

INFORMATION PAPER

DHA-IHB
2 January 2018

SUBJECT: Adenovirus Disease and Adenovirus Vaccine

1. Purpose. To describe adenoviral infection and the vaccine to prevent it.
2. Facts.
 - a. Microbiology. Adenoviruses are medium-sized, non-enveloped icosahedral viruses containing double-stranded DNA. There are at least 52 immunologically distinct serotypes that can cause human infections. Adenoviruses are unusually stable to chemical and physical agents and to varied pH, thus allowing for prolonged survival outside of the body.
 - b. Disease. Adenoviruses most commonly cause respiratory illness. However, depending on the infecting serotype, adenoviruses may also cause conjunctivitis, gastroenteritis, cystitis, and, less commonly, neurologic illness. Respiratory illness symptoms caused by adenovirus infection range from common cold symptoms, pharyngitis, and rhinitis, to bronchitis or pneumonia. Young infants and patients with compromised immune systems are more susceptible to severe complications from adenovirus infection. Acute respiratory disease (ARD) is a non-specific term, used since the era of World War II, to describe respiratory infections in military training that may be caused by adenovirus.
 - c. Epidemiology. Adenoviruses are transmitted by respiratory droplets, fecal-oral transmission, and, occasionally, through contact with contaminated objects or water. Some adenovirus serotypes 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, adenovirus serotypes 4 and 7 most commonly cause respiratory illness. 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. In military enlisted training centers, adenoviruses have historically caused substantial and prolonged outbreaks of respiratory illness.
 - d. Vaccines. Live, oral vaccines against adenovirus serotype 4 and adenovirus serotype 7 were developed by the United States military and successfully used to limit respiratory illness in enlisted training centers from the 1960s to 1990s. In March 2011, the United States Food and Drug Administration (FDA) licensed Teva Pharmaceuticals /Barr Laboratories, Inc., to manufacture live, oral vaccines against adenovirus serotype 4 and

adenovirus serotype 7. These vaccines contain viable, selected strains of adenoviruses prepared in human-diploid fibroblast cell cultures (strain WI-38); the virus strains have not been attenuated. These vaccines are distributed as enteric-coated tablets, and packaged in a carton of two bottles of 100 tablets each. Vaccine tablets must be refrigerated between 2°C and 8°C (between 35°F and 46°F) and never frozen. All bottles of vaccine must be protected from moisture and remain tightly closed. The desiccant canister, which protects vaccine tablets from moisture, should not be removed from the bottle.

- e. Immunization. Adenovirus vaccines are live-virus vaccines approved for one-time use in new military members, ages 17 to 50 years. The vaccines are administered orally, as a single dose of two enteric-coated tablets; one tablet protects against adenovirus serotype 4 (white tablet) and one tablet protects against adenovirus serotype 7 (peach-colored tablet). Each tablet must be swallowed whole and cannot be chewed or crushed.
- f. Precautions.
 - (1) The following people should not receive adenovirus vaccines:
 - a. Pregnant women or women who are considering pregnancy within six weeks of being vaccinated.
 - b. People who are immunocompromised.
 - c. People with known severe allergic reactions to any component of the vaccine.
 - d. People who are incapable of swallowing an entire tablet, whole, without chewing. Chewing a tablet could, in theory, expose the upper respiratory tract to live adenovirus leading to disease.
 - e. People with vomiting and/or diarrhea, and those with moderate to severe acute illness, should not receive adenovirus vaccines until their illness has resolved.
 - (2) Because adenovirus vaccines contain live adenovirus that is shed in the stool for up to 28 days, vaccine recipients should use caution and wash hand frequently when living or working with young children, immunocompromised individuals, or pregnant women during the 28 days following vaccination.

- g. Adverse Events. The most common adverse events after adenovirus vaccine receipt are headaches, stuffy nose, sore throat, joint pain, abdominal pain, cough, nausea, diarrhea, or fever. More serious problems have been reported by approximately 1% of vaccinees within 6 months of adenovirus vaccination, and include: blood in the urine or stool, pneumonia, and inflammation of the stomach or intestines. It is not clear whether these serious adverse events are caused by the vaccine or occurred by chance.
- h. DoD Policy. Adenovirus vaccines will be administered to military enlisted basic trainees before or at the beginning of collective training, at the same time that other live-virus vaccines are administered. Routine administration of adenovirus vaccines in other populations is not generally recommended, except when directed by preventive medicine guidance, based on disease incidence and severity.
- i. Special Considerations.
 - (1) When dispensing adenovirus vaccines, wear gloves. Healthcare providers and staff should use universal precautions and wash hands thoroughly before and after vaccine administration.
 - (2) Once an adenovirus vaccine tablet has been removed from the vaccine bottle, it cannot be returned to the bottle. If a tablet is not administered, or if the tablet is damaged, it must be disposed as hazardous waste.
 - (3) If the enteric coating on an adenovirus vaccine tablet in the bottle is broken, label the bottle "DO NOT USE," and contact USAMMA (the US Army Medical Materiel Agency) for instructions on disposition of the vaccine bottle. USAMMA contact information is: 301-619-3017 or 301-619-4318 (DSN 343-3017 or DSN 343-4318) or email usarmy.detrick.medcom-usamma.mbx.doc@mail.mil.
 - (4) At the end of each work day, all adenovirus vaccine administration stations should be wiped down using disinfectant, as designated by the local command.

3. References.

- a. Multiple resources, including the vaccine package insert, published research reports, and Vaccine Information Statement, available on: www.health.mil/adenovirus

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Pacific Region Vaccine Safety Hub/ 877-438-8222
Approved: Chief, Immunization Healthcare Branch