THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

JAN 25 2006

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Department of Defense Influenza Pandemic Preparation and Response Health Policy Guidance

The prospect of an influenza pandemic affecting our nation and, in particular, the readiness posture of our military is untenable. While it is far from certain that the current avian flu virus, the highly pathogenic H5N1 strain, will result in a pandemic, we must be well prepared for the eventuality that a pandemic flu virus will affect this country at sometime in the future.

Because of this threat, I have had my public health and preventive medicine experts develop the attached comprehensive pandemic influenza policy document for use in the writing of the Combatant Command's and the installation's pandemic influenza plans. I ask that you carefully consider and incorporate the assumptions, facts, and other considerations that are contained in the document. My point of contact for questions is Colonel George Johnson at (703) 578-8523 or George.Johnson@ deploymenthealth.osd.mil.

William Winkenwerder, Jr., MD

Attachment:
As stated

cc:
Under Secretary of Defense (Acquisition, Technology & Logistics)
Under Secretary of Defense (Policy)
Under Secretary of Defense (Personnel and Readiness)
Assistant Secretary of Defense (Reserve Affairs)
Assistant Secretary of Defense (Homeland Defense)
Directors, J-3 and J-4
Service Surgeons General
Medical Officer of the Marine Corps
Joint Staff Surgeon

Department of Defense
Influenza Pandemic Preparation and Response Health Policy Guidance

December 23, 2005

I. References. See Appendix 5.

II. Situation. Influenza epidemics occur seasonally, generally in winter months. Medical plans and annual vaccines minimize impacts of annual influenza epidemics in the United States (references a, c, d). Influenza pandemics occur infrequently and cause substantially higher morbidity and mortality. Whereas annual, seasonal epidemics have the greatest impact on elderly and medically high-risk groups, pandemics are likely to cause high levels of morbidity and mortality in all populations. Because of this, an influenza pandemic could have a significant impact on military operations. The US Department of Health and Human Services (HHS) and the World Health Organization (WHO) drafted influenza pandemic preparedness plans (references l and s). The Department of Defense (DoD) must also prepare for an influenza pandemic.

III. Purpose. This document supersedes reference b. This guidance provides policy and instructions to prepare for and respond to an influenza pandemic. The goal of this guidance is to maintain operational effectiveness by minimizing death, disease, and lost duty time due to an influenza pandemic. It provides assumptions and considerations at the DoD level and directs subordinate units throughout the DoD to develop plans appropriate for their areas of responsibility. This DoD guidance facilitates integration into the National Strategy for Pandemic Influenza (reference n), outlines an appropriate response for military installations and contingency operations around the world, and provides guidance for defense support to civil authorities (reference h). This document only addresses a pandemic due to influenza virus. Other strategies will be necessary to deal with non-influenza pandemics.

IV. Applicability. This guidance applies to the Military Departments, the Joint Staff, and the Combatant Commands. It is provided to the US Coast Guard as a reference.

V. Assumptions.

A. Pandemic influenza assumptions:

1. An influenza pandemic could occur in any season and could affect a substantial portion of the world population.

2. Most US military personnel would be susceptible to the illness.

3. Once an influenza pandemic is introduced into the United States, it could spread quickly to all parts of the country.

4. A pandemic in the US could result in 20-35% of the population becoming ill, 3% being hospitalized, and 1% dying.

5. In an affected community, a pandemic outbreak will last about 6-10 weeks. Multiple pandemic disease waves are likely.

B. Civil support assumptions:

1. The DoD will support the HHS in the national effort by, among other things, conducting medical and laboratory surveillance and diagnostic testing through DoD members of the Laboratory Response Network (LRN), and by participating on the Food and Drug Administration Vaccines and Related Biologic Products Advisory Committee and the Centers for Disease Control (CDC) Advisory Committee on Immunization Practices as influenza vaccine recommendations are formulated (reference f).

2. In the event of a pandemic, DoD may, under applicable authorities, assist civil authorities by providing logistical and medical support (e.g., emergency immunization clinics, antiviral drug distribution, and supportive medical care as needed.)

3. In an emergency, combatant commanders, local military commanders and responsible officials of the DoD components located in areas affected by the influenza pandemic may, upon a civilian request, respond immediately to save lives, mitigate human suffering, minimize property damage, or restore essential operations and services (reference h).

C. Antiviral drug assumptions:

1. Should pandemic influenza occur before vaccine is available, use of antiviral drugs may reduce the impact on military units.

2. Due to limitations in manufacturing capacity and competing civilian public health requirements, the amount of anti-influenza drugs available to the DoD for treatment and prophylaxis will most likely be insufficient to meet demands.

D. Medical care assumptions:

1. In an influenza pandemic, military and civilian medical treatment facilities may be overwhelmed, particularly with patients with viral and bacterial pneumonia.

2. Support of critically ill patients could require increased medical staff, increased numbers of ventilators, and increased monitoring equipment.

3. Shortages of medical supplies, food deliverables, medical care personnel, support staff, and other important commodities may seriously impede the ability of hospitals to meet the increased demand for medical care.

4. In a moderate pandemic, there will be a 25% increase in demand for intensive care and in-patient beds as estimated by the CDC. Depending on the extent of the pandemic, the demand could be larger.

5. Demand for mortuary affairs support may be considerable.

E. Vaccine assumptions:

1. The DoD will use the same vaccine formulation as the US civilian population.

2. The HHS and the DoD will cooperate to assure that DoD vaccine requirement priorities are recognized and are met as appropriate for national security needs, in light of national health care priorities.

3. The time between identification of a new strain and vaccine availability may be six to nine months.

4. A vaccine against the pandemic strain would either be licensed by the FDA, probably through a supplement to a prior influenza vaccine license, be authorized for use through the process applicable to Emergency Use Authorizations (EUA) (21 USC 360bbb-3), or be available through the process applicable to Investigational New Drugs (IND) used for Force Health Protection (reference i).

5. Once a licensed vaccine is available and supplies are adequate, military units could be immunized within a few months. Timetables and immunization rates with vaccine under EUA or IND rules are more uncertain.

6. Individuals would require two immunizations, and a total of 6 weeks (from the time of the first vaccination) for maximum immunity.

F. Laboratory Assumptions:

1. Both DoD and non-DoD laboratories that are LRN reference and national laboratories will conduct rule in/rule out testing for the pandemic virus in active duty and beneficiary populations.

2. A pandemic could quickly overwhelm existing laboratory diagnostic capabilities. The most intense testing will be during the early stages of the pandemic.

3. Department of Defense clinical laboratory assets may be called upon to supplement testing capabilities of the US civilian sector.

4. Critical laboratory reagents/shipping supplies for identifying pandemic strains are likely to become scarce.

G. Operational assumptions:

1. It is possible that medical response to an influenza pandemic will be required while military forces are simultaneously engaged in armed conflict.

2. Ground Operations. Should an influenza pandemic affect US forces during field operations, the number of ill, dying, and dead personnel would have a significant impact on force strength, perhaps causing curtailment of the operation. Opposing forces would be similarly affected.

3. Air Operations.

a. It is possible that entire aircrews could become ill simultaneously in flight.

b. Influenza may be rapidly spread across long distances by persons traveling by air.

c. Curtailing passenger air transportation completely might temporarily delay movement of influenza from one region to another, but the disease would probably arrive eventually.

d. Restriction of movement between affected and unaffected areas may be helpful. Civilian air transportation may be seriously affected in a worldwide pandemic resulting in inability to move people and supplies, including emergency medical supplies.

e. In most instances, it would be best not to utilize air evacuation to transport patients with pandemic influenza (PI). However, if the patient must be moved, infection control procedures must be utilized in accordance with reference o.

4. Sea Operations. Influenza pandemic outbreaks on shipboard are likely to spread with great efficiency. Consequently, a large proportion of crews are likely to be ill simultaneously. Onboard medical facilities will be quickly overwhelmed.

VI. Legal Considerations.

A. CONUS installation commanders are authorized to implement emergency health powers on their installations in order to protect military personnel and property (reference j). These special powers include restriction of movement and use of disease containment strategies (isolation, quarantine, social distancing) as well as medical evaluation and treatment. In exercising emergency health powers, installation commanders should obtain advice from their installation's Medical Treatment Facility Commander, Public Health Emergency Officer (PHEO), and legal staff.

B. Installation commanders at OCONUS locations will be restricted in implementation of Emergency Health Powers by Host Nation law and applicable international agreements. This may affect any movement of host nation assets.

VII. Execution.

A. Operational priorities. Other than for categories 1 and 2 below, actual priorities for use of limited supplies of vaccine and antiviral drugs will be addressed based on emerging circumstances. In addition, priorities may change with the phase of the pandemic, both globally, as well as locally. Potential priority uses include:

1. Maintaining the health and operational capability of the fighting force. This is accomplished through preventive methods and appropriate medical treatment.

a. Air Operations. If crews have not been immunized, then antiviral drugs should be considered, or, if not available, consideration should be given to canceling flights from heavily affected areas.

b. Sea Operations. Ships' crews should receive high priority for early immunization with newly manufactured influenza vaccine and should be considered for use of antiviral drugs. If operationally feasible, ships that are spared outbreaks during a pandemic should consider remaining at sea or seek alternative ports until the on-shore epidemic as subsided.

c. Combat Operations. Personnel involved in combat or assigned to alert status should be given high priority for vaccination and use of antiviral drugs considering the devastating effect that an outbreak of PI could have on the combat mission.

2. Maintaining medical capabilities through surging to meet excess demand and by preventing and promptly treating illness among healthcare providers and supporting personnel.

3. Preventing death and disease in the beneficiary population. This priority includes treating those who become sick.

4. Treating allied forces with whom we are deployed. To the extent possible, US forces should provide necessary vaccine and/or antiviral drugs to allied forces engaged in coalition operations if these medications are not available from their own countries. This assistance would not only assist mission accomplishment, but also provide herd immunity to protect our fighting forces working alongside allied forces.

5. Assisting the military of host nations where US forces are assigned.

6. Assisting civil authorities in efforts to minimize the impact of a pandemic.

7. Assisting in humanitarian assistance and disaster relief operations.

B. Concept of Pandemic Progression. An influenza pandemic is expected to evolve in six phases. These phases have been specified by HHS and WHO (references l, s). The predominant pandemic phase and associated tasks may vary by location. Notification of movement through the pandemic phases will be as follows: The Secretary, HHS, will notify the Secretary of Defense and the Assistant Secretary of Defense for Health Affairs who will in turn notify the Joint Staff and the Surgeons General. Commanders will be informed via command channels, augmented by reports in the news media. A brief definition of the phases follows.

C. Tasks. For each pandemic phase, certain tasks should be undertaken within DoD and its subordinate entities. However, because of variable distances of DoD installations from outbreaks, not all tasks will be accomplished simultaneously in each location.

1. WHO Phase 1: (Interpandemic Period) No new influenza virus subtypes have been detected in humans, although a subtype that has caused human infection may be present in animals. The risk of human infection is considered to be low. Ongoing seasonal influenza activity is dealt with by existing organized systems of surveillance, vaccine production and standard public health practices.

a. The Office of the Secretary of Defense:

(1) Provides guidance in pandemic planning.

(2) Provides policy guidance for prioritization of limited resources such as antiviral medicines (reference e) and vaccines.

(3) Coordinates with the World Health Organization, HHS, allies, coalition members, and other Federal agencies in developing pandemic response guidance.

(4) Ensures interoperability with the interagency Joint Operations Center, as established by the lead federal agency (HHS), and ensures communications with all Federal agencies are sufficient to accomplish the mission.

b. The Joint Staff:

(1) Provides planning guidance and direction to Combatant Commands

(2) Ensures COCOMs develop medical contingency response plans to an influenza pandemic outbreak. Include plans for force health protection, defense support of civilian authorities, and support to humanitarian assistance and disaster relief operations.

c. The Military Departments:

(1) Develop contingency medical response plans to an influenza pandemic outbreak. Include plans for force health protection, conduct of epidemiological investigations, defense support of civilian authorities, and support to humanitarian assistance and disaster relief operations.

(2) Maintain rosters of service epidemiologists and other public health personnel trained to conduct epidemiological investigations.

d. Installation commanders:

(1) Designate a PHEO (reference j). The PHEO is the Medical Treatment Facility Commander, or senior clinician with experience and training in functions essential to effective public health emergency management (reference i).

(2) Develop an installation influenza pandemic plan. At a minimum include in the plan: timing, and implementation of emergency health powers, medical care, alternate medical facilities, quarantine, risk communication, prioritization of vaccine and antiviral drugs, coordination/support from and to local communities and host nations, coordination with appropriate personnel for chaplain services, and mortuary affairs.

e. MTF commanders:

(1) Develop the medical portion of the installation pandemic plan. Coordinate plan with their Service, Combatant Command Surgeon, local and state health departments, and if appropriate, Host Nation ministries of health. At a minimum, the plans should include the following issues:

(a) Inpatient Bed Surge Capacity. Demand for inpatient care is anticipated to increase at least 25% during a pandemic. Conversion of buildings outside

of hospitals, such as schools and churches, may be required to augment the hospital facility. This will require support from installation commanders.

(b) Staffing needs. Provision should be made to augment staff or to accomplish emergency training for volunteers. If healthcare staffing is augmented through cross training, privileging will need to be addressed. JACHO has tenets for emergency privileging. All staff members need to be trained in protocols once a pandemic begins.

(c) Occupational Health Program. Laboratory and healthcare workers will need to be monitored continuously for signs of infection, and removed from the workplace, if symptomatic, until influenza or other contagious disease is ruled out. Employees at increased risk may need to be removed from patient care, or to provide care for low risk patients without infectious disease. Depending on availability of supplies, health care personnel should be immunized (appendix 4) and provided antiviral prophylaxis.

(d) Durable medical equipment, medical supplies, and medications.

i Planning should include additional supplies of personal protective equipment, ventilators, antibiotics to treat secondary pneumonia, and other necessary equipment to meet anticipated surge capacity.

ii Pandemic Influenza Vaccine. If available, the DoD will supply installations with vaccine for designated military personnel, medical personnel, and high-risk individuals according to a schedule of priorities listed in appendix 4. Military Treatment Facilities (MTFs) will obtain vaccine for other beneficiaries through their usual MHS logistics mechanism or the local or state health department.

iii Antiviral Drugs. Similarly, the DoD will supply some antivirals to MTFs for use according to DoD policy, both for prophylaxis and treatment (reference e). Military Treatment Facilities will go through usual MHS logistics channels or through the health department to access the Strategic National Stockpile established by the HHS to obtain antiviral medications for civilian beneficiaries.

(e) Public Health Education. Effective risk communication will be an integral component of an effective response. Messages should be pre-drafted for each pandemic stage and varying disease scenarios, using multiple formats. These should include basic information regarding the disease and progression, and the rationale for movement restriction and use of snow days. Education materials should include discussion of emotions in themselves, colleagues and families (to include children) during a pandemic, and the availability of support services, including

mental health and chaplains' services. These materials should also include information regarding family and unit communication plans. Public affairs should assist with message writing and take the lead in dissemination.

(f) Fever Triage Clinics/Influenza hotlines. These should be used during a pandemic to try to separate well patients from sick patients in order to decrease the spread of infection in the community.

(g) Mental Health Services. The senior medical officer should integrate installation mental health assets with community-based and non-governmental organizations who have expertise in, and the resources for, psychosocial support services and training.

(h) Use of laboratory assets. As stated in assumptions, it is likely that laboratory assets will not be adequate to meet demand. The plan should include a prioritization of these resources according to DoD clinical guidelines (appendix 1). Before the start of the pandemic, DoD laboratory testing will focus on seasonal influenza surveillance, detection of novel influenza strains, and preparedness planning for a pandemic.

(i) Patient tracking mechanisms. Patient tracking for all patients, whether inpatients, outpatients, or telephone triaged patients should be planned. Civilian and Host Nation medical care of beneficiaries should also be reported.

(2) Continue to support seasonal surveillance for influenza-like illnesses. MTF commanders will support the DoD Flu Surveillance Program with sentinel site lab-based specimen collection where biological specimens are obtained for respiratory viral isolation and typing. Laboratory-based enhanced surveillance should be done by non-sentinel sites when significant elevations of influenza-like-illness are observed, and after consultation with Service Health Surveillance Centers using DoD or other LRN labs. The Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) is used for routine monitoring of syndromic diseases seen in MTFs. Service-specific guidance and the Reportable Medical Events (RME) Guidelines should also be used for to report confirmed PI cases (reference q). Deployed medical units should report in accordance with Joint Task Force (JTF) requirements. The JTF may choose to augment established DNBI and RME reporting.

f. Public Health Emergency Officers:

(1) Aid the installation commander and the tenant commanding officers in development of the installation pandemic influenza plan, including:

(a) Ascertaining existence of cases suggesting a public health emergency.

(b) Recommending implementation of proper control measures.

(c) Advising MTF commander, installation, and tenant commanders on medical aspects in declaration of public health emergency

(d) Maintaining functional relationships with State/local health authorities, and Joint Regional Medical Planners.

(e) Coordinating appropriate risk communication efforts with public affairs offices

(2) Assume a central role in disease notification and pandemic planning, coordinating with local and state public health departments and the Centers for Disease Control and Prevention (CDC) to ensure a coordinated medical response by the installation, and its civilian community.

2. WHO Phase 2: (Interpandemic Period). No new influenza virus subtypes have been detected in humans, but a circulating animal influenza virus subtype poses a substantial risk of human disease. DoD surveillance measures are increased.

a. Joint Staff ensures Combatant Commands:

(1) Review their plans and the plans of their subordinate organizations.

(2) Review Host Nation support agreements, and if necessary, augment Host Nation surveillance and containment capabilities. Arrange for Host Nation support to deployed US personnel, if necessary.

b. Military Departments review their own plans and the plans of their subordinate organizations.

c. Installation Commanders:

(1) Exercise pandemic plans, including mass immunization plans and containment strategies.

(2) Develop training programs to improve performance in exercises.

(3) Work with tenant commanders to ensure unit readiness at the lowest level.

d. MTF Commanders work with the PHEO to increase surveillance activities and contact with civilian public health surveillance systems as appropriate.

3. WHO Phase 3: (Pandemic Alert Period). Human infections(s) with a new subtype occur, but without human-to-human spread, or at most, rare instances of spread to a close contact.

a. DoD, Joint Staff, and Combat Commands review all tasks corresponding to WHO Phases 1-2, and accomplish any that have not been completed.

b. Military Departments:

(1) Review all tasks corresponding to WHO Phases 1-2, and accomplish any that have not been completed.

(2) Ensure that MTFs accomplish any training necessary for health care providers. At a minimum, ensure that medical personnel receive the training delineated in the MTF Commander responsibility section below.

c. Installation Commanders:

(1) Review all tasks corresponding to WHO Phases 1-2, and accomplish any that have not been completed.

(2) Schedule, conduct, and evaluate training to meet requirements of this document, as well as their own pandemic plans.

(3) Exercise and prepare to implement containment measures.

d. MTF Commanders:

(1) Develop medical response capability, prepare to treat influenza patients, and prepare for surge capability as delineated in the installation plan.

(2) Establish stockpiles of personal protective equipment, medical supplies, food, fuel, laboratory shipping materials, and medications, as available.

(3) Identify sources for additional medical supplies.

(4) Assign, train, and exercise epidemic, immunization, medical treatment, and all other contingency response teams.

(5) Exercise triage clinics, phone centers, and home health medical teams to provide support within the community.

(6) Exercise surge capability by using volunteers and professionals from the community or outside the area.

(7) At a minimum, train staff on:

(a) Clinical diagnosis/detection of Pandemic Influenza (PI).

(b) Clinical guidelines for treatment of PI, including immunization, timing and use of antivirals and other medications, timing of hospitalization, and prevention of transmission.

(c) Policies and procedures for performing laboratory diagnostic tests on patients with suspected PI, including safe handling of laboratory specimens from patients with PI.

(d) Infection control for PI patients admitted to the hospital or seen in the clinic.

(8) Enroll staff (according to MTF pandemic plan) in an ongoing occupational health-screening program, and monitor laboratory and medical personnel for influenza-like-illnesses during the Pandemic Phase, and treat as necessary (see appendix 1 on Clinical Guidelines).

(9) Appoint Vaccination Site Coordinators, and prepare for staff to conduct rapid, mass immunization against PI at other than hospital or clinic locations.

(10) Continue and refine medical surveillance for influenza-like-illnesses (febrile, upper respiratory), and report cases of influenza-like-illness via the reportable medical event (RME) process. Exercise plans for increased laboratory-based surveillance during an outbreak and for telephonic reporting of suspected cases via hotlines.

(11) Exercise plans for increased medical surveillance during an outbreak, particularly laboratory-based surveillance, and ensure that all laboratory reporting mechanisms are in place.

4. WHO Phase 4: (Pandemic Alert Period). Small clusters with limited human-to-human transmission occur, but spread is highly localized, suggesting that the virus is not well adapted to humans.

a. DoD, Joint Staff, Combat Commands, and Military Departments review all tasks from WHO Phases 1-3, and accomplish any that have not been completed.

b. Installation Commanders, with advice from the MTF Commanders and Public Health Emergency Officers (PHEOs):

(1) Review all tasks from WHO Phases 1-3, and accomplish any that have not been completed.

(2) Ensure that tenant commands are implementing their influenza control plans in accordance with the installation plan.

(3) Continue medical surveillance as in Phases 1-3, and consider increased surveillance activities, including screening (surveys, checking vital signs, and further evaluation of those with suspicious signs/symptoms) of individuals arriving from affected locations.

(4) Consider institution of disease containment strategies. Emergency Health Powers can be used to protect military personnel and property (reference e).

(5) Consider restrictions for non-essential travel to affected areas.

(6) Consider other community containment measures listed in appendix 3.

(7) Implement risk communication plan.

c. MTF Commanders, with advice from the PHEO, increase active surveillance and ESSENCE monitoring to 7 days a week if cases have been identified within 100 miles of the installation.

5. WHO Phase 5: (Pandemic Alert Period). Larger cluster(s) occur, but human-to-human spread is still localized, and the virus is becoming better adapted to humans but not yet fully transmissible.

a. DoD, Joint Staff, Combat Commands, and Military Departments prepare for release of stockpiles. Release of vaccine and antiviral medication will be at the direction of the ASD (HA).

b. Installation Commanders, with advice from the MTF Commanders and PHEOs:

(1) Continue medical surveillance as in Phases 1-4 and consider increased surveillance activities, including screening (surveys, checking vital signs, and further evaluation of those with suspicious signs/symptoms) of individuals arriving from affected locations.

(2) Ensure tenant commands are implementing their pandemic plans in accordance with the installation plan.

(3) Consider institution of disease containment strategies. Emergency Health Powers can be used to protect military personnel and property (reference j).

(4) Consider restrictions for non-essential travel to affected areas.

(5) Consider other community containment measures as listed in appendix 3.

(6) Begin immunization of personnel, if vaccine is available.

(7) Continue to execute risk communication plan.

c. MTF Commanders focus laboratories on detection of cases until the pandemic is underway. Increase active surveillance and ESSENCE monitoring to 7 days a week.

6. WHO Phase 6: (Pandemic Period). A pandemic is confirmed with increased and sustained transmission in the general population.

a. The Secretary of Defense:

(1) Authorizes DoD forces to provide civil support (reference h) and support of emergency functions of the National Response Plan (reference m).

(2) Relying on competent public health advice, may consider curtailment of air transportation to specific regions.

(3) Through the Office of the Assistant Secretary of Defense (Public Affairs), assists HHS to prepare news releases for the media. The HHS develops public-affairs guidance under the National Response Plan (reference m). The Assistant Secretary of Defense for Public Affairs is the point of contact for all media inquiries concerning DoD support. The interagency Joint Information Center, using health risk communication principles, will provide information to the media.

b. The ASD(HA):

(1) Authorizes the Defense Logistics Agency to release stockpiles in accordance with reference e.

(2) Directs overall distribution of stockpiles.

c. The Joint Staff:

(1) Executes distribution of stockpiles to Combatant Commands.

(2) Arbitrates conflicts among Combatant Commands if concerns arise about equitable distribution of supplies.

(3) Provides instructions to implement available medical and non-medical countermeasures.

(4) Receive reports from COCOMs in accordance with paragraph (5)(c) below and provide copies to ASD (HA).

(5) Ensure Combatant Commands:

(a) Distribute vaccine and antiviral medications to MTFs using DoD prioritization guidelines (appendix 4 and reference e).

(b) Receive reports of influenza cases and coordinate logistical efforts.

(c) Provide summary PI status reports to the Joint Staff on a daily basis starting with the first report from the installations. Continue to report until there have been no cases in the Area of Responsibility for 10 days or until otherwise directed. Report the actual percentage of personnel unable to work. Categories for reporting are as follows:

i No impact - Less than 5% of government employees/contract support are not able to work.

ii Minimal Impact - At least 5% and less than 15% of government employees/contract support are not able to work.

iii Moderate Impact - At least 15% and less than 30% of government employees/contract support are not able to work.

iv Severe Impact - 30% or more of government employees/contract support are not able to work.

(d) Have their COCOM Surgeon staff coordinate with influenza pandemic response staff at Host Nation ministries of health to synchronize information exchange for military chains of command.

(e) Have their COCOM Surgeon staff coordinate communications with state, territorial, national, and international public health authorities.

(f) Have their COCOM Surgeon staff coordinate activities of DoD influenza pandemic response teams.

(g) May designate an influenza pandemic coordination cell consisting of medical, logistics, and subject matter experts, which will receive Service reports of influenza cases and provide advice for medical and logistical support. The cell will coordinate with the Office of the Assistant Secretary of Defense (Health Affairs), the Military Services, the CDC, the FDA, and other federal and non-federal agencies.

d. Military Departments:

(1) Oversee distribution of stockpiles within respective Services.

(2) Prepare to quickly augment clinical staff of MTFs overwhelmed with influenza patients.

(3) Ensure that units and individuals not under COCOM control and not located on installations are undertaking appropriate actions.

e. Installation Commanders:

(1) Evaluate their installations and units to determine the preparedness of medical surveillance for influenza cases on the installation.

(2) Perform ongoing assessment of impact on forces throughout the epidemic and provide Installation PI Status Reports as directed by the Combatant Command.

(3) Continue to execute the risk communication plan. Coordinate with civil authorities for effective use of military capabilities requested to support federal and civil response plans

(4) Coordinate with law-enforcement officials to provide security of DoD personnel and equipment.

(5) With advice of the PHEO, the Medical Commander and legal counsel, consider implementation of all post-outbreak control measures as described in appendix 3, including snow days, individual quarantine, alternate location fever clinics, cancellation of public events, and community quarantine.

(6) Implement infection control measures for workplaces, community settings, and DoD installations. Persons at high risk for complications should avoid public gatherings. While wearing surgical masks in these settings is not recommended by CDC, it might be effective at reducing transmission and the risk of infection. Infection control in these settings should focus on keeping sick individuals at home while they are infectious, and promoting respiratory hygiene/cough etiquette and good hand hygiene. Participate in consequence management operations with Federal, state, territorial, and local agencies. Similarly participate in foreign consequence management operations with host nations when requested to do so and when the operational mission permits.

f. MTF Commanders:

(1) Make final preparations to accommodate an increased workload, both in outpatient clinics and inpatient facilities, including establishment of Auxiliary Treatment Facilities.

(2) Ensure medical personnel are briefed/trained on clinical guidelines, including triage in emergency room and clinics, inpatient care, utilization of laboratory services, and limiting transmission of disease. Encourage hand washing and use of hand sanitizer gel for providers.

(3) Promptly identify suspected or confirmed cases or clusters of disease. Initially, focus MTF laboratories' efforts on detection of cases until the pandemic is underway. Once the pandemic has occurred, make presumptive diagnoses based upon clinical symptomatology.

(4) Provide care for influenza patients, and increased numbers of patients with secondary bacterial pneumonia.

(5) Initiate influenza hotline to facilitate screening of a large number of potentially infected people. Those who suspect that they have influenza, may call special influenza hotlines that can provide advice on staying home, reporting to an influenza clinic, or directly to the hospital. Implement home health care delivery as appropriate.

(6) Use containment measures (appendix 3), including:

(a) Infection Control Measures for MTFs. Infection control precautions may include a combination of standard and contact precautions, with droplet or airborne precautions, depending on transmissibility of the disease. Isolate infected patients from non-infected patients. Implement occupational health surveillance programs detect infected medical personnel.

(b) Infection Control Measures for ambulatory patients. These patients should limit contact with other persons in the home, as well as outside the home, for a period of five days after the onset of symptoms, except if medical care is necessary. Those persons with immune deficiencies

should limit contact with others for a more extended time as determined by their health care provider. When it is necessary to interact with other persons, the patient should follow respiratory hygiene/cough etiquette procedures, with the use of a simple surgical mask, if available. All persons in the home should follow recommendations for good hand hygiene.

(c) Contact tracing. Due to the period of contagiousness prior to the development of symptoms, and the short incubation period, this may be of limited usefulness with influenza. As the pandemic of influenza progresses, this becomes even less useful.

(d) Immunize beneficiaries as vaccine becomes available. Use DoD (HA) guidance to prioritize beneficiaries until vaccine is available for all (appendix 4). If vaccine is not available, provide anti-influenza medications as available (reference e).

(e) Targeted chemoprophylaxis with antivirals. Most likely, the supply of antivirals will be extremely limited. However, the use of chemoprophylaxis may be considered if consistent with the DoD Policy for Release of Antiviral (Tamiflu®) Stockpile During an Influenza Pandemic (reference e) and the Clinical Guidelines (appendix 1).

(7) Medical unit reports. Report daily, starting from the first confirmed (or highly suspicious) case of pandemic influenza. Report through the installation chain of command to the Combat Commands, with informational copies to the Services, NLT 2400 Zulu each day, using proper classification in the report. Continue to report until there have been no cases on the installation for 10 days, or until otherwise directed by higher headquarters. Include confirmed and highly suspicious cases of PI, with the following information:

(a) Deaths from PI (new/cumulative numbers).

(b) Inpatients with PI (current/cumulative).

(c) Inpatient bed availability (total # available/total # of beds).

(d) Intensive care unit bed availability (total # available/total # of beds).

(e) Total number of patients presumptively diagnosed with PI (inpatient/outpatient/telephone triage), both new and cumulative in each category.

(f) Doses of vaccine available (# doses available/# doses required for population (assuming two doses per person)).

(g) Courses of antiviral medication available (# courses available/# of courses required for the population).

(h) Number of ventilators available (# available/total # of ventilators).

(i) Other medical supplies in short supply.

(j) Medical staff health status – report categories and percentages as defined in this document (paragraph VII.C.6.c.(4)(c)).

7. WHO Pandemic has ended. This determination can be made when indices of influenza activity have reverted to pre-pandemic levels, and immunity to the novel virus strain is widespread in the population. At this time, after-action reports and lessons learned should be prepared at all levels as directed, and forward through the Combat Commands to be documented in the Joint Lessons Learned Databases.

VIII. Logistics. The principal materiel requirements for an influenza pandemic include specially formulated influenza vaccine, antiviral drugs, ventilators, and personal protective equipment. The DoD will coordinate its purchases of antiviral drugs and influenza vaccine through the Defense Supply Center Philadelphia. Supplemental funds will have to be appropriated for this purpose. Considerable demand for ventilators is likely, especially in the event that the pandemic occurs before vaccine is available. Consideration should be given to stockpiling instead of "just-in-time" acquisition of adequate numbers of ventilators, antiviral drugs, and other medical supplies.

Influenza Pandemic Preparation and Response Guidance
APPENDIX 1: Pandemic Influenza Facts and Clinical Guidelines

I. General background.

A. Influenza A viruses infect many different animals including birds and mammals and can cross from one species to another. When this occurs, a new virus may develop, either through mutation of that single virus or mixing of individual viruses. The result can create a new influenza virus that is highly infective, capable of effective person-to-person transmission and able to cause a high proportion of deaths or serious illness in people. Pandemic influenza is an explosive global event in which populations worldwide are at risk. Previous pandemics have spread across the globe within months. With modern transportation the spread of disease will occur much faster. When such a pandemic virus strain emerges, 25% to 35% of the population could become ill with a substantial proportion dying. A more detailed discussion of influenza A viruses and pandemic influenza can be found in appendix B of references (http://www.hhs.gov/pandemicflu/plan/appendixb.html).

B. Influenza usually spreads by inhalation of droplets released when an infected person coughs or sneezes. Recent experience in Southeast Asia suggests that infection can also occur after handling infected poultry. Symptoms found in recent cases of Avian Influenza begin with a febrile respiratory disease which progresses to severe disease in a high proportion of cases. Most have cough, difficulty breathing and diarrhea. Some have developed what appears to be a cytokine storm with multisystem involvement. Seasonal influenza symptoms begin one to four days after exposure however a conservative estimate of the incubation period for pandemic influenza is ten days. Infected individuals can pass the disease to others for one to two days before symptoms develop. Patients with seasonal influenza generally recover over a week to 10 days. Following the 1918 pandemic the recovery period for some individuals was measured in months.

C. As epidemiologic and clinical data is obtained clinical and laboratory guidelines will be adjusted accordingly. To obtain the most current information regarding clinical and laboratory guidelines refer to the DoD Pandemic Influenza Watchboard: https://fhp.osd.mil/aiWatchboard/index.html.

II. Pandemic Influenza Vaccine. Appendix 4 provides information regarding the pandemic influenza vaccine as does the MILVAX web site at http://www.vaccines.army.mil/default.aspx?cnt=disease/minidv&dID=57.

III. Antiviral drugs for prevention and treatment of influenza.[1]

A. Four antiviral drugs are currently licensed in the United States for prevention and/or treatment of influenza. These drugs are likely to be limited in supply and potentially ineffective due to resistance. Antiviral drugs are not a substitute for specific influenza vaccines but may prove to be useful during the period before a vaccine is available. Antiviral use is an adjunct to effective public health measures and treatment. It should not be expected to result in rapid resolution of symptoms in all patients.

1. Amantadine is licensed for prophylaxis and treatment of infection caused by various strains of influenza A virus. A significant problem with long-term use is that resistance can develop in a matter of days. The drug is currently not indicated for H5N1 avian influenza due to widespread resistance.

2. Rimantadine is licensed for prophylaxis and treatment of illness caused by various strains of influenza A virus in adults and children. Rimantadine has been shown to cause fewer central nervous system side effects than amantadine. The safety and effectiveness of rimantadine prophylaxis have not been demonstrated for longer than six weeks. Like Amantadine, resistance develops quickly. It is currently not indicated for use against H5N1 avian influenza due to widespread resistance.

3. Oseltamivir (Tamiflu®) is approved for both prevention and treatment of influenza A and B. The current recommended treatment course is one capsule twice daily for five days. However, this could change, expect dosage guidelines to be adjusted. Recent experience suggests that Tamiflu®, when used early in the course of Avian Influenza is effective. Resistance to Tamiflu® occurs in approximately 4% of adults and up to 20% of children. While approved for the prevention of influenza, oseltamivir is not a substitute for early vaccination. DoD has a stockpile of Tamiflu®, for use during an influenza pandemic (reference e).

4. Zanamavir (Relenza®) is approved only for treatment of influenza A and B. Relenza® is not approved for use in prevention of influenza (prophylaxis) and is not a substitute for influenza vaccine. Relenza® is a powder that is inhaled using a Diskhaler. Unlike Tamiflu®, Relenza® cannot be used for influenza with concomitant complications, nor does it reduce the incidence of complications. Relenza®, as yet, does not promote the development of resistance. The DoD is currently pursuing the addition of Relenza ® to the DoD antiviral stockpile.

B. Antiviral use should be based on availability and effectiveness of antiviral medications, the severity of symptoms and probability of serious complications or death should antiviral medication be withheld. Prioritization of antiviral use begins with those who are hospitalized with pandemic influenza; however, antiviral medications should not be used in those where treatment is considered futile or in those in whom symptoms have been present for more than 48 hours. Prophylaxis may be indicated in some instances

[1] General information may be found in Couch RB, "Prevention and Treatment of Influenza," *New England Journal of Medicine*, 2000; 343: p. 1778-87.

for either protection or containment; however, prophylactic use of antiviral agents significantly increases the consumption of a limited resource. For example, given a 30% attack rate, for every infection avoided during a 6 week course of prophylaxis twelve individuals could be treated. Should administration of antiviral medication be effective in reducing the severity and course of disease, close surveillance of selected personnel with prompt initiation of treatment will foster the development of an immune cadre of personnel and decrease overall antiviral expenditures. This approach also assumes adequate staffing resources and the ability to cohort staff and patients to avoid inadvertent transmission during pre-symptomatic viral shedding. Prudent choices involving prophylaxis and treatment are necessary to achieve balance between long-term impact on troop strength and short-term protection of critical assets.

IV. The ability to rapidly recognize initial and subsequent cases of a novel or pandemic strain of influenza in a community will have a significant impact on disease containment strategies, as well as on monitoring and responding to disease within a community. During the interpandemic and pandemic alert periods, training of health care personnel should include information on case definitions for potential pandemic strains of influenza, procedures for screening individuals, guidelines for infection control, availability and appropriateness of laboratory diagnostic testing, and indications for and restrictions in the use of antivirals. Providers should know about laboratory diagnostic capabilities within DoD, as well as in their surrounding community. Guidelines for sample submission and processing should be well defined. During the early phases of a developing pandemic, diagnosis will likely be established based upon clinical, epidemiological, and laboratory findings . As the pandemic is established, clinical diagnosis will likely predominate; guidelines also should be modified as case definitions, screening processes, laboratory diagnostic testing, and treatment algorithms change.

V. Current case definition:

A. During the Pandemic Period, the primary goal will be rapid and accurate identification of people with disease. Outpatient clinics, emergency rooms and laboratory assets are likely to be overwhelmed. Diagnosis will be based on clinical and basic laboratory findings rather than reliance on epidemiologic criteria and confirmatory laboratory diagnostics, which may be either in short supply or unavailable.

B. Clinical Criteria: Currently, a suspected case of influenza would include fever (>38^{o} C) plus one of the following: sore throat, cough, or dyspnea. To date, all cases of H5N1 have had abnormal chest radiographs and half have had diarrhea. It is uncertain what the clinical syndrome of the next pandemic will be. Should they differ, the modified criteria will be posted at www.cdc.gov/flu or http://pandemicflu.gov/, and should also be available through DoD public health or preventive medicine sources.

C. Epidemiological Criteria: During the interpandemic and pandemic alert phases, epidemiologic criteria will focus on the risk of exposure to a novel influenza virus. The incubation period for seasonal influenza is one to four days; however, incubation periods for novel influenza viruses may vary. The maximum incubation period is currently set conservatively at 10 days. During the pandemic phase, exposure history will have marginal utility particularly if there is widespread disease in the community.

In this instance, clinical criteria alone will be adequate for classification of suspected cases.

D. Exposure Risks: Exposure risk include those who have recently traveled to an area where there are birds with highly pathological avian influenza, or with confirmed human cases of novel influenza who have had close contact with poultry or with people with suspected or confirmed novel influenza. Occupational exposure risk includes persons who have contact with potentially infected poultry to include handling birds, processing poultry meat, and contact with bird droppings or blood. Additional occupational risk groups include laboratory workers in contact with infected animals or novel influenza viruses, as well as healthcare workers who have direct contact with patients with suspected or confirmed novel influenza.

E. For a more detailed description of diagnostic criteria and exposure risk see the HHS Pandemic Plan Supplement 5-III & IV at http://www.hhs.gov/pandemicflu/plan/sup5.html#novclin

VI. Initial clinical management

A. It will be necessary to follow local, state and DoD regulations for reporting patients who meet the criteria for pandemic influenza. All suspected or confirmed cases should be reported to the installation PHEO who will notify, through approved reporting channels, DoD Chain of Command, the CDC, and State/local health agencies.

B. Initial management should include droplet infection control precautions. Clinical management includes use of antiviral agents, if available, as well as supportive care with emphasis on rapid identification and treatment of secondary complications. As more information regarding the pandemic strain is obtained, further guidance will be made available. Care can be provided in an outpatient or inpatient setting. The decision to hospitalize an individual, with suspected novel influenza will be based on the physician's clinical assessment of disease severity, available resources, and suitability of the home environment for ongoing care. Possible admission to a critical care unit for ventilatory and other intensive support will be based upon the physician' clinical assessment of disease severity and available resources.

C. Clinical evaluation and assessment of patients with influenza-like-illness during the Interpandemic and Pandemic Alert Periods

1. Patients who have influenza-like-illness without a definitive alternative diagnosis should be questioned about recent travel to areas affected by avian influenza, direct contact with potentially diseased poultry or persons with confirmed or suspected novel influenza or potential occupational exposure to novel influenza.

2. Patients should be screened on admission for receipt of a recent seasonal influenza and pneumococcal vaccination. Those without a history of immunization should be vaccinated, if indicated, before discharge.

3. Diagnostic testing should include collection of appropriate specimens and arrangement of laboratory diagnostic testing. Guidance for other diagnostic testing

can be found in Supplement 5 of the HHS pandemic plan (http://www.hhs.gov/pandemicflu/plan/sup5.html)

D. Special situations and exceptions to the clinical evaluation and management guidelines

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

2. High-risk groups may present with atypical symptoms. These groups include young children or infants, elderly, those with underlying chronic illness, and those in long term care facilities. A strong epidemiologic risk may be adequate to prompt further evaluation. Children may present with gastrointestinal symptoms before respiratory symptoms are evident. Infants may present with fever, hypothermia or apnea without the usual symptoms associated with influenza.

VII. Home care infection control guidance

A. Most who develop pandemic influenza will not require hospitalization and can be cared for at home. Anyone who has been in a household of an infected individual during the incubation period is at risk for contracting the disease. The goal in the home care setting is to limit transmission within and outside the home.

B. Those cared for at home should be separated from other members of the household as much as reasonably possible. If possible one person should be designated as the primary care provider while other family members limit contact with the infected individual. Inasmuch as possible, patients should not leave the home as much as possible for the first five days after symptoms begin.

C. Infection control measures are recommended to include good hand hygiene. Used tissues should be placed in a plastic bag by the patient, to be sealed and disposed with the household waste. Masks are not recommended for routine use in the home, nor are separate eating utensils, provided that the utensils are washed with warm soapy water. Masks should be worn if it is necessary to leave the home while still infectious. Wearing a procedure or surgical mask when providing direct patient care may be beneficial. No special precautions regarding laundry are necessary except for avoiding self-contamination when handling contaminated laundry. Not hugging laundry and hand washing or using a hand sanitizer gel after handling laundry will avoid contamination.. Environmental surfaces should be cleaned normally.

D. Household members should be vigilant for the development of possible novel influenza symptoms and report them to their health care provider.

E. Health care providers who enter homes where there is a person with confirmed or suspected novel influenza illness should comply with droplet precautions. Professional judgment should be used to decide when to don a protective mask (e.g. when entering the patients room or upon entry into the dwelling).

F. Home care instructions can also apply to those housed in military sponsored group housing facilities.

VIII. Hospital care Infection Control Guidance

A. As the pandemic progresses, hospitalization should be reserved for those with severe complications who cannot be adequately cared for outside an inpatient setting. Hospitalized patients, whenever possible, should be admitted to a single room or cohorted with others with similar symptoms. Droplet precautions, to include respiratory hygiene/cough etiquette, should be reinforced. Droplet precautions sould be maintained for a minimum of five days from the onset of symptoms. If possible, patients should be placed in an airborne isolation room. These rooms should have monitored negative air pressure (in comparison to corridor pressure) with 6 to 12 air changes per hour and an exhaust to the outside, or air recirculation via a high efficiency particulate air (HEPA) filter. As the pandemic progresses this level of protection may not be feasible.

B. A National Institute of Occupational Safety and Health (NIOSH) approved N-95 disposable particulate respirator is required as the minimal level of respiratory protection for personnel providing direct patient care to those with, or suspected of having, an infection caused by a novel influenza. All NIOSH-approved N-95 disposable filtering face pieces require fit testing. Should provision of a N95 respirator not be available or feasible, surgical masks provide an adequate level of protection. Further information regarding use of respiratory protection can be found at the following web sites:

1. http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html
2. http://www.cdc.gov/flu/avian/professional/protect-guid.htm
3. http://www.cdc.gov/flu/avian/professional/infect-control.htm

C. Hand washing or use of a hand sanitizing gel is imperative after contact with potentially contaminated items, after removing gloves and between patient contacts. Personal protective equipment (PPE), to include gloves, gown, face/eye protection and an approved respirator should be worn when touching blood, body fluids, secretions, excretions and contaminated items as well as during procedures and direct patient care activities that are likely to generate splash or spray of blood, body fluids, secretions or secretions. A N-95 respirator should be added to the PPE ensemble during procedures that are likely to generate aerosols of respiratory secretions.

IX. Further guidelines regarding specific clinical practice recommendations will be issued subsequently to include specific treatment recommendations and laboratory diagnostic guidelines. Additional information can be found in the HHS Pandemic Influenza Guidance Supplement 5 at http://www.hhs.gov/pandmeicflu/plan/sup5.html.

Influenza Pandemic Preparation and Response Policy Guidance
APPENDIX 2: Laboratory Diagnostics

I. Situation. Laboratory services will be very important in early detection of an influenza pandemic and in the treatment of patients with the illness. Because of the risks of handling body fluids and specimens there is also risk of spreading the disease. This appendix provides guidance on laboratory planning for pandemic influenza, the utilization of laboratory services for identification of the disease, and reporting results.

II. Laboratory service planning for Pandemic Influenza (PI) should include:

A. Possible accommodations for shortages of available staff.

1. Cross-training laboratory staff in the areas of the laboratory most likely to be affected by increased workload during a pandemic influenza outbreak.

2. Interfacing with local and state public health laboratories and Veterans Administration hospitals to provide mutually beneficial support.

3. Developing criteria to possibly curtail non-critical testing or referring them to commercial reference laboratories.

B. Supplies

1. Augment laboratory supplies for pandemic influenza diagnosis and surveillance, personal protection, shipping, and mortuary services. On-hand stock levels of critical supplies should sustain operations for 6 to 8 weeks.

2. Determine trigger points for ordering extra supplies.

3. Consider alternative sources of supplies, or the use of acceptable substitute items.

C. Emergency plans to expand mortuary affairs capabilities.

D. Compliance with infection control and personal protective practices used in processing, testing, storing, and shipping infectious agents that may contain novel influenza viruses.

E. Increased medical surveillance of laboratory personnel following the identification of an index case within the community.

F. Prioritization of workload during periods of peak demand.

G. Pandemic influenza testing processes internal and external to the organization.

H. Support agreements with Laboratory Response Network (LRN) and civilian reference laboratories.

III. The following patients should be tested for PI:

A. Hospitalized patients with:

1. Radiographically confirmed pneumonia, acute respiratory distress syndrome or other severe respiratory illness for which an alternative diagnosis has not been established, and

2. History of travel within 10 days of symptoms onset to a country with documented avian influenza A (H5N1) or other novel influenza virus infections in poultry and/or humans. (For a regularly updated listing of affected countries, see the WHO website at http://www.who.int/en/)

B. Hospitalized or ambulatory patients with:

1. Documented temperature of >100.4ºF (>38ºC), and

2. One or more of the following: cough, sore throat, or shortness of breath, and

3. History of close contact either with poultry (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an H5N1 or other novel influenza virus-affected country, or with a known or suspected human case of influenza A (H5N1) or other novel influenza virus infection within 10 days of onset of symptoms.

IV. Testing for PI virus. Since the optimal specimens for detecting pandemic influenza virus infections are currently unknown, all of the following respiratory specimens should be collected, if feasible: nasopharyngeal swab; nasal swab, wash, or aspirate; throat swab; tracheal aspirate (for intubated patients); and bronchoalveolar lavage. Nasopharyngeal washes/aspirates are the specimen of choice for detection of most respiratory viruses and the preferred specimen type for children less than two years old.

V. Flow of testing for patients at risk for pandemic influenza virus infection is as follows:

A. Rapid antigen test (to include, when available, an immunofluorescence assay performed on an original clinical sample) under BSL-2 biocontainment conditions.

B. Reverse transcriptase polymerase chain reaction (RT-PCR). A negative rapid influenza test result does not necessarily exclude human infection with pandemic influenza viruses. Therefore, both negative and positive rapid influenza test and immunofluorescence results should be interpreted with caution, and RT-PCR performed at the nearest LRN reference laboratory.

C. Viral culture. Only performed if the rapid antigen test is negative. Should be utilized after consultation with the CDC. Laboratory personnel should utilize BSL-3 biocontainment practices with the following enhancements:

1. Controlled access double-door entry.

2. Negative-pressure, HEPA-filtered respirators or positive air-purifying respirators.

3. Clothing change and personal showering protocols.

4. Decontamination of all wastes.

VI. Submitting laboratory specimens to the CDC. Laboratories, per consultation with the supporting LRN reference laboratory and/or the CDC, should send original clinical specimens to the CDC for any of the following issues:

A. A sample tested by the nearest LRN reference laboratory is positive for H5 or another novel influenza subtype.

B. 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.

C. Rapid antigen detection, is negative for influenza A(H1) and A(H3), and the referring jurisdiction is not equipped to test for specific strains.

D. The referring jurisdiction is not equipped to test samples for novel influenza viruses by RT-PCR and requests testing at CDC.

VII. Reporting of laboratory results to the CDC.

A. If a test result is positive for a pandemic influenza virus, contact the CDC immediately for guidance. The CDC Emergency Response Hotline (770-488-7100) is available 24 hours a day, 7 days a week. A CDC case screening and report form (obtained from the Hotline) must be completed by the appropriate hospital personnel and faxed to the CDC at 888-232-1322 with a cover sheet that says: "ATTN: Influenza case reporting."

B. DoD LRN reference laboratories report immediately to the CDC any influenza cases that:

1. Test positive for a novel influenza subtype (other than H5), or

2. Meet the enhanced surveillance case definition in effect at that time, and cannot be subtyped because appropriate reagents or biocontainment equipment is not available.

VIII. Reporting Procedures.

A. Positive pandemic influenza virus results will be immediately reported to the Preventive Medicine Officer (or equivalent individual). The Preventive Medicine Officer and LRN reference laboratory will both report positive results to the State Public Health Laboratory Director and State Epidemiologist/Health Officer per LRN protocol, the installation's Public Health Emergency Officer, the appropriate Command element, the laboratory referring the specimen, and the health care provider.

B. Negative pandemic influenza virus results. The LRN reference laboratory will ensure negative results are reported in a timely manner back to the referring laboratory.

IX. Autopsy specimens. The CDC can perform immunohistochemical (IHC) staining for pandemic influenza 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.

X. Shipment of specimens. Per 42 CFR 72, influenza viruses (all types) are classified as etiologic agents. All pandemic influenza specimens (confirmed or suspected) must be shipped as an infectious agent, not a specimen. Use applicable guidance as provided in the appropriate shipping reference (Appendix 5) to prepare the etiologic agent(s) for shipment. Laboratories should call the CDC Emergency Hotline (770-488-7100) before sending packages for influenza A reference testing. This number is available 24 hours a day, 7 days a week.

   A. Infectious agents should be sent 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 -70ºC 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).

   B. Follow protocols for standard interstate shipment of etiologic agents located at http://www.cdc.gov/od/ohs/biosfty/shipregs.htm

XI. Select Agent Handling Instructions. Pandemic influenza viruses (highly pathogenic), including H5N1, are classified as select agents by the USDA. Laboratories not registered to handle these select agents will follow guidelines as specified in 9 CFR 121.5 upon confirmed identification of an H5N1 or other highly pathogenic avian influenza virus (reference t).

Influenza Pandemic Preparation and Response Policy Guidance
APPENDIX 3: Public Health Measures for Community Containment

I. Situation. Until supplies of effective vaccines and antiviral medications are available and administered, community containment and infection control measures may play a significant role in containing the spread of disease during the Pandemic Alert Period (Pandemic Phases 3-5). It is DoD policy to use the Health and Human Services (HHS) Pandemic Influenza Plan, Part II Supplements on Public Health Guidance (http://www.hhs.gov/pandemicflu/plan/#part2) within the DoD. Note that HHS guidance may be updated as the pandemic progresses. The following paragraphs summarize the HHS guidance.

II. Goal of Community Containment and Infection Control Measures. The goal of community containment and infection control measures in the community, used in Phases 3-5, is to contain infections at their source or, if containment is not possible, to prevent or slow the spread of the disease. Public health measures during this time should be tailored to maximize impact on preventing and slowing disease transmission while minimizing, to the degree possible, restrictions on individual movement. Measures to be used in Pandemic Phase (Phase 6) may include a different set of containment considerations. Periodic reassessment of viral characteristics and the distribution and clinical presentation of cases will help guide the most appropriate responses. For example, movement restrictions may have limited efficacy due to a very short incubation period and the ability of asymptomatic individuals to shed the virus.

III. Planning for Community Containment (primarily for Pandemic Phases 3-5):

A. All installations should establish community containment plans that include triggers/thresholds for implementation of containment measures.

B. The plans should include the identification of appropriate outpatient, treatment, isolation, and quarantine facilities and communications networks.

C. All installations should exercise the plans with traditional partners (e.g., public heath and healthcare workers) and non-traditional community partners (e.g., transportation workers).

IV. Considerations for all Pandemic Alert and Pandemic Periods (Pandemic Phases 3-6):

A. Developing and implementing community-wide risk communications plans with key messages for each phase of the pandemic.

B. Community-wide infection control education including decreasing social contact and social distancing, and hygiene (coughing, sneezing, and handwashing and optional use of masks).

C. Medical evaluation and isolation or quarantine of persons who are exhibiting signs of influenza-like illness.

D. Delivery of medical care, food, and services to persons in isolation or quarantine taking into account special needs of children and persons with disabilities.

E. Protocols for monitoring and, when necessary, enforcing quarantine measures.

F. Mental health services for persons in isolation or quarantine, as well as to family members of affected persons and other community members.

G. Telephone hotlines for reporting influenza-like symptoms and for obtaining directions for self care or instructions to report for professional medical care.

H. Developing protocols for staff members that include training and triage decision trees/algorithms.

V. Considerations for Community Containment in the Pandemic Period (Pandemic Phase 6) when widespread transmission is occurring and medical resources (people, supplies, and space) may be constrained.

A. Community-based containment measures:

1. Measures, including quarantine, that affect groups of exposed or at-risk persons.

2. Measures applying to use of specific buildings.

3. Measures that affect communities.

a. "Snow days" for at least an initial 10-day period and self-shielding (choosing to stay home).

b. Alternative/additional location fever clinics.

c. Cancellation of public events and closure of offices, churches, shopping centers (commissary and exchanges), schools, child care facilities, and public transportation.

d. Widespread community quarantine (home or community-based) with provisions for supplies and service for monitoring and enforcing, when required.

B. At termination of Phase 6, scaling back community containment measures.

Influenza Pandemic Preparation and Response Policy Guidance
APPENDIX 4: Pandemic Influenza Immunization Guidance

a. Purpose. This appendix provides policy guidance to prepare an effective immunization plan in response to an influenza pandemic. The DoD is implementing a pandemic influenza immunization program to preserve combat capabilities and readiness, save lives, and reduce human suffering.

b. Influenza Vaccines.

A. Seasonal influenza vaccine. Each year seasonal influenza morbidity and mortality are successfully prevented in military populations through the use of the same influenza vaccine used in civilian communities. A network of laboratories, coordinated by the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), collects and analyzes thousands of influenza virus isolates. DoD's laboratory-based influenza surveillance program augments both the global and national programs. Following annual review of data from isolates and epidemiological studies, the Vaccines and Related Biological Products Advisory Committee (VRBPAC), a federal advisory committee to the US Food and Drug Administration (FDA), makes recommendations for the contents of the next season's influenza vaccine. Usually, the influenza vaccine is tri-valent (i.e., contains 3 strains representing the 3 circulating strains expected to cause the most morbidity and mortality). The seasonal influenza vaccine typically protects against A/H1N1, A/H3N2, and B types of influenza.

B. Pandemic influenza vaccine. For a new pandemic strain of influenza, VRBPAC will make recommendations regarding emergency manufacture of a new influenza vaccine, probably a monovalent vaccine to counter the strain causing the pandemic. The expected interval from a decision to make a new vaccine to initial distribution of the vaccine is 6 to 9 months.

C. Currently, a potential H5N1 avian influenza vaccine is in production that may be available before a pandemic occurs. This vaccine, known as "1203," is based on a seed virus isolated from a young boy from Viet Nam who died of H5N1 influenza in 2004. Clinical trials indicated that two 90 mcg immunizations, 28 days apart are required to induce presumptive immunity. Pending additional studies, the amount of vaccine required may be reduced. Because this vaccine is being produced using licensed processes, at a licensed plant, FDA approval could be completed quickly via a document called a "Biological License Application Supplement." This vaccine, based on a strain of H5N1 influenza from Viet Nam, was evaluated against isolates of an H5N1 influenza virus from Indonesia, and demonstrated no cross-reactivity. Therefore, the efficacy of the current stockpile of bulk vaccine for an influenza pandemic arising from a H5N1 strain is unknown. Additional manufacturers are developing both killed and live attenuated avian influenza vaccines that may prove to have more cross-reactivity.

D. Regardless of whether the next influenza strain arises from the current H5N1 virus or not, an influenza pandemic will represent a novel strain of the influenza virus. In order to gain an appropriate immune response following immunization, a primer dose of the vaccine and a booster, weeks apart, are required. If the pandemic results from an H5N1 virus, the current

pre-pandemic H5N1 vaccine may be effective as a priming dose followed by a pandemic specific H5N1 vaccine. Use of this vaccine could decrease the requirement of the pandemic specific vaccine to one dose and speed the overall process of achieving an adequate density of fully vaccinated service members. There is a possibility that the pre-pandemic vaccine may also offer some degree of protection or may in fact be an adequate antigenic match for use as both a primer and booster.

E. In a pandemic situation, FDA may or may not choose to allow the vaccine containing the pandemic strain to be included under existing vaccine licenses. Regardless of whether pandemic influenza vaccine is provided as an FDA-licensed product or under an Emergency Use Authorization (EUA), all potential recipients will be given information on the vaccine, its contents, and its risks and benefits, in accordance with FDA requirements, CDC guidance, and national standards. Documentation of informed consent is not required for administration of a licensed vaccine (references p, g).

c. Immunization priorities. The general immunization priorities appear below. Specific immunization priorities customized to the pandemic scenario will be published as circumstances arise.

A. Immunization tiers. Vaccine administration will be determined according to vaccine availability, operational considerations and the pandemic phase. The decision to initiate the pandemic immunization program will be made by the ASD (HA), with guidance from the Joint Preventive Medicine Policy Group (JPMPG), Joint Chiefs of Staff Surgeon and potentially the Armed Forces Epidemiology Board (AFEB). Following vaccine release to the respective Components, commanders will have the responsibility of ensuring that this vaccine will be distributed and administered in accordance with this and subsequent policy guidance. The overall goal is to immunize all personnel using the following prioritization tiers:

1. Tier 1. Those personnel necessary to respond to global military contingencies and provide essential health care for the force structure. Sub-categories for prioritization within this group include:

   a. Those required to maintain national strategic and critical operational capabilities as defined by JS (critical personnel for specific COOP/COG requirements)

   b. Deployed forces engaged in or supporting armed conflict

   c. Those personnel necessary to maintain a functioning health care system

2. Tier 2 Non-deployed forces that are on alert or designated to conduct critical contingency operations as defined by JS

3. Tier 3. Personnel necessary to maintain critical mission-essential capabilities at each organizational level.

4. Tier 4. All other Active Component or mobilized Reserve Component personnel.

5. Tier 5. All other beneficiaries not included previously according to CDC priority tiers.

B. While it is the DoD's intent to procure enough vaccine to provide coverage for all eligible personnel and beneficiaries, vaccine supply may not permit immunization of all personnel represented in all tiers at the same time. It is also likely that adequate vaccine will not permit even completion of all members within a designated tier. Final vaccine prioritization will depend on further operational assessments regarding the national defense requirements at that time as well as the progression and virulence patterns of the pandemic. Should the pandemic be localized to a specific area of operation (AOR), one or more tiers may be vaccinated. However, if the pandemic affects all AORs simultaneously, the supply of vaccine will be insufficient to meet the demand. The Joint Staff will provide reprioritization recommendations based on what is assessed to be more critical command AORs.

d. Adverse reactions and contraindications. Influenza vaccines are generally safe, typically producing injection-site tenderness or fever.

A. Groups susceptible to adverse vaccine reactions. People severely allergic to eggs should not receive influenza vaccines made in eggs (i.e., all currently licensed influenza vaccines). Severe allergy to thimerosal is also a contraindication. Each of these conditions is very rare.

e. Adverse events should be reported via the VAERS system. This can be completed on line at www.vaers.org or the necessary reporting form can be downloaded from the same site.

f. Pregnancy. In an influenza pandemic, the need to provide protection against infection takes precedence over the usual principle of minimizing medications given to pregnant women. No harm is known to result from administration of killed influenza vaccine to pregnant women. In contrast, influenza infections during pregnancy have been associated with pre-term delivery. Women who will be in any trimester of pregnancy during the pandemic, especially pregnant women who have medical conditions that increase the risk for complications from influenza, should be vaccinated with the killed influenza vaccine (reference i).

g. Concept of Operations. Activities during WHO Pandemic Phases:

A. WHO Phase 1-2, Interpandemic Period: During these phases routine annual influenza immunization is required. This will decrease the potential of reassortment of an avian influenza virus with the seasonal influenza strain as well as decreasing the difficulty of distinguishing early pandemic influenza from seasonal influenza. Seasonal influenza virus immunization will be administered to all military members (active duty and Reserve component) in accordance with Service-specific policies (reference r) and offered to eligible beneficiaries as appropriate. Public relations messages should reinforce the need for universal influenza immunizations.

B. WHO Phase 3, Pandemic Alert Period: Public Health Emergency Officers (PHEOs) should coordinate with commanders and the local community to develop and test mass

immunization plans in accordance with DoD Directive 6200.3, "Emergency Health Powers on Military Installations" (reference l).

C. WHO Phase 4, Pandemic Alert Period: Vaccine development occurs at this phase. Commanders and PHEOs continue to plan mass immunization programs.

D. WHO Phase 5, Pandemic Alert Period: If vaccine is available, consideration of administering a priming dose may be indicated. Commanders and PHEOs continue to plan mass immunization programs.

E. WHO Phase 6, Pandemic Period: If available, vaccine should be administered based both on overall health risk and operational requirements.

h. Medical Planning & Response.

A. During a pandemic, it is likely that the number of people requiring immunization will exceed the resources of the MTF. To continue the non-immunization medical mission, it may be unwise to conduct mass immunization activities at the MTF. In expanding patient care capacity, additional resources (to include staff and equipment and facilities) will be needed. Additional immunization teams will need to be available in a timely manner. These teams may be composed of hospital personnel, volunteers, or augmentees from areas not affected by the pandemic. These immunization teams should be pre-designated and pre-trained according to DoDI 6205.2, sections 3.1 through 3.5, (reference k) and service-specific immunization tracking programs, at a minimum. Specific training requirements are consistent with those locally used to provide seasonal influenza vaccination programs. Education, training, and risk communications, before and during an outbreak, will be critical for a prompt, disciplined, and effective response.

B. The following areas, at a minimum should be addressed in the MTF plans:

1. Preparation of Military Treatment Facilities (MTFs) and other facilities to provide mass immunizations (including supplies such as syringes, needles, etc.)

2. Transportation and storage of vaccine. Influenza vaccines are temperature-sensitive products and cold-chain management principles must be implemented and followed. Consult Service-specific vaccine logistic centers for planning guidance

3. Communication strategies to inform DoD personnel and beneficiary populations of vaccine availability, immunization prioritization tiers, risk of disease, and benefits and risks of immunization

4. Documentation of immunizations in individual medical records and DoD-approved electronic immunization tracking systems

5. Documentation and reporting of adverse events after immunization.

C. Facilities. To respond to pandemic influenza, military treatment facilities should have contingency plans that address mass immunizations. Conversion of non-medical facilities may be required. Active support from military installation commanders will be needed as buildings and personnel outside of medical facilities are pressed into

action. The suitability of off-site immunization areas should be evaluated by conducting training developed to assess both process and structural aspects of mass immunization programs.

i. Medical Materiel. DoD will coordinate its purchases of influenza vaccine through the Services' logistics centers up to the Defense Supply Center Philadelphia (DSCP), as is done for annual influenza vaccine purchases, except that vaccine for pandemic influenza may have to be purchased in a rush and at atypical times. Supplemental funds, if not already appropriated, will be appropriated for emergency purchase of pandemic influenza vaccine.

Influenza Pandemic Preparation and Response Policy Guidance
APPENDIX 5: References

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