

**Vaccine to Protect Children from Anthrax
Public Engagement Workshop
Hosted by the Anthrax Vaccine Working Group
National Biodefense Science Board
Questions and Answers**

The population has been told by public health authorities that they were in an area deemed to be exposed to anthrax spores. Public health officials have antibiotics and anthrax vaccine available.

Dialogue of parent to provider:

1. Q - Is my child at risk for developing anthrax?
A - Yes. If your child was exposed to anthrax spores, your child is at risk.
2. Q - What treatments are available?
A - Your child will need to take an antibiotic for two months. A vaccine is also available.
3. Q - Should I get my child vaccinated?
A - Based on what we know about the use of the vaccine in adults, public health officials believe it will provide benefit to your child, however, this has not been previously examined. Your child would still need to take the antibiotics. The vaccine should prevent the disease from occurring after the antibiotics have been stopped.
4. Q - What is the anthrax vaccine?
A - The vaccine is a preparation of proteins from the anthrax bacteria. Vaccination results in an immune response (the body develops antibodies to the proteins in the vaccine). The immune response is believed to neutralize toxins produced by anthrax bacteria in the body and may indirectly affect clearing of bacteria.
5. Q - Has this product ever been given to children before?
A - No, the product has never been given-to or evaluated-in children before.
6. Q - How do you know this vaccine is safe for my child?
A - Public health and other experts have reviewed all the available safety data collected as this vaccine is used in adults and from that believe that the vaccine should be safe in children. Like other vaccines, anthrax vaccine is expected to produce local discomfort, pain, and swelling at the injection site that usually goes away.
7. Q - Do you know if the anthrax vaccine will work in children?
A - Based on the data used to support FDA licensure, public health officials and other experts, believe it will work, however, there are no data on effectiveness in children or in adults for that matter.
8. Q - How do you know how much vaccine to use for children?
A - The pediatric dose is based on the dose given to adults. We expect this dose will result in the same protective response. We simply will not know unless we study the immune response in children of different ages.
9. Q - Why does my child need both an antibiotic and a vaccine? What are the risks if my child does NOT receive the anthrax vaccine?
A - If your child was exposed to anthrax spores, your child will need to complete a 2-month course of antibiotics. Antibiotics do not kill anthrax spores. The antibiotics work directly against the active anthrax bacteria. The bacteria were delivered as

**Vaccine to Protect Children from Anthrax
Public Engagement Workshop
Hosted by the Anthrax Vaccine Working Group
National Biodefense Science Board
Questions and Answers – continued**

- spores, which are very hardy and when they germinate, or “hatch” the resulting bacteria cause the disease. These spores can last several months in the body before hatching. The anthrax vaccine prepares the immune system to directly attack the anthrax bacteria and gives protection beyond the 60-days of antibiotics. As with other bacteria, anthrax bacteria may develop resistance to antibiotics. Also, we do not know enough yet about long-term exposure risks from living in an area that has been contaminated with spores from an attack.
10. Q - Does the anthrax vaccine cause anthrax disease?
A - No. The vaccine cannot cause anthrax.
11. Q - What are the risks if my child does get vaccinated – will the vaccine harm my child?
A - The vaccine causes a local reaction that can be mild or severe, with local pain, swelling and difficulty moving the arm. This reaction can last for days or even longer before going away. As with other vaccines, your child may experience muscle aches, fatigue, and headache. These will go away. Rarely, your child may have a serious allergic reaction within minutes after vaccination and require medication to treat. We will watch for this after your child has been given the vaccine.
12. Q - Will my child be protected against anthrax for life?
A - No. The three doses of vaccine your child will receive are for this particular event. Based on the data we have at this time, it will not protect your child for life.
-
13. Q - If your child were exposed to anthrax, would you want them to get the vaccine?
14. Q - Since we do not know the exact dose of vaccine to give your child and its protective ability, except for the adult dose and data, would you want the US government to collect data on pediatric dosing and protective ability ahead of time, that is, before an exposure? A study done prior to an exposure would help us decide whether the dose that we would use after an exposure is the preferred dose for protecting your child while likely minimizing any side effects.
15. Q - Since we do not know the exact dose of vaccine to give your child and its protective ability, except for the adult dose and data, would you want the US government to collect data on pediatric dosing and protective ability during an event, that is, after an exposure? A study done only after an exposure would need to start with the adult dose that we believe will be effective, as a lower dose may not be effective. We will not know if this is necessary, since a lower dose may be as protective, but with fewer side effects. Enrolling your child in a study will help us figure this out for future children (or future doses for your child).