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CDC HEALTH ADVISORY

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Statement by the Department of Health and Human Services Regarding Additional Options for Preventive Treatment for those Exposed to Inhalational Anthrax

Many of those who were exposed to inhalational anthrax in the recent mail attacks are presently concluding their 60-day course of preventive antibiotic treatment. Some of these persons, especially those who may have been exposed to very high levels of anthrax spores, may wish to take additional precautions. The Department of Health and Human Services (HHS) is providing two additional options beyond the 60-day antibiotic course, for those who may wish to pursue them: an extended course of antibiotics, and investigational post-exposure treatment with anthrax vaccine.

HHS will make anthrax vaccine available to those who were exposed to inhalational anthrax, who have concluded their antibiotic treatment and who wish to receive the vaccine as an investigational product. The vaccine is being made available in this investigational mode, under an investigational new drug application (IND) at the option of the individual, in recognition of the limited nature of the data now available concerning inhalation anthrax treatment and the factors underlying development of the disease, as well as uncertainty concerning the extent of exposure to spores that some persons may have received in the recent anthrax incidents. The decision to use this vaccine is at the discretion of the individual, in consultation with his or her physician.

Background

Existing data, based especially on animal models, indicate that inhalational anthrax is unlikely to occur after 60 days following exposure. This is the basis of the recommendation for 60 days treatment with an effective antibiotic. So far, no known cases have developed in individuals who were recently exposed to inhalation anthrax and who were prescribed the 60-day antibiotic course. HHS health agencies continue to recommend that those who were prescribed the 60-day antibiotic course and who conclude this course of treatment, or who stopped taking the medicine prior to 60 days, should remain watchful of their health and be in close communication with a physician who is aware of their exposure status. A number of individuals have already concluded the 60-day course, or have stopped taking the antibiotics prior to the 60-day conclusion, and no cases have been reported among them.

At the same time, other animal data indicate that live spores may continue to reside in the lungs beyond the 60-day period, even though these animals did not develop disease. Traces of live spores have been detected in the lungs up to 100 days following exposure. This raises the theoretical possibility that the spores remaining in the lung area might still, after 60 days, result in anthrax. If such a late infection were to occur, HHS scientists believe that the infection could be successfully treated, as were cases of inhalation anthrax that were identified early during the anthrax mail attacks. At the same time, HHS recognizes that some individuals may wish to take extra precautions, especially those whose exposure may have been especially high.

Options

There are three options for individuals exposed to inhalational anthrax:

- Current Recommendation -- 60 days of antibiotic treatment, accompanied by careful monitoring for illness.

- Additional Option 1 -- 40 additional days of antibiotic treatment -- This course would be intended to provide protection against the theoretical possibility that spores might cause infection up to 100 days after exposure. It should be accompanied by monitoring for illness or adverse reactions.

- Additional Option 2 -- 40 additional days of antibiotic treatment, plus anthrax vaccine as an investigational treatment -- In addition to the 40 days of additional protection, this option would involve three doses of anthrax vaccine over a four-week period, to provide immunity to infection over a longer period of time. This is not currently an FDA-approved use of the vaccine, however the vaccine may provide additional protection by inducing an immune response to the anthrax organism. As an investigational new drug, the vaccine would need to be administered with the full informed consent of the individual as to possible risks. Individuals would also be asked to take part in a follow-up study measuring the effect of the vaccine when administered after exposure.

All those who are concluding a 60-day course of antibiotic treatment should monitor their health and be in close contact with their physician. Those who may wish to continue taking antibiotics for an additional 40 days should consult their physician about this course. Those who may wish to take part in the investigational post-exposure use of the anthrax vaccine should consult their physician or a physician at the site where vaccine is being administered.

Contact: HHS Press Office, (202) 690-6343
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