THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 2 1 2000

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (MRAI&E)
USCG, DIRECTOR OF HEALTH AND SAFETY
DIRECTOR, TRICARE MANAGEMENT ACTIVITY

SUBJECT: Preparation for Influenza Vaccine Shortage - 2000-2001 Influenza Season

For the 2000-2001 influenza season there will be substantial delay in the availability and therefore a functional shortage of influenza vaccine throughout the United States, including vaccine for the Department of Defense (DoD) and the U.S. Coast Guard. The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) have developed recommendations for the 2000-2001 influenza season. Their statements on the anticipated shortage do not specifically address military readiness. The Joint Preventive Medicine Policy Group (JPMPG) has adopted the CDC and ACIP recommendations and developed an immunization prioritization plan that balances our primary task to maintain optimal military readiness with our responsibility to protect our most vulnerable populations. For eligible beneficiaries enrolled in DEERS, Military Treatment Facilities and operational force surgeons should prioritize administration of influenza vaccine based on the attached JPMPG recommendations.

The Department will delay organized influenza vaccination campaigns until early to mid-November, pending receipt of adequate supplies of vaccine. Defense Supply Center Philadelphia will provide 50 percent of on hand vaccine to support CINC identified operational requirements. Remaining vaccine will be distributed proportionally to the Services and the Coast Guard based on existing requirements as of 1 September 2000, with 2,500 doses initially held in reserve to address contingency situations including outbreaks or operational deployments. Steps to minimize wastage of vaccine are important, including refraining from placing duplicate orders with multiple companies resulting in the need to return vaccine to manufacturers.

Influenza vaccine prioritization and possible access limitation within DoD and the Coast Guard will necessitate close coordination between Medical and Public Affairs personnel. The TRICARE Management Activity will direct a robust Public Affairs campaign to assure a clear risk communication plan and education of commanders and beneficiaries.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

Attachment:
As stated

cc:
Director Joint Staff
Defense Supply Center Philadelphia
Assistant Secretary of Defense (Reserve Affairs)

Plans for Influenza Vaccine Shortage
2000-2001 Influenza Season

1. For the 2000-2001 influenza season there is an anticipated substantial delay in the availability and therefore a functional shortage of influenza vaccine throughout the United States, including the Department of Defense (DoD) and the U.S. Coast Guard. There are two principal reasons for the shortage:

   a. Lower than expected production yields for the influenza A(H3N2) vaccine component, and

   b. Food and Drug Administration (FDA) manufacturing issues with two of the four companies producing the vaccine, one of which provides the large majority of vaccine (about 2.5 million doses) to the Armed Services.

2. Historically, the military services have used about 2.8 million doses of the vaccine to cover all active duty and eligible vaccine-seeking beneficiaries. There are 230,680 doses at the Defense Supply Center Philadelphia (DSCP) now. Another 2,584,400 doses are expected due by October-November (2,562,800 of these doses depend on when the FDA will allow the manufacturer to release vaccine), and 41,000 doses due by November-December.

3. The following prioritization attempts to balance our primary task to maintain optimal military readiness with our responsibility to protect our most vulnerable populations. Where possible, vaccination of mission critical military personnel and high-risk medical individuals will proceed in parallel (categories 3.a-c). Medically high risk persons will be vaccinated through a process as described in 4.b below, ordinarily by prescription from a military provider until adequate availability of vaccine supply is assured to enable vaccination through standing orders. For eligible beneficiaries, Military Treatment Facilities (MTFs) and operational force surgeons should prioritize administration of influenza vaccine in the following order:

   a. Operational military personnel:

      1) Operational forces forward deployed in support of CINC operational requirements in areas of high security risk (e.g., Southwest Asia, Korea, Eastern Europe) [If vaccine supplies are sufficiently limited to restrict this category, persons stationed in the Pacific should receive higher priority than other geographic areas due to earlier seasonal influenza activity];

      2) Those who are deployed aboard a ship underway for two or more weeks--this may include pre-deployment underway work-up periods and vaccine should be administered at least two weeks prior;

      3) Special duty personnel expected to regularly transit multiple geographic areas or otherwise pose particular operational and epidemiologic risks, such as airlift aircrews and those who are deployed aboard a ship underway. This may include pre-deployment

underway work-up periods. Ideally, vaccine should be administered at least two weeks prior to deployment.

4) Those on 24 hour alert status (Service-specific determination).

b. Health-care workers (including civilian employees and volunteers) with direct patient contact (due to the increased potential to transmit influenza virus infection to high-risk persons);

c. Defense Enrollment Eligibility Reporting System (DEERS) enrollees, whether or not on active duty, with true high risk medical conditions including:

1) Persons over 65 years of age enrolled in TRICARE Senior Prime at an MTF, or who otherwise receive the majority of their medical care at the MTF through an identified primary care manager (PCM) or ongoing patient-provider relationship. [Note reversion to previous age recommendations. This age group historically has about 90% of the mortality from pneumonia and influenza];

2) Adults and children with chronic disorders of the pulmonary or cardiovascular system, including asthma;

3) Adults and children who have required regular medical follow-up or hospitalization during the preceding year for chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);

4) Residents of long term care facilities (where applicable);

5) Women who will be in the second or third trimester of pregnancy during the influenza season. Pregnant women who have medical conditions that increase their risk for complications from influenza should be vaccinated, regardless of the stage of pregnancy;

6) Children and teenagers (age 6 months to 18 years) who are receiving long-term aspirin therapy, and therefore might be at risk for developing Reye's syndrome after influenza infection.

d. Trainee populations, including basic and advanced trainees, academy students and officer trainees. [These groups are at higher risk for epidemic influenza, but are theoretically easier than operational active duty members to prophylax if necessary with antiviral drugs against influenza A. Epidemiologic data suggest influenza B is less common than influenza A, particularly in these groups, and influenza B incidence usually peaks later in the season when vaccine supplies may be more widely available. Trainee groups should be under special hand-washing precautions at all times to reduce person-to-person transmission of respiratory viruses, including influenza and adenovirus];

e. Other groups in close contact with high-risk persons, such as employees in long term care facilities, household members (age 6 months and older) of high risk patients, and military training instructors;

f. All other military members in priority for deployment;

g. Other active duty members (including Guard and Reserve on active status) and mission critical DoD civilians at OCONUS facilities:

   1) Between 50 and 64 years of age
   2) Younger than 50 years of age;

h. All other beneficiaries:

   1) Between 50 and 64 years of age.
   2) Younger than 50 years of age.

Note: This priority scheme may be altered in the occurrence of an epidemic outbreak requiring a focused management effort for a specific population. Alteration of priorities will be at the direction of the Service epidemiology centers and higher headquarters (SG) level preventive medicine authority.

4. The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) statement on the anticipated shortage does not specifically address military readiness. However, from their recommendation in the 14 July issue of the Morbidity and Mortality Weekly Report (MMWR) (available on line for download at http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4927a4.htm), the following points are relevant:

   a. Organized influenza vaccination campaigns should be delayed until early to mid November. Influenza vaccine administered after mid-November will provide substantial protective benefits.

   b. Influenza vaccination of persons at high risk (see 3.c. above) for complications from influenza should proceed routinely during regular health-care visits (e.g. clinics, offices, hospitals, nursing homes) as vaccine becomes available. This is particularly important for those young children (age six months to eight years) at high risk who are receiving influenza vaccination for the first time and require two doses, administered at least one month apart.

   c. Influenza antiviral drugs are useful for controlling outbreaks in specific and circumscribed situations, but are not recommended for routine, widespread use as chemoprophylaxis against influenza. This is an untested and expensive strategy that could result in many adverse effects.

d. Steps to minimize wastage of vaccine are important, including refraining from placing duplicate orders with multiple companies resulting in the need to return vaccine to manufacturers.

e. Vaccination of health-care workers in direct patient contact is important to reduce transmission to high-risk persons.

5. Influenza vaccine prioritization and possible access limitation within DoD and the Coast Guard will necessitate close coordination between Medical and Public Affairs personnel to assure a clear risk communication plan and education of commanders and beneficiaries.

6. The services will not be able to provide occupational health influenza vaccinations previously provided as a courtesy to DoD civilian employees, except those providing direct patient care and mission critical stationed OCONUS, until such time as a sufficient supply of the vaccine is available. Civilian employees should be directed to their own health care providers, who may also be in a situation of delay and prioritization.

7. The target groups for influenza and pneumococcal vaccination overlap considerably. For persons at high risk who have not previously been vaccinated with pneumococcal vaccine, health-care providers should strongly consider administering pneumococcal vaccine. ACIP recommends that the vaccine be administered to all persons in the following groups: a) persons aged greater than or equal to 65 years, b) immunocompetent persons aged greater than or equal to two (2) years who are at increased risk for illness and death associated with pneumococcal disease because of chronic illness, c) persons aged greater than or equal to two (2) years with functional or anatomic asplenia, d) persons aged greater than or equal to two (2) years living in environments in which the risk for disease is high, and e) immunocompromised persons aged greater than or equal to two (2) years who are at high risk for infection.

   Source: Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). April 04, 1997 / 46(RR-08);1-24
   http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00047135.htm

8. Antiviral drugs are not a substitute for influenza vaccine. Even if an influenza vaccine shortage develops, CDC and ACIP do not support the routine and widespread use of antiviral drugs as chemoprophylaxis against influenza because this strategy is untested, expensive, and could result in large numbers of persons experiencing adverse effects.

   a. Treatment with antivirals is a clinical decision made by the provider and patient. In otherwise healthy individuals already ill with influenza symptoms, these drugs shorten the disease by 24 to 36 hours if started within 48 hours of symptoms. There is no evidence they prevent influenza complications. Therefore, therapeutic use of antivirals should be relatively uncommon and limited to specifically indicated situations.

   b. Prophylactic use of antivirals should be considered for persons at increased risk in accordance with the CDC recommendations and the prioritization scheme above. Presently, the CDC recommends prophylaxis with antivirals for:

1) Persons at high risk who are vaccinated after influenza activity has begun. [Development of antibodies in adults after vaccination can take as long as 2 weeks.]
2) Persons who are unvaccinated and provide care to those at high risk.
3) Persons who have immune deficiency.
4) Persons at high risk who should not be vaccinated.
5) The control of influenza outbreaks in institutions (as in shipboard settings and recruit or trainee populations where epidemic spread is more likely). Antivirals should be continued for at least two weeks or until approximately one week after the end of the outbreak.

Source: CDC. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4903a1.htm

c. There are currently four drugs available for the treatment of influenza including amantadine, rimantadine, zanamivir, and oseltamivir. Amantadine and rimantadine are used only for influenza A, which occurs more commonly than influenza B. In addition these agents are much less expensive then zanamivir and oseltamivir. The other two agents can be used for influenza A and influenza B. All four agents have been tested for prophylaxis and appear to be effective; however, the FDA has approved only amantadine and rimantadine for influenza prophylaxis. Zanamivir is used as an inhaler, which requires careful patient education and has been reported to cause bronchospasm in patients with asthma. Oseltamivir causes mild gastrointestinal side effects. Amantadine and rimantadine can cause central nervous system (CNS) side effects (12% and 6%, respectively). The incidence of CNS side effects is more frequent in the elderly. Because of the CNS side effects, use of these agents will necessitate flying restrictions in aircrew. Use with caution in other operational personnel. In such situations, rimantadine is preferable to amantadine. Due to its lower cost and the predominance of influenza A, amantadine would be the first-line drug of choice in most other circumstances of use.

d. There is potential for overuse of these drugs, and each MTF should institute measures to ensure proper use. Local outbreaks in institutional settings should also include other public health measures (e.g., hand washing, droplet control, and cohorting).

9. Rapid diagnostics for influenza can aid clinical judgment and help guide treatment decisions, particularly if antivirals are considered for treatment, keeping in mind the benefits of treatment are relatively small. Facilities that use antiviral drugs for treatment may want to use rapid diagnostics to test for influenza. In the presence of an established local epidemic presumptive treatment in patients presenting with influenza-like symptoms may be warranted. Rapid laboratory testing for influenza is available at many MTF's, but there are problems with their use in the clinic setting.

a. As shown in the summary of Rapid Diagnostic Tests, there are sensitivity/specificity differences which may be a consideration in whether to test, and which test to choose. An important consideration in the interpretation of any lab result is the issue of pre-test probability. The predictive value of a positive test is greater in populations with a higher likelihood of disease. In a setting of low influenza prevalence, the positive predictive value

of the rapid tests can be less than 10%. Ensuring that rapid tests are used only in patients exhibiting clinical signs and symptoms suggestive of true influenza will minimize the number of false positive test results. The Febrile Respiratory Illness (FRI) case definition provided below may be helpful in this regard. Keep in mind this case definition helps narrow clinical suspicion for influenza but includes other causes of disease. In the setting of potential outbreaks with limited availability of preventive measures, false positive tests should be avoided to the greatest extent possible. All medical personnel should consider these points in the decision to utilize a rapid diagnostic test.

b. Febrile Respiratory Illness Case Definition

Patient seeking care for the following symptoms within 72 hours of onset.
Fever - Oral temperature $\geq$ 100.5°F (38°C)
and at least one of the following symptoms: cough, sore throat, or headache
or a person with clinical or radiographic evidence of acute, non-bacterial pneumonia

c. Despite the availability of rapid diagnostic tests, the gold standard remains the viral culture, with nasal washings achieving the greatest sensitivity. Only culture isolates can provide specific information on circulating influenza subtypes and strains. This information will also help guide population-based decisions about influenza treatment and prophylaxis. Information regarding virology-capable clinical laboratories within the DoD is available from the epidemiology consultation centers listed in paragraph 9 below. Information on obtaining viral culture media may be obtained through the local clinical laboratory or the DoD Global Influenza Surveillance Program (Air Force is Executive Agent, see contact information in following section).

10. Syndromic surveillance at the local level is the first line of defense against respiratory illness outbreaks. The FRI case definition is a practical starting point in the clinical setting. Recognition of a respiratory illness outbreak requires a heightened awareness on the part of clinicians and preventive medicine/public health officers, with attention to local historical and seasonal illness rates for comparison. Note that increased emphasis on recognition can result in increased reporting rates relative to a previous time of lower emphasis. Close collaboration with local health departments can facilitate recognition of true increases in pathogen activity in the local community. Confirmed influenza cases for reporting should meet the case definition for FRI above along with laboratory verification by culture or rapid diagnostic test. Confirmed influenza cases should be reported promptly through existing service-specific reportable events systems. This information is forwarded to the Service-specific project officer at the central epidemiology and surveillance centers:

- Army — Army Medical Surveillance Activity (AMSA)
  DSN 662-0471 http://amsa.army.mil/AMSA/amsa_home.htm

- Navy — Naval Environmental Health Center (NEHC)
  DSN 253-5500 http://www-nehc.med.navy.mil/index.htm

- Air Force — Institute of Environment, Safety, and Occupational Health Risk Analysis (IERA)

DSN 240-3471 http://pestilence.brooks.af.mil/

- Coast Guard Directorate of Health and Safety (G-WKH-1)
  COMM (202)267-1725 e-mail sludwig@comdt.uscg.mil