NEWS IN FOCUS

KENNY KATOMBE/REUTERS

Health Ministry officials carry the first batch of experimental Ebola vaccines in Kinshasa, Democratic Republic of the Congo, on 16 May 2018.

PUBLIC HEALTH

Experimental drugs poised for use in Ebola outbreak

International health groups are in discussions with the Democratic Republic of the Congo.

BY ERIKA CHECK HAYDEN

Aid workers responding to the Ebola virus outbreak in the Democratic Republic of the Congo (DRC) are seeking approval to treat patients with experimental drugs. These include three potential treatments — ZMapp, favipiravir and GS-5734 — that were given to patients during the 2014–16 Ebola epidemic in West Africa.

The drugs are being considered in addition to the use of an experimental vaccine; none of the treatments has been definitively proved to lower the risk of death from Ebola.

The move to test experimental drugs and vaccines early in the outbreak, which was confirmed on 8 May, is part of a push to start research as soon as possible after Ebola cases are detected to save lives. That's a change from the past, when doing research during an outbreak was seen as a distraction.

The switch has been driven by the availability of new vaccines and drugs — and by memories of the 2014–16 epidemic. Officials were so slow to deploy potential vaccines and drugs that the epidemic had waned before clinical trials could start. Now, "there's an acceptance that research during an outbreak is something we need to do", says Daniel Bausch, director of the UK Public Health Rapid Support Team in London.

The DRC allowed the use of an experimental Ebola vaccine during the country's last outbreak, in May 2017, although the outbreak ended before the vaccine was shipped. Earlier this month, the government approved the first shipments of the vaccine and the country now has more than 7,500 doses on hand. The vaccine was given to health-care workers beginning on 21 May, and could be administered this week to patients and their contacts.

Public-health experts hope that the experimental vaccine, called rVSV-ZEBOV, will help to control the outbreak. Forty-six people have been infected and 26 have died, the World Health Organization (WHO) said on 21 May. The virus has spread over a wide area and infected at least one person in a major city, Mbandaka — home to 1.2 million people.

The rVSV-ZEBOV vaccine, manufactured by Merck, was shown to protect against Ebola in a trial run during the West African epidemic. None of the 5,837 volunteers who took the vaccine in that trial became infected.

Officials in the DRC have quashed eight ▶

previous outbreaks through conventional public-health measures, such as tracking down people with Ebola and their contacts to understand the disease's path. But they worry about how far the virus has already travelled this time and about the possibility that it could spread even farther — as it did in the West African epidemic, which took root in 3 countries and claimed more than 11,000 lives. "We think the outbreak could become complicated, as it did in West Africa, so we must do everything to stop it," says Jean-Jacques Muyembe-Tamfum, director-general of the National Institute for Biomedical Research in Kinshasa.

Whether that will include deploying experimental drugs is now under discussion. The WHO is consulting experts to consider the evidence for such treatments, and the medical humanitarian organization Médecins Sans Frontières (MSF) is talking to DRC officials about using them, says Annick Antierens, who coordinates Ebola clinical trials for MSF.

Although the rVSV-ZEBOV vaccine could help prevent new infections, Antierens says, experimental drugs might still be needed because officials lack a good understanding of where Ebola first emerged during this outbreak or how it is spreading. So there are likely to be very many people who are already infected.

Using experimental vaccines and drugs in an outbreak raises logistical and ethical complexities, such as delivering them to remote settings by aeroplane or motorbike and designing humane and rigorous clinical trials. The 2014–16 Ebola outbreak saw controversy over whether potential drugs and vaccines should be tested in trials that randomly assign patients to receive either the experimental treatment or standard care. MSF and officials at the WHO argued that withholding the medicines from desperate patients would be unethical.

Some of the treatments MSF is now considering were given to varying numbers of people in the 2014–16 epidemic. ZMapp, an antibody treatment made by Mapp Biopharmaceutical in San Diego, California, was tested in a 72-person trial; 22% of the 36 people who received the drug died, compared with 37% of the 35 who did not receive it. Favipiravir, an antiviral drug from the Japanese company Toyama Chemical, was given to 126 patients in the West African outbreak, and a few dozen in other trials. The antiviral drug GS-5734 was given to three people.

The Congolese Ministry of Health and a national ethics review board would need to approve new drug trials. Observers say that studies must proceed more equitably than they did in the 2014–16 outbreak, when experimental treatments were given first to international doctors and aid workers.

"We were pretty tone deaf," says Lawrence Gostin, director of the WHO Collaborating Center on Public Health Law and Human Rights at Georgetown University in Washington DC. "We need to do that completely differently this time." ■

POLICY

Indonesia plans strict foreign research laws

Regulations could hamper international collaborations.

BY DYNA ROCHMYANINGSIH

Scientists in Indonesia fear that a government plan to introduce stringent rules for foreign researchers will scare off potential collaborators and hamper experiments. The proposals also suggest tough new penalties, including prison sentences, for foreign scientists who break some existing rules, such as the requirement to have a research permit.

Next month, representatives from two science academies will meet with politicians in the hope of convincing them to reconsider the proposals.

"The new regulations will only repel foreign scientists to do research in Indonesia, and this is not good for Indonesia's science," says Berry Juliandi, a member of the Young Academy of Sciences and a biologist at Bogor Agricultural University. The contribution of international scientists is crucial for Indonesian research because foreign science agencies have larger budgets and more sophisticated technology, he says.

Government documents state that the proposed regulations for international science are meant to protect Indonesia's natural resources and to increase local science capacity. The proposals are among several outlined in a draft law submitted to the House of Representatives in August 2017.

If the law is approved by the house, international scientists will have to submit their raw data to the research ministry; involve Indonesian colleagues as equal partners in research projects; and name all Indonesian researchers involved in a project on every peer-reviewed paper that arises from the work.

The draft law also imposes harsh penalties on foreign researchers who break existing regulations. Foreign scientists will still need a government permit to do research, and a special transfer agreement to remove specimens, but breaking these rules would be upgraded to a criminal offence. Researchers could face a prison sentence of up to 2 years, or hefty fines of as much as 2 billion Indonesian rupiah (US$143,000). The current penalty for a researcher who violates a permit can vary from a verbal warning to the permit being revoked. There has been no national policy or penalty for scientists who remove specimens without an agreement.

The draft law would also require that international scientists do research that produces "beneficial output for Indonesia".

Erik Meijaard, a conservation scientist at the University of Queensland in St Lucia, Australia, who studies orangutans in Borneo, says the proposal is "unworkable" for foreigners: "You could do a few years' research, find out that the outcomes do not benefit Indonesia, and then you cannot publish."

Meijaard adds that, overall, the draft law seems vague and is "certain to turn away foreign researchers and stop people from studying in Indonesia if there is an unclear risk of being fined or sent to jail".

The ministry's director-general for research and development reinforcement, Muhammad Dimyati, doesn't think the rules will stop collaboration. "We encourage foreign scientists to publish their research conducted in Indonesia. But they should not write alone and they have to involve Indonesian scientists. This will certainly give benefits to Indonesia's science."

Dimyati says every country has a right to protect its natural resources for the welfare of its people. "The sanctions are intended to remind scientists about their role in society, which is to find innovation that is beneficial for mankind without violating regulations of a country," he says.

"We encourage foreign scientists to publish research conducted in Indonesia. But they should not write alone."

Not all researchers think the penalties are a bad idea. Laksana Handoko, a physicist at the Indonesian Institute of Sciences in Jakarta, supports criminal punishments for researchers who take specimens out of the country without a transfer agreement. It's stealing, he says.

Jason von Meding of the University of Newcastle in Australia, who studies disaster risk-reduction in southeast Asia, says that scientists in developing countries need protection for their work — and that international scientists should not be afraid of the draft law if they've done nothing wrong. But he thinks that less-severe sanctions would be more appropriate than the proposed criminal penalties.

The research ministry's director of intellectual property, Sadjuga, says it could be some time before the proposals become law, because members of the house have to debate the draft, and they are preparing for an election in 2019. ■