Who Gets Ebola Drugs? AIDS, Dialysis and Cancer 'Cures' Point the Way

By Susan Donaldson James
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As limited supplies of an experimental Ebola treatment arrived in Liberia and with an untested vaccine on the way, thorny questions remain that could determine the difference between life and death.

There is no treatment or vaccine proven to work against Ebola. So those who receive the first doses of ZMapp or a vaccine provided by Canada are essentially guinea pigs — for better or worse.

The epidemic raises a host of ethical questions about who can get these drugs and how they will be distributed. Historical crises, from the scourge of AIDS in the 1980s to illegal drug-testing on Nigerian children in the 1990s, may help point the way.

And at least one expert warned that the humanitarian effort by the World Health Organization in the escalating Ebola epidemic could “prove to be disastrous.”

“If you hold out even a sliver of hope to desperate people, as shown with the AIDS crisis, they will go for it,” Dr. Philip Rosoff, director of clinical ethics at Duke University, told NBC News.

“Furthermore, the few patients who have been treated with this first-in-people drug for Ebola have all been white residents of Europe of the United States, a fact that could raise issue of preferential treatment.”

Before two American aid workers received the treatment, a medical team from WHO and Doctors Without Borders in Sierra Leone debated whether to treat Dr. Sheik Umar Khan with ZMapp. They decided against it, concerned that he was too sick to benefit. Khan died July 29.

The medicine was sent on to Liberia and eventually used to treat two American volunteers, Dr. Kent Brantly and aid worker Nancy Writebol, who are recovering now at Emory University Medical Center. A third Ebola patient, a 75-year-old Spanish priest who worked in Liberia, also got the drug but later died.

So far, more than 1,000 people have died of the virus in the West African countries of Guinea, Sierra Leone, Liberia and Nigeria.

WHO has declared the Ebola epidemic a global health emergency and has defended its use of the drug, saying it would seek patient consent and collect medical data.

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"In the particular circumstances of this outbreak, and provided certain conditions are met, the panel reached consensus that it is ethical to offer unproven interventions with as yet unknown efficacy and adverse effects, as potential treatment or prevention," WHO said in a statement this week.

Rosoff, who has worked in planning for pandemic influenza and allocation of drugs during shortages, said "extra caution and thought" must be paid to using these drugs on populations where he says proper consent is "meaningless."

"In the current epidemic of Ebola, there is the added ingredient of the long and sordid history of pharmaceutical companies from Western industrialized nations performing clinical trials in poor, undereducated populations for the benefit of the potential wealthy patients back in their home countries," he said.

In 1996, the pharmaceutical company Pfizer allegedly broke international law by testing the powerful antibiotic Trovan on 100 children with brain infections during a meningitis epidemic.

Five children died and many others developed arthritis symptoms after receiving the drug; six died on a comparison drug. It was never proven that the drug caused the deaths.

In 2006, after a year-long investigation, the Washington Post obtained a confidential government report that said the experiment was a "clear case of exploitation of the ignorant."

The Post said the company had planned to sell the drug in the United States, grossing up to $1 billion a year in profits. But it was never approved for children following reports of liver damage and deaths.

Pfizer said at the time that the Nigerian government had full knowledge of its program and it had heeded patient consent and safety protocols.

Alta Charo, professor of law and bioethics at both the University of Wisconsin's law and medical schools, says WHO's plan “makes sense, if [those treated] know they are taking a gamble. There is always a risk-benefit balance, especially in an impoverished area.”

“Personally, I don't think it's problematic to offer experimental drugs to people because they are facing serious, potentially lethal consequences,” she said.

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Charo points to the AIDS/HIV virus, which first appeared in the United States in 1981, killing 50 percent of its victims, mostly gay men, within a year of diagnosis.

Zidovudine or AZT, the drug that stemmed the tide of the crisis, got regulatory approval from the Food and Drug Administration in 1987, a record 19 months after several phases of clinical trials.

But until then, FDA regulations were so tight, because of the drug's “experimental nature,” that only 200 to 300 of the nation's 10,000 AIDS patients had access to AZT, according to a 1986 analysis by the Cato Institute.

By 1987, the FDA launched its “compassionate care” program that allowed large numbers of patients to get treatment.

“It was the only drug developed at the time, and clinical trials were full and there were a lot of people who thought they would die soon and couldn't get it to trials,” said Charo.

But, she cautions, geography can make a difference in how well a drug works, and ZMapp may not work as well in Africa as it does in the United States, where the Americans are being treated.

“We have clean water and intensive care support, and if the respiratory system is compromised, a ventilator,” she said. “If you get an infection, there are antibiotics here. If there is bleeding, we can give blood replacement.”

As for who gets the drugs, Charo said “we ration all the time in transplantation when we don't have enough organs.”

In public health crises, usually medical workers get the drugs first. “You want to keep them alive so the others can live.”

Local countries must weigh which patients will benefit the most treatment, usually those who have the greatest chance of survival.

But history also has ethical lessons in preferential treatment, according to Rosoff, who wrote the 2014 book, “Rationing Is Not a Four-Letter Word: Setting Limits of Healthcare.”

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When kidney dialysis technology first emerged in Washington state in 1960, demand greatly exceeded the capacity to treat those with failing organs, and officials had to decide which patients could get the expensive treatment.

"The first ethics committee in Seattle was headed by a local priest," said Rosoff. "They were talking about social characteristics ... does a lawyer supporting a family get access to the life-saving machines or a longshoreman or a housewife?"

People were outraged, and in 1972, the National Kidney Foundation lobbied Congress, which passed the Medicare End Stage Renal Disease program, giving anyone with renal failure access to the new technology.

But perhaps the most compelling scientific concern among ethicists is how WHO researchers can know how well these experimental Ebola drugs will work.

Some patients with Ebola will recover spontaneously, according to the Centers for Disease Control and Prevention. But the only way to know the drug's effectiveness is to conduct randomized controlled clinical trials.

Arthur L. Caplan, founding head of the Division of Bioethics at New York University Langone Medical Center and an NBC contributor, argues that WHO should set up an “emergency ethics review committee.”

“Rather than just handing out vaccine to a small group of people in countries that have seen Ebola outbreaks,” he writes, “it is important to learn as much as possible about whether the vaccine has any efficacy in humans and is safe.”

Duke's Rosoff says the danger is giving patients — and the research world — the “false hope” that there is a “miracle drug.”

“If you have 100 doses of a drug and you have never given it to people, should we do it in a controlled clinical trial or do we just give it to people and see if it works?” he asked. “It might be impossible to learn.”

“Even if you pick people carefully, there is selection bias,” said Rosoff. “Will people get better anyway?”

He cites controversial treatment for advanced breast cancer cases in 1986, using high-dose chemotherapy and patient's own bone marrow that was considered a “miracle therapy.”

Early clinical trials were so promising that it became the standard of care. Women even sued for insurance coverage for the procedure. But after later trials, the autotransplantation was considered “marginal at best,” and many women died from the treatment, according to Rosoff.

He sees parallels in the controversy over untested Ebola drugs.

“Say it's terribly toxic and you give it to someone with Ebola who is desperately ill and the patient dies,” he said. “You don't know if the patient died because of the drug or because of Ebola.”

“It would be a tragedy if you concluded the drug was toxic when it was actually terrific,” said Rosoff. “Either way, you make an error.”