Centers for Disease Control and Prevention
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Questions and Answers on Experimental Treatments and Vaccines for Ebola

This FAQ addresses questions the public has about potential treatments and vaccines for Ebola.

For further information on drug development, approval process, and research please contact the appropriate agency:

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What is ZMapp?

ZMapp, being developed by Mapp Biopharmaceutical Inc., is an experimental treatment, for use with individuals infected with Ebola virus. It has not yet been tested in humans for safety or effectiveness. The product is a combination of three different monoclonal antibodies that bind to the protein of the Ebola virus.

How effective is the experimental treatment?

It is too early to know whether ZMapp is effective, since it is still in an experimental stage and has not yet been tested in humans for safety or effectiveness. Some patients infected with Ebola virus do get better spontaneously or with supportive care. However, the best way to know if treatment with the product is efficacious is to conduct a randomized controlled clinical trial in people to compare outcomes of patients who receive the treatment to untreated patients. No such studies have been conducted. It's important to note that the standard treatment for Ebola remains supportive therapy.

This includes the following measures:

- balancing the patients' fluids and electrolytes;
- maintaining their oxygen status and blood pressure; and
- treating them for any complicating infections.

In addition, the most effective way to stop the current Ebola outbreak in West Africa is meticulous work in finding Ebola cases, isolating and caring for those patients, and tracing contacts to stop the chains of transmission. It means educating people about safe burial practices and having health care workers strictly follow infection control in hospitals. This is how all previous Ebola outbreaks have been stopped.

Why aren't more people getting ZMapp?

At this time, very few courses of this experimental treatment have been manufactured. The manufacturer has indicated that the available doses have been distributed. Since the product is still in an experimental stage, it is too early to know whether ZMapp is effective. The manufacturer of this experimental treatment continues to research and evaluate the product's safety and effectiveness. It has not yet been tested in humans for safety or effectiveness and much more study is needed.

Did the NIH play a role in getting the experimental therapy to the two U.S. patients in Liberia?

This experimental treatment was arranged privately by Samaritan's Purse, the private humanitarian organization, which employed one of the Americans who contracted the virus in Liberia. Samaritan's Purse contacted the Centers for Disease Control and Prevention (CDC), who referred them to the National Institutes of Health (NIH). NIH was able to provide the organization with the appropriate contacts at the private company developing this treatment. The NIH was not involved with procuring, transporting, approving, or administering the experimental treatments.

Will patients in West Africa be able to access this experimental treatment? How much supply is there?

The product is still in an experimental stage, and the manufacturer reports that there is a very limited supply, so it cannot be purchased and is not available for general use. The manufacturer has been planning for phase 1 clinical trials and does not have the capacity to manufacture large quantities of the treatment. The drug has not gone through clinical trials, meaning its safety and effectiveness has not yet been tested in humans. The manufacturer of the experimental treatment continues to research and evaluate the product's safety and effectiveness. The most effective way to stop the current Ebola outbreak in West Africa is meticulous work in finding Ebola cases, isolating and caring for those patients, and tracing contacts to stop the chains of transmission. It means educating people about safe burial practices and having health care workers strictly follow infection control in hospitals. This is how all previous Ebola outbreaks have been stopped.

Is ZMapp available under the Food and Drug Administration's expanded access to investigational drugs?

Currently there are only experimental treatments for Ebola virus infection in the earliest stages of development. When a drug is not approved, the FDA can authorize access to potentially promising products through other mechanisms, such as through an emergency Investigational New Drug (IND) application. In order for an experimental treatment to be administered in the U.S., such a request must be submitted to and authorized by the FDA. The FDA cannot comment on the specifics of ongoing drug development programs and cannot reveal information that is not otherwise public concerning submissions covering such programs such as IND applications submissions. The FDA stands ready to work with companies and investigators treating these patients.

Is ZMapp a vaccine?

No. ZMapp is being developed as a therapeutic product for treatment of people infected with Ebola virus, but not to prevent infection in the same manner as a vaccine. The best way to prevent infection currently is with stringent infection control measures.

What's the difference between therapy and vaccine?

Vaccines are usually given to people before they are exposed to a virus or bacteria that causes a disease. A vaccine stimulates the immune system to generate antibodies and cellular immunity that can fight off an infection if it were to occur. Typically, therapeutics are provided to people who are already infected with the virus. With the experimental ZMapp treatment, the monoclonal antibodies bind to the virus, so that the human immune system can clear the virus.

Are there Ebola vaccines available for use or in development?

There are currently no FDA approved vaccines for Ebola. The NIH's National Institute of Allergy and Infectious Diseases is working on developing an Ebola vaccine. NIH recently announced they are expediting their work and are launching phase 1 clinical trials of an Ebola vaccine.

On August 28, 2014, NIH announced that initial human testing of an investigational vaccine to prevent Ebola virus disease will begin next week by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

The early-stage trial will begin initial human testing of a vaccine co-developed by NIAID and GlaxoSmithKline (GSK) and will evaluate the experimental vaccine's safety and ability to generate an immune system response in healthy adults. Testing will take place at the NIH Clinical Center in Bethesda, Maryland.

The study is the first of several Phase 1 clinical trials that will examine the investigational NIAID/GSK Ebola vaccine and an experimental Ebola vaccine developed by the Public Health Agency of Canada and licensed to NewLink Genetics Corp. The others are to launch in the fall. These trials are conducted in healthy adults who are not infected with Ebola virus to determine if the vaccine is safe and induces an adequate immune response.

In parallel, NIH has partnered with a British-based international consortium that includes the Wellcome Trust and Britain's Medical Research Council and Department for International Development to test the NIAID/GSK vaccine candidate among healthy volunteers in the United Kingdom and in the West African countries of Gambia (after approval from the relevant authorities) and Mali.

NIH is also supporting the Crucell biopharmaceutical company in its development of an Ebola/Marburg vaccine as well as Profectus Biosciences in its development of an Ebola vaccine. Additionally, NIH and the Thomas Jefferson University are collaborating to develop a candidate Ebola vaccine based on the established rabies vaccine.

Is the U.S. government involved in the development of ZMapp?

The U.S. government, specifically, the NIH's National Institute of Allergy and Infectious Diseases, the Department of Defense's Defense Threat Reduction Agency (DTRA), and the HHS' Biomedical Advanced Research and Development Authority (BARDA), has provided support for the development of this experimental treatment.

Are there other companies developing experimental treatments or vaccines?

Two other companies, Tekmira and Biocryst Pharmaceuticals, receive funding from the Department of Defense's Defense Threat Reduction Agency and have therapeutic candidates for Ebola in early development. The Department of Defense is working with a company called Newlink to develop an Ebola vaccine candidate. BioCryst, with NIH support, is working to develop an antiviral drug to treat Ebola virus that is expected to begin Phase 1 testing later this year.

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