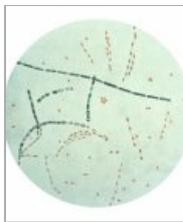


Wednesday 04 August 2010

Pregnant women to get anthrax jab

US CDC updates advice on use of vaccine against intentional release of the bacteria



Bacillus anthracis
from agar culture.

Image credit: CDC

Pregnant women and mothers who breast feed will be advised to get vaccinated against anthrax if they become exposed to the aerosolised form of the bacteria in a bioterrorist attack, according to updated guidelines issued by the US Centers for Disease Control and Prevention (CDC).

The advice, which replaces recommendations made in 2002, was put in place in spite of limited knowledge about the risk of adverse effects following use of the vaccine or antimicrobial drugs. This is because infection with *Bacillus anthracis* bacteria can cause severe illness, said the Advisory Committee on Immunization Practices (ACIP). The bacteria, one of the most serious bioterrorism agents, can kill up to 89% of people who become infected through inhalation.

"ACIP concluded that AVA [anthrax vaccine adsorbed] is safe to administer during pregnancy but recommended that pregnant women defer vaccination unless exposure to anthrax poses an immediate risk for disease," write¹ Jennifer Wright and colleagues from the CDC in the *Morbidity and Mortality Weekly Report*.

After an incident where the bacteria are released intentionally, pregnant or breastfeeding women at high risk of having inhaled anthrax bacteria should receive three doses of the vaccine and take antimicrobial drugs for 60 days, according to ACIP. The same applies to children at high risk of exposure and to previously unvaccinated adults.

Eric Toner, Senior Associate at the Center for Biosecurity of UPMC in Pennsylvania, USA, believes that public health authorities might come across two major obstacles when called on to implement this advice. The first relates to the recommended antibiotics, he says, which can have side effects that are minor but uncomfortable enough to stop people from taking the full course.

Allergic reactions and gastrointestinal symptoms are possible side effects resulting from use of the antibiotics for long periods, according to the report. There may also be a risk of poor bone growth and dental staining for foetuses when tetracyclines are taken during pregnancy. For women who breast feed, "little is known about the safety of long-term use," adds ACIP.

Although some evidence suggests that using antibiotics for just 14 days could offer enough protection against inhalation anthrax, the expert committee calls for more research before concluding that the course can be shortened.

Concerns over the safety of the vaccine could also be a problem when implementing the recommendations, adds Toner, even though they are "mostly unfounded".

Toner does not believe there are lessons to be learned from the 2009 influenza H1N1 pandemic, where safety concerns led many pregnant women to refuse available vaccines even in light of a higher risk of severe illness. "I think that a comparison to H1N1 is not apt," he explains. "The case-fatality rate for H1N1 was one in several thousand, even for pregnant women. The case-fatality rate for inhalational anthrax we expect would be about one in two."

In recommending that pregnant women get immunised against anthrax the CDC considered the results of a large study, published² in 2008, which examined the link between vaccination and birth defects in pregnant military women who were given the jab accidentally. The authors, led by Margaret Ryan, found a slightly higher risk for birth defects associated with vaccination in the first trimester of pregnancy.

The association was not statistically significant when these women were compared with women vaccinated outside the first trimester. But the small increase in risk, seen most clearly for atrial septal defect, was significant when those immunised in early pregnancy were compared with women who never received the jab, or women vaccinated after pregnancy.

Ryan and colleagues said that the results are "reassuring", but added that "a causative association cannot be completely ruled out". They also note that rare birth defects or other effects, such as premature birth, were not assessed in the study.

"The association observed was small but relatively consistent across a number of alternative models and sensitivity analyses," write the authors. "Findings were not explained by simple confounding of available demographic variables, which were adjusted in multivariable analyses."

A separate, smaller study published in 2002 found no evidence of any problems after looking at the effect of anthrax

vaccination on pregnancy, birth rates and other adverse effects, says the CDC. The authors noted the limited statistical power of their study to detect adverse birth outcomes.

"I am not unduly worried that the vaccine is harmful to pregnant women or their babies," says Toner. "I do think that generally there is a lot of vaccine phobia in the general public." But how people perceive the safety of vaccination against anthrax will change "dramatically" after a bio-attack, he adds.

"The vaccine would only be used after an *B. anthracis* release and then the risk/benefit equation is very clear", explains Toner. "Whatever tiny risk to the mother or fetus there might be from the vaccine would be greatly outweighed by the risk of dying from inhalational anthrax."

The CDC has called for more research into the safety and efficacy of the vaccine when used in pregnancy, and for ongoing postmarketing safety studies as required by the US Food and Drug Administration.

The advice for pregnant and breastfeeding women is one of a handful of changes made to the previous guidelines, which include a recommendation for emergency-response staff to get vaccinated before they become exposed to the bacteria. Two other updates — a reduction in the number of vaccine **doses** from six to five, and a change in the type of vaccination from a subcutaneous to intramuscular injection — were announced in February 2009.

References and link

1. Wright JG, Quinn CP, Shadomy S, Messonnier N; Centers for Disease Control and Prevention (CDC). Use of anthrax vaccine in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. *MMWR Recomm Rep* 2010, **59**:1–30. **Report**
2. Ryan MA, Smith TC, Sevick CJ, Honner WK, Loach RA, Moore CA, *et al.* Birth defects among infants born to women who received anthrax vaccine in pregnancy. *Am J Epidemiol* 2008, **168**:434–42. doi: [10.1093/aje/kwn159](https://doi.org/10.1093/aje/kwn159)

CDC information on anthrax

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