

Adenovirus Vaccination Program Questions and Answers

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The Disease

Overview

1) What are adenoviruses?

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.

2) Can adenoviruses cause acute respiratory disease?

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.

3) What are the symptoms of adenovirus infection?

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.

4) Can adenovirus infections be prevented?

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).

Rate and Spread

1) Are respiratory infections a problem for military populations?

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.

Over the past 10 years adenoviruses have affected about 15,000 military basic trainees annually, with 3-4 days of illness per event and 1-2 deaths occurring per year due to the virus. The United States military processes thousands of recruits each year who arrive from all regions of the country as well as some foreign countries, and from a variety of different environments. The recruits are then formed into close-quartered military units. They may arrive as hosts or with mild cases of respiratory infections endemic to their own particular region of the country; they are housed in close contact with individuals from other parts of the country who may be susceptible. New recruits may also be exposed to

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respiratory infections that are endemic to the recruit training center. Close contact, coupled with the unique stressors of military operations, often put military recruits at a greater risk for respiratory disease than other cohorts.

2) What can be done to prevent transmission of respiratory infections including adenovirus infection?

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.

Adenovirus Types 4 and 7 Vaccine

Immunization

1) Is there an FDA licensed vaccine for adenovirus?

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.

2) Who should get adenovirus vaccine?

The current DoD policy requires the Services to administer adenovirus vaccine to all enlisted military recruits in accordance with <u>Immunizations and Chemoprophylaxis for the Prevention of Infectious</u> Diseases (Joint Publication).

3) What side effects have been reported with the adenovirus vaccine?

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. Several 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.

4) How effective is the adenovirus vaccine?

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.

5) What are the components of the adenovirus vaccine?

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.

Administration

1) How is this vaccine given?

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.

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2) How many doses of adenovirus vaccine are needed?

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.

3) Can the adenovirus vaccine be administered with other vaccines, including live vaccines? Adenoviruses vaccine types 4 and 7 can be administered simultaneously or at any interval before or after other vaccines, including live vaccines.

4) How is the vaccine stored?

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.

5) How long does protective immunity of adenovirus vaccine types 4 and 7 last? The duration of immunity and persistence of circulating antibody following immunization has not yet been determined. The vaccine is very effective in reducing disease.

Contraindications

1) Who should NOT receive this vaccine?

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

2) Are there any warnings or precautions associated with the vaccine?

Yes. Vaccinees should use precaution when around children 7 years of age and younger, immunocomprised 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.

3) Is pregnancy a contraindication for the adenovirus vaccine?

Yes. The adenovirus vaccine should not be administered to pregnant females or nursing mothers.

4) Is pregnancy testing necessary before administration of the adenovirus vaccine?

Pregnancy testing is part of a routine serology panel for newly enlisted female recruits upon accession because pregnancy is a disqualifying condition for basic training. Do not delay vaccination pending routine recruit pregnancy testing unless pregnancy is suspected. If a female recruit has a positive HCG do not administer live vaccines including adenovirus vaccine and refer the female for follow-up per Service policy. Verbal screening for pregnancy in non-recruit populations is standard practice before administering of live vaccines.

5) Is HIV a contraindication for the adenovirus vaccine?

No. However, the safety and effectiveness of the Adenovirus Types 4 and 7 Vaccine, Live, Oral in immunocompromised individuals has not been evaluated. A documented negative HIV test is not required before administering live vaccines when the vaccinee is screened for immunocompromising conditions. Verbally screen individuals for HIV/AIDS, medical conditions, and/or medications that may affect the immune system before administering the adenovirus vaccine.