to patients in an outpatient setting or the emergency department. Health care personnel who develop these symptoms should be instructed not to report to work, or if at work, to cease patient care activities and notify their supervisor and infection control personnel. Health care personnel without evidence of a febrile respiratory illness may continue to work. Asymptomatic health care personnel who have had an unprotected exposure to H1N1 may also continue to work if they are started on antiviral prophylaxis.
  - (q) Establish an “alternative site” location for all high-risk patients (e.g., immunocompromised, pregnant women, etc.) for their healthcare during escalation of the pandemic phase
- (5) Use of antivirals during the Federal Government Response Stages 0-2 (WHO Phases 1-5)
- (a) Although it is DoD policy to adhere to CDC recommendations regarding use of antivirals for pandemic influenza (see Section I.A.2.b.(5)(d), and <http://www.cdc.gov/h1n1flu/recommendations.htm>, there are operational considerations that supersede the CDC recommendations. Refer to the appropriate section of the DoD PI Watchboard at [www.dod.mil/pandemicflu](http://www.dod.mil/pandemicflu) for these exceptions.
  - (b) Usually, antiviral treatment doses should be initiated in patients who meet both epidemiological and clinical criteria for PI due to a novel influenza virus. Such treatment should be initiated as early as possible and targeted to patients who ideally present within 48 hours of symptom onset. Treatment should be continued with positive laboratory confirmation. If laboratory tests are negative but high clinical and epidemiological suspicion remains, treatment should be continued. If laboratory tests are negative and an alternative diagnosis is established, treatment should be discontinued.
  - (c) However, persons with suspected novel S-OIV (H1N1) influenza who present with an uncomplicated febrile illness typically do not require treatment unless they are at higher risk for influenza complications, or are otherwise in a higher category to receive treatment (see section VI). In

areas with limited antiviral medication availability, local public health authorities might provide additional guidance about prioritizing treatment within groups at higher risk for infection. Clinical judgment is an important factor in treatment decisions, and if treatment is indicated for S-OIV (H1N1) virus infection, either oseltamivir or zanamivir are recommended. Recommendations for use of antivirals may change as data on antiviral effectiveness, clinical spectrum of illness, adverse events from antiviral use, and antiviral susceptibility data become available.

(d) Recommendations of the CDC for treatment of the S-OIV with antiviral medications are currently limited to:

- All hospitalized patients with confirmed, probable or suspected novel influenza (H1N1).
- Patients who are at higher risk for seasonal influenza complications (see above).
- If a patient is not in a high-risk group or is not hospitalized, healthcare providers should use clinical judgment to guide treatment decisions, and when evaluating children should be aware that the risk for severe complications from seasonal influenza among children younger than 5 years old is highest among children younger than 2 years old.
- Many patients who have had novel influenza (H1N1) virus infection, but who are not in a high-risk group, have had a self-limited respiratory illness similar to typical seasonal influenza. For most of these patients, the benefits of using antivirals may be modest. Therefore, testing, treatment and chemoprophylaxis efforts should be directed primarily at persons who are hospitalized or at higher risk for influenza complications.
- Once the decision to administer antiviral treatment is made, treatment with zanamivir or oseltamivir should be initiated as soon as possible after the onset of symptoms. Evidence for benefits from antiviral treatment in studies of seasonal influenza is strongest when treatment is started within 48 hours of illness onset. However, some studies of oseltamivir treatment of hospitalized patients with seasonal influenza have indicated benefit, including reductions in mortality or duration of hospitalization even for patients whose treatment was started more than 48 hours after illness onset. Recommended duration of treatment is five days. Antiviral doses recommended for treatment of novel H1N1 influenza virus infection in adults or children 1 year of age or older are the same as those recommended for seasonal influenza ([Table 1](#)). Oseltamivir use for children <1 year old was recently approved by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA), and dosing for these children is age-based ([Table 2](#)) (<http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>).

- Note: Areas that continue to have seasonal influenza activity, especially those with circulation of oseltamivir-resistant seasonal human influenza A (H1N1) viruses, might prefer to use either zanamivir or a combination of oseltamivir and rimantadine or amantadine to provide adequate empiric treatment or chemoprophylaxis for patients who might have seasonal human influenza A (H1N1) virus infection.
- (e) Coordinate with installation/command PHEO and local public health authorities in considering whether it is necessary and feasible to trace a patient's close contacts (e.g., household contacts, healthcare personnel, workmates, fellow passengers) and provide them with post-exposure antiviral prophylaxis (duration generally consists of at least 10 days.)
  - (f) Because the supply of antivirals may be limited, and the development of resistance is likely to increase with overuse, criteria for antiviral use should be enforced by the MTF (e.g., Pharmacy and Therapeutics Committee, Infectious Diseases Department use authorization, etc.).
  - (g) Serious adverse events associated with the use of antiviral drugs for prophylaxis and treatment of influenza should be reported to the MTF Pharmacy and Therapeutics committee and to the Food and Drug Administration using the MedWatch monitoring program.
- (6) Complications of influenza during the Federal Government Response Stages 0-2 (WHO Phases 1-5)
- (a) Patients may present with primary viral pneumonia, often with Acute Respiratory Distress Syndrome. Primary influenza pneumonia usually begins abruptly, with rapid progression to severe pulmonary disease within 1 - 4 days. Recovery may take 1 - 2 weeks or longer.
  - (b) Exacerbations of underlying chronic diseases are among the most common serious complications of influenza. Complications are frequently related to co-morbid conditions, especially cardiac and respiratory disease. Typical influenza symptoms might be brief or minimal compared to the exacerbation of the underlying disease, particularly in the elderly. Other complications of influenza may include:
    - systemic inflammatory response syndrome
    - toxic shock syndrome without bacterial co-infection
    - bronchiolitis, laryngotracheobronchitis, and otitis media (in children)
    - peri- and myocarditis, coronary vasculitis, and arrhythmia
    - myositis that can progress to rhabdomyolysis and renal failure in some cases.
    - Reyes Syndrome

- febrile seizures (in children)
  - encephalopathy
  - Guillain-Barre Syndrome and transverse myelitis
  - gastrointestinal manifestations including transient hepatic inflammation in rare circumstances.
  - bacterial sinusitis
- (c) Secondary bacterial pneumonia occurs frequently and 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 sputum smears positive for leukocytes and bacteria. The most commonly isolated pathogens are *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Streptococcus pyogenes*, and *Haemophilus influenzae*. *S. aureus* also can present as a concurrent pneumonia with influenza.
- (d) Use extended spectrum macrolides and fluoroquinolones to treat community- acquired pneumonias (CAP). Doxycycline, amoxicillin/clavulanate, and 3<sup>rd</sup> generation cephalosporins such as ceftriaxone are alternative agents that have reasonable activity against *S. pneumoniae*, *S. pyogenes*, *S. aureus*, and *H. influenzae*. *S. aureus* (including community-acquired and healthcare-acquired methicillin-resistant *S. aureus* or MRSA) and *H. influenzae* can also be treated with trimethoprim-sulfamethoxazole.
- (e) In order to reduce the incidence of post-influenza secondary bacterial infections, maximize vaccination against *S. pneumoniae*, *Neisseria meningitidis*, and *H. influenzae* in accordance with the current CDC Advisory Committee on Immunization Practice (ACIP) guidelines and Service immunization regulations.<sup>1</sup>
- (f) Sepsis caused by invasive coinfection with *S. aureus*, including Methicillin Resistant *S. aureus* (MRSA), or other bacteria, such as *N. meningitidis*, has been reported. Antibiotic therapy for these infections should be guided by local resistance patterns.
- (g) Prevent healthcare-associated infections (HAIs) by strict adherence to infection prevention and control practices. Antibiotic therapy for HAIs should be guided by local resistance patterns.
- c. **Hospitalization (Intensive Care Unit):** Follow local MTF policy regarding admission and discharge criteria, patient care, and support.
- d. **Outpatient/Home/Congregate Housing:** Generally, for a novel influenza virus whose virulence is still poorly defined, Patients who meet epidemiological criteria, but not the clinical criteria above, can be sent home. The MTFs shall

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<sup>1</sup> Air Force Joint Instruction 48-110; Army Regulation 40-562; BUMEDINST 6230.15; Coast Guard COMDTINST M6230.4E.

develop a system to track and follow up these patients within 24 hours. Those patients in non-traditional or congregate settings (e.g., barracks, deployed settings) may be considered for admission. If patients develop symptoms consistent with clinical criteria, they should be instructed to limit exposure to others and to immediately contact their provider for instructions regarding prompt referral and evaluation. MTFs shall establish 24/7 systems to receive incoming calls and provide telephonic consultation (e.g., command duty desk, nurse advice line, etc.).

#### (1) Infection Control Practices

- (a) Physically separate the patient with influenza from non-ill individuals living in the home as much as possible, preferably in a separate room with a designated primary caregiver.
- (b) When care is provided by a household member, basic infection control practices must be emphasized (e.g., segregating the ill patient, hand hygiene, and cough etiquette). Infection within the household may be minimized if a primary caregiver is designated (ideally this should be someone who does not have an underlying condition that places them at increased risk of severe influenza disease).
- (c) Patients should not leave the home during the period when they are most likely to be infectious to others (i.e., for 5 days after onset of symptoms or for the duration of entire illness for children and immunocompromised individuals). 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 a surgical mask if available. Whenever possible, maintain a safe distance (> than 3-6 feet) from others.
- (d) Scrupulous attention to hand hygiene is required after direct or indirect contact with an influenza patient, their belongings/equipment, or the environment in which care is provided. Hand hygiene includes both hand washing with either plain or antimicrobial soap and water or use of alcohol-based products (gels, rinses, foams) containing an emollient that do not require the use of water if hands are not visibly soiled.
- (e) Dishes or utensils should not be reused without cleaning. Soiled dishes and eating utensils can be washed together in a dishwasher or by hand with hot water and soap. Separation of eating utensils for use by a patient with influenza is not necessary.
- (f) Laundry can be washed in a standard washing machine with warm or cold water and detergent. Use of a mechanical dryer is preferred. It is not necessary to separate soiled linen and laundry used by a patient with influenza from other household laundry. Hand hygiene should be performed after handling soiled laundry.

- (g) 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.
  - (h) Perform routine cleaning of environmental surfaces in the home with a household disinfectant. Pay special attention to frequently touched surfaces (e.g., banisters, door-knobs, telephones, keyboards, etc.)
  - (i) Although no studies have assessed the use of masks at home to decrease the spread of infection, use of surgical 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.
- (2) Use of antivirals and other medications (see Section I.A.2.b(5)(d)). The CDC has recommended that for the 2009 S-OIV (H1N1) strain, use of antiviral medications be limited to inpatients and individuals at high-risk for complications. However, these recommendations may change if the characteristics of the virus change over time. Please see the CDC website for the most current recommendations. (See <http://www.cdc.gov/h1n1flu/recommendations.htm>.)

## **B. Federal Government Response Stages 3-6 (WHO Phase 6)**

### **1. Evaluation of Patients with ILI**

During the Pandemic Period, the primary goal is to rapidly triage and identify cases of PI. During this period, MTFs may be overwhelmed with suspected cases, restricting the time and laboratory resources available for evaluation. Evaluation will therefore focus predominantly on clinical and general laboratory findings, with less emphasis on specific viral laboratory diagnostic testing and epidemiologic criteria. All suspected, presumptive positive, or confirmed cases of PI shall be reported to the respective military installation/command PHEO. The PHEO will then notify, through established reporting channels, the appropriate chain-of-command, the CDC, State/local government public health agencies, and host nations if OCONUS (subject to Status of Forces Agreement or other international agreements). The installation/military commander in consultation with the PHEO may exercise emergency health powers, including restriction of movement (e.g., isolation and quarantine) and use of other disease containment strategies (e.g., social distancing, snow days, mission essential personnel only, shelter-in-place, etc.).

#### **a. Epidemiologic Criteria**

- (1) During the Federal Government Response Stages 3-6 (WHO Phase 6), an exposure history will be marginally useful for clinical management when disease is widespread in a community. There will be a relatively high likelihood that any case of ILI during that time period will be PI. Clinical criteria will be sufficient for classifying the patient as a presumptive case of PI.

- (2) Clinicians in communities without PI activity should question suspect cases about recent travel from a community with PI activity or close contact with a suspected or confirmed PI case.
- (3) Clinicians should maintain awareness of the most current CDC case definitions by frequently checking the DoD PI Watchboard at [www.dod.mil/pandemicflu](http://www.dod.mil/pandemicflu)

**b. Clinical Criteria. See I.A.1.b above**

**2. Management of Patients with PI during the Federal Government Response Stages 3-6 (WHO Phase 6)**

**a. Hospitalization (Inpatient)**

- (1) Admission and Referral Criteria during the Federal Government Response Stages 3-6 (WHO Phase 6): Once a pandemic is underway, hospital admission of patients may be limited to those with severe complications who cannot be cared for outside the hospital setting. The decision to hospitalize a patient will be based on the physician's clinical assessment of the patient, as well as the availability of hospital resources and personnel, as well as alternate care facilities. Providers may be required to triage patients and consider limiting the number of admissions and reserving inpatient beds for those most likely to benefit from admission. (For more on this topic, please consult the U.S. Department of Health and Human Services Publication, "Providing Mass Medical Care with Scarce Resources: A Community Planning Guide" at <http://www.ahrq.gov/research/mce/>.) Clinical management of severe influenza should address supportive care and the rapid identification and treatment of secondary complications. Restrictive visitor policies will have to be invoked to minimize disease spread.
- (2) Work-up during the Federal Government Response Stages 3-6 (WHO Phase 6): During a pandemic, a comprehensive work-up may not be indicated for all patients. The work-up (see above work-up during the Federal Government Response Stages 0-2 (WHO Phases 1-5), section I.A.1.) should be guided by clinical indications, epidemiological findings, and resource constraints.
  - (a) Respiratory specimens may be collected for surveillance purposes, including changes in viral prevalence and characterization of emerging antiviral resistance patterns, as directed by DoD.
  - (b) Diagnostic testing to confirm PI might aid in the management of patients (to include cohorting, isolation, and quarantine decisions) at the beginning or end of a wave of a pandemic within a community, but may be optional or unnecessary in the setting of high local prevalence.
- (3) Infection Control Practices. In addition to Federal Government Response Stages 0-2 (WHO Phases 1-5) recommendations (Section I.A.2.b.(4)), the following actions may be indicated:
  - (a) As the scope of a pandemic escalates, it may be beneficial to consider setting up a separate triage area for individuals presenting with symptoms

of respiratory infection. Because not every patient presenting with symptoms will have PI, strict attention to respiratory hygiene/cough etiquette, as well as use of surgical masks on patients with respiratory symptoms, will be important in preventing further spread.

- (b) To the extent possible, both clinical (e.g., physicians, nurses, respiratory therapists, etc.) and non-clinical personnel assigned to cohorted patient care units designated for PI patients should be dedicated for this purpose and should not “float” or otherwise be assigned to other patient care areas for the duration of the pandemic phase. The number of personnel entering the cohorted area should be limited to those necessary for patient care and support.
  - (c) Differentiate truly symptomatic individuals requiring evaluation from “worried well” who should receive information regarding influenza transmission and symptoms.
  - (d) Limit patient movement and transport outside the isolation area to medically necessary purposes. If transport or movement is necessary, ensure that the patient wears a surgical mask. Patients and staff should perform hand hygiene before leaving the room.
  - (e) Once patients with PI are admitted to the hospital, surveillance should be heightened for evidence of transmission to other patients and healthcare personnel. (Once PI is firmly established in a community, this may not be feasible or necessary.)
  - (f) See Section IV (Occupational Health Guidelines for Health Care and Medical Research Personnel) for further infection control practice recommendations specific to healthcare personnel.
  - (g) Implement a plan for shortages of personnel and logistical support during the pandemic phase (e.g., inadequate staffing, housekeeping support, overflowing linen/trash, food services, mortuary care and other services/supplies).
  - (h) Implement the plan for “alternative site” location for all high-risk patients (e.g., immunocompromised, pregnant women, etc.) for their healthcare during escalation of the early pandemic phase.
- (4) Use of Antivirals during the Federal Government Response Stages 3-6 (WHO Phase 6):
- (a) Available antivirals for treatment should be prioritized for patients with PI who present within 48 hours of onset of symptoms. The DoD follows the recommendations of the CDC (see Section I.A.2.b.(5)(d), and <http://www.cdc.gov/h1n1flu/recommendations.htm>), unless there are applicable overriding operational priorities. Oseltamivir use for children <1 year old was recently approved by the U.S. Food and Drug Administration (FDA) (<http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>) under an Emergency Use Authorization (EUA) , and dosing for these children is age-based.

- (b) There are currently no data on the effectiveness of treatment in severely ill patients. If available antiviral drug supplies are very limited, the priority of these patients could be reconsidered based upon the epidemiology of the pandemic and any additional data on effectiveness of antivirals in this population of patients.)
  - (c) If no pandemic vaccine is available, the use of antivirals for prophylaxis should be considered for all healthcare personnel with direct and regular contact with patients with PI and, in consultation with the PHEO, close contacts of PI cases, especially high-risk groups (e.g., pregnant women, immunocompromised individuals, barrack and ship mates, etc.).
- (5) Complications of Influenza during the Federal Government Response Stages 3-6 (WHO Phase 6): In addition to Complications of Influenza during the Federal Government Response Stages 0-2 (WHO Phases 1-5) (I.A.2.a(5)),
- (a) Aggressively identify and treat secondary bacterial infections as resources are available, and
  - (b) Expand existing inventory (stockpile) of formulary stores of medical countermeasures such as antibiotics and other critical medical materiel.
- b. Hospitalization (Intensive Care Unit)**
- (1) Follow local MTF policy regarding critical care unit admission and discharge criteria, patient care, and support. Recognize that critical care beds/mechanical ventilators may become limited and judgments may be needed about using limited resources for patients with the best chances of survival. Effective use of critical care staff and resources will be necessary to achieve the greatest good for the most patients.
  - (2) The principles of antibiotic selection for patients with influenza-related pneumonia are similar to those for the management of sporadic CAP in general, except that adequate coverage for *S. aureus* and hospital-acquired pathogens should be included in any empirical regimen.
  - (3) Data are not available currently on the effectiveness of antivirals in treating severely ill patients with PI. If available antiviral drug supplies are very limited, the priority of these patients could be reconsidered based upon the epidemiology of the pandemic and any additional data on effectiveness of antivirals in this population of patients.
- c. Outpatient/Home/Congregate Housing**
- (1) Infection Control Practices. See also Outpatient Infection Control Practices during Federal Government Response Stages 0-2 (WHO Phases 1-5) (I.A.2.d(1)).
    - (a) Visitors to a residence or domicile should be restricted if individuals in the household are ill with PI.

- (b) Military installations/commands (including MTFs), local health authorities, and the CDC may recommend or enforce restriction of movement and social distancing strategies to decrease exposure to others.
- (2) Use of Antivirals and other medications (see above Hospital-based Use of Antivirals and other medications, Section I.A.2.b.(5)(d)) .

## **II. Guidelines for Laboratory Diagnostics – 2009 H1N1 Flu**

### **A. General Information**

#### **1. Additional References**

- a. HA Policy 99-008, “Policy for DoD Global, Laboratory-Based Influenza Surveillance”
- b. HHS “Pandemic Influenza Plan,” November 2005
- c. AFI 48-105, “Surveillance, Prevention, and Control of Diseases and Conditions of Public Health or Military Significance”
- d. 49 CFR Parts 171-178, Hazardous Materials Regulations
- e. Domestic Mail Manual, Mailing Standard 601.10.17
- f. International Air Transport Association (IATA) Dangerous Goods Regulations
- g. 42 CFR Part 73, “Select Agents and Toxins” as amended in the *Federal Register*, March 18, 2005
- h. 9 CFR Part 121, “Possession, Use, and Transfer of Select Agents and Toxins” as amended in the *Federal Register*, March 18, 2005

#### **2. Surveillance and Diagnostic Testing Goals**

- a. Serve as an early warning system and detect increases in ILI at the local level.
- b. Implement enhanced surveillance for detection of the first U.S. cases of novel influenza virus infection.
- c. Detect the introduction of the virus into local areas and communities.
- d. Facilitate disease containment activities to delay spread within and between local areas and communities
- e. Facilitate clinical treatment by distinguishing patients with influenza from those with other respiratory illnesses.
- f. Monitor the clinical course of affected patients for changes in patterns of secondary bacterial infections.
- g. Facilitate the establishment of cohorts, if used within the medical treatment facility, of patients hospitalized with severe complications of a pandemic influenza (PI) infection.
- h. Monitor changes in the pandemic virus, including development of antiviral resistance.

#### **3. Laboratory Planning Guidance**

- a. Influenza A viruses other than the currently circulating seasonal H1 and H3 subtypes should be considered as potentially pandemic if detected in humans.
  - (1) As the most widely distributed seasonal and novel influenza typing/subtyping assays are distributed by the CDC’s Coordinating Center for Infectious

Diseases, National Center for Immunization and Respiratory Diseases, Influenza Division, the primary national capability for seasonal/novel influenza typing/subtyping resides in the State Public Health Laboratories.

- (a) The influenza virus targets included in the CDC's 5-target FDA-cleared influenza typing/subtyping assay are Flu A, Flu B, seasonal H1, seasonal H3, and Influenza A/H5 (Asian Lineage).
  - (b) The 2009 H1N1 Flu assay developed by the CDC has **NOT** received 510k clearance from the FDA and must be performed IAW an Emergency Use Authorization (EUA) issued by the FDA for use of the assay – see <http://www.fda.gov/cdrh/emergency/H1N1influenza.html> . The 2009 H1N1 reverse transcriptase polymerase chain reaction (RT-PCR) assay is for specific identification of the 2009 H1N1 Flu virus. Activities utilizing this assay must ensure the 'Fact Sheet for Healthcare Providers' and 'Fact Sheet for Patients' are included with reports of the results of the 2009 H1N1 Flu assay IAW guidance contained within the EUA. The influenza targets included in the 2009 H1N1 assay are Flu A, swine Flu A, and swine H1 specific for the 2009 H1N1 Flu virus.
- (2) Currently, the 2009 H1N1 novel influenza virus shows the following typing/subtyping results pattern: Flu A (+), seasonal H1 (-), and seasonal H3 (-) on the 5-target panel, and Flu A (+), sw Flu A (+), and sw H1 (+) on the 2009 H1N1 Flu assay.
- (3) Influenza typing/subtyping services will generally be available at State Public Health Laboratories and within DoD at the U.S. Air Force School of Aerospace Medicine (USAFSAM) and the Naval Health Research Center (NHRC).
- (a) Currently, DoD medical treatment facility (MTF) laboratories should generally refer specimens for the diagnosis of 2009 H1N1 Flu to their State Public Health Laboratory. Referral of specimens to USAFSAM or NHRC for influenza typing/subtyping should be IAW established DoD and/or Service guidance/policy.
  - (b) Plans are ongoing to implement influenza typing/subtyping capability at certain DoD medical center laboratories and, if appropriate for additional capability to support surge operations, at non-MTF laboratories that are registered laboratories within the DoD's Clinical Laboratory Improvement Program (DoD CLIP) and therefore are authorized to perform diagnostic testing and report patient-specific results for patient care purposes. DoD medical center/non-MTF laboratories that come online with influenza typing/subtyping capability will be announced on the DoD Pandemic Influenza Watchboard at <http://fhp.osd.mil/aiWatchboard/> .
  - (c) As DoD medical center/non-MTF laboratories come online with the CDC's 5-target influenza typing/subtyping panel and/or the 2009 H1N1 Flu panel, DoD MTF laboratories may be directed to shift the referral of specimens for diagnosis of the 2009 H1N1 Flu to DoD medical

center/non-MTF laboratories per established geographic support relationships and/or per issuance of DoD and/or Service-specific guidance/policy.

- (d) DoD MTF laboratories that have been contacted by their State Public Health Laboratory and asked to submit specimens to the State will continue referring their specimens to the State Public Health Laboratory unless DoD and/or Service-specific guidance/policy directs referral to DoD activities. If a significant backlog begins to develop at a State Public Health Laboratory, MTF laboratory management staff will contact their respective Service Laboratory Consultant for guidance on shifting referral of specimens.
- b. In an affected community, a pandemic outbreak will last about 6 to 8 weeks. At least two pandemic disease waves are likely.
  - (1) During a pandemic wave in a community, between 25 percent and 35 percent of individuals will become ill. Of those who become ill with influenza, approximately 50 percent will seek outpatient medical care.
  - (2) CDC models estimate an increase in hospitalization and intensive care unit demand of more than 25 percent even in a moderate pandemic.
  - (3) At the peak of the pandemic, significant numbers of the workforce (i.e., up to 40 percent) may be absent due to illness, caring for family members, or staying at home due to fear of becoming infected.
- c. Enhanced surveillance will be conducted during the introduction, initial spread, and first waves of a pandemic.
  - (1) The most intense testing will be necessary during the early stages of a pandemic, when detecting the introduction of the virus into a state or community is the primary goal. Laboratory staff should anticipate shipping a much larger number of specimens in a very short time, especially during the early stages of a pandemic.
  - (2) USAFSAM designated sentinel sites must continue their participation in the DoD influenza surveillance program and ensure submission of surveillance specimens per USAFSAM guidance.
  - (3) Routine febrile respiratory illness surveillance, including influenza surveillance, and avian/PI projects conducted under the direction of NHRC will continue as planned or operationally modified per NHRC guidance.
- d. Shortages of available staff may occur due to increased testing needs for ruling in/ruling out influenza caused by a novel influenza virus (i.e., early in a Pandemic Period); an overall increase in laboratory workload in support of patient care related to secondary complications of PI (e.g., pneumonia, dehydration, and worsening of chronic lung and heart problems); increased mortality and the need for receipt, storage, and release of remains; and staff absences caused by influenza illness among the staff, family member care requirements, or a fear of continued exposure to the PI virus. Medical center laboratory operational capabilities, if the

laboratory is involved in the outbreak/epidemic/pandemic response via influenza typing/subtyping, may be acutely affected. This affect on operational capabilities may be magnified if DoD medical center laboratories participate in the national response and become responsible for novel influenza typing/subtyping in support of State Public Health Laboratory response operations. Possible accommodations for shortages of available staff due to increased workload requirements or personnel absences related to a PI outbreak include the following:

- (1) Cross-train laboratory staff in the areas of the laboratory most likely to be impacted by surge and increased workload requirements.
  - (2) Determine the availability of support from local and State public health laboratories and Veterans Administration hospitals (if located nearby).
  - (3) Consider the curtailment and referral of non-critical testing to commercial reference laboratories.
- e. Laboratory supplies for influenza diagnosis and PI surveillance, PPE, supplies for shipping specimens suspected of containing an infectious substance, and mortuary supplies may be rapidly depleted. The ability to replenish supplies may be limited due to a widespread need for such supplies. On-hand stockage levels of critical supplies and sources of replenishment supplies should be assessed for the ability to sustain necessary operations for a 6 - 8 week period. Trigger points for ordering extra supplies should be determined. Alternative sources of supplies, or the use of acceptable substitute items, should be considered, especially when other laboratories in the community use the same item(s) and source(s) of supply. Cross-leveling of critical supplies during a PI outbreak across various levels of Command and/or Services may be required to meet DoD needs.
- f. High mortality rates expected in a PI outbreak will most likely exceed the autopsy/morgue capabilities of DoD healthcare facilities and their surrounding communities. Emergency plans to expand autopsy/morgue capabilities should be reviewed to determine whether the plans currently in place would accommodate the increase in deaths anticipated should a PI outbreak occur.
- g. Adherence to infection control and personal protective practices used in processing, testing, storing, and shipping specimens that may contain novel influenza viruses must be emphasized by laboratory management personnel. Upon the identification of an index case within the community, increased medical surveillance of laboratory personnel should be immediately implemented.
- h. If a request for clinical laboratory testing support is received from a local civilian hospital's laboratory director or manager or State Public Health Laboratory, the request should be referred through the chain of command to the appropriate level for consideration IAW with DoDD 3025.1 and DoDD 3025.15. If the request for support is approved, related costs should be captured for reimbursement purposes.

#### **4. DoD Influenza/Population-based Surveillance Programs**

- a. USAFSAM – Influenza Surveillance.

- (1) The Surgeon General of the Air Force is the Executive Agent for the DoD influenza surveillance program.
  - (2) The USAFSAM has management responsibility for the DoD influenza surveillance program and coordinates with Service representatives and with the DoD Global Emerging Infections Surveillance and Response System.
  - (3) Any DoD medical treatment facility may participate; however, select sentinel sites are chosen according to their location and mission (i.e., potential for emergence of new strains, importation, future military operations, areas with high service member concentrations, and highly mobile/rapid response units). New sentinel sites are added at the discretion of the USAFSAM.
  - (4) All influenza isolates are typed as A or B and a portion are subtyped using hemagglutination inhibition or polymerase chain reaction procedures. A sample of these isolates also undergoes molecular sequencing. Select isolates and all sequence data are sent to the CDC for further subtyping and antigenic characterization.
  - (5) Further information on the USAFSAM's seasonal influenza surveillance program may be obtained from the program's web site:  
<https://gumbo.brooks.af.mil/pestilence/Influenza/>
- b. NHRC - Population-based surveillance.
- (1) Recruit training center surveillance.
    - (a) Continue program as usual with increases in sampling number and turnaround time as indicated by NHRC.
    - (b) All specimens will undergo influenza and adenovirus testing by PCR. All adenovirus (-) and all influenza (+) specimens will be submitted for viral culture. Twenty percent (20 percent) of adenovirus (+) specimens will also be submitted for viral culture.
  - (2) Shipboard surveillance.
    - (a) Continue program as usual with increased emphasis on shipboard testing using provided equipment/reagents/training and expedited shipping of specimens to NHRC as appropriate (NHRC will arrange expedited shipping if contacted).
    - (b) All specimens are submitted for viral culture.

## **5. General Influenza Testing Guidance**

### **a. Laboratory Management Personnel**

- (1) A rapid antigen test capable of specifically identifying an influenza type A viral infection should be considered for addition to a laboratory's test menu if the rapid antigen test currently in use is not capable of such discrimination.
- (2) The specific testing sites where rapid antigen testing is offered within medical treatment facilities must be reviewed by the Chief, Medical Staff (or designee) and Laboratory Director/Laboratory Manager to ensure rapid antigen testing is

available at the appropriate sites to properly support the facility's PI plan. DoD Clinical Laboratory Improvement Program certificates for laboratories will be requested/modified as required according to the Armed Forces Institute of Pathology Pamphlet 40-24, "Technical Instructions for the DoD Clinical Laboratory Improvement Program."

- (3) The sensitivity and specificity of any rapid antigen test offered should be reviewed with the medical staff to ensure the medical staff is knowledgeable concerning the positive and negative predictive values of the test method and the appropriate use of test results in determining patient care actions given the incidence of influenza in the community. False positive (and true negative) results are more likely to occur when disease prevalence in the community is low; false negative (and true positive) results are more likely to occur when disease prevalence in the community is high. An awareness of the current incidence of influenza in the community should be maintained so appropriate advice concerning interpretation of test results can be provided.
- (4) As new laboratory tests for the identification of a PI virus(es) become available, comply with published DoD guidance on the implementation and use of these tests.
- (5) Ensure that specimen collection/handling instructions for tests utilized for influenza diagnosis and/or surveillance are available to all healthcare personnel.
- (6) As directed by OASD(HA) or Service-specific guidance, if a specimen must be referred to a non-DoD laboratory for further testing and sufficient specimen is available, split the patient specimen and maintain an aliquot of the specimen. The retained aliquot of the specimen will be stored under the conditions required to maintain specimen integrity.
- (7) Ensure that personnel responsible for shipping specimens are trained on shipping procedures and maintain inventories of necessary supplies. An individual(s) trained and certified in shipment of infectious substances must be available. (The individual(s) must be recertified every two years.) The US Army Center for Health Promotion and Preventive Medicine (USACHPPM) provides such training and certification ["Transport of Biomedical Materials" and "Transport of Biomedical Materials (Refresher) On-line"]. Information on this training is provided on the USACHPPM web page at <https://usachppm.apgea.army.mil/TrainCon/datePage.aspx>.
- (8) Confirm support capabilities, novel influenza virus typing/subtyping testing capabilities, and referral arrangements with the nearest State Public Health Laboratory and/or DoD medical center/non-MTF laboratory.
- (9) Sites in OCONUS remote locations should work with their respective Service Laboratory Consultant to identify alternative testing sites if specimens cannot be shipped to a DoD medical center laboratory within a reasonable time frame. Alternative influenza testing sites may include other OCONUS DoD

non-MTF activities, World Health Organization-associated laboratories, or host nation laboratories.

- (10) Emergency contact information for the installation/command PHEO and other local command designated points-of-contact must be readily available.
- (11) Ensure points-of-contact for receiving and reporting results from State Public Health Laboratories and/or DoD medical center/non-MTF laboratories are identified and confirmed.

**b. DoD Medical Center/non-MTF Laboratories**

- (1) As coordinated/provided by the CDC or as developed in-house, establish novel influenza A virus testing capability if consistent with Service-specific guidance and MTF/activity capabilities. Influenza A viruses other than the currently circulating seasonal H1 and H3 subtypes should be considered potentially pandemic if detected in humans. (Laboratory management personnel must ensure compliance with regulatory requirements regarding the use of non-FDA cleared or approved tests for patient care.)
- (2) Accept specimens for testing for novel influenza virus subtypes from DoD and/or non-DoD laboratories IAW the laboratory's geographic support mission and approved requests for support of civilian laboratory/State public health laboratory response operations.
- (3) As directed by OASD(HA) or Service-specific guidance, if a specimen must be referred to a non-DoD laboratory for further testing and sufficient specimen is available, split the patient specimen and maintain an aliquot of the specimen. The retained aliquot of the specimen will be stored under the conditions required to maintain specimen integrity.
- (4) Ensure contact information, information on testing capabilities, and specimen collection and submission guidelines are available to its own health care provider staff and to DoD/non-DoD laboratories in the community or surrounding area that may submit specimens for analysis.
- (5) Emergency contact information for the CDC (for use when needed to report patient case screening information, to consult regarding CDC-distributed influenza typing/subtyping assay results, or to coordinate the submission of specimens), the installation/command PHEO, and other local command-designated points-of-contact must be readily available.
- (6) CDC-distributed influenza typing/subtyping assay-related performance questions should be referred to the point-of-contact identified in the assay protocol. The CDC's on-call epidemiologist can be contacted for questions concerning a suspected PI case and also must be contacted before sending specimens to the CDC. The on-call epidemiologist can be contacted by calling (404) 639-3747/3591, Monday – Friday, 8:30 a.m. – 5:00 p.m., or through the CDC's Emergency Operations Center at (770) 488-7100 at all other times. A CDC case screening and report form (obtained from the Hotline or from Epi-X) that includes the CDC case ID number provided during the phone consultation must be completed by the appropriate hospital

personnel (e.g., the PHEO, the patient's healthcare provider, other local command-designated points-of-contact, and/or the laboratory point-of-contact, as necessary) and faxed to the CDC at (888) 232-1322 with a cover sheet that says: "ATTN: Influenza case reporting." CDC staff will assist, as needed, in completing the form.

- (7) Identify and confirm points-of-contact for reporting results to referring laboratories, and receiving and reporting results from the State Public Health Laboratory and/or other DoD medical center/non-MTF laboratories.

## **B. Testing Flow and Reporting Procedures**

### **1. Testing Flow – PI Virus Exposure Risk Factors Are Not Present**

Routine diagnostic test procedures (e.g., rapid antigen test, viral culture, direct or indirect immunofluorescence antibody assays, and hemagglutination/hemagglutination inhibition tests) are performed as requested/required for patient care on patients *without* 2009 H1N1 novel influenza virus exposure risk factors (refer to CDC's 2009 H1N1 Guidance for Professionals web page at <http://www.cdc.gov/h1n1flu/guidance/> for up-to-date epidemiologic and clinical risk criteria). No change to normal operations.

### **2. Testing Flow – PI Virus Exposure Risk Factors Are Present**

#### **a. Heightened vigilance for ILI patients at increased risk of infection with the 2009 H1N1 or other novel influenza viruses**

- (1) The health care provider must ensure that appropriate supervisory personnel in the laboratory (e.g., the Chief, Lab Manager, or Non-Commissioned Officer-in-charge (NCOIC) within the Department of Pathology/Laboratory, or the Chief, NCOIC, or civilian supervisor within the Microbiology Section) are alerted regarding the submission of a specimen from a patient with PI exposure risk factors.
- (2) Diagnostic laboratory work on clinical specimens from patients who are suspected cases of 2009 H1N1 influenza virus infection should be conducted in a biosafety level 2 (BSL-2) laboratory. All sample manipulations should be done inside a biosafety cabinet (BSC). NOTE: This guidance is *not* for clinics or clinicians performing rapid influenza antigen tests.
- (3) Viral isolation on clinical specimens from patients who are suspected cases of 2009 H1N1 influenza virus infection should be performed in a BSL-2 laboratory with BSL-3 safety practices.

#### **b. Flow of testing for ILI patient with 2009 H1N1 or other novel influenza virus infection risk**

- (1) Rapid antigen test (testing may include, when available, an immunofluorescence assay performed on an original clinical sample) is requested and performed.
- (2) Because the sensitivity of rapid antigen tests might not be optimal, laboratory management personnel should warn clinical providers that they should take

the test's positive and negative predictive values into consideration when interpreting test results. A negative test result (especially by a rapid antigen test) might not rule out influenza and should not affect patient management or infection control decisions. False negative tests could result from suboptimal specimen collection conditions, viral shedding that is not detectable, or the sensitivity of the test.

- (3) When assessing whether a patient is infected with a novel influenza virus, both negative and positive rapid antigen influenza test (and immunofluorescence assay, if performed) results should be interpreted with caution. A negative rapid antigen influenza test result does not necessarily exclude human infection with either seasonal or novel influenza type A viruses due to potential sensitivity problems. A positive rapid antigen influenza test result could be a false positive or represent infection with either seasonal or novel influenza A viruses.
  - (a) All specimens with a Flu A (+) rapid antigen (or immunofluorescence assay) result from patients with suspected 2009 H1N1 Flu infections should be referred for influenza typing/subtyping and/or 2009 H1N1 Flu RT-PCR testing.
  - (b) Specimens with a Flu A (-) result from patients with epidemiological risk/high clinical suspicion of exposure to the 2009 H1N1 Flu virus should be referred for viral culture or influenza typing/subtyping and/or 2009 H1N1 RT-PCR.
  - (c) If shipment of specimens is required, use guidelines for the shipment of specimens containing infectious substances to prepare the specimen(s) for shipment.
- (4) DoD Medical Center/non-MTF Laboratories. Perform viral culture or RT-PCR or other assays, if available, to identify the presence of the 2009 H1N1 novel influenza virus. Perform RT-PCR procedures in compliance with CDC protocol and safety guidance. The minimum biosafety level for DoD medical center/non-MTF laboratories performing tests to identify the 2009 H1N1 Flu is all BSL-2 requirements with the use of BSL-3 safety practices.
  - (a) The Influenza 5-target RT-PCR panel test developed by the CDC has received 510k clearance from the FDA and is intended for the in vitro qualitative detection of influenza virus RNA either directly in patient respiratory specimens or in viral cultures. The five influenza virus targets included in the CDC's assay are Flu A, Flu B, seasonal H1, seasonal H3, and Influenza A/H5 (Asian Lineage).
  - (b) The 2009 H1N1 Flu assay developed by the CDC has **NOT** received 510k clearance from the FDA and must be performed IAW an EUA issued by the FDA for the CDC-developed 2009 H1N1 RT-PCR. The 2009 H1N1 RT-PCR test is for specific identification of the 2009 H1N1 Flu virus. See <http://www.fda.gov/cdrh/emergency/H1N1influenza.html>

(c) **Positive 2009 H1N1 RT-PCR results should be considered “presumptive positive.”** Definitive identification of the 2009 H1N1 Flu virus requires additional laboratory testing, along with clinical and epidemiologic assessment in consultation with national influenza surveillance experts. Subsequent referral to the CDC for definitive confirmation may be facilitated by contacting CDC’s on-call epidemiologist at (404) 639-3747/3591 (Monday – Friday, 8:30 a.m. – 5:00 p.m.) or the CDC Emergency Operations Center at (770) 488-7100 (all other times).

(5) **If the RT-PCR test result is negative** for the presence of the 2009 H1N1 Flu virus, consultation with the local or State public health laboratory and/or CDC may be required if any concerns regarding the accuracy of the negative test result exist or to determine if referral for further testing is appropriate based on the epidemiological criteria and the inability, through appropriate laboratory tests, to verify an alternative diagnosis.

(6) **If the RT-PCR test result is positive** (including “presumptive positive” if using the CDC-developed 2009 H1N1 Flu virus RT-PCR - result must be confirmed at the CDC) for the presence of the 2009 H1N1 Flu virus, the laboratory point-of-contact must immediately contact their installation’s/command’s PHEO and the CDC for guidance. Assay-related performance questions should be referred to the point-of-contact identified in the CDC’s RT-PCR protocol. The CDC’s on-call epidemiologist can be contacted for questions concerning a suspected PI case and also must be contacted before sending specimens to the CDC. The on-call epidemiologist can be contacted by calling (404) 639-3747/3591, Monday – Friday, 8:30 a.m. – 5:00 p.m., or through the CDC’s Emergency Response Hotline (770) 488-7100) at all other times. A CDC case screening and report form (obtained from the Hotline or from Epi-X) that includes the CDC case ID number provided during the phone consultation must be completed by the appropriate hospital personnel (i.e., the PHEO, the patient’s healthcare provider, other local command-designated points-of-contact, and/or the laboratory point-of-contact, as necessary) and faxed to the CDC at (888) 232-1322 with a cover sheet that says: “ATTN: Influenza case reporting.” CDC staff will assist, as needed, in completing the form.

(7) DoD medical center/non-MTF laboratories should also immediately report to the CDC any influenza cases that test positive for a novel influenza subtype (other than the 2009 H1N1 Flu), or meet the enhanced surveillance case definition in effect at that time and cannot be subtyped because of the lack of appropriate reagents or biocontainment equipment.

**c. Laboratory actions**

Laboratories, per consultation with the supporting DoD medical center/non-MTF laboratory and/or the CDC, should send original clinical specimens to the CDC if:

- (1) A sample tested by the nearest State Public Health Laboratory or DoD medical center/non-MTF laboratory is positive for the 2009 H1N1 Flu virus; or
- (2) 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<sup>2</sup>, is negative for seasonal influenza A (H1) and A (H3), and the referring jurisdiction is not equipped to test for specific strains; or
- (3) The referring jurisdiction is not equipped to test samples for novel influenza viruses by RT-PCR and is requesting testing at CDC.
- (4) To prepare the specimen(s) for shipment, use guidelines for the shipment of specimens containing infectious substances.

**d. After the Pandemic Virus has been Identified**

After the pandemic virus has been identified in the community, laboratory management personnel will coordinate with the State Public Health Laboratory and/or the DoD medical center/non-MTF laboratory utilized to determine the volume of specimens from possible PI patients that will be referred for further characterization. DoD medical center/non-MTF laboratories may be asked by the USAFSAM, NHRC, or the CDC to forward select specimens for use in monitoring antigenicity, RNA sequence, and drug sensitivities of the pandemic virus over time.

**3. Reporting Procedures**

**a. DoD Medical Center/non-MTF Laboratories**

- (1) Positive PI Virus Results (including “presumptive positive” if using the CDC-developed 2009 H1N1 Flu RT-PCR). Immediately report positive 2009 H1N1 Flu virus results to their installation/command PHEO after consultation with the CDC is completed. The PHEO, with assistance as necessary from the DoD medical center/non-MTF laboratory point-of-contact, will report positive results to the appropriate chain of command, appropriate state/local public health officials, the laboratory referring the specimen tested, and the PHEO of the referring laboratory’s installation/command. The EUA-specified ‘Fact Sheet for Healthcare Providers’ and ‘Fact Sheet for Patients’ must be provided with the report of the result. The laboratory referring the specimen will notify the patient’s clinical provider.
- (2) Negative PI Virus Results. The DoD medical center/non-MTF laboratory will ensure negative results are reported in a timely manner back to the referring laboratory.

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<sup>2</sup> Because the sensitivity of commercially available rapid diagnostic tests for influenza may not always be optimal, the CDC also will accept specimens taken from individuals 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 nearest State Public Health Laboratory or DoD medical center/DoD non-MTF laboratory.

## **b. Referring Laboratory**

- (1) Positive PI Virus Results. Laboratory management personnel from the referring laboratory will receive results from both DoD and non-DoD laboratories and will ensure that their installation's PHEO and the patient's clinical provider are/have been notified.
- (2) Negative PI Virus Results. Laboratory management personnel will ensure that the clinical provider is notified. Other personnel will be notified per local guidance.

## **C. Special Instructions – Autopsy Specimens and Shipping of Specimens**

### **1. Autopsy Specimen Instructions**

The CDC can perform immunohistochemical (IHC) staining for novel influenza A viruses on autopsy specimens. Viral antigens may be focal and sparsely distributed in patients with influenza, and are most frequently detected in respiratory epithelium of large airways. Larger airways (particularly primary and segmental bronchi) have the highest yield for detection of influenza viruses by IHC staining. Collection of the appropriate tissues ensures the best chance of detecting the virus by IHC stains.

**Advance consultation is required for the submission of all suspected 2009 H1N1 Flu cases. Please contact: Centers for Disease Control and Prevention, Coordinating Center for Infectious Diseases, National Centers for Zoonotic, Vector-Borne & Enteric Diseases, Division of Viral & Rickettsial Diseases, Infectious Diseases Pathology Branch, [pathology@cdc.gov](mailto:pathology@cdc.gov), phone: (404) 639-3133, and fax: (404) 639-3043.**

- a. If novel influenza infection is suspected, the following specimens are recommended:
  - (1) Obtain and submit a minimum total of 8 blocks or fixed-tissue specimens representing samples from each of the following sites for evaluation: central (hilar) lung with segmental bronchi, right and left primary bronchi, trachea (proximal and distal), and representative pulmonary parenchyma from right and left lung.
  - (2) In addition, submit representative tissues from major organs for evaluation. In particular, for patients with suspected myocarditis, encephalitis, or rhabdomyolysis, specimens should include myocardium (right and left ventricle), CNS (cerebral cortex, basal ganglia, pons, medulla, and cerebellum), and skeletal muscle, respectively.
  - (3) Include specimens from any other organ showing significant gross or microscopic pathology.
- b. Specimens may be submitted as:
  - (1) Paraffin-embedded tissue blocks. In general, this is the preferred specimen and is especially important to submit in cases where tissues have been in formalin for a significant time. Prolonged fixation (> 2 weeks) may interfere with some IHC and molecular diagnostic assays.

- (2) Wet tissue. If available, submit unprocessed tissues in 10% neutral buffered formalin in addition to paraffin blocks.
- (3) Unstained slides. Although not optimal, it may be possible to utilize unstained sections cut at 3 – 5 microns (10 slides per block) if paraffin blocks are unavailable.
- (4) Fresh-frozen tissue. Send separately on dry ice.
- c. Send tissue blocks, wet tissue, and unstained slides at room temperature (NOT FROZEN).
- d. Shipping considerations.
  - (1) Domestic packages should be mailed Monday – Wednesday for receipt by Friday.
  - (2) International packages should also be mailed so as to be received by Friday and may require an import permit. If needed, this permit can be provided following a phone consultation.
  - (3) U.S. Federal holidays should be taken into consideration before mailing the packages. Exceptions can be made on urgent cases with prior approval.
  - (4) Specific regulations for packaging, labeling, and shipping may be found at <http://www.cdc.gov/ncidod/srp/specimens/shipping-packing.html> , [http://www.iata.org/whatwedo/cargo/dangerous\\_goods/infectious\\_substances.htm](http://www.iata.org/whatwedo/cargo/dangerous_goods/infectious_substances.htm) , and at <http://www.cdc.gov/od/ohs/biosfty/shipdir.htm> .
  - (5) Provide the shipper's package tracking number(s) to the CDC.
  - (6) During the warmer months (June – August), in order to prevent the melting of paraffin-embedded tissue blocks during transit, it is advisable to ship the block(s) with a frozen gel ice pack.
  - (7) When shipping frozen specimens from long distances or from international locations, it is best to use a combination of dry ice and frozen gel ice packs. The gel ice packs will remain frozen for a day or two after the dry ice has dissipated.
- e. Include a copy of the autopsy report (preliminary, or final if available), and a cover letter outlining a brief clinical history, copy of any pertinent laboratory reports (including rapid antigen, culture, and PCR test results), and the submitter's full name, title, complete mailing address, e-mail address, phone, and fax numbers, in the event that CDC pathologists require further information. Referring pathologists may direct specific questions to CDC pathologists. The contact number for the Infectious Disease Pathology Activity is (404) 639-3133, or the pathologists can be contacted 24 hours a day, 7 days a week through the CDC Emergency Operations Center at (770) 488-7100.

## **2. General Specimen Shipment Instructions**

- a. Per current hazardous material shipment guidelines, influenza viruses (all types) are classified as infectious substances. Under strict interpretation of exempt

human specimen/patient specimen versus infectious substance guidelines, once a rapid antigen or other test for influenza viruses is performed on a patient specimen, and the test result is positive, the specimen, if shipment is required, must be shipped as an infectious substance. Up to that point in time, specimens may be shipped as exempt human specimens/patient specimens. However, given the threat posed by novel influenza viruses, any specimen from a patient satisfying the criteria specified by the CDC at CDC's 2009 H1N1 Guidance for Professionals web page at <http://www.cdc.gov/h1n1flu/guidance/> that must be shipped, to include a specimen upon which no influenza testing has been performed, should be handled/shipped as an infectious substance. The applicable guidance as provided in the appropriate shipping reference (see Section II.A.1.d – h) must be utilized to prepare the specimen(s) for shipment.

- b. Shipment of specimens to the CDC. Laboratories should contact the CDC's on-call epidemiologist before sending specimens to the CDC. The on-call epidemiologist can be contacted by calling (404) 639-3747/3591, Monday – Friday, 8:30 a.m. – 5:00 p.m., or through the CDC Emergency Operations Center (770) 488-7100) at all other times.
  - (1) In some cases, a DoD reference laboratory may be asked to arrange for a supported laboratory to send samples directly to the CDC.
  - (2) Send specimens by Priority Overnight shipping for receipt within 24 hours. Samples (such as fresh-frozen autopsy samples for RT-PCR or other clinical materials) may be frozen at -70°C if the package cannot be shipped within a specified time (e.g., if the specimen is collected on a Friday but cannot be shipped until Monday).
  - (3) When sending clinical specimens, include the CDC-provided specimen inventory sheet. Annotate the assigned CDC case ID number and note “Influenza Surveillance” on all materials and specimens sent.
  - (4) Follow protocols for standard interstate shipment of infectious substances, which are available at <http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>

## **D. Guidelines for Collection of Clinical Specimens**

The specimen collection guidelines provided below are general in nature. It is therefore advisable to confirm all specimen collection procedures with the supporting laboratory.

### **1. Collecting Respiratory Specimens**

#### **a. General Collection Information**

##### **(1) Timing of Respiratory Specimen Collection**

Respiratory specimens for detection of most respiratory pathogens, and influenza in particular, are optimally collected as soon as possible upon presentation, and preferably within the first 3 days of the onset of illness. If possible, obtain serial specimens over several days from the same patient. Before collecting specimens, review infection control precautions provided by

the CDC at CDC's 2009 H1N1 Guidance for Professionals web page at <http://www.cdc.gov/h1n1flu/guidance/> .

(2) Handling/Storage Temperatures

In most instances, place specimens at 4°C immediately after collection; however, if the specimens cannot be delivered to the laboratory within 24 – 48 hours, they should be frozen at or below -70°C and shipped on dry ice. Avoid repeated freeze/thaw cycles.

(3) 2009 H1N1 Flu Diagnosis

For 2009 H1N1 Flu diagnosis, nasopharyngeal swabs/aspirate or nasal wash/aspirate are the preferred respiratory specimens. If these specimens cannot be collected, a combined nasal swab with an oropharyngeal swab is acceptable. For patients who are intubated, an endotracheal aspirate should also be collected. Specimens should be placed into vials containing 1 – 3 ml of sterile viral transport media (VTM) and immediately placed on ice or cold packs (maintain specimen at approximately 4°C) for transport to the laboratory.

**b. Collecting Specimens from the Upper Respiratory Tract**

(1) Nasopharyngeal or Oropharyngeal Swabs

- (a) Use only sterile dacron or rayon swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit PCR testing.
- (b) To obtain a nasopharyngeal swab, insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nostrils.
- (c) To obtain an oropharyngeal swab, swab the posterior pharynx and tonsillar areas, avoiding the tongue.
- (d) Place the swabs immediately into sterile vials containing 2 ml of viral transport media. Break the applicator sticks off near the tip to permit tightening of the cap. Label each specimen container with the patient's identification number and the date the sample was collected.
- (e) Place the specimens at 4°C immediately after collection. However, if the specimens cannot be delivered to the laboratory within 24 – 48 hours, they should be frozen at or below -70°C and shipped on dry ice. Avoid repeated freeze/thaw cycles.

(2) Nasopharyngeal wash/aspirate

Nasopharyngeal wash/aspirates are the specimen of choice for detection of most respiratory viruses and are the preferred specimen type for children aged <2 years. These are collected in the following manner:

- (a) Have the patient sit with head tilted slightly backward.

- (b) Instill 1-1.5 ml of nonbacteriostatic saline (pH 7.0) into one nostril. Flush a plastic catheter or tubing with 2-3 ml of saline. Insert the tubing into the nostril parallel to the palate. Aspirate nasopharyngeal secretions. Repeat this procedure for the other nostril.
- (c) Collect the specimens in sterile vials. Label each specimen container with the patient's identification number and the date collected.
- (d) Place the specimens at 4°C immediately after collection. However, if the specimens cannot be delivered to the laboratory within 24 – 48 hours, they should be frozen at or below -70°C and shipped on dry ice. Avoid repeated freeze/thaw cycles.

**c. Collecting Specimens from the Lower Respiratory Tract**

**(1) Bronchoalveolar Lavage, Tracheal Aspirate, Or Pleural Fluid Tap**

- (a) During bronchoalveolar lavage or tracheal aspirate, use a double-tube system to maximize shielding from oropharyngeal secretions.
- (b) Centrifuge half of the specimen, and fix the cell pellet in formalin. Place the remaining unspun fluid in sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm<sup>®</sup>. Label each specimen container with the patient's identification number and the date the sample was collected.
- (c) Place the specimens at 4°C immediately after collection. However, if the specimens cannot be delivered to the laboratory within 24 – 48 hours, they should be frozen at or below -70°C and shipped on dry ice. Avoid repeated freeze/thaw cycles.

**(2) Sputum**

- (a) Educate the patient about the difference between sputum and oral secretions.
- (b) Have the patient rinse the mouth with water, take three deep breaths, and then expectorate deep cough sputum directly into a sterile screw-cap sputum collection cup or sterile dry container. Label each specimen container with the patient's identification number and the date the sample was collected.
- (c) Place the specimens at 4°C immediately after collection. However, if the specimens cannot be delivered to the laboratory within 24 – 48 hours, they should be frozen at or below -70°C and shipped on dry ice. Avoid repeated freeze/thaw cycles.

**2. Blood Components**

As directed by OASD(HA) or Service-specific guidance, collect and store both acute and convalescent serum specimens as a pair for antibody testing - acute within 7 days of illness onset and convalescent 3–4 weeks after the onset of illness. (Note: The ability of the supporting laboratory to store acute/convalescent serum specimens long-

term should be confirmed before wholesale collection of such specimens is initiated.) Collection of such specimens is useful primarily during Federal Government Response Stage 2 and early in Stage 3 (early WHO Phase 6). To collect serum for antibody testing:

- a. Collect 5-10 ml of whole blood in a serum separator tube. Allow the blood to clot, centrifuge briefly, and collect all resulting sera in vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm<sup>®</sup>.
- b. The minimum amount of serum preferred for each test is 200 microliters, which can easily be obtained from 5 ml of whole blood. A minimum of 1 cc of whole blood is needed for testing of pediatric patients. If possible, collect 1 cc in an ethylenediaminetetraacetic acid (EDTA) tube and in a clotting tube. If only 1cc can be obtained, use a clotting tube.
- c. Label each specimen container with the patient's identification number and the date the specimen was collected.
- d. Specimens should be refrigerated at 4°C or frozen for future testing at -20°C to -80°C.

### **III. Occupational Health Guidelines for Health Care and Medical Research Personnel**

The following guidelines amplify the guidelines in Sections I-III above.

#### **A. Surveillance**

Medical surveillance of personnel can help to ensure that workers who are at risk of occupational exposure to novel animal or human influenza strains and who develop symptoms of illness receive appropriate medical evaluation and treatment, both for the benefit of their health and to prevent further transmission to others. Installation/command PHEOs should ensure that plans for an influenza-like illness surveillance system and employee tracking registry for health care personnel within their health care/medical research facilities is developed and ready to be implemented prior to declaration of Federal Government Response Stages 3-6 (WHO Phase 6).

Although human-to-human transmission may not be occurring in the local community until WHO Phase 6 is reached, it may be occurring long before that depending on the geographic location of the early cases. For example, with the current swine-origin influenza A (H1N1) virus, several states have reported large numbers of cases before reaching WHO Phase 6, and occupational health surveillance would be required in those geographic areas.

#### **Communities with Transmission of S-OIV:**

In communities where swine-origin influenza A (H1N1) virus (S-OIV) transmission is occurring, healthcare personnel should be monitored daily for signs and symptoms of febrile respiratory illness before each shift. Symptomatic individuals should be evaluated (see below) and excluded from duty accordingly. Healthcare personnel who develop these symptoms should be instructed not to report to work, or if at work, should cease patient care activities and notify their supervisor and infection control personnel.

#### **Communities without Transmission of S-OIV:**

In communities without S-OIV transmission, healthcare personnel working in areas of a facility where there are patients being assessed or isolated for influenza infection should be monitored daily for signs and symptoms of febrile respiratory infection. This would include healthcare personnel exposed to patients in an outpatient setting or the emergency department. Healthcare personnel who develop these symptoms should be instructed not to report to work, or if at work, should cease patient care activities and notify their supervisor and infection control personnel.

Healthcare personnel who do not have a febrile respiratory illness may continue to work. Asymptomatic healthcare personnel who have had an unprotected exposure to S-OIV also may continue to work if they are started on antiviral prophylaxis. Interim guidance on antiviral recommendations for close contacts of patients with confirmed or suspected S-OIV infection can be found at <http://www.cdc.gov/h1n1flu/recommendations.htm>.

Employee tracking registries should include a log of health care personnel who have provided care for PI-infected patients, absenteeism due to health reasons, and those workers who have been diagnosed and who have recovered from PI.

## **B. Influenza vaccine**

According to CDC ACIP and DoD Policy, MTFs should vaccinate all personnel for seasonal influenza who have direct patient care responsibilities or who handle clinical laboratory specimens. In addition, medical research laboratories should vaccinate all personnel working with influenza viruses. Vaccination might reduce the chance of illness from exposure to human influenza viruses currently circulating in the community that could lead to confusion in monitoring for novel influenza virus such as the S-OIV. When available, administer vaccines against novel influenza viruses in accordance with DoD guidance found on the DoD PI Watchboard at [www.dod.mil/pandemicflu](http://www.dod.mil/pandemicflu).

## **C. Pre-exposure antiviral prophylaxis** (also see previous sections on antiviral use). Pre-exposure antiviral chemoprophylaxis should only be used in limited circumstances. <http://www.cdc.gov/h1n1flu/recommendations.htm>.

1. Pre-exposure or outbreak antiviral prophylaxis should be reserved for only those who are providing prolonged, close, direct patient care to known cases.
2. When considering pre-exposure antiviral prophylaxis, be sure to evaluate appropriate candidates for contraindications, answer their questions, review adverse effects, and explain the benefits.
3. Pre-exposure prophylaxis should not be considered unless infection control practices such as PPE are proven to be ineffective.
4. MTFs and medical research laboratories should maintain a log of healthcare personnel prescribed antivirals, healthcare personnel evaluated and not prescribed antivirals, doses dispensed, and adverse effects.
5. Periodically evaluate and update antiviral use, consistent with the Policy for Release of Antiviral Stockpile during an Influenza Pandemic.

## **D. Follow-up of Suspected Exposures**

Laboratory and health care personnel who are believed to have had an exposure to an animal-origin influenza A virus or other novel influenza strain should be evaluated, counseled about the risk of transmission to others, and monitored for fever or lower respiratory symptoms as well as for sore throat, rhinorrhea, chills, rigors, myalgia, headache, or diarrhea based on the identity and virulence of the virus.

## **E. Post-exposure prophylaxis**

Conditions for use of antivirals for post-exposure prophylaxis include a known or strongly suspected close, prolonged exposure to live S-OIV for an individual not already on antivirals. An appropriate healthcare provider should be available to immediately perform an evaluation and dispense antivirals if the exposure occurs during working hours. Animal data suggests that many of those receiving post-exposure

prophylaxis may develop immunity if they were in the incubation phase of disease when therapy was initiated. If possible, individuals receiving post-exposure prophylaxis should be tracked and tested for serological evidence of immunity following their course of therapy. There is also animal data that strongly demonstrates that a BID dosage schedule is superior to QD regimens regardless of the dose administered. Strong consideration should be given to providing a traditional BID treatment course following exposure rather than using the QD schedule recommended for routine prophylaxis.

## **F. Personal Protective Equipment**

Please see I.A.2.b(4) (Infection Control Practices for S-OIV during the Federal Government Response Stages 0-2 (WHO Phases 1-5)). All healthcare personnel must comply with their Respiratory Protection program (including fit-testing and training) before use of all NIOSH-certified N-95 filtering face piece respirators. Healthcare personnel should also perform a user seal check to ensure the respirator is properly seated to the face before each use.

## **G. Management of ILI in Health Care Personnel with Suspected Exposure to Novel Influenza Viruses**

### **1. General procedures**

Potentially exposed individuals should promptly notify their supervisor and receive prompt medical evaluation. The clinical provider should inform the installation/command PHEO. If illness or infection is confirmed, PHEO will notify appropriate chain of command, local and/or State public health agencies. Supervisors and workers' compensation authorities (in the case of civilian personnel) should also be notified of exposures and illnesses in laboratory and healthcare personnel. (Note: Viral culture of specimens from cases of suspected exposure to novel influenza viruses should be attempted only in laboratories that meet the biocontainment conditions for biosafety level 3 (BSL-3) with enhancements or higher.)

### **2. Evaluation and Management**

Workers should report any ILI and any potential exposures to the supervisor, and report for evaluation and treatment as directed (See Sections I.A.1, I.A.2, I.B.1., I.B.2)

#### **a. During Regular Working Hours**

- (1) The affected employee should notify their supervisor. The supervisor should immediately consult an appropriate healthcare provider and facility contacts (e.g., occupational health, infection control, or designee).
- (2) Upon arrival at the designated clinic, place the employee in a private room for isolation where a healthcare provider can perform an appropriate evaluation.

- (3) The healthcare provider should obtain a respiratory specimen(s) and send for appropriate diagnostics testing. See Section I (Guidelines for Patient Evaluation and Management) regarding clinical specimens to be collected.
- (4) Based on the clinical evaluation and results of diagnostic testing, the healthcare provider should determine whether the patient will return to work, be sent home, or be referred on for further evaluation. If employees are sent home, appropriate personnel notifications should be made according to whether the employee is civilian or military, and the case should be reported to the respective military installation/command Public Health Emergency Officer (PHEO) for other necessary notifications. In addition, household and other close contacts should be considered for antiviral prophylaxis in consultation with the installation/command PHEO.

**b. During Working Hours When the Employee Calls from Home**

- (1) The employee should notify the supervisor. The supervisor should discuss the situation with an appropriate healthcare provider and determine where and by whom the employee will be evaluated and clinical specimens sent for appropriate diagnostic testing.
- (2) The worker should come to an on-site clinic for evaluation and disposition.
- (3) If infection of the worker is confirmed, household and other close contacts should be considered for antiviral prophylaxis in consultation with the installation/command PHEO.

**c. After working hours**

The worker should notify the current shift supervisor. The supervisor, in turn, should direct the worker where to go for evaluation and disposition.

## **IV. Guidelines for Community Disease Containment**

Non-pharmacologic measures are an integral component of the overall community response efforts during a pandemic. If interventions are initiated early, past experience strongly suggests that the overall burden of disease on a community can be significantly reduced, resulting in a decreased requirement for antiviral medications as well as reduced demands on the medical infrastructure to include both inpatient and outpatient resources.

### **A. Surveillance**

The effectiveness of community containment measures mandates early intervention. To achieve this goal, surveillance activities should be increased in accordance with the stage of the pandemic. During the pre-pandemic period, preexisting surveillance activities, if employed, should prove to be adequate. As the threat increases, community-based surveillance must also increase to ensure near real-time identification of initial cases. Public awareness programs and the establishment of reporting requirements for local clinics, providers, MTF's, public health assets and the garrison will facilitate this process.

## **B. Targeted Layered Interventions<sup>3</sup>**

### **1. Transmission of S-OIV (H1N1)**

Limited data available on S-OIV indicate that this virus is likely transmitted in ways similar to other influenza viruses, primarily through large-particle respiratory droplet transmission between people. This requires close contact because droplets do not remain suspended in the air and generally travel only a short distance (< 6 feet). Contact with contaminated surfaces is another possible source of transmission and transmission via small-droplet nuclei (also called “airborne” transmission) might also occur, but the contribution of these modes of transmission to influenza epidemiology is uncertain. Because data on the transmission of S-OIV are limited, the potential for ocular, conjunctival, or gastrointestinal infection is unknown. All respiratory secretions and bodily fluids (diarrheal stool) of S-OIV cases should be considered potentially infectious.

*Close contact*, for the purposes of this document, is defined as having cared for or lived with a person who is a confirmed, probable or suspected case of S-OIV, or having been in a setting where there was a high likelihood of contact with respiratory droplets and/or body fluids of such a person. Examples of close contact include kissing or embracing, sharing eating or drinking utensils, physical examination, or any other contact between persons likely to result in exposure to respiratory droplets. Close contact typically does not include activities such as walking by an infected person or sitting across from a symptomatic patient in a waiting room or office.

No one single non-pharmacologic measure is likely to have a profound impact, but layered interventions can have an additive or synergistic effect. If interventions are implemented early and combined with antiviral therapy, drastic reductions in disease transmission can be achieved. The following interventions are representative but not exhaustive:

### **2. Timing**

For interventions to be effective, timing is critical. Experience in 1918 demonstrated that nonpharmaceutical interventions had a marginal effect if their implementation was delayed until a community epidemic was well-established. (This was the pattern observed in Philadelphia, Montreal, Baltimore, Newark, Washington DC, etc.) In contrast, many communities that introduced nonpharmaceutical measures early avoided the overwhelming stress on critical infrastructure caused by an unmitigated epidemic. (This pattern was observed in Atlanta, Minneapolis, Milwaukee, Seattle, St. Louis and other cities.) Following implementation, interventions should be maintained for the duration of time the pandemic wave is affecting the community. With the potential of multiple waves, this process is likely to be repeated. Modeling suggests that implementation of

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<sup>3</sup> More detailed information regarding Targeted Layered Interventions, to include pandemic severity categories, mitigation measures, and triggers, can be found in the CDC publication: “Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States – Early, Targeted, Layered Use of Nonpharmaceutical Interventions” (February, 2007).

targeted, layered interventions at threshold attack rates as low as 0.1 to 2.0% can offer a substantial benefit in reducing the peak attack rate.

### **3. Closure of Schools, Child Care Centers, and Other Child-based Programs**

During outbreaks due to a novel influenza virus, installation commanders should strongly consider school closure, as this may be one of the most effective community measures. To effectively reduce the burden of disease within an installation or community, this measure should be initiated **early** following identification of disease in the community. With respect to influenza outbreaks, children are “super spreaders” who serve to amplify disease transmission. As such, children pose a significant transmission risk to the community. Epidemics peak in children and teens before they do in older age groups, often with increased mortality. It is projected that during a moderately severe pandemic, pediatric deaths equaling those expected over two decades will occur during the course of the pandemic. The interruption of influenza epidemics by school holidays has been associated with marked declines in emergency department visits for respiratory illness and in national reporting of influenza cases. Recent modeling strongly suggested that early closure of schools and day care centers, particularly if coupled with deliberate efforts to reduce the social circulation and congregation of children and teens, is likely to have a significant effect on transmission rates within a community. Commanders should also ensure that appropriate Service members have family care plans that are up-to-date.

However, new information on disease severity of the 2009 swine-origin influenza A (H1N1) virus (S-OIV), and its extent of community spread within the US, warrant revision of the initial school closure guidance for that particular strain. The extent of the spread of that virus within communities now makes individual school closure less effective as a control measure. In addition, most U.S. cases have not been severe and are comparable in symptoms to seasonal influenza. Instead, CDC recommends the primary means to reduce spread of S-OIV influenza in schools is to focus on early identification of ill students and staff, staying home when ill, and good cough and hand hygiene etiquette. School closure is no longer advised for a suspected or confirmed case of S-OIV, and, in general, is not advised unless there is a magnitude of faculty or student absenteeism that interferes with the school’s ability to function.

Students, faculty or staff with influenza-like illness (fever with a cough or sore throat) should stay home and not attend school or go into the community except to seek medical care for at least 7 days even if symptoms resolve sooner. Students, faculty and staff who are still sick 7 days after they become ill should continue to stay home from school until at least 24 hours after symptoms have resolved. Students, faculty and staff who appear to have an influenza-like illness at arrival, or become ill during the school day, should be isolated promptly in a room separate from other students and sent home. Parents and guardians should monitor their school-aged children, and faculty and staff should self-monitor every morning for symptoms of influenza-like illness. Ill students should not attend alternative child care or congregate in settings other than school. School administrators should

communicate regularly with health officials to obtain guidance about reporting of influenza-like illnesses in the school. Schools can help serve as a focus for educational activities aimed at promoting ways to reduce the spread of influenza, including hand hygiene and cough etiquette. Students, faculty and staff should stringently follow sanitary measures to reduce the spread of influenza, including covering their nose and mouth with a tissue when coughing or sneezing (or coughing or sneezing into their sleeve if a tissue isn't available), frequently washing hands with soap and water, or using hand sanitizer if hand washing with soap and water is not possible.

#### **4. Social Distancing**

To facilitate social distancing in the presence of a novel influenza virus, installation commanders should consider closing facilities such as theaters and recreational venues where crowds may gather. Activities that would foster the formation of crowds may be canceled or modified to circumvent crowd formation. If feasible, this action should be initiated in communities prior to the arrival of PI and continued throughout the period of time the pandemic wave is affecting the community. Planning with local clergy to establish ways that the community might receive pastoral care and engage in worship without exposure to crowds should be undertaken as part of pre-pandemic planning. If enclosed spaces cannot be avoided, then at least 3-6 feet should be provided between individuals. Ceremonial formations should not be held when pandemic influenza is affecting a community. Required formations such as training and drills should be limited. Teleconferencing should be employed whenever possible in preference to face-to-face meetings and nonessential meetings canceled. In the workplace additional measures should be implemented if appropriate, to include telecommuting and liberal leave policies for those in isolation or in quarantine. Restructuring the workplace and work practices to facilitate social distancing, while maintaining operational effectiveness, should also be employed. This may include staggered work hours, provision of increased public transportation with seating to ensure safe distancing, and consultation with vendors to develop “push packages” of essential supplies that can be picked up via drive-through/drive-by.

However, in the case of the S-OIV, the CDC has already modified its recommendations on school closures based on the apparent low virulence of the virus, and its growing distribution in many states. CDC is also emphasizing the benefit of encouraging persons with ILI to stay home and away from large gatherings. It is recommended that before any decisions are made regarding modifying or cancelling large gatherings on base, that the latest CDC recommendations on public gatherings be reviewed at <http://www.cdc.gov/h1n1flu/guidance/gatherings.htm>, because they are currently being rewritten.

#### **5. Open Barracks**

In open barracks settings, bed space should be as widely spaced as possible and head-to-toe sleeping positions should be adopted. Hanging bed sheets in between beds also may be effective. Those living in open barracks should have decreased

exposure to the community particularly if there is a paucity of disease in the barracks as opposed to high burden of disease in the community.

## **6. Prompt Isolation**

Prompt isolation of the ill and quarantine of those immediately exposed will be especially important in open barracks. (Early antiviral treatment and post exposure antiviral prophylaxis for those with close and prolonged contact may have a synergistic effect in decreasing viral transmission. )In this setting it may be necessary to designate a separate facility or area to diminish exposure to the general barracks population. In modular barracks settings use of individual pods or bedrooms may be adequate for both quarantine and isolation.

## **7. Post-Exposure Prophylaxis**

- a. Depending on the availability of antiviral medications, post-exposure prophylaxis should be considered for contacts of known cases. For the novel influenza virus S-OIV circulating in 2009, both oseltamivir and zanamivir are effective. Strategies for post exposure prophylaxis can represent either a high dose-short duration or an alternative low dose-long duration approach. Both approaches are initiated simultaneous to the treatment of a known case. Only those with close and prolonged contact with the case should be considered for therapy. This may include immediate family members or in a barracks setting, those that occupy the same bedroom. In open bay settings this might include those with beds immediately adjacent to the case. Animal data suggests that this will increase survival and induce immunity in those who are in a pre-symptomatic incubation phase.
- b. Oseltamivir administered at 75mg, twice daily may potentially treat pre-symptomatic individuals with infection and, therefore, decrease the possibility of both administering a sub-therapeutic dose and the subsequent development antiviral drug resistance. The disadvantage of this approach is the potential exposure to viral shedding from the initial case, after the 5-day post-exposure treatment course concludes. Animal data supports this approach with associated advantages of decreased viral shedding and asymptomatic vs. symptomatic disease even with reduced dosages. Despite the absence of symptoms, subsequent immunity in those who received antivirals during the incubation period post exposure has been demonstrated in a number of animal models.
- c. The administration of one 10-day antiviral course consistent with a typical prophylaxis course (e.g., Oseltamivir, 75mg, once daily) is another option. This is the course of chemoprophylaxis recommended by the CDC for adults, including close contacts of cases (confirmed, probable, or suspected) who are at high-risk for complications of influenza, as well as for certain occupational exposures. (<http://www.cdc.gov/h1n1flu/recommendations.htm>.) The advantage of this approach is a longer period of protection that may exceed the potential period of viral shedding by the initial case. The disadvantages are providing a sub-therapeutic dose to those with infection following exposure and the subsequent development of antiviral drug resistance. Animal data suggests that this treatment strategy will improve survival in those in whom therapy was

initiated during a pre-clinical or incubation period but will have a limited impact on diminishing symptoms or viral shedding. For doses of zanamivir as well as childrens' doses, including those under the age of 1, see the CDC website. (<http://www.cdc.gov/h1n1flu/recommendations.htm>.)

- d. It will be necessary to track those who have received post-exposure antiviral therapy. If possible, serologic assessment of potential immunity should be determined. This is particularly true for individuals in critical or high risk occupations.

## **8. Graded response**

With increasing disease severity, the importance of early intervention and the extent that each of these measures are undertaken increases accordingly. A pandemic characterized by mild disease, such as the current S-OIV, may not require widespread use of quarantine measures and school closure may be reactive rather than proactive. Conversely, a pandemic characterized by severe disease will require a proactive school closure and the effective use of isolation and quarantine practices as well as widespread social distancing measures.

## **9. Communication**

A key factor influencing the success or failure of a layered community-based disease containment strategy is acceptance by the community. Long before a pandemic is imminent, education programs, reflecting transparency and containing factual information on the rationale for such measures, should be developed; opportunities for community stakeholders to share in planning and implementation should be offered as well.

## **9. Community mask use**

Due to the lack of evidence, facemask use alone should not be assumed to have an appreciable impact on reducing transmission of pandemic influenza. Facemasks do provide a potential barrier that might limit spread of disease. Rather than relying on masks and respirators, people should engage in social distancing whenever possible. If close contact and crowded conditions cannot be avoided, then wearing a mask or respirator should be considered. Respirators should be worn in cases where close contact with infected persons is unavoidable. This includes, but is not limited to, people who are providing home care for a sick family member. When combined with other layered mitigation measures, the use of mask or respirators may have a benefit in reducing the spread of disease within a community. There are a number of respirators that are recently FDA approved for use in non-hospital settings during public health emergencies. These devices are expected to provide some degree of protection depending on the fit and user compliance. These masks are for single use. The wearer should not wash, disinfect, reuse or share their respiratory with others. It is likely that the availability of masks and respirators will be limited. Reuse of masks and respirators by single individuals may still provide some unknown degree of risk reduction provided steps are taken to reduce self contamination with repeated use.

## **V. Special Considerations for Deployed Settings**

The following special considerations for deployed settings amplify the MTF-based guidelines above. Information on PI (to include minimizing exposure) should be a routine part of pre-deployment briefings. Unit surgeons/PHEOs are responsible for maintaining situational awareness on PI and should also be familiar with principles of PIP, Standard Precautions, and Infection Control Practices (Sections I.A.2.b(4), I.A.2.d(1), I.B.2.a(3), and I.B.2.c(1)) and how these could be adapted in battlefield and operational settings.

### **A. Guidelines for Patient E&M during the Federal Government Response Stages 0-2 (WHO Phases 1-5)**

#### **1. Evaluation and Management of Patients with ILI with PI risk factors – Role I**

- a. Prior terminology was “Echelon” or “Level 1.
- b. Evaluate using clinical and epidemiological criteria. According to WHO guidance, investigate unexplained cluster of 3-5 cases of respiratory disease. In areas experiencing WHO 4-5 situations, contacts of suspected PI cases should be aggressively evaluated.
- c. Use PIP in addition to Standard Precautions.
- d. Evacuate, IAW COCOM/theater evacuation policy, to other higher medical roles (II or III) via ground/air evacuation to access additional diagnostic capabilities. Use surgical mask on the patient. If patient is severely ill, evacuate to Role III (or equivalent facility with laboratory culture capabilities). If evacuation is required, notify all parties of the potential for infection with PI.
- e. Notify higher headquarters.
- f. Review plans for isolation of cases, health care surge capacity, and social distancing (e.g., chow lines, telephone tents, exercise areas, etc.)
- g. Identify close contacts (e.g., same tent or berthing space, office space, vehicle, etc.) Recommend quarantine for 7-10 days of close contacts of symptomatic patients. Consider restriction of movement for other members of the unit.
- h. Monitor close contacts daily for temperatures  $>100^{\circ}\text{F}$  ( $>38^{\circ}\text{C}$ ) and other ILI symptoms and medically re-evaluate if ill.
- i. Administer antivirals (if available) and treat secondary complications. Operational commanders should maintain a log of all personnel/units prescribed antivirals, personnel evaluated and not prescribed antivirals, doses dispensed, and adverse effects. Consider antivirals for use in close contacts of suspected PI cases. (See also V.B.6 – Guidelines for Community Disease Containment, Post-Exposure Prophylaxis)

#### **2. Evaluation and Management of Patients with ILI with PI risk factors – Role II**

- a. Prior terminology was “Echelon” or “Level 2.”

- b. If possible, isolate and cohort respiratory versus non-respiratory patients. Use PIP in addition to Standard Precautions, including the provision of dedicated staff if possible.
- c. Obtain respiratory specimens for diagnosis. Perform rapid antigen diagnostics if available. Check DoD PI Watchboard at [www.dod.mil/pandemicflu](http://www.dod.mil/pandemicflu) to identify nearest laboratory or other designated testing facility capable of performing the FDA-cleared RT-PCR (or other appropriate test) for the PI virus. Transport specimens to this identified facility via military air. Coordinate with appropriate authorities, including Logistic Services (for priority 1 cargo movement) and COCOM Surgeon (for validation of requirement) in order to rapidly transport specimens. Positive test results will be reported by the reference laboratory to the referring medical unit. The referring medical unit will notify their respective command PHEO, who will then report the results through the established chain-of-command.
- d. Administer antivirals (if available) and treat secondary complications. Operational commanders should maintain a log of all personnel/units prescribed antivirals, personnel evaluated and not prescribed antivirals, doses dispensed, and adverse effects. Antivirals should be considered for use in close contacts of suspected PI cases. (See also V.B.6 – Guidelines for Community Disease Containment, Post-Exposure Prophylaxis)
- e. Consistent with USTRANSCOM policy, evacuation from theater of patients with suspected or confirmed PI due to a novel strain may be restricted, as may movement of patients with other morbidities (e.g., trauma) out of theater. However, after consideration of the characteristics of the novel swine-origin influenza A (H1N1) virus (S-OIV) strain, USTRANSCOM has issued the following statement:

*Patient movement for suspected, probable, or confirmed H1N1 does not fall under the TRANSCOM contagious contaminated policy letter and does not require Sec Def approval. These patients can be moved using influenza precautions outlined in AFI 41-307. Additional H1N1 clinical information is available on the CDC web site and should be referenced as the situation evolves...*

*GPMRC [is to] be notified for all H1N1 patient movements, and that the sending and receiving PMRCs notify their chain of commands. (as of 1 May 2009).*

### **3. Evaluation and Management of Patients with ILI with PI risk factors – Role III**

- a. Prior terminology was “Echelon” or “Level 3.”
- b. If possible, isolate and cohort respiratory versus non-respiratory patients. Use PIP in addition to Standard Precautions, including the provision of dedicated staff if possible.

- c. Obtain respiratory specimens for diagnosis. Perform rapid antigen diagnostics if available. Refer to the DoD PI Watchboard at [www.dod.mil/pandemicflu](http://www.dod.mil/pandemicflu) to identify nearest LRN reference laboratory or other designated testing facility capable of performing the FDA-cleared RT-PCR (or other appropriate test) for the PI virus. Transport specimens to this identified facility via military air. Coordinate with appropriate authorities, including Logistic Services (for priority 1 cargo movement) and COCOM Surgeon (for validation of requirement) in order to rapidly transport specimens. The reference laboratory will report positive test results to the referring medical unit. The referring medical unit will notify their respective installation/command PHEO, who will then report the results through the established chain-of-command.
- d. Administer antivirals (if available) and treat secondary complications. Operational commanders should maintain a log of all personnel/units prescribed antivirals, personnel evaluated and not prescribed antivirals, doses dispensed, and adverse effects. Antivirals should be considered for use in close contacts of suspected PI cases. (See also V.B.6 – Guidelines for Community Disease Containment, Post-Exposure Prophylaxis)
- e. Identify unprotected exposures among personnel involved with patient transportation and care. Evaluate these individuals for symptoms, consider restriction of movement (including quarantine), and use antivirals, if available.
- f. Consistent with USTRANSCOM policy, evacuation from theater of patients with suspected or confirmed PI due to a novel strain may be restricted, as may movement of patients with other morbidities (e.g., trauma) out of theater. However, after consideration of the characteristics of the novel swine-origin influenza A (H1N1) virus (S-OIV) strain, USTRANSCOM has issued the following statement:

*Patient movement for suspected, probable, or confirmed H1N1 does not fall under the TRANSCOM contagious contaminated policy letter and does not require Sec Def approval. These patients can be moved using influenza precautions outlined in AFI 41-307. Additional H1N1 clinical information is available on the CDC web site and should be referenced as the situation evolves...*

*GPMRC [is to] be notified for all H1N1 patient movements, and that the sending and receiving PMRCs notify their chain of commands. (as of 1 May 2009).*

## **B. Guidelines for Patient Evaluation and Management during the Federal Government Response Stages 3-5 (WHO Phase 6)**

- 1. If pandemic strain vaccine is available, conduct mass-vaccinations.
- 2. Execute plans for social distancing to the extent possible.
- 3. Consistent with USTRANSCOM policy, evacuation from theater of patients with suspected or confirmed PI due to a novel strain may be restricted, as may movement of patients with other morbidities (e.g., trauma) out of theater. However, after

consideration of the characteristics of the novel swine-origin influenza A (H1N1) virus (S-OIV) strain, USTRANSCOM has issued the following statement:

*Patient movement for suspected, probable, or confirmed H1N1 does not fall under the TRANSCOM contagious contaminated policy letter and does not require Sec Def approval. These patients can be moved using influenza precautions outlined in AFI 41-307. Additional H1N1 clinical information is available on the CDC web site and should be referenced as the situation evolves...*

*GPMRC [is to] be notified for all H1N1 patient movements, and that the sending and receiving PMRCs notify their chain of commands. (as of 1 May 2009).*

4. Movement of patients with suspected or confirmed PI within theater also may be restricted as part of disease containment strategies. The theater commander would make this decision in consultation with the Combatant Command (COCOM) PHEO and Surgeon.
5. Address unique medical support requirements such as mental health.
6. To support “treatment in place,” request additional critical medical materiel and equipment, treatment teams, and enhanced diagnostics.
7. Support surveillance activities to track changes in viral resistance patterns.
8. Coordinate with logistics community to prepare for an increase in deaths.
9. Once a pandemic is underway, health care providers may be required to triage patients and consider utilizing limited resources (e.g., antibiotics, antivirals, ventilators, etc.) for those most likely to benefit from such care. Clinical management of severe influenza should address supportive care and the rapid identification and treatment of secondary complications, including bacterial infections.

## **VI. Prioritization of Medical Care**

**The following guidelines are taken from the Department of Defense Policy for Prioritizing Delivery of Medical Care during Pandemics and Other Public Health Emergencies of National Significance, Sept 1, 2008, HA POLICY: 08-010.**

Public health emergencies of national significance such as an influenza pandemic will result in surge requirements that overwhelm the response capacity, capability, and resources of both medical facilities and health care providers. Under these conditions, alternate standards of care will be adopted, and difficult decisions regarding the allocation of limited resources will be required.

### **A. OBJECTIVES**

The MHS direct care system has two primary objectives. The first is to support the national security mission and the second is to provide care for TRICARE Prime and TRICARE Plus enrolled beneficiaries with Military Treatment Facility (MTF) primary care managers. Other objectives of the direct care system have lesser priority. It is DoD policy that MTF Commanders will fulfill both of these primary objectives. Under emergency conditions, the allocation of resources may not be based solely on medical necessity or risk, but also may be based on operational or other national security requirements, as directed by the President or Secretary of Defense. Some uniformed personnel, for example, may receive a higher level of care due to operational requirements, independent of their immediate medical risk. This does not preclude the responsibility to continue to care for beneficiaries enrolled with MTF primary care managers. These beneficiaries have an understandable expectation of continued access to their primary care.

### **B. STANDARDS OF CARE**

1. Commanders will make arrangements that ensure that the minimum level of care provided to all enrolled beneficiaries is, at the very least, comparable to local community standards in the context of the public health emergency. Such arrangements may include special work schedules, increased use of reserve component members, intermittent employees, reemployed annuitants, contractor personnel, and volunteers, and coordination with the TRICARE managed care support contractor.
2. Planning to ensure for the smooth transition of care for MTF-enrolled patients by non-DoD providers, to the extent that is necessary, must be accomplished well in advance of emergency conditions and the agreed-upon arrangements clearly communicated to all enrolled beneficiaries.
3. Determination of critical personnel, rather than blanket policies affecting all Service members in an area of responsibility, will help meet the two seemingly conflicting

objectives affecting mission requirements and beneficiary care. This will require a critical analysis at local levels of what represents a critical role.

4. To fully manage expectations and appropriately educate the beneficiary population on the emergency response plan relating to access to care, it is imperative that risk communication messages and products include instructions pertaining to where to receive care in the event of a public health emergency.

5. As in any mass casualty event, when resources are inadequate, the adoption of altered community standards of care will be required. In non-deployed settings, the standard of care, at the very least, should be comparable to local civilian community standards. In many settings, the standard of care may exceed that of the local civilian community. In deployed settings, the altered standard of care will not necessarily mirror that of the host nation but will be based on available assets and requirements consistent with preexisting medical triage practice.

## **C. TRIAGE**

1. When all available resources are insufficient to meet the health care needs of beneficiaries in a public health emergency, the MHS shall use the limited resources to achieve the greatest good for the greatest number. Under these circumstances, “good” is defined as lives saved and suffering alleviated. In an environment of insufficient resources, MHS commanders shall not require expenditure of resources if treatment likely would prove futile or if a disproportionate amount of assets would be expended for one individual at the cost of many other lives that otherwise could be saved. MHS commanders are to ensure the most competent medical authority is available, at the lowest level of command possible, to make medical judgments of this nature.

2. Decisions involving triage for care and the allocation of medical supplies also must take into account the values of personal rights and fairness to all. Critical mission requirements may require allocation of resources based on operational rather than medical risk. MTFs will provide care to their enrolled populations as noted previously. Other eligible beneficiaries are expected to seek care at the facilities where they routinely receive primary care.

3. MTF commanders must communicate regularly and clearly on the resource limitations that exist at their facilities to maximize the communities’ effective response to a public health emergency. Access to MTF care will comply with the beneficiary group priority list at 32 CFR 199.17. However, availability of care is always subject to mission requirements directed by the President or Secretary of Defense.

## **D. OTHER PRIORITIZATION ISSUES**

1. Commanders and health care providers throughout DoD need to include this prioritization framework in ongoing planning.

Commanders and health care providers must effectively communicate these decisions to each other and the community before emergencies, as well as during emergencies when conditions change.

2. Conditions affecting decisions include, but are not limited to, availability of health care providers and resources such as pharmaceuticals, ventilators, and hospital beds, all in the context of evolving disease characteristics on target and at-risk populations. A decision made in one area may not be appropriate for another due to conditions such as population demographics, susceptibility, capacity, and resources.

4. A discussion of planning challenges, including ethical issues, is in the Agency for Healthcare Research and Quality document “Mass Medical Care with Scarce Resources” (2007) ([www.ahrq.gov/research/mce/](http://www.ahrq.gov/research/mce/)).