

INFORMATION PAPER

Military Vaccine Agency
31 March 2011

SUBJECT: Adenovirus Information for Healthcare Providers

1. Purpose: To describe adenoviral disease and the vaccine to prevent it.

2. Facts.

a. Microbiology. Adenoviruses are medium-sized, non-enveloped icosohedral viruses containing double-stranded DNA. There are at least 52 immunologically distinct types that can cause human infections. Adenoviruses are unusually stable to chemical and physical agents and to adverse pH conditions, thus allowing for prolonged survival outside of the body.

b. Disease. Adenoviruses most commonly cause respiratory illness. However, depending on the infecting serotype, they may also cause various other illnesses such as gastroenteritis, conjunctivitis, cystitis (bladder infection), and rash illness. Symptoms of respiratory illness caused by adenovirus infection range from the common cold syndrome to pneumonia, croup, and bronchitis. Young infants and especially patients with compromised immune systems are more susceptible to severe complications of adenovirus infection. Acute respiratory disease (ARD), which was first recognized among military recruits during World War II, can be caused by adenovirus infections.

c. Epidemiology. Adenoviruses vary somewhat, but all are transmitted by direct contact, fecal-oral transmission, and occasionally water-borne transmission. Some types can establish persistent asymptomatic infections in tonsils, adenoids, and intestines of infected people who can shed these viruses for months or years. In the United States, ARD is often associated with adenovirus types 4 and 7. Adenovirus type 7 infection acquired by inhalation can cause severe lower respiratory tract disease, whereas infection acquired orally usually causes no or mild disease. Outbreaks of adenovirus-associated respiratory disease are more common in the late winter, spring, and early summer; however, adenovirus infections can occur throughout the year.

d. Vaccine. The Food & Drug Administration (FDA) licensed Teva Pharmaceuticals USA, Inc./Barr Laboratories, Inc. to manufacture a live, oral adenovirus vaccine against type 4 and type 7 on 16 March 2011. The vaccine consists of a single dose administered as two live, oral enteric-coated tablets (type 4 - white tablet, type 7- light peach tablet). The vaccine is packaged in a carton of two bottles of 100 tablets each and must be refrigerated between 2° and 8°C (35° and 46° F) and never frozen. All bottles must be protected from moisture and remain tightly closed. The desiccant canister should not be removed from bottle. The vaccine contains viable, selected strains of human adenovirus type 4 and human adenovirus type 7 prepared in human-diploid fibroblast cell cultures (strain WI-38). The virus strains have **not** been attenuated.

e. Cautions. The following people should not receive the vaccine: pregnant women or women who are considering pregnancy within six weeks of being vaccinated, and people with known severe allergic reactions to any components of the vaccine. It is not known whether vaccinating pregnant women can cause fetal harm or can affect reproduction. Individuals incapable of swallowing an entire tablet, whole, without chewing should not receive the vaccine. Chewing a tablet could expose the upper respiratory tract to live adenovirus leading to disease. Because adenovirus vaccine contains live adenovirus that is shed in the stool for up to 28 days following vaccination, vaccinees should use precaution when around children less than 7 years of

Military Vaccine Agency
SUBJECT: Adenovirus Vaccine

age, immunocompromised individuals, and pregnant women during the 28 days following vaccination. Healthcare providers and ancillary staff should utilize universal precautions and wash hands thoroughly before and after each patient or contact with potential bio-hazardous substances. At the end of each work day all stations should be wiped down by using facility approved disinfectant solution or other preparations as designated by local command.

f. Immunization. Adenovirus vaccine is administered orally, as a single dose consisting of two tablets; one tablet of adenovirus type 4 (white tablet) and one tablet of adenovirus type 7 (light peach tablet). Each tablet must be swallowed whole and cannot be chewed or crushed. Postpone administration to individuals with vomiting and/or diarrhea and those with moderate to severe acute illness. The vaccine is indicated for all military populations 17 to 50 years of age.

g. Adverse Events. Pre-licensure studies show the most common adverse events experienced within two weeks of receiving the vaccine were upper respiratory tract infections, headache, nasal congestion, pharyngolaryngeal pain, cough, arthralgia, nausea, abdominal pain, diarrhea, and vomiting. Serious adverse events were experienced by about 1 person in 100, within 6 months of vaccination, such as blood in the urine or stool, pneumonia and inflammation of the stomach or intestines. It is not clear whether these common and serious events were related or unrelated to the vaccine.

h. DoD Policy. Adenovirus vaccine will be administered to all military recruit populations.

i. Special Considerations. Adenovirus vaccine is recommended for use in military populations (aged 17 to 50 years) at risk of developing ARD caused by adenovirus. Use of this vaccine is not recommended for other populations. Females who are inadvertently vaccinated with the adenovirus vaccine while pregnant or who became pregnant within 6 weeks of receiving the live virus vaccine will receive additional information about the Adenovirus Vaccine Pregnancy Registry during discharge/separation counseling. Interested parties should contact the registry at 1-866-790-4549.

3. References. Multiple resources (e.g., package insert, published research papers, and Vaccine Information Statements assembled by Military Vaccine Agency: www.vaccines.mil/adenovirus).

Ms. Traci Vactor/ 703-325-6538

Approved by Dr. Hayley Hughes