INFORMATION PAPER

Military Vaccine Agency
27 September 2010

SUBJECT: Meningococcal Disease and Meningococcal Vaccines

1. Purpose. To describe meningococcal disease and the vaccines to prevent it.

2. Facts

a. Microbiology. Meningococcal disease results from infection with *Neisseria meningitides* bacteria. It is a serious health threat, because it often causes meningitis (inflammation of membranes around the brain and spinal cord) or blood infections (meningococcemia). These conditions are referred to as meningococcal disease.

b. Disease. Meningitis is caused by a virus or bacterium. Dependent on the cause, the severity of illness and the treatment can vary. Viral meningitis is generally less severe and resolves without specific treatment. Bacterial meningitis can be extremely severe resulting in brain damage, hearing loss, or learning disability. High fever, headache, and stiff neck are common symptoms in anyone 2 years of age and older. These symptoms can develop over several hours, or they may take 1 to 2 days. Other symptoms may include nausea, vomiting, discomfort looking into bright lights, confusion, and sleepiness. In newborns and small infants, the classic symptoms may be difficult to detect. The infant may appear slow, inactive, irritable,, have vomiting, or loss of appetite. As the disease progresses, patients of any age may develop seizures.

c. Epidemiology. Serious (also called invasive) meningococcal disease occurs most often in infants younger than 1 year of age and surges a second time in adolescence. College freshmen living in dormitories and military trainees have a greater risk of developing meningococcal disease than others of their age, likely due to crowded living conditions. Other high-risk groups include people with immune deficiencies, travelers to areas where the disease is common (sub-Saharan Africa), and people who do not have a spleen or whose spleen is not functioning (e.g., sickle-cell anemia). There are 13 serotypes of meningococcal bacteria. Serotype B accounts for more than 50% of meningococcal disease in infants younger than 1 year of age, but there is no vaccine licensed in the U.S. to prevent serotype B disease. Serotypes C, Y, and W-135 cause more than 75% of illness in people 11 years of age and older. Serotype A disease occurs primarily in Africa and Asia. Despite the use of effective antibiotics, meningococcal disease still results in death in 10% to 14% of those who become ill. Meningococcal disease can be disfiguring or disabling (i.e., limb amputations, hearing loss, brain damage) in up to 20% of those who recover.

d. Vaccines. Three vaccines are licensed in the United States prevent meningococcal disease.

(1) Sanofi Pasteur's vaccine, Menomune, is a freeze-dried polysaccharide vaccine for serotypes A/C/Y/W-135. The diluent for the multi-dose vial contains thimerosal as a preservative. All vial stoppers contain dry natural latex rubber.

(2) Sanofi Pasteur's vaccine, Menactra, is a polysaccharide diphtheria toxoid conjugate vaccine for serotypes A/C/Y/W-135. Single dose syringes are both thimerosal and latex free. Vials do contain dry natural rubber latex within the stopper, or are thimerosal free.

(3) Novartis' vaccine, Menveo, is a oligosaccharide diphtheria CRM conjugate vaccine for serotypes A/C/Y/W-135 Menveo consist of a liquid MenCYW-135 conjugate component that is combined through reconstitution with a MenA lyophilized vaccine component, both in single dose vials. The product is both thimerosal and latex free.

e. Cautions. Do not immunize people with known allergy to any of the vaccine components. Immunize pregnant women only if the benefit clearly justifies the risk. The stoppers of the Menactra (vial only) and Menomune contain dry natural rubber latex which may cause allergic reactions in latex sensitive people. Menveo should not be administered to people with bleeding disorders or those on anticoagulants ("blood thinners"), unless the potential benefit justifies the risk. Due to a possible increase risk of post-vaccination Guillan-Barre Syndrome (GBS) individuals with a history of GBS should not be vaccinated with Menactra and should discussion vaccination options with their provider.

f. Immunization. Those previously vaccinated with MPSV4, revaccination with either MCV4 or MPSV4 may be indicated for those who remain at high risk for infection (e.g., asplenia, persons who reside in areas in which disease is endemic, living in a dormitory for the first time). Revaccination with MCV4 is preferred for individuals 11-55 years of age, but MPSV4 is acceptable.

(1) Menomune is licensed for people 2 years and older and is administered as an injected single 0.5-mL subcutaneous injection. Per ACIP recommendations individuals previously vaccinated who are at prolonged increased risk for meningococcal disease should be revaccinated. Persons who previously were vaccinated ≥7yers should be revaccinated 5 years after their previous meningococcal vaccination, and persons who were vaccinated at ages 2-6 years should be revaccinated 3 years after their previous meningococcal vaccine.

(2) Menactra is licensed for persons between 2 and 55 years of age and is administered as a single 0.5-mL intramuscular injection. Per ACIP recommendations individuals previously vaccinated who are at prolonged increased risk for meningococcal disease should be revaccinated. Persons who previously were vaccinated ≥7yers should be revaccinated 5 years after their previous meningococcal vaccination, and persons who were vaccinated at ages 2-6 years should be revaccinated 3 years after their preview meningococcal vaccine.

(3) Menveo is licensed for use in persons 11 to 55 years of age and is administered as a single 0.5 mL intramuscular injection after reconstitution. The duration of protection following immunization is not yet known and no revaccination recommendations have been released.

g. Adverse Events. Reported adverse effects after immunization with either Menomune or Menactra were similar during safety studies and included fever and injection-site reactions (e.g., soreness, redness) for all vaccines. Drowsiness and diarrhea in children and headache along with fatigue in adolescents and adults, were reactions found with the use of Menomune. In Menveo clinical trials, the most frequently occurring adverse events in all subjects who received Menveo were pain at the injection site, headache, myalgia, malaise and nausea.

(1) Guillain-Barre Syndrome (GBS). Menactra and Menveo warn against use in patients with a history of GBS. An evaluation of post-marketing adverse events suggests a potential for increased risk of GBS after a Menactra or Menveo vaccination. Patients previously diagnosed with GBS should not receive these vaccines. GBS is a serous neurologic (nerve) disorder that can occur either spontaneously or after certain infections (e.g., Campylobacter).

h. DoD Policy. Meningococcal immunization is mandatory for basic trainees and cadets at Service academies within the first two weeks of training. Immunize personnel traveling to sub-Saharan Africa during the dry season (December to June), and other countries as recommended by the CDC. Contact preventive-medicine offices for specific guidance.

i. Special Considerations. Chemoprophylaxis prevents meningococcal disease faster than immunization in close contacts of infected people post-exposure. Ideally, antibiotics should be given within 24 hours after identifying an index infection.

3. References.

a. Advisory Committee on Immunization Practices.

b. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by Military Vaccine Agency: www.vaccines.mil/meningococcal

Jateya Jones/ 703-325-6579

Approved by LTC Lahr