



THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

SEP 21 2004

HEALTH AFFAIRS

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 Guidance for Preparation and Response to an
Influenza Pandemic caused by the Bird Flu (Avian Influenza)

The attached Department of Defense (DoD) Pandemic Influenza Preparation and Response Planning Guidance provides instructions on activities to undertake in order to prepare the DoD for the possibility of an influenza pandemic. This guidance implements the recommendations from the National Pandemic Influenza Response plan by the Department of Health and Human Services (HHS) and is tailored to the unique needs of the DoD.

Epidemics of influenza occur annually around the world. In the northern hemisphere, they occur over the winter between October and March. Influenza pandemics occur infrequently and cause substantially higher morbidity and mortality. Whereas most annual epidemics impact the elderly and other medically high-risk groups, pandemics or uncontrolled global outbreaks cause significantly higher illness and death rates in generally healthy groups (such as young adults or military personnel) who are not usually affected by annual epidemics.

History has shown that new strains of human influenza frequently develop from influenza in animals, particularly swine and poultry. Recently, a novel strain of influenza has emerged in poultry in Southeast Asia. Many world health experts are concerned that this strain of flu virus (H5N1 or "bird flu") could mutate into a pandemic strain. Most people in the world would not have any immunity to this new virus and the resulting pandemic could cause significant numbers of deaths world wide. While the scientists at the National Institutes of Health and elsewhere are working to develop a vaccine for this strain of virus, there is no guarantee the virus that could cause a pandemic would be covered by this vaccine. Experts predict it would take up to six months to develop and produce an effective vaccine after the emergence of the pandemic. During this time, antiviral medications such as oseltamivir (Tamiflu) will be used to prevent and treat illness. There is evidence that H5N1 is sensitive to oseltamivir; however, its supply is extremely limited world wide, and its use will be prioritized.

Pandemic influenza poses a distinct threat to military operations. Infected individuals may be able to spread the virus before actually showing symptoms of illness, the disease can spread rapidly and infect large numbers of military personnel.

The DoD's top priority for use of vaccine or antiviral medications is in forward deployed operational forces. The attached plan discusses prioritization and distribution of these resources during a pandemic. Maintaining our medical personnel to be able to deal with large numbers of sick individuals is a priority we share with HHS. We are currently working with HHS on agreements to share in the HHS/Centers for Disease Control and Prevention (CDC) strategic national stockpile (SNS) of critical medicines and materiel if needed during a pandemic in the continental U.S. Additionally, we are acquiring antiviral medications for DoD forward-deployed forces so they will have timely access to these medications.

Each Service already has epidemiological expertise to investigate outbreaks of disease. Additionally, DoD has in place extensive surveillance systems to help alert us to the emergence of an influenza pandemic, and we cooperate with the CDC and World Health Organization in these efforts. The military medical services are directed to ensure that their surveillance systems are taking the necessary steps to maximize efforts involving influenza and other respiratory diseases.

There is a great deal of uncertainty within the scientific community as to whether this current "bird flu" will emerge as the next influenza pandemic. The behavior of this virus bears some similarities to previous (1968, 1957, 1918) pandemic viruses. The pandemic of 1918 killed over 43,000 military recruits. While medical care has advanced since earlier pandemics, there is still reason for concern with today's threat.

Service Surgeons General should ensure that their military treatment facilities have response plans to public health emergencies and pandemic influenza that are coordinated and synchronized with local health authorities. Additionally, installation commanders should review their plans for emergency response and ensure that they have appointed a Public Health Emergency Officer in accordance with DoDD 6200.3, Emergency Health Powers on Military Installations. Please advise me no later than November 1, 2004, on your implementation of this planning guidance. My point of contact for this matter is LTC(P) Steve Phillips, 703-575-2669, Stephen.Phillips@ha.osd.mil.



William Winkenwerder, Jr., MD

Attachment:
As stated

cc:

USD (P&R)

PDUSD (P&R)

Vice Chief of the Army

Vice Chief of the Navy

Vice Chief of Air Force

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Surgeon, Joint Staff

Special Assistant to the Secretary of Defense

Special Assistant to the Deputy Secretary of Defense

Department of Defense
Pandemic Influenza Preparation and Response Planning Guidance
Washington, DC
15 September 2004

REFERENCES:

- a. Federal Response Plan: <http://www.fema.gov/rrr/frp/>
- b. DOD Directive 3025.15, SUBJECT: Military Assistance to Civil Authorities
http://www.dtic.mil/whs/directives/corres/pdf/d302515_021897/d302515p.pdf
- c. GAO Report: Influenza Pandemic Plan needed for Federal and State Response. October, 2000.
<http://www.gao.gov/new.items/d014.pdf>
- d. ASD(HA) Charter of DOD Select Agents Response Task Force, dated July 26, 2002. Established goal of developing a DoD Pandemic Influenza Response Plan.
- e. WHO Influenza Pandemic Preparedness Plan. The Role of WHO and Guidelines for National and Regional Planning. Geneva, Switzerland, April 1999:
<http://www.who.int/emc-documents/Influenza/whocdscsredc991c.html>
- f. CDC/NVPO Pandemic Influenza Response Plan (Draft), August 2004:
<http://www.hhs.gov/nvpo/pandemicplan>
- g. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Vol 51, No RR03;
<http://www.cdc.gov/mmwr/PDF/rr/rr5306.pdf>
- h. Policy for DoD Global, Laboratory-Based Influenza Surveillance (HA 99-008)
<http://www.ha.osd.mil/policies/1999/clin9908.htm>
- i. Armed Forces Epidemiological Board: Vaccines in the Military: A Department of Defense-Wide Review of Vaccine Policy and Practice. August 1999. Recommendation 11: "...DoD continue to participate in developing a comprehensive US Pandemic Influenza Planning Document, and actively devise, disseminate and test a DoD-wide plan that would be activated world-wide once an Influenza pandemic is declared."
<http://www.ha.osd.mil/afeb/reports/vaccines.pdf/>.
- j. Armed Forces Epidemiological Board Recommendation, Subject: Prevention/Minimization of Adenovirus Infection, dated November 23, 2001.

k. DoD Instruction 6490.2, Subject: Implementation and Application of Joint Medical Surveillance for Deployments, dated 7 August 1997.

http://www.dtic.mil/whs/directives/corres/pdf/i64903_080797/i64903p.pdf

1. Situation.

a. General. Epidemics of influenza occur annually, usually over winter between November-December and March of the following year. Recommendations, medical plans, and vaccines for preventing/minimizing the impacts of these annual influenza epidemics are made annually (references h, i, j). Influenza pandemics occur infrequently and cause substantially higher morbidity and mortality. Whereas annual epidemics cause morbidity and mortality in the elderly and medically high-risk groups, pandemics cause significantly higher morbidity and mortality in groups not usually affected by annual epidemics.

(1) Purpose. This document provides instructions and planning guidance to prepare for and respond to a pandemic of influenza. The goal of this planning guidance is to maintain operational effectiveness by minimizing disease and lost duty time, as well as death due to pandemic influenza. The guidance provides an outline of considerations at the DoD level and directs that subordinate units throughout DoD develop plans appropriate for their areas of responsibility.

(2) Global and Interagency Coordination: The World Health Organization, many nations, the US Department of Health and Human Services, and many individual states have drafted pandemic influenza preparedness plans. In August 2004, DHHS released the draft national plan (reference f). This DoD guidance amplifies and implements the Pandemic Influenza Response Plan drafted by the Department of Health and Human Services (see references f and g) outlines an appropriate response to pandemic influenza that may affect military installations and contingency operations around the world, and provides general guidance for military assistance to civil authorities (reference b).

(3) Applicability. This guidance document applies to the departments of the Air Force, Army, Navy, Marine Corps, nonmilitary persons under military jurisdiction, selected Federal employees, and family members and other people eligible for care within the military health care system. The guidance document will also be provided to the US Coast Guard.

(4) Summation. Appendix 1 to this document summarizes the overall planning guidance on one page. Appendix 4 provides a summary of tasks specified in this guidance document.

b. Influenza infections.

(1) Influenza is a contagious, sometimes fatal illness that generally affects the upper respiratory tract of infected patients. The virus that causes influenza is spread from person to person in respiratory secretions. Following exposure, an incubation period of about three days passes before symptoms develop. The spread of the virus may be facilitated in closed environments such as in barracks and on buses, ships, and aircraft.

Occasionally, influenza viruses mutate into viral strains that few people have immunity against. These strains spread from person to person and develop the capacity to infect both the upper and lower respiratory tract, causing pneumonia that can be fatal.

(2) Deaths due to influenza virus. Influenza virus causes disease by infecting the surface cells of the upper respiratory tract. More severe infections can result if strains are able to infect the surface cells in the lung tissue of the lower respiratory tract. When cells in the lungs are infected, viral pneumonia can result and can be fatal. In addition, bacterial infection can complicate influenza infections, also adding to the number of deaths during epidemics. In most years, excess mortality occurs in the very young and very old. Usually, there are between 3,000 and 20,000 deaths per year due to pneumonia in the United States that can be attributed to influenza. In the 1918 pandemic, there were 546,000 deaths in the United States, or over 25 times more than in a typical year. This mortality figure includes 43,000 uniformed soldiers who were mobilized for World War I. During the 1918 pandemic, about 1 in 20 persons in the 18 to 50 year-old group, the age of the majority of military personnel, died during a 10-week epidemic. Respiratory support, the use of antibiotics, and the use of vaccine to prevent pneumococcal disease should reduce mortality. This planning guidance is designed to improve preparation for an instance like the pandemic in 1918.

(3) Transmission of influenza virus. Certain types of influenza viruses circulate primarily in pigs and birds (especially chickens). Occasionally, the viruses that are normally confined to animals can be transmitted to nearby humans, resulting in significant disease. If transmission of these viruses from human to human begins and is sustained, a pandemic may result because most humans will not have antibodies to the new strain. Infected soldiers may infect several other soldiers and family members a day before they become ill themselves. They will continue to be infectious for about 5 days after becoming ill. This ability to infect people early in the illness facilitates rapid spread of influenza virus among populations.

(4) Influenza vaccine. Studies conducted over many years in military populations have shown that influenza can be successfully prevented with influenza vaccine (Appendix 3), provided the vaccine strain and the epidemic strain are closely matched. In most years, influenza morbidity and mortality are successfully prevented in military populations through the mandated use of the same influenza vaccine as 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 each year. The DoD has its own laboratory-based surveillance program that augments both the global and national program. Following annual review of the data from isolates and from 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 vaccine. Usually, the influenza vaccine is tri-valent (i.e., contains three strains representing the circulating strains expected to cause the most morbidity and mortality). In the event of circulation and identification of a radically altered strain with potential to cause a pandemic, the same panel that does the annual review (VRBPAC) would be called upon to make a recommendation regarding emergency manufacturing of a new vaccine. This vaccine could be a monovalent vaccine containing the strain causing the pandemic. The minimum time from a decision to make a new vaccine to distribution of the vaccine is six to nine months. In the event that a pandemic occurs before a vaccine is ready, substantial numbers of illnesses, hospital admissions and deaths may occur.

(5) Adverse reactions after influenza vaccination. Influenza vaccines are quite safe, producing only small amounts of local tenderness and rare fevers. The side effects associated with administration of a vaccine are referred to as the vaccine's reactogenicity. Before 1976, significant reactogenicity was reported from time to time. With increasing purity and limitations on vaccine potency, reactogenicity was reduced to very low levels. In 1976, a paralytic illness (Guillain-Barre syndrome, GBS) was associated in some analyses with administration of influenza vaccine. The relationship was sought in military populations, but was not found. The effect has not been observed since 1976 in civilian populations, with one exception. With the 1992--1993 and 1993—1994 influenza vaccines, 1 additional case of GBS per million vaccinees was identified, but this effect was not found in other years. Nevertheless, the possibility that such an event might be observed again, causally or coincidentally, must be taken into consideration.

(a) Groups susceptible to adverse vaccine reactions: Because the vaccine is made in eggs, people who are allergic to eggs should not receive influenza vaccine. Severe allergy to thimerosal is also a contraindication, though it is rare. Vaccines with reduced amounts of thimerosal are available. Influenza vaccine contains killed (not-infectious) virus.

(b) Pregnancy: If a pandemic of influenza is ongoing, the need to provide immediate protection would take precedence. Although no harm is known to result from administration of influenza vaccine to pregnant women, until recently it was considered prudent to wait to immunize pregnant women until after they have been pregnant for 14 weeks to avoid associating vaccination with a preexisting risk of miscarriage. Women who will be in any trimester of pregnancy during the influenza season, especially those who have medical conditions that increase the risk for complications from influenza, should be vaccinated.

(6) Anti-influenza drugs. Though not used to a great extent, anti-influenza drugs may be used to treat influenza illness. They have been shown to reduce the severity of influenza infections if used early in the illness. Some of these drugs are approved as prophylaxis, but chemoprophylactic drugs are NOT a substitute for vaccination. Anti-influenza drugs may have an impact on a pandemic strain, but the magnitude of that impact is not known. See Appendix 3, paragraph 5 for a discussion of anti-influenza drugs.

(a) Threat Assessment: Influenza virus. Influenza poses a distinct threat to military operations. Because infected persons may shed significant numbers of infectious virus particles before becoming ill, influenza can spread very rapidly and infect large percentages of individuals. During interpandemic periods, routine annual vaccination with influenza vaccine significantly minimizes morbidity and mortality from current circulating influenza strains. During a pandemic, immunity to the pandemic strain will most likely be minimal. As a result, many individuals in a military unit may be rendered non-functional at the same time. The impact of such an epidemic on readiness is potentially great.

(1) Availability of influenza for intentional release: Influenza viruses are easily isolated and may be stored in hundreds of laboratories worldwide. Stored strains from past epidemics, especially those that did not cause high morbidity or mortality and those against which most living people have immunity, would probably be of limited interest for deliberate release.

(2) Theoretical feasibility of deliberate release of virulent influenza virus: Influenza is not widely recognized as a biowarfare/bioterrorism agent. Theoretically, however, one could imagine deliberate release of older influenza strains in populations where few are immune. Moreover, genetic modifications associated with heightened virulence are fairly well known and may be introduced into existing strains. In addition, influenza recombinants that might elude prevalent immunity could theoretically be constructed. Because of the potential difficulties in controlling transmission of influenza after deliberate release, influenza may not be attractive to those who would employ biological weapons. Risks to an adversary's own forces could be reduced if the adversary used the releasable strain to make a vaccine and then immunized his own forces with this vaccine. In this scenario, the enemy's forces might be protected while friendly forces and people would be vulnerable. The adversary might gain at least a temporary advantage over US Forces.

(3) Potential effect of influenza on readiness: Pandemic influenza would significantly affect military readiness. An outbreak would degrade combat-mission capability among vulnerable troops, stress military medical operations to maximum capacity, restrict military operations, and divert military manpower for health care or crowd control. The ability of all military units to conduct their missions could be greatly reduced for an extended period of time.

(4) Vaccine availability: In a normal year, the US market consumes 80-100 million doses of influenza vaccine (3.2 million in DoD for 2004-05). During a pandemic, vaccine would be needed for the total population of the US, or about 300 million doses, possibly produced out of cycle. Therefore, in the event of a threatening pandemic, every effort will have to be taken to minimize the time between virus isolation and vaccine preparation. Currently, the minimum time is about 6 to 9 months. In addition, the number of manufacturers of influenza vaccine has decreased. Vaccine shortages or delayed distribution of vaccine occurred between 1998 and 2004. In a theoretical future pandemic, the small number of manufacturers available may severely limit the amount of influenza vaccine that can be made in a timely fashion.

d. Friendly Force: Impact of Pandemic Influenza and Shared Resources: In a pandemic of influenza, US and allied forces are likely to be affected. Should a specific vaccine be ready before the pandemic strikes, demand for the vaccine by allied forces will be high. Some forces may come from countries that have advanced capabilities to manufacture influenza vaccine; however, some countries have no capability to manufacture influenza vaccine. The DoD may be asked to provide vaccine with which to protect unprotected troops, particularly if forces are engaged in combat activities. If vaccine is not available in time, antiviral drugs may represent the next best option. Allied forces may request access to anti-influenza drugs. The supply of drugs is likely to be insufficient to meet the anticipated needs. To the extent possible, where their own domestic supplies of influenza vaccine are lacking, US forces should provide vaccine needed to protect deployed personnel engaged in coalition operations.

e. Assumptions. The following assumptions guide subsequent recommendations.

(1) Assumptions about the pandemic influenza virus strain:

(a) A pandemic of influenza results from a major antigenic change in influenza virus. Past experience with such pandemics suggests that severe epidemic activity may occur at seasons not

normally associated with influenza activity. Emergency mass influenza immunization programs for the entire general population, rather than the traditional focus on medically high-risk populations, may have to be conducted at other than the normal fall-winter times.

(b) Since influenza strains may reappear 30 years after previous circulation, most military personnel will be completely susceptible to such reappearing pandemic strains. For these personnel, the strains may appear relatively novel, though they may be, in fact, reintroductions of earlier strains.

(c) Only those military personnel who were living when the new strain last circulated might have developed immune memory of the pandemic influenza strains.

(d) In interpandemic years, multiple strains of influenza virus circulate during seasonally predictable months. In a pandemic, the pandemic strain would predominate, and it may circulate during unusual months.

(e) For approximately two days before becoming ill, and while ill, infected people may be capable of spreading the virus to others. For this and other reasons, aggressive public health measures such as isolation of sick individuals, population movement control, and military post closures may have a limited impact on the course of an influenza pandemic.

(2) Coordinating assumptions:

(a) The Department of Health and Human Services will lead the national effort in reviewing surveillance and epidemiological data, determining the risk of a pandemic, coordinating vaccine development, assuring quality of licensed vaccine, coordinating the distribution of vaccine, and determining priorities for immunization.

(b) The DoD will participate by conducting medical and laboratory surveillance, providing isolates of influenza virus to CDC, sharing pertinent epidemiological information with CDC and WHO, participating on the FDA Vaccines and Related Biologic Products Advisory Committee and the CDC Advisory Committee on Immunization Practices (ACIP) as influenza vaccine recommendations are formulated.

(3) Scheduling assumptions:

(a) Although laboratories generally process specimens quickly, work backlogs or inadequate resources may delay processing of critical specimens for unpredictable periods of time.

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

(c) Once vaccine is available and supplies are adequate, military units can be immunized very quickly, over a few weeks.

(d) Following vaccine, a protective immune response will require at least two weeks to develop.

(e) Once pandemic influenza is introduced into the United States, it will spread quickly to all parts of the country.

(f) Medical response to epidemic influenza may be required while military forces are simultaneously engaged in armed conflict.

(4) Antiviral drug assumptions:

(a) Should a pandemic spread before vaccine is available, antiviral drugs may reduce the impact on military units.

(b) Due to limitations in manufacturing capacity and competing civilian public health requirements, the amount of anti-influenza drugs available to DoD will be insufficient to meet all demands.

(5) Medical care assumptions:

(a) In a pandemic, military and civilian treatment facilities may be overwhelmed, particularly with patients with viral pneumonia and pneumonias from bacterial superinfections.

(b) Support of critically ill patients will require increased medical staff, increased numbers of ventilators, increased monitoring equipment, and antibiotics for secondary bacterial infections.

(c) Demand for mortuary affairs support may be considerable.

(6) Vaccine assumptions:

(a) The DoD will use the same vaccine formulation as the civilian population.

(b) The DHHS and DoD will work cooperatively to assure that DoD vaccine requirement priorities are recognized and are met as is appropriate for national security needs, in light of national health care priorities.

(c) Although vaccine will be made available as quickly as possible, pandemic influenza may spread even before vaccine is available.

(d) Other respiratory viruses: This document addresses only a pandemic due to influenza virus. Other strategies will be necessary to deal with non-influenza causes of respiratory illnesses, although this planning guidance can serve as a template.

f. Legal Considerations.

(1) Military commanders' actions regarding isolation or quarantine on a military installation of infected or possibly infected DoD and non-DoD personnel will be determined by the nature of the

outbreak and the laws, regulations and policies concerning those specific types of situations, especially regarding people other than military personnel. Commanders must obtain legal and medical advice on individual situations from their legal and medical staffs. Local legal advice will reflect state law and coordination with civilian authorities.

(2) The Robert T. Stafford Disaster Relief and Emergency Assistance Act, P.L. 93-288, 42 USC 5121. Under the Stafford Act, a Governor may request that the President declare a major disaster or emergency if an event is beyond the combined response capabilities of the affected state, territorial, and local governments. Based on the severity and magnitude of the situation, the President may issue a major disaster or emergency declaration. Following a declaration, the President may direct any federal agency to use its authorities and resources in support of state and local assistance efforts. If an emergency involves an area or facility for which the federal government exercises exclusive or primary responsibility and authority, the President may unilaterally direct the provision of emergency assistance. The Governor of the affected State will be consulted if possible. Under the Stafford Act and DoD Directive 3025.15, commanders retain their "immediate response" authority.

2. Mission.

The mission described in this document is to prepare the DoD to preserve combat capabilities and readiness, save lives, and reduce human suffering in the face of a pandemic of influenza. DoD organizations/units will develop plans to respond to a pandemic of influenza in accordance with this document. In case of a pandemic of influenza, DoD will respond in accordance with this document and subordinate plans derived from this document. When authorized by the Secretary of Defense, DoD will provide support to civil authorities in accordance with the Federal Response Plan.

3. Execution.

a. DoD Intent.

(1) General: US military forces must remain dominant across the full spectrum of military operations, able to engage adversaries in any theater concurrent with support to the civil authorities who will lead the national and international response to a pandemic influenza outbreak. In order to remain dominant in the face of a pandemic of influenza, military personnel will be immunized with an influenza vaccine containing the strain of influenza causing the pandemic. If vaccine is unavailable, military readiness may be compromised because many personnel will be sick and many medical personnel will be required to care for those who are ill. In the absence of a specific vaccine, a degree of dominance may be preserved through the judicious use of antiviral drugs. Non-vaccine acute respiratory disease interventions (reference j) and restriction of movement may slow the spread of disease. In order to preserve life, the military medical system will have to be prepared to respond to dramatic increases in the numbers of soldiers and dependents with influenza and viral pneumonia. Increased use of intensive-care support may be required.

(2) Response of US Military Forces: DoD will respond in accordance with this planning guidance and will support the Federal Response Plan. Pandemic influenza may affect all populations in a similar way. Based on experience in past pandemics, particularly the pandemic of 1918, the worst case scenario would occur when a pandemic strikes before vaccine becomes available. In this case,

perhaps greater than 50 percent of the total population will become ill and 1 percent of the total population will die within a 10-week period. The DoD will provide administrative and medical responses (e.g., emergency immunization clinics, antiviral drug distribution, and supportive medical care as needed) to minimize operational impact through vaccination of targeted subpopulations. Deployed forces, especially those engaged in armed conflict, would receive priority for preventive and supportive medical care resources, including evacuation where needed.

(3) **Military Support to Civil Authorities (MSCA).** US military forces will support DoD-approved requests for military assistance and provide DoD capabilities to respond to the consequences of a pandemic influenza situation in the US, its territories and possessions. While maintaining command and control of DoD assets, commanders will ensure close coordination with civil authorities and the effective use of military capabilities to satisfy validated requests. Local military commanders and responsible officials of the DoD components located in areas affected by pandemic influenza may, upon a civilian request, execute an immediate response within their unit capability to save lives and prevent human suffering.

(4) The operational priorities will be:

(a) Maintain operational and medical readiness.

(b) Immunization and/or chemoprophylaxis of deployed forces, especially those engaged in armed conflict.

(c) Immunization of non-deployed forces who are on alert or designated to conduct contingency operations.

(d) Immunization of all other active duty personnel and critical civilian support.

(e) Immunization and/or chemoprophylaxis of other beneficiaries thought to be at risk of pandemic influenza.

(f) Preparation of Military Treatment Facilities to provide mass immunization and to care for potentially large numbers of patients ill with viral pneumonia.

(g) Communication with beneficiary populations to inform them of the initial signs and symptoms of influenza and those symptoms that may require medical treatment or hospitalization.

(h) Other steps appropriate to the situation, such as increasing or redirecting staff to respond to evolving medical needs presented by the pandemic (e.g., restriction of movement, isolation) or in large metropolitan areas, informing beneficiaries whether to seek vaccination from public-health sites closest to home or from facilities on military installations.

b. **Concept of Operations.** Pandemic influenza is expected to evolve in six phases. These phases have been specified by HHS based on years of experience in managing influenza epidemics in the US. Actions required during these phases vary greatly. Routine annual influenza immunization is required in Phase 0. Preparation for a pandemic is required during Phase 1. Emergency response is required in

Phases 2, 3, and 4. Recovery and recording of lessons learned is required in Phase 5. These phases, while expected to occur sequentially, may be prolonged or may be greatly shortened, lasting only days. The definitions of the phases and of actions required by DoD follow here.

(1) Phase 0: Phase 0 is the interpandemic period during which ongoing influenza activity is dealt with by existing organized systems of medical and laboratory surveillance, vaccine production, and vaccine administration. Routine activities are punctuated by the occasional isolation of antigenic variants, some of which may go on to cause pandemics. Actions by DoD personnel are required in phases 2-5, described below. The DoD conducts medical surveillance of influenza-like illness and laboratory based surveillance of specimens received and isolates obtained.

(a) Phase 0 Level 0: Epidemic influenza viruses circulate in human populations causing yearly outbreaks. There is no evidence that a novel influenza virus has infected humans. Laboratories conduct ongoing surveillance of antigenic drift and of the severity and extent of influenza activity associated with antigenic drift. These data are used to update the antigenic composition of the influenza vaccine. Periodic assessments are necessary to account for new scientific developments and to determine if the public health and health care systems maintain the capacity to respond to pandemic as well as epidemic influenza. Annual immunization campaigns and year-round immunization of troops entering basic training will reduce the operational impact of influenza to low levels. Military treatment facilities can develop contingency plans and make necessary personnel and stockpile adjustments. Medical and laboratory surveillance specifically to monitor influenza will occur. All data will be shared with CDC/WHO for consideration in vaccine strain selection.

(b) Phase 0 Level 1: Identification of a novel influenza virus in humans. Phase 0, Preparedness Level 1, commences when a novel influenza strain has been identified in humans, but before it has been determined if the novel strain can cause severe disease or transmit from person to person to cause a pandemic. Twice in recent history (in 1976 and 1997), novel influenza viruses have been isolated from severely ill humans. (See Gaydos JC. Swine influenza A at Fort Dix, New Jersey (January-February 1976). II. Transmission and morbidity in units with cases. *Journal of Infectious Diseases* 1977;136(Suppl):S363-8 and Mounts AW, et al. Case-control study of risk factors for avian influenza A (H5N1) disease, Hong Kong, 1997. *Journal of Infectious Diseases* 1999;180:505-8) In neither case, however, was sustained transmission from person to person demonstrated. In both cases, no pandemic occurred. During this phase, military treatment facility commanders should review and exercise their influenza contingency plans. FDA will begin investigating the feasibility of making a vaccine from the isolated strain.

(c) Phase 0 Level 2: Confirmation that the novel influenza virus has infected two or more humans, indicating that the novel virus is infectious for humans. This phase may commence before it has been determined if the novel strain can cause severe disease or transmit from person to person to cause a pandemic. Should the initial outbreak occur in non-US populations, the WHO would investigate in consultation with the CDC. Should the initial outbreak occur in a US military population, DoD epidemiological teams would have the lead in performing an investigation. This initial investigation would focus on determining whether or

not person to person transmission of influenza was occurring (see reference 1 for a description of a DoD investigation of an outbreak of a novel influenza strain at Ft. Dix, New Jersey, in 1976.)

(d) Phase 0 Level 3: Confirmation of human-to-human transmission. Before announcing this preparedness level, WHO, coordinating with CDC and others, will convene an international consultation to assess the available evidence on the epidemiology of the virus, including its source and transmission, and clinical evidence suggesting human-to-human transmission. Confirmation of human-to-human transmission will depend upon a combination of clinical, laboratory and epidemiological investigation of individual cases as well as epidemiological investigations, such as cohort and case-control studies. Alternatively, human-to-human spread within the general population may be assumed if large outbreaks of laboratory-confirmed illness cases consistent with human-to-human spread of infection are documented. This phase commences when it has been determined that the novel viral strain can cause severe disease and can spread sufficiently to cause a pandemic, although a pandemic has not yet occurred. Members of military units should be alert for evidence of increasing spread of influenza-like illness in their unit. (Meyer HM, Hilleman MR, et al. New Antigenic Variant in Far East Influenza, 1957. *Proceedings of the Society for Experimental Biology and Medicine* 1957;95:609-616) Large outbreaks should be investigated. Decisions to proceed with large-scale production of specific influenza vaccine will be made. It is highly desirable that vaccine be available before the epidemic proceeds to Phase 1.

(2) Phase 1: Confirmation that a novel influenza virus is spreading and causing severe disease or death in one or more countries; an influenza pandemic has been confirmed. Declaration of an influenza pandemic by WHO requires that the novel virus cause several outbreaks in at least one country, that it has spread to other countries, and that it is associated with increased morbidity or mortality in at least one age group. If the novel influenza strain spreads very rapidly, this could be the phase at which the novel influenza virus is first identified. If the novel virus is not recognized until phase 1, vaccine is unlikely to be available for several months and the need for antiviral drugs and medical treatment will be much greater. Military operations in a range of locations will be affected. Medical care will begin to be strained.

(3) Phase 2: Regional and multi-regional epidemics of pandemic influenza abroad, or outbreaks in the United States, are occurring. Phase 2 is an extension of Phase 1 and may include outbreaks in the United States. Outbreaks and epidemics are occurring in multiple countries and spreading region by region across the world. Members of military units will likely be affected. Military treatment facilities will be operating beyond standard capacity.

(4) Phase 3: The end of the first wave of the pandemic has occurred. Public health officials remain on alert, as second or third "waves" of influenza disease are likely to occur and may cause much more severe morbidity and mortality. In Phase 3, incidence of influenza will decrease in communities where the novel virus strain first appeared while outbreaks of the novel strain continue to occur elsewhere.

(5) Phase 4: Confirmation that a second outbreak of the same novel virus strain has occurred. This event may occur within three to nine months in the same area where the outbreak previously occurred. Such waves, which have been observed in previous pandemics, are caused

by essentially the same strain of novel virus and may affect different segments of the population. In the 1918 pandemic, the second wave was more severe than the first wave. (See: Kolata G. *Flu: The Story of the Great Influenza Pandemic of 1918 and the Search for the Virus That Caused It*. Touchstone.) The reasons for distinct waves of pandemic influenza are not fully understood, but they do underscore the importance of continuing surveillance, prevention, and control efforts for at least several months after the initial wave has subsided. In the absence of a vaccine, military activities may be most heavily affected during this phase. Military Treatment Facilities may be completely overwhelmed. DoD forces will coordinate with the Federal Emergency Management Agency (FEMA) and the primary agencies under the Federal Response Plan to plan for the second wave. Coordination will include the FEMA Disaster Field Office (DFO), Federal Coordinating Officer, and state-level DFOs.

(6) Phase 5: 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. Military activities can resume at full strength. After-action reports and lessons learned will be documented in the Joint Lessons Learned Databases and as otherwise directed. US Forces should return to full strength. In the event that catastrophic numbers of deaths occurred (1% of military age personnel died in 1918), Service recruiting commands will increase efforts to replenish the ranks.

c. Tasks:

(1) Supporting Plans. Commanders will include preparation for pandemic influenza in their medical and non-medical contingency planning. Planning should address out-of-season influenza immunization clinics, immunization tracking systems, medical triage and plans to expand provision of medical care in order to minimize morbidity and mortality. The Combatant Commands and the Services should develop and exercise DoD-specific contingency plans for response to a pandemic influenza outbreak, building on existing DoD command structure and both medical and non-medical assets. These plans will need to be coordinated and synchronized with local, state, regional, and national public health response plans. The DoD will coordinate with the WHO, HHS, allies and coalition members on pandemic influenza response programs.

(2) Training. Commanders will schedule, conduct, and evaluate training to meet requirements of this document. The military medical departments will train health-care providers in the special surveillance, immunization, chemoprophylaxis and chemotherapy of influenza, and medical care needed to cope with pandemic influenza surveillance and response.

d. Coordinating Instructions.

(1) Early pandemic. If a pandemic influenza threatens or occurs, the Secretary, Department of Health and Human Services 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. Upon notification, military commanders will evaluate their installations and units to determine the needed intensity of medical surveillance for influenza cases among these personnel. Commanders will review plans for responding to pandemic influenza. The specific

national situation will determine whether vaccine will be available before the pandemic strikes. If not, as is more likely, plans should emphasize the judicious use of antiviral drugs, non-vaccine acute respiratory disease interventions, and restriction of movement, isolation, etc. If vaccine is available, plans for emergency influenza immunization should be implemented. If the pandemic strikes before vaccine is available, plans to minimize the impact of influenza by using medicines available for this purpose should be reviewed and implemented appropriately. In addition, military treatment facilities must be readied to accommodate a greatly increased workload, both in outpatient clinics and inpatient facilities that deal with cases of viral pneumonia.

(2) Medical Planning & Response.

(a) Surveillance. A network of laboratories worldwide conduct influenza surveillance year-round but especially during the annual influenza season (September through March). The laboratory network is coordinated by the WHO with considerable assistance from the CDC. Input of viruses from DoD laboratory surveillance programs contributes a supplement to viruses from many other laboratories. Medical surveillance data (e.g., ESSENCE, DMSS) also contribute to vaccine deliberations and recommendations regarding viral content of the vaccine. The Global Emerging Infectious Diseases Surveillance program (GEIS) coordinates year round influenza surveillance for DoD (See www.geis.ha.osd.mil/GEIS/SurveillanceActivities/Influenza/influenza.asp). Several systems are supported by GEIS, including the Electronic Surveillance System for the Early Notification of Community-based Epidemics, which is used to detect influenza-like illnesses among DoD beneficiaries. In addition, the Defense Medical Surveillance System is capable of detecting clusters of influenza and influenza complications in both inpatient and outpatient populations. Military Treatment Facility (MTF) commanders will support year round surveillance for influenza-like illness and for viruses associated with influenza-like illnesses. They will input appropriate patient data and provide appropriate specimens to laboratories capable of isolating influenza virus (Reference h) Enhanced surveillance will be instituted during suspected influenza pandemics.

(b) Epidemiological investigations. In the event that clusters of febrile respiratory illnesses of undetermined etiology occur among military personnel or other DoD populations, the Services must ensure that appropriate epidemiological investigation takes place to describe the illness, determine the possible etiologies and transmission risk factors, determine the natural history of the illnesses, and make appropriate recommendations for treatment of patients, containment of the disease, implementation of medical countermeasures, and other force health protection measures. Composition of the epidemic response teams should be similar to the Smallpox Epidemic Response Teams (Health Affairs Policy Memorandum dated September 12, 2002, Subject: Policy for DoD Smallpox Epidemiological Response (SER Teams).

(c) Medical Treatment Teams and Immunization Teams. During a pandemic, it will be very likely that the numbers of patients requiring care will exceed the resources of the MTF. In expanding patient care capacity, additional resources (to include staff and equipment) will be needed. Additional treatment teams will need to be available in a timely manner. These teams may be composed of hospital personnel from the local MTF, volunteers, or augmentees from areas not affected by the pandemic. These medical treatment teams will need to be pre-designated and appropriately trained. If vaccine is available, pre-designated and pre-trained immunization teams will be needed to organize mass immunization campaigns.

(d) Facilities. To respond to pandemic influenza MTFs must have contingency patient-care plans that address vaccine administration, prophylactic and therapeutic drugs, treatment, respiratory support, general medical support, stress management, patient movement, and evacuation requirements. Due to the overwhelming numbers of seriously ill patients in past pandemics of influenza, particularly in 1918, buildings outside of hospitals, such as schools and churches, were converted into treatment facilities. Such conversion may be required in the future. Active support from military installation commanders will be required as buildings and personnel outside of medical facilities are pressed into action. Provision for increased staff or for emergency training of volunteer staff should be made. Education, training, and risk communications, before and during an outbreak, will be critical for a prompt, disciplined, and effective response.

(e) Immunization Policy. In general, DoD immunization policy will follow the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the CDC, modifying them to suit the special circumstances of the DoD. The Armed Forces Epidemiological Board (AFEB) may be called upon to make recommendations to the Assistant Secretary of Defense for Health Affairs. These recommendations will be promulgated to all military units to be tailored to meet local situations, and implemented. Normally, the US Food and Drug Administration allows each new year's influenza vaccine to be included under existing product licenses. In a pandemic situation, FDA may or may not allow the vaccine containing the pandemic strain to be included under existing licenses. All potential recipients should be given adequate information on the vaccine, its contents, and its risks and benefits. Documentation of informed consent is not required for administration of a licensed product. Priority for immunization of the Armed Forces will be operational forces. Priority for the civilian population will be given to medically high-risk populations and health care workers.

(f) Mental Health and Chaplain Services. Commanders will plan for mental health and chaplain services for emergency workers and their families, especially when these workers are deployed away from their home base. Mental health and chaplain services should also be provided for influenza casualties and their families. Depending on the size of an outbreak, it may be appropriate for the installation community activity center to act as a family support center, in coordination with personnel from the American Red Cross, to assist the military family. Stress management teams will be used as appropriate.

(3) Force Protection. Commanders will institute appropriate force protection measures, and coordinate with local law-enforcement officials to provide for the security of DoD personnel and equipment. The best force protection measure against pandemic influenza is immunization. However, because of the irreducible time required to manufacture vaccine, a pandemic may spread and strike US Forces or other DoD populations before vaccine is available. Use of non-vaccine interventions to include isolation, quarantine, and/or restriction of movement of individual soldiers and whole units will not likely be effective in preventing spread, but may slow the spread of disease and should be considered as an adjunct to vaccination or medical treatment. Influenza is highly contagious and patients are likely to be infectious a day or two before becoming ill themselves. Also, influenza has a relatively short incubation period of about three days. Consequently, spread throughout a community and the nation can occur very rapidly. Also, if entire military units were isolated during a pandemic (e.g., ships at sea), they might be temporarily spared the disease.

However, without vaccine, the entire unit would be susceptible. Consequently, such unit members who had been protected by virtue of isolation might quickly become ill once isolation is broken.

(a) Mass Immunization. To manage large numbers of people arriving at vaccination sites, the main strategy of security personnel should be to secure a limited-access perimeter at a designated distance from the physical plant; and secure the clinic itself (e.g., interior perimeter, main and secondary entrances, front drive, parking area) and maintain order within the facility. To avoid disrupting operations at military hospitals and clinics, it may be appropriate to administer vaccinations at an alternate location (e.g., auditorium, recreation center, school). Care should be taken to assure that individual medical records and electronic immunization tracking systems are properly annotated.

(b) Antiviral drugs. There are four licensed products that lessen the severity of influenza A infections: Amantadine (Symmetrel®), rimantadine (Flumadine®), oseltamavir (Tamiflu®), and zanamavir (Relenza®). (See Appendix 3, paragraph 5) Each of these drugs may lessen the duration of illness from influenza A by a few days, if given within two days of illness onset. Oseltamavir and zanamavir can also reduce the duration of uncomplicated influenza B illness. Both amantadine and rimantadine are approved for the chemoprophylaxis of influenza A infection, but not for influenza B. Only oseltamavir has been approved for chemoprophylaxis against influenza B. The impact of these antiviral drugs on a pandemic strain is unknown. In a pandemic situation where vaccine has not become available, use of these drugs may be life saving. Unfortunately, national stockpiles of these drugs are limited and expensive. Services should formulate policies regarding acquisition or stockpiling of these drugs and their prioritized use in servicemembers and other DoD beneficiaries. ASD (HA) will promulgate policy guidance regarding prioritization of a limited DoD stockpile of antiviral medications.

(4) Operational Constraints. The scope of the DoD response to pandemic influenza will depend upon the geographic distribution of influenza outbreaks.

(a) Ground Operations. Should pandemic influenza strike US Forces during field operations, the numbers of ill, dying, and dead personnel will almost certainly have a significant impact on force strength, perhaps causing curtailment of the operation. Opposing forces should be similarly affected. If opposing forces are not similarly affected, they may gain a substantial advantage during the pandemic.

(b) Air Operations. The possibility of entire aircrews becoming ill simultaneously in flight should be anticipated. If crews have not been immunized, then antiviral drugs should be made available. If antiviral drugs are not available, consideration should be given to canceling flights from heavily affected areas. Influenza may be transmitted across long distances by persons traveling by air, but it can also be transmitted by persons traveling by other means (e.g., car, train, bus) as well. Curtailing passenger air transportation completely might temporarily delay movement of influenza from one region to another, but the disease would probably arrive eventually. Restriction of movement between affected and unaffected areas may be helpful.

(c) Sea Operations. Pandemic influenza outbreaks on shipboard are likely to spread with great efficiency, particularly among servicemembers who bunk in large numbers in confined spaces. Consequently, a large proportion of crews is likely to be ill simultaneously. Onboard medical

facilities will be quickly overwhelmed. Ships' crews should receive high priority for early immunization with newly manufactured pandemic influenza vaccine and for antiviral drugs. In addition, ships that are spared outbreaks during a pandemic should be kept at sea until the on-shore epidemic has subsided.

(d) Intelligence. In most conceivable pandemic influenza situations, initiation of the epidemic would be a result of natural events. Should a biological attack on the United States be suspected, the FBI, with support from CDC and other agencies, would have a lead role in investigating any intentional act. Features that might suggest a biological attack might include many personnel ill simultaneously with an influenza-like illness in the absence of reports of similar illness in neighboring populations, or isolation of a new influenza virus known to have been present in an adversary's biological warfare laboratory. Virus isolation from acutely ill persons would be an important part of the investigation. In such an event, reporting should move quickly up the chain of command to the Office of the Assistant Secretary of Defense for Health Affairs. Technical support (for virus isolation) should be requested from the Air Force Institute for Operational Health (AFIOH) (starview.brooks.af.mil/afioh/afiera_fact_sheet.htm), the Navy Health Research Center (NHRC) (www.nhrc.navy.mil/), or the Armed Forces Institute of Pathology (AFIP) (www.afip.org/). Health Affairs, the Service Surgeons General, and the CDC should be informed as well.

(e) Media Impact. The media will play an important role in reporting the events associated with a pandemic of influenza. Any DoD response must take into account media coverage. The lead federal agency (i.e., DOJ/FBI or FEMA) handles public-affairs guidance under the Federal Response Plan. The interagency Joint Information Center (JIC), using health risk communication principles, will provide information to the media. The Office of the Assistant Secretary of Defense (Public Affairs) is the point of contact for all media inquiries concerning DoD support. For strategic reasons, news releases to media should be carefully reviewed by DoD leadership.

(f) Medical. Medical and public health needs will be significant factors. The National Disaster Medical System (NDMS), which includes DoD coordination of participating federal and non-federal fixed hospitals and DoD-provided patient evacuation, is the primary federal-level medical-response element. The NDMS will be used when DoD resources are taxed. Other DoD medical capabilities external to NDMS may be requested, if necessary, to augment or sustain the federal/local response to save lives and minimize human suffering. The time-sensitive nature of such requirements requires early and rapid interagency coordination. Restrictions on the use of military medical stocks and on military personnel immunizing civilians may need to be addressed in mission planning. The DoD unit commanders, upon notification of deployment in support of the lead federal agency, will need to ensure full implementation of appropriate force health protection measures.

(g) Mortuary Affairs. Despite efforts to save lives and prevent injury, pandemic influenza may create mass fatalities. One percent of the US population between 18 and 50 years of age died in 10 weeks during the influenza pandemic of 1918. Modern medical treatment and support will likely reduce the fatality rate somewhat, but considerable numbers of people might still die, particularly if the pandemic occurs before a vaccine can be made available. The DoD may be requested to assist in mitigating the potential health risks posed by mass fatalities. See also Joint Publication 4-06, Joint Tactics, Techniques, and Procedures for Mortuary Affairs in Joint Operations, 28 August 1996 (www.dtic.mil/doctrine/jel/new_pubs/jp4_06.pdf).

(h) Domestic Transportation Assets. Transportation of DoD and other federal personnel and equipment during a pandemic of influenza will be critical to a successful response. The DoD transportation assets are in high demand and require advanced planning. All transportation modes should be considered to support domestic consequence-management operations. Unlike overseas deployments, ground transportation is an option in a domestic situation. Under the Federal Response Plan Emergency Support Function (ESF) #1, Department of Transportation's Movement Coordination Center will coordinate deployment of federal resources, including DoD resources, to support consequence-management operations.

(i) Communications with Other Agencies. Planners should ensure interoperability with the interagency Joint Operations Center, as established by the lead federal agency (DHHS) and take the potential requirements into account to ensure communications with all agencies are sufficient to accomplish the mission.

(j) Noncombatant Evacuation Operations (NEO). Standard procedures for NEO operations will be followed. See also Joint Publication 3-07.5, Joint Tactics, Techniques, and Procedures for Noncombatant Evacuation Operations.

(5) Operational Security (OPSEC).

(a) Federal, state, territorial, and local agencies conduct consequence-management operations in an unclassified forum. To ensure consistency and expeditious flow of information, DoD will be an active participant in the unclassified forum. Commanders will develop Critical Information Lists (CIL) indicating specific information that relate to DoD deployments and consequence-management operations.

(b) Notification of Strategic Forces. If an influenza pandemic is confirmed, the Joint Staff or Combatant Commanders will provide strategic forces with instructions to implement available medical (vaccine and antivirals) and non-medical countermeasures.

4. Administration and Logistics.

a. Medical Materiel. The principal materiel requirements for dealing with pandemic influenza include specially formulated influenza vaccine, antiviral drugs (i.e., amantadine, rimantidine, oseltamivir, zanamavir), ventilatory support, and antibiotics for secondary bacterial infections. The 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 other than normal times for the annual program. Supplemental funds will have to be appropriated for emergency purchase of pandemic influenza vaccine. Similarly, antiviral drugs can be purchased through DSCP, but supplemental funding will also have to be identified for these purposes. Considerable demand for ventilators is likely, especially in the event that the pandemic strikes before vaccine is available. Consideration should be given to stockpiling or "just-in-time" acquisition of adequate numbers of ventilators and antiviral drugs. Agreements with HHS to obtain additional critical medicines and material from the Strategic National Stockpile are being developed.

b. Reports. Ongoing reports of the impact of pandemic influenza on unit readiness should be provided through the chain of command. Reports of the medical impact of the disease, the success with which countermeasures are being applied, anticipated shortages of vaccine, antiviral drugs, ventilators, other medical supplies, and support staffing should be forwarded up the medical chain as well. Higher headquarters will review reports promptly and, where possible, provide relief. Movement of supplies to heavily affected areas may be required. Use of the Internet and of dedicated interactive websites, managed by the Military Vaccine Agency, will facilitate transmission of these reports. At the conclusion of the pandemic, summary reports will be prepared. Close coordination among the services will be required to replenish depleted supplies.

5. Command and Control. Close coordination will be required among the appropriate federal and non-federal agencies, DoD, the Joint-Staff, Combatant Commands, Services, medical surveillance centers, the Military Vaccine Agency, and logistics elements. As an influenza pandemic outbreak develops, the Combatant Commander responsible for conducting consequence-management operations (e.g., Northern Command for the United States) may designate an influenza pandemic Coordination Cell to augment the usual crisis-action process. The influenza pandemic coordination cell will consist of medical, logistics, and other relevant subject-matter experts. The cell will receive Service reports of influenza cases and provide advice for medical and logistical support. The cell will coordinate with pandemic influenza-response coordinating cell at Assistant Secretary of Defense (Health Affairs), the Military Services, the CDC, the FDA, and other federal and non-federal agencies. The purposes of these cells will be to synchronize information exchange for military chains of command; coordinate communication with local, state, territorial, national, and international public-health authorities; and coordinate activities of the DoD-wide pandemic influenza response.

DoD APPENDIX 1

DoD Influenza Response Planning Guidance – Summary of Actions.

1. Before an influenza pandemic outbreak. DoD will develop, exercise and improve its pandemic influenza response plans at command and installation levels.

a. Installation commanders will:

(1) Identify facilities other than normal hospital or clinic locations at which mass influenza vaccinations can be effectively delivered outside of the usual influenza immunization period.

(2) Identify facilities that could serve as expanded military treatment facilities in the event of overwhelming numbers of patients with severe influenza pneumonia.

b. Medical commanders will establish programs and policies to:

(1) Determine the priority of personnel to receive anti-influenza drugs in the event of vaccine shortages.

(2) Train healthcare providers in influenza recognition and response.

(3) Continue and refine surveillance for influenza-like (febrile, upper respiratory) illnesses during non-pandemic seasons.

(4) Develop and exercise plans for increased active surveillance during an outbreak, particularly laboratory-based surveillance.

(5) Set up triage clinics to distinguish those who may need hospitalization from those who can be cared for at home.

(6) Train and exercise epidemic and medical treatment response teams.

(7) Maintain a supply of shipping materials for influenza-infected specimens.

(8) Report cases of influenza-like illness via reportable disease chain.

(9) Staff MTFs to treat influenza patients.

2. Once an influenza pandemic outbreak is confirmed:

a. Military commanders will:

(1) Evaluate their installations as “unaffected” (no cases), “moderately affected” (up to 10 percent affected), or “severely impacted” (more than 10 percent of forces incapacitated) by

the pandemic of influenza based on the proportion of individuals unable to perform their military duties. Report status to higher authorities.

(2) Communicate with their communities regarding the pandemic situation.

(3) Designate an Influenza Coordination Cell to coordinate the DoD response and provide a focal liaison with federal and local influenza response coordinators.

b. Aircrew: Decisions to curtail air transportation will be made by DoD authorities with medical consultation regarding the particulars of the current situation.

c. Military Treatment Facility commanders will:

(1) Conduct active surveillance to identify influenza cases (Annex A).

(2) Provide readily accessible emergency immunization clinics.

(3) Immunize beneficiaries as vaccine becomes available.

(4) If vaccine not available, provide anti-influenza medications as available.

(5) Provide care for influenza patients.

(6) Implement contingency plans to increase patient care capacity for massive epidemic.

(7) Provide care for excess load of pneumonia cases.

3. After an influenza pandemic has subsided, after-action summaries will be provided by Military Commanders and Military Treatment Facility Commanders.

DoD APPENDIX 2
Military Assistance to Civil Authorities.

1. DoD Directive 3025.15, Military Assistance to Civil Authorities, dated 18 February 1997 (http://www.dtic.mil/whs/directives/corres/pdf/d302515_021897/d302515p.pdf):

a. Governs military assistance during times of civil emergency. The Directive states that the “Department of Defense shall cooperate with and provide military assistance to civil authorities as directed by and consistent with applicable law, Presidential Directives, Executive Orders, and this Directive.”

b. States “All requests by civil authorities for DoD military assistance shall be evaluated by DoD approval authorities.” The directive designates the Secretary of the Army as the “approval authority for emergency support in response to natural or man-made disasters....”

c. States “Requests for immediate assistance (i.e., any form of immediate action taken by a DoD Component or military commander to save lives, prevent human suffering, or mitigate great property damage under imminently serious conditions) may be made to any Component or Command. The DoD Components that receive verbal requests from civil authorities for support in an exigent emergency may initiate informal planning and, if required, immediately respond as authorized in DoD Directive 3025.1 (reference (b)).”

DoD APPENDIX 3

Information Paper on influenza Infection and influenza Vaccine and antiviral drugs for prevention and treatment of influenza.

1. **Influenza.** Influenza is a contagious viral disease that spreads from one person to another. Influenza usually spreads in exhaled or coughed out droplets. Influenza symptoms (e.g., cough, fever, fatigue, muscle aches, and backache) begin three to five days after exposure. Patients with influenza generally recover over a week or ten days. A small proportion may develop complicating bacterial pneumonia. When a very large number of people are infected with influenza, it is called a pandemic. Some patients may develop viral pneumonia (infection in the lungs), which may be fatal. Pigs, horses, and birds may be infected by influenza viruses, and, indeed may be the animals in which dangerous mutations first occur. Pandemic influenza may result when an influenza virus that typically infects one of these animal species becomes adapted to human beings.

2. **Pandemic Influenza:** A leading textbook of infectious diseases (See Mandell GL, Douglas RG, Bennett JE, and Dolin R. Principles and practice of infectious diseases. Churchill Livingstone, page 1828, 2000.) defines pandemic influenza as follows: "In contrast to the familiar pattern of epidemic influenza, pandemics are severe outbreaks that rapidly progress to involve all parts of the world, associated with the emergence of a new virus to which the overall population possesses no immunity. Characteristics of pandemics include extremely rapid transmission with concurrent outbreaks worldwide; the occurrence of diseases outside the usual seasonality, including the summer months; high attack rates in all age groups, with high levels of mortality particularly in healthy young adults, and multiple waves of disease immediately before and after the main outbreak. The interval between pandemics is quite variable and unpredictable, but it is likely that pandemics of influenza will continue to occur in the future." In general, influenza experts associate the isolation from a human of a strain with a hemagglutination designation different from those in previous isolates to be an important event that may lead to a pandemic. For example, the isolation of an H5N1 strain in Hong Kong several years ago was considered an alarming event, though no pandemic resulted.

3. **Controlling Transmission.** Because influenza virus shedding may occur up to 24 hours before patients are actually ill, no reliable method of mechanically halting the spread of influenza virus from person to person has been found. Isolation or confinement of infected persons may reduce the number of people infected, but, given the high community attack rates, eventual infection from other sources is likely. To limit spread of influenza, it may be useful to encourage people to voluntarily limit their movements from the time they are ill until about 6 days after the onset of symptoms.

4. **Influenza Vaccine.** The history of influenza vaccine use in military has been one of relatively dramatic success. In the most vulnerable populations of highly stressed basic trainees, the nearly year round use of influenza vaccine (along with adenovirus vaccine, when it was available) has reduced the incidence of respiratory disease to very low levels. This success was achieved through intensive, focused effort over many years.

a. Discovery and early use: Because of the recognized strategic threat to readiness posed by influenza and the terrible impact of influenza on the military in 1918, prevention of influenza through the use of trivalent influenza vaccines has long been a high priority for the military forces, and early influenza vaccines were developed under military sponsorship. Army Regulations required universal immunization against influenza by 1942. Because of the devastating impact of influenza on US Forces at the end of WWI, the Armed Forces Epidemiological Board sponsored development of the first influenza vaccines early in WWII. Universal immunization of military personnel was codified in regulation by 1942. Vaccine contents are adjusted each year to conform to changes in predominantly circulating virus. Many studies of the immunogenicity and efficacy of influenza vaccines have been conducted. Influenza vaccines stimulate antibody responses in about 60 to 90 percent of recipients. Studies of the efficacy of influenza vaccine in preventing diseases have shown that the vaccine is about 40-80% efficacious when the vaccine contains the actual epidemic strains. Landmark studies of influenza vaccine were conducted under Army sponsorship at Lowry Air Force Base, where a thirty year (1952 - 1982) study of influenza in Air Force Personnel was conducted. "Unvaccinated recruit populations were extremely vulnerable to explosive outbreaks of influenza A. Ten controlled trials demonstrated the protective efficacy of inactivated vaccines. Recent military vaccines have raised the hemagglutination-inhibiting antibody levels of most persons into the "protective" range. Despite repeated introduction of influenza viruses onto the base, when all personnel were vaccinated the impact of influenza was reduced to an insignificant level except in one year of antigenic shift (1968) and one of major antigenic drift (1972)... Overall rates of febrile respiratory diseases have been greatly reduced." (See Meiklejohn G. Viral respiratory disease at Lowry Air Force Base in Denver, 1952-1982. *Journal of Infectious Diseases*, 1983;148:775-84.)

b. Current use of influenza vaccine: Decisions regarding the selection of strains for influenza vaccines are coordinated between the WHO, US FDA, CDC, DOD and manufacturers. A worldwide network of laboratories processes influenza virus isolates. In February of each year, the FDA Advisory Committee makes recommendations for final vaccine content. In recent years, influenza vaccines have contained representatives of each of the major circulating viruses (A/H1N1, A/H3N2, and B), and is therefore referred to as tri-valent. Through the summer and fall, vaccines are manufactured in quantities adequate to meet anticipated National demands (currently about 90 million doses per year in the United States). The trivalent vaccine is made by pooling a total of 270 million doses of 3 monovalent components. The DOD uses about 3 million of trivalent vaccine. Surge capacity may not be adequate to produce an additional 300 million monovalent doses of influenza vaccines. Attempts to manufacture an influenza vaccine in response to an outbreak of a new strain of influenza may have unexpected difficulties. Therefore, immediate availability of a vaccine to confront a pandemic cannot be assumed. The virus for influenza vaccines is grown in hens' eggs, purified and inactivated. The process is subject to limitations in supply of eggs. In the event of a rapidly moving pandemic, it is likely that the vaccine prepared will contain only the pandemic influenza strain, simplifying and speeding the manufacturing process. Nevertheless, manufacturing and distribution of a new influenza vaccine in response to a pandemic will probably take at least 6-9 months. A rapidly moving influenza epidemic may move more quickly than the vaccine production system, leaving most people, who will be non-immune, at high risk of infection. (In 1918, the first phase of the epidemic occurred in April, but the brunt of the epidemic struck the United States in September.

In 1968, the Hong Kong influenza epidemic began in the United States in July.) Vaccine production will have to be accomplished as quickly as possible once a likely pandemic strain is identified. In addition, should the new influenza strain be of avian origin, as was the H5N1 strain that recently threatened Hong Kong, there is the theoretical possibility that hens themselves will succumb, leaving the Nation with no way to produce vaccine. Thus, the availability of influenza vaccine to protect US forces in the face of a future pandemic cannot be assumed. Influenza vaccine protects about a variable percentage of healthy people who receive it. Efficacy studies are not done every year, but when studies are done, efficacy is in the 40 - 80% range. Efficacy is generally higher when there is a close match between epidemic strains and vaccine contents. (See Kilbourne ED and Arden NH, Inactivated influenza vaccines, in Plotkin SA and Orenstein WA, editors, Vaccines, W.B. Saunders, page 541.)

c. **Influenza vaccines under development:** Newer vaccines that contain live attenuated virus administered in a spray into the nose have been developed and have been reviewed by the US FDA, and may be available soon. Other approaches to manufacture of influenza vaccine, including cultivation of the virus in cells, rather than eggs, and use of purified hemagglutinin in nose drops are under evaluation.

d. **Cautions Before Immunization.** Some people are likely to develop adverse vaccine reactions to influenza vaccine. Because the vaccine is made in eggs, anyone with an allergy to eggs should be excluded from immunization.

5. **Antiviral drugs for prevention and treatment of influenza** (See Couch RB, Prevention and treatment of Influenza. *New England Journal of Medicine*, 2000; 343: 1778-87.)

Four antiviral drugs are currently licensed in the United States for prevention and/or treatment of influenza. These drugs may have a limited effect in reducing the impact of pandemic influenza due to the limited supplies of these drugs and limited surge capacity for production. Antiviral drugs are not a substitute or replacement for annual immunization with specific influenza vaccines. The package inserts, as published in the Physicians Desk Reference (PDR), or the following website (<http://www.fda.gov/cder/drug/antivirals/influenza/>) should be consulted for detailed descriptions of the appropriate use of these drugs.

a. Amantadine is licensed for prophylaxis and treatment of signs and symptoms of infection caused by various strains of influenza A virus. (Usual adult dosage is 100 mg by mouth twice a day for the period of exposure if no vaccine available. If vaccine is available, give amantadine for 2-4 weeks following administration of the vaccine, at which time immunity will have developed.)

b. 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. For example, in one controlled study, 3.4% of rimantadine vs. 7.0% of amantadine recipients reported insomnia.) (Usual adult dosage is 100 mg by mouth twice a day during the period of exposure.) Following vaccination during an influenza outbreak, rimantadine prophylaxis should be considered for the 2 to 4 week time

period required to develop an antibody response. However, the safety and effectiveness of rimantadine prophylaxis have not been demonstrated for longer than 6 weeks.

c. Osetamivir is approved for both prevention and treatment of influenza A and B. (Usual preventive dose is 75 mg by mouth per day through 7 days after the period of exposure.) While approved for prevention of influenza, oseltamivir is not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control's Immunization Practices Advisory Committee.

d. Zanamivir is approved for treatment of influenza A and B. (Usual treatment dose is 2 inhalations containing 5 mg each inhalation twice a day.) Zanamivir is not approved for use in prevention of influenza (prophylaxis) and is not a substitute for influenza vaccine.

These drugs are relatively expensive, have limited efficacy, may have associated toxicity, are available in limited supply, require many doses to provide prophylaxis over the period of a pandemic, and will also be needed for civilian use. Drug requirements will be substantially greater if a pandemic occurs before a vaccine is available. Therefore, optimal use of the antiviral drugs that may be available to the DOD will have to be carefully considered, preferably in advance of the need for them. A plan to acquire, stockpile, distribute, and actually use these drugs in a logical response to a threatening or actual pandemic is being developed. Given that the entire force will be at risk, and that there is little likelihood that sufficient supply will be available, a policy giving key leaders and troops in combat situations the highest priority for the limited number antiviral drugs available offers the best opportunity to preserve the command and control and fighting strength of the Department of Defense in the face of a pandemic of influenza. Drugs should be distributed as early as possible during the spread of influenza to susceptible populations in the United States or abroad. Finally, some provision will be needed for monitoring of reactogenicity of drugs, particularly of drugs that may have side effects that may interfere with abilities to carry out military duties.

DoD APPENDIX 4

Summary of Specified Tasks.

1. Installation and Unit Commanders.

a. Pre-Outbreak.

(1) Initiate planning for implementation of the DoD influenza Response Plan. See Plan, paragraph 3c(1), "Supporting Plans."

(2) Schedule, conduct and evaluate training for influenza response. Plan, paragraph 3c(2), "Training."

(3) Identify facilities other than normal hospital or clinic locations at which mass vaccinations can be effectively delivered. (Plan, paragraph 3c(1), "Supporting Plans"; Appendix 1, paragraph 1a(1)).

(4) Identify facilities that could serve as expanded military treatment facilities in the event of overwhelming numbers of patients with severe influenza pneumonia. (Appendix 1, paragraph 1a(2)).

b. Post-Outbreak.

(1) Implement post-outbreak control measures. Plan, paragraph 3c(1), "Supporting Plans."

(2) Perform ongoing assessment of forces throughout the 10 weeks of the epidemic, then report to higher headquarters. Plan, paragraph 3d(1), "Early Pandemic."

(3) Coordinate with civil authorities for effective use of military capabilities requested to support federal and civil response plans. See DOD response, paragraph 3a(2), "Response of US Military Forces."

(4) Coordinate with law-enforcement officials to provide security of DoD personnel and equipment. Plan, paragraph 3d(2), "Medical Planning and Response."

2. Military Treatment Facility (MTF) Commanders.

a. Pre-Outbreak.

(1) Initiate deliberate planning for implementation of the DoD influenza Response Plan. Plan, paragraph 3b(1)(a). "Preparedness level 0."

(2) Undertake appropriate planning and education to detect influenza cases. Plan, paragraph 3c(1), "Supporting Plans."

(3) Prepare to staff to conduct rapid, mass immunization against pandemic strain of influenza, possibly during an unusual time of year.

(4) Identify and staff facilities other than normal hospital or clinic locations at which mass vaccinations can be effectively delivered.

(5) Identify sources for increased requirements of medical supplies.

(6) Appoint Vaccination Site Coordinators.

b. Post-Outbreak.

(1) Promptly report through medical and post chains of command when installation becomes affected by pandemic influenza.

(2) Designate vaccination coordinator responsible for vaccine administration.

(3) Develop criteria for appropriate triage of persons ill with influenza (Plan Appendix 1, paragraph 1b(5..))

(4) Set up triage clinics to evaluate people concerned they may have early symptoms of influenza. (Plan, Appendix 1, paragraph 1b(5)).

3. Vaccination Site Coordinators.

a. Institute prevaccination screening to identify contraindications.

b. Provide verbal and written counseling to vaccine recipients before vaccination.

c. Administer influenza vaccinations.

d. Document vaccinations in individual medical records and in electronic Immunization Tracking System.

e. Report daily number of influenza vaccinations to higher headquarters.

f. Report any observed adverse events to the FDA's Vaccine Adverse Events Reporting System (VAERS) (See: <http://www.fda.gov/cber/vaers/what.htm>.) VAERS accepts reports of adverse events that may be associated with U.S. licensed vaccines.

4. Military Medical Departments.

a. Pre-Outbreak.

(1) Ensure that Health Care Providers in all Military Treatment Facilities and Units are trained in influenza recognition, surveillance and response. Plan, paragraph 3c(2), "Training."

(2) Ensure that routine surveillance for influenza-like illnesses is conducted. Plan, paragraph 3c(2), "Training". Plan, Appendix 1, paragraph 1b(3).

(3) Ensure that Military Treatment Facilities develop and exercise plans for active surveillance during an outbreak. Plan, Appendix 1, paragraph 1b(3).

(4) Ensure that Military Treatment Facilities train and exercise response teams. Plan, Appendix 1, paragraph 1b(6).

b. Post-Outbreak.

(1) Promptly report outbreaks of influenza-like-illness. Plan, Appendix 1, paragraph 1b(8).

(2) Be prepared to augment clinical staff of hospitals overwhelmed with influenza patients.

(3) Manage adverse-event programs after vaccinations, including detailed adverse event reporting.

5. Combatant Commanders.

a. Pre-Outbreak. Develop and exercise DoD-specific contingency plans for response to an influenza pandemic. Plan, paragraph 3c(1).

b. Post-Outbreak.

(1) Receive reports of influenza cases and coordinate logistical efforts. Plan, paragraph 3c(1).

(2) Coordinate with pandemic influenza-response staff at CDC and other agencies, synchronize information exchange for military chains of command. Plan, paragraph 3b(3).

(3) Coordinate communications with local, state, territorial, national and international public health authorities. Plan, paragraph 3b(3).

(4) Coordinate activities of DoD Pandemic influenza response teams. Plan, paragraph 3d(1).

6. Military Services.

a. Pre-Outbreak

(1) Develop, train, and exercise various pandemic influenza response teams (Epidemiology, Vaccination, and Health Care Providers). Plan, paragraph 3c(2), "Training."

b. Post-Outbreak. Establish medical surveillance for influenza-like-illness through existing disease-reporting channels.

7. Office of the Secretary of Defense.

a. Pre-Outbreak.

(1) Provides overarching guidance.

(2) Coordinate annual influenza program in DoD with other federal and non-federal agencies.

b. Post-Outbreak.

(1) Provide policy guidance for prioritization of limited resources such as antiviral medicines or vaccines.

(2) Authorize DoD forces to provide civil support IAW Federal Response Plan. Plan, paragraph 2.