

Ebola drug testing sparks ethics debate

November 12 2014, by Matthew Perrone



In this Oct. 27, 2014 file photo, health workers unload the lifeless body of a man suspected of contracting the Ebola virus, as they carry him to a grave site on the outskirts of Monrovia, Liberia. Health officials in the U.S. and Europe are scrambling to begin testing a handful of experimental Ebola drugs in Africa, but an ethical debate is brewing over how to appropriately test medicines amid an outbreak that has already killed nearly 5,000 people. (AP Photo/Abbas Dulleh, File)

Health officials are scrambling to begin human testing of a handful of experimental drugs for Ebola. But the effort has sparked an ethical

debate over how to study unproven medicines amid an outbreak that has killed nearly 5,000.

U.S. officials say the studies must include one critical feature of traditional medical testing: a control group of patients who do not receive the drugs.

But many European and African authorities argue that withholding drugs from study participants is unethical, given that the current outbreak kills between 50 and 80 percent percent of those infected in West Africa, according to Doctors Without Borders. They favor alternative studies in which every patient receives drug therapy.

The split in testing philosophies means different researchers may wind up testing the same drugs using different approaches.

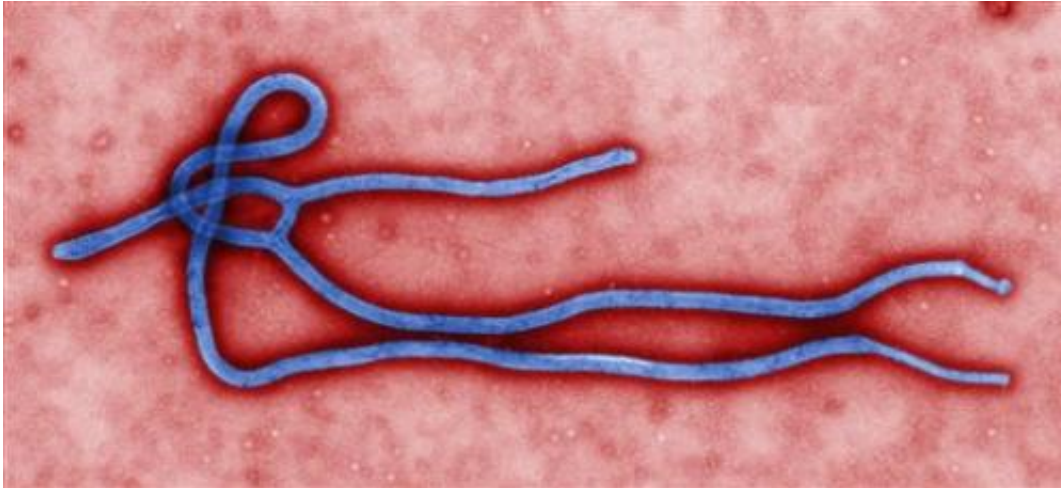
While there are no established drugs for Ebola, the Food and Drug Administration has allowed the emergency use of several experimental ones in U.S. patients. But agency officials say it's impossible to tell what affect the drugs have because patients in the U.S. also receive aggressive medical care, including fluid replacement, oxygen therapy and antibiotics.

Comparing patients receiving drug therapy to patients who are not is a long-established testing technique considered the gold standard of medical research. Officials from the FDA and the National Institutes of Health say the Ebola trials must stick to this model to get an accurate picture of whether the therapies are safe and effective.

FDA officials laid out plans last week for a study that would randomly assign patients to receive one of several drugs or aggressive medical care. Researchers would regularly assess patients taking the drugs, with the aim of switching over patients from the control group if one drug

appears effective.

Dr. Luciana Borio, the FDA's director for counterterrorism and emerging threats, said she understands the ethical concerns associated with the approach.



This undated file image made available by the Centers for Disease Control (CDC) shows the Ebola virus. Health officials in the U.S. and Europe are scrambling to begin testing a handful of experimental Ebola drugs in Africa, but an ethical debate is brewing over how to appropriately test medicines amid an outbreak that has already killed nearly 5,000 people. (AP Photo/Centers for Disease Control, File)

"People do not like the idea of not receiving something that they think might help them, even though the fact is that we do not know yet if this stuff is going to help or hurt," Borio said.

FDA plans is to begin testing the approach on Ebola patients brought to the U.S. and then transfer the model over to Africa, where an estimated 13,270 people are infected.

U.S. medical ethicists tend to agree with the approach.

"It would be terrible to have a drug that we thought would work and offer it to these poor, suffering, and desperate people only to find out later— because we screwed up the clinical trials—that we were wrong," said Dr. Philip Rosoff, a professor of bioethics at Duke University.

But a coalition including Doctors without Borders, Oxford University and the French National Institute of Health and Medical Research plans to announce a study on Thursday that will give experimental drug therapy to all patients enrolled. Organizers say the current outbreak is so deadly that patients should have access to medicines that can potentially help them—even if their safety and effectiveness is uncertain.

"We have chosen this design because we think that it's not ethical to randomize patients to standard care in the conditions where these studies are conducted," said Piero Olliaro, an Oxford University professor and WHO official.

Under the study plan, researchers will measure the death rate of Ebola patients given an experimental drug over two weeks. If the mortality rate falls as low as 20 percent, researchers say they will know they have an effective treatment.

Similar trial designs are sometimes used to study deadly forms of cancer for which there are no established treatments. In the 1980s, some of the earliest HIV drugs were also tested in trials where all patients received drug therapy. But at the time AIDS was a fatal disease with no known cure. Ebola, on the other hand, is well understood and can be cured via traditional medical care.

Olliaro said he could not name the drug that would be used in the European study, but he pointed out that the WHO has outlined several

drugs that could be suitable for study in Africa, including antiviral pills from Chimerix and BioCryst Pharmaceuticals. Both of those drugs are designed to block enzymes that allow viruses to reproduce, though they have not yet been tested specifically against Ebola.

A WHO report released last week attempted to find consensus among researchers, stating that all testing methodologies should be considered ethical. However, the report notes that officials from Guinea and Liberia said that randomized, controlled trials "would not be acceptable to local communities."

Additionally, the report states that cultural and ethical factors could make it difficult to obtain permission for randomized studies in Africa.

For now, Olliaro says officials must move past ethical debates and begin testing, regardless of the method.

"I think it's high time to stop discussing and start acting," he said.

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