

This Ebola drug is heading to the Congo. Can it be tested during civil war?

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As the fast-moving Ebola virus sweeps through eastern Congo, scientists are braving war zones hoping to test new medicines on sick patients there.

Despite civil unrest in the region, Doctors Without Borders has set up testing sites in the cities of Butembo and Beni, the latest hot spots of the current Ebola outbreak in the Democratic Republic of the Congo. But researchers have plans to chase the virus as it moves throughout the region, which it does at a rather rapid pace.

Here in San Diego, where scientists have long been studying the deadly virus, a [biotech company](#) is getting a rare shot at seeing how its drug compares to three other experimental treatments that are part of this trial, including ones made by biotech giants Regeneron and Gilead Sciences.

The San Diego firm—Mapp Biopharmaceutical—leaped into national news in 2014, when its experimental medicine, ZMapp, was used during the West African Ebola epidemic. The drug is a mixture of three antibodies meant to knock down levels of the Ebola virus in the body, hopefully buying time for the patient's immune system to rally and defeat the disease.

Anecdotal accounts indicated ZMapp might have helped save the lives of infected patients such as American missionaries Dr. Kent Brantly and Nancy Writebol.

ZMapp spiked in demand during the 2014 outbreak, but the company wasn't set up to make its drug at mass scale back then. By early 2015, when a clinical trial was finally authorized to start treating patients with ZMapp, the epidemic was waning. The study moved forward anyway but had a hard time recruiting patients to test. In the end, the data showed some evidence ZMapp helped Ebola patients survive. But not enough patients were enrolled in the trial for the drug to prove statistical significance.

Of course, fewer grievously ill people is a good thing. But it's hard to test

whether a [drug](#) works when proper [trials](#) can't be conducted.

"It's challenging to do [clinical trials](#) in a way that will satisfy (regulators) because we obviously would never intentionally infect people with Ebola," said Larry Zeitlin, founder and president of Mapp Biopharmaceutical.

And so data on ZMapp—and other newer drugs designed to fight the virus—are slim. And that means scientists must rely on animal trials to learn how Ebola reacts to drugs, which can be a hindrance to understanding the virus.

This is why researchers are rushing into regions of eastern Congo to set up new trial sites at area hospitals where outbreaks arise, despite the political unrest in the area. The National Institutes of Health is leading the trial, and it's overseen by a World Health Organization steering committee, along with other national and international actors.

But it's a difficult task. In December, an Ebola treatment center was stormed by rioters in Beni, who protested the postponement of an election by setting fire to the facility.

Virus researcher Erica Ollman Sapphire, who works at The Scripps Research Institute of La Jolla, helped Mapp determine the molecular structure of ZMapp and is familiar with the new trial sites in eastern Congo. She said the trial might be able to tell researchers which of these four anti-Ebola drugs work best, how well and at what stage of the virus' progression.

But that's assuming best case scenario. Sapphire said she's worried the data might be "noisy" if the trial stumbles into difficult circumstances, like not having enough patients to sort into a truly randomized trial.

"Can we be sure the people getting 'Therapy A' is an identical population to the people getting 'Therapy B'?" Sapphire said. "In a traditional randomized trial, more people would be involved."

Not to mention, she said, the instability in the region could shake up a clinical trial's best efforts.

"They're working under very difficult circumstances," Sapphire said. "This is an Ebola outbreak in an unstable zone. Getting a trial done at all would be a good outcome."

The drugs being tested in the trial are Gilead's Remdesivir, mAb114, Regeneron's REGN-EB3 and ZMapp, which is the control arm.

Zeitlin said the trial would likely not play into ZMapp's future regulatory approval in the U.S., however. The company is taking a different route through the U.S. Food and Drug Administration via the "Animal Rule," which allows drugs like ZMapp to get approval by showing efficacy in animals only. If all goes well in ZMapp's trials, the company will ask the FDA for approval around 2022, Zeitlin said.

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