

Ebola: Questions, answers about an unproven drug

August 11 2014, by Lauran Neergaard

A Spanish missionary priest is the third Westerner with Ebola to be treated with an experimental drug that's never been tested in people and is said to be in very limited supply.

Spanish authorities' disclosure on Monday raised further ethical questions about why no Africans have received the drug and how to decide who gets access to an unproven drug in an emergency. The first two recipients were Americans.

The World Health Organization debated the issue Monday, even as Ebola experts have warned that scarce doses of experimental drugs are not going to stop an outbreak that has now spread to four African countries.

Some questions and answers about the Ebola drug:

Q: What is this drug?

A: Called ZMapp, it is a cocktail of specially engineered antibodies designed to target and inactivate the Ebola virus.

Q: What is known about whether it works?

A: Very little. Various antibodies have been tested in small numbers of monkeys, but not people. In one study, 43 percent of treated monkeys survived when the drug was given after the animals showed symptoms.

Manufacturer Mapp Biopharmaceutical Inc. now is developing a combination of three antibodies that seemed most promising in those animal studies.

Q: Why isn't ZMapp being tested more widely to find out if it works in people?

A: There's not enough available; Mapp Biopharmaceutical says it has very limited supplies. The antibodies are grown inside tobacco plants, and then extracted and purified, a slow process. U.S. officials have estimated that only a modest amount could be produced in two or three months, unless some way to speed production is found.

Q: What does it mean that the two American aid workers who received the drug are reported to be slowly improving?

A: Top U.S. health officials stress that there's no way to know if the drug really helped, or if those two patients would have been among the 40 percent of people who are surviving this outbreak anyway. Without human studies, there also isn't any way to know if the drug might harm instead of help.

There is no proven treatment for Ebola. But basic supportive care—things like keeping patients hydrated, maintaining their blood pressure and treating any complicating infections—can make a difference in survival, says Dr. Tom Frieden, director of the Centers for Disease Control and Prevention.

The two U.S. patients, both infected in Liberia, are being treated at Emory University Hospital in Atlanta.

Q: How were the Westerners chosen to get some of those limited doses, rather than Africans?

A: The international relief organization Samaritan's Purse and Emory University Hospital requested that the manufacturer provide some of the drug for the two Americans, and the manufacturer agreed. As for the Spanish missionary priest, it wasn't clear exactly how Spanish officials obtained a dose that apparently was in Geneva. The priest also was infected in Liberia and is in isolation at a Madrid hospital.

Typically, the Food and Drug Administration doesn't regulate shipments of unapproved drugs for emergency use in individual patients outside the U.S.

The World Health Organization is debating if any further limited supplies of experimental drugs should be used during the outbreak, and under what conditions. But the agency cannot force a manufacturer to go along. Indeed, using an [experimental drug](#) outside of a research study isn't just a gamble for patient safety. What if a drug might benefit patients early in the disease, but doctors can't tell because it was given only to the most gravely ill?

Q: Are any other drugs in the pipeline?

A: Canada's Tekmira Pharmaceuticals Corp. is developing a drug that targets Ebola's genetic material. The FDA had halted a small safety study with questions about a reaction in healthy volunteers. Last week, Tekmira announced that FDA had modified its restriction, clearing a roadblock to possible experimental use in infected patients; the company said at the time that it was "carefully evaluating options."

A handful of other companies are in earlier stages of [drug](#) development; a possible vaccine to prevent the disease is expected to begin first-stage safety studies sometime in the fall.

Q: If experimental drugs won't stop the outbreak, what will?

A: Frieden and other experts say old-fashioned public health measures: rapidly finding and isolating the sick, quarantining those exposed and educating the public on how to avoid the risk of infection. Ebola is spread through direct contact with bodily fluids of sick patients. Frieden said the two main drivers of the outbreak are improper infection control during patient care and traditional but risky burial practices that have mourners handling bodies that are still infectious.

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