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July 15, 2019

MEMORANDUM FOR: DoD Personnel

FROM: Chief, Immunization Healthcare Division

SUBJECT: Adenovirus Disease and Vaccine

In the United States, adenovirus serotypes 4 and 7 most commonly cause respiratory illness. However, depending on the infecting serotype, adenoviruses may also cause conjunctivitis, gastroenteritis, cystitis, and, less commonly, neurologic illness.

In military enlisted training centers, adenoviruses have historically caused substantial and prolonged outbreaks of respiratory illness. 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. Here are some frequently asked questions about adenovirus and its vaccine:

Q1: What are adenoviruses?

Answer: Adenoviruses are medium-sized, nonenveloped 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.

Q2: Can adenoviruses cause acute respiratory disease?

Answer: Yes. In the United States, acute respiratory disease is often associated with adenovirus Types 4, 7, and 14. The epidemiology of adenoviruses vary by type; all are transmitted by direct contact, fecal-oral transmission, and occasionally waterborne transmission. Some types can establish persistent asymptomatic infections in tonsils, adenoids, and intestines of infected individuals, and viral shedding can occur for months or years.

Q3: What are the symptoms of adenovirus infection?

Answer: Adenoviruses cause a wide range of illnesses, depending on the virus type. Adenovirus types 4 and 7 can cause respiratory (breathing) problems, fever, sore throat, cough, eye infections, runny nose, headache, and pneumonia. The incubation period of the disease is 4 to 5 days. These symptoms can last up to 10 days. Young infants and especially patients with compromised immune systems are more susceptible to severe complications of adenovirus infection.

Q4: Can adenovirus be prevented?

Answer: Yes. Strict attention to good infection-control practices, including contact and droplet precautions is effective for stopping nosocomial outbreaks of adenovirus associated disease. Frequent handwashing is effective for preventing the spread of adenoviruses.

Additionally, there is a U.S. Food and Drug Administration (FDA) approved/licensed vaccine for adenovirus types 4 and 7. Adenovirus types 4 and 7 can be prevented with a single vaccine dose administered as two live, oral enteric-coated tablets (type 4 - white tablet, type 7- light peach tablet).

Q5: Are respiratory infections a problem for military populations?

Answer: Acute infectious respiratory diseases are a significant preventive medicine problem for military populations living in close quarters. Crowded conditions are often found at training centers, dormitories, tent cities, and deployment-staging areas. Other potential transmission environments include recruit training centers, classrooms, dining facilities, and areas where items, such as resuscitation mannequins and water fountains are shared.

Q6: What can be done to prevent transmission of respiratory infections including adenovirus infection?

Answer: To prevent spread of disease, it is important to practice good hand hygiene and infection control. Some respiratory diseases are vaccine-preventable including adenovirus types 4 and 7.

Q7: Is there an FDA licensed vaccine for adenovirus?

Answer: Yes. The FDA licensed the adenovirus vaccine on 16 March 2011 for types 4 and 7 for military populations, 17 to 50 years of age.

Q8: Who should get adenovirus vaccine?

Answer: The current DoD policy requires the Services to administer adenovirus vaccine to all enlisted military recruits in accordance with the [Joint Regulation on Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases \(AR 40-562, BUMEDINST 6230.15B, AFI 48-110 IP, CG COMDTINST M6230.4G\)](#).

Q9: What side effects have been reported with the adenovirus vaccine?

Answer: Adenovirus vaccines appear to be safe and well tolerated. Mild problems were reported within 2 weeks of getting the vaccine: headache, upper respiratory tract infection (about 1 person in 3), stuffy nose, sore throat, joint pain (about 1 person in 6), abdominal pain, cough, nausea (about 1 person in 7), diarrhea (about 1 person in 10), and fever (about 1 person in 100). More serious problems have been reported by about 1 person in 100, within 6 months of vaccination. These problems included: blood in the urine or stool, pneumonia, and inflammation of the stomach or intestines. It is not clear whether these common or serious adverse events were caused by the vaccine or occurred after vaccination by chance. Vaccine recipients should always report concerning symptoms to their healthcare provider.

Q10: How effective is the adenovirus vaccine?

Answer: Large-scale studies of the new vaccine in U.S. military recruits showed high efficacy rates in preventing wild type 4 adenovirus-associated febrile acute respiratory disease and inducing neutralizing antibody to type 7 adenovirus.

Q11: What are the components of the adenovirus vaccine?

Answer: The adenovirus 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. The cells are grown and the virus growth maintained in Dulbecco's Modified Eagle's Medium, fetal bovine serum, and sodium bicarbonate.

Q12: How is the vaccine administered?

Answer: Adenovirus vaccine types 4 and 7 are tablets and are given orally. 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.

Q13: How many doses of adenovirus vaccine are needed?

Answer: A single dose is needed, which consists of two live, oral enteric-coated tablets (type 4 - white tablet, type 7- light peach tablet). Adenovirus vaccine types 4 and 7 is administered only once and no booster dose is required.

Q14: Can the adenovirus vaccine be administered with other vaccines, including live vaccines?

Answer: Adenovirus vaccine types 4 and 7 can be administered simultaneously or at any interval before or after other vaccines, including live vaccines.

Q15: How is the vaccine stored?

Answer: The vaccine 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 the bottle.

Q16: How long does protective immunity of adenovirus vaccine types 4 and 7 last?

Answer: The duration of immunity and persistence of circulating antibody following immunization has not yet been determined. The vaccine is very effective in reducing disease.

Q17: Who should NOT receive this vaccine?

Answer: Individuals with known severe allergic reactions to any components of the vaccine; women considering pregnancy within 6 weeks of receiving the vaccine; individuals incapable of swallowing an entire tablet, whole, without chewing should not receive the vaccine.

Q18: Are there any warnings or precautions associated with the vaccine?

Answer: Yes. Vaccinees should use precaution when around children 7 years of age and younger, immunocompromised individuals and pregnant women during the 28 days following vaccination. Because the vaccine contains live adenovirus that is shed in the stool for up to 28 days following vaccination, strict hand washing and personal hygiene is required to minimize risk of transmitting or infecting others with the virus.

Q19: Is pregnancy a contraindication for the adenovirus vaccine?

Answer: Adenovirus vaccine should not be given to pregnant women.

Q20: Is pregnancy testing necessary before administration of the adenovirus vaccine?

Answer: Pregnancy testing is part of routine screening for new accessions. However, it is not necessary to delay vaccination pending pregnancy testing unless pregnancy is suspected. If a woman believes she may be pregnant or has a positive pregnancy test, do not administer adenovirus (or other live) vaccines, and refer the woman to a healthcare provider.

Q21: Is HIV a contraindication for the adenovirus vaccine?

Answer: The safety and effectiveness of adenovirus vaccines in immune-compromised individuals have not been evaluated. Although HIV testing is performed for new accessions, it is not necessary to wait for results before administering vaccines unless an immune-compromising condition is suspected. Verbally screen individuals for HIV/AIDS, other immune-compromising medical conditions, and medications that may affect the immune system before administering adenovirus vaccines.

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