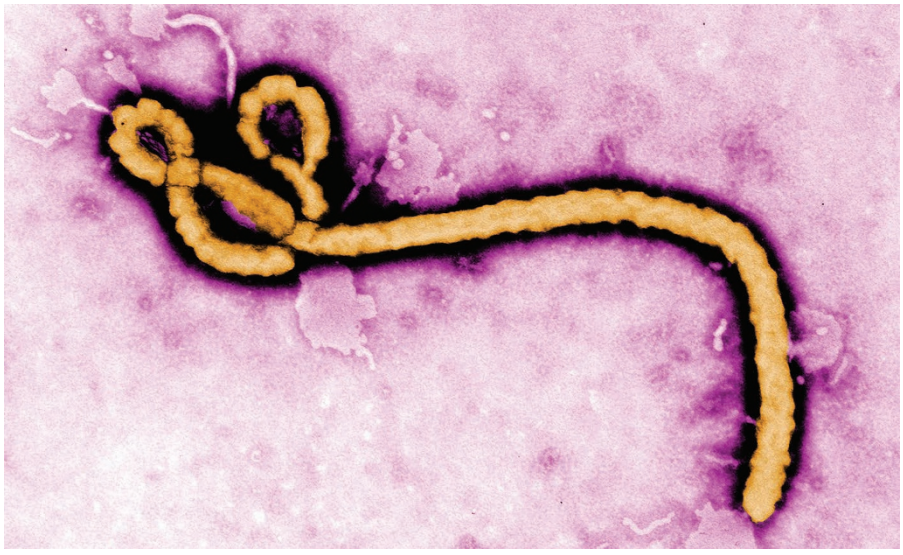
Merck vaccine heads Ebola countermeasures

Swift intervention by local and international health authorities, combined with the rollout of mobile diagnostic labs and an effective vaccine, appear, so far, to have contained the current Ebola virus outbreak in the Democratic Republic of the Congo (DRC), which began in April. A ring vaccination campaign, focused on front-line healthcare workers, as well as infected patients' primary and secondary contacts, seems to have played a decisive role in limiting the spread of the virus. However, just one super-spreading event—traditional burial customs proved to be tragically potent at propagating infection during the calamitous 2013–2016 outbreak in West Africa—could alter the current cautiously optimistic outlook. Should the present outbreak escalate, the DRC and its international allies will also have recourse to five investigational drugs (**Table 1**), which, if necessary, will be administered under a compassionate-use protocol.

"It's a far better set of options than was available in the 2013–2016 outbreak," says Larry Zeitlin, president of Mapp Biopharmaceutical (MappBio), producer of ZMapp, an antibody cocktail directed against Ebola virus glycoprotein (GP). "I think there was a lot of desperation in that outbreak, and people just wanted to do something. This time we have more data, and there are validated options that can be used." The live attenuated vaccine developed by Merck and Newlink is the only Western-developed Ebola vaccine that has completed a phase 3 trial and is being administered under an expanded access clinical protocol sponsored by the Geneva-based World Health Organization (WHO). (Although vaccines have gained approval in China and Russia, neither is being deployed in the DRC.)

Merck's vaccine appears to act fast. Investigators on the Ebola Ça Suffit ('Ebola, that's enough') study in Guinea and Sierra Leone reported 100% efficacy after a single shot of the recombinant vesicular stomatitis virus–Zaire Ebola virus (rVSV-ZEBOV), which was administered to 5,837 individuals as part of a ring vaccination campaign. No cases of infection (with an onset of ten days or more after vaccination) occurred among those who received the vaccine immediately after randomization, whereas 23 such cases occurred among a control group who received the vaccine 21 days after randomization (*The Lancet*, **389**, 505–518, 2017).

"I'm not a biostatistician, but the data in that paper look incredibly strong, no matter how you look at it," says Tom Geisbert, professor in the department of microbiology and immunology at The University of Texas Medical Branch. Geisbert has long experience of working with anti-Ebola agents in biocontainment safety level 4 (BSL-4) facilities. "The VSV [vector] outperforms everything else consistently, probably because it's replication competent," he says. The vaccine's immunization schedule—a single shot—is an attribute that is particularly useful during an acute outbreak. Its rapid induction of protective immunity is probably due to an activation of the innate immune system, although the vaccine's duration is not yet



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The first Ebola virus epidemic left a legacy of countermeasures, which were readily deployed during the recent outbreak.

Gates unveils biotech-within-a-charity

Last month at BIO 2018, the biotech industry's annual convention, in Boston, the Bill & Melinda Gates Foundation took the wraps off its nonprofit biotech spinoff. First announced just over a year ago, the Gates Medical Research Institute (MRI) has set up shop in Cambridge, Massachusetts, with about 20 employees and plans to grow to as many as 120 in three years. Armed with $100 million a year in funding, the biotech-within-a-charity will focus on developing new treatments and vaccines for tuberculosis, malaria, and enteric and diarrheal diseases, which together kill 3 million people a year in the developing world, but are low priorities at pharma companies because of limited commercial prospects. Gates MRI hopes to apply new understanding of the human immune system learned from cancer research to prevent infectious disease, and plans to take drugs, vaccines and other assets from preclinical stages all the way through clinical trials to regulatory approval. The project is headed by Penny Heaton, former director of the Gates Foundation, and prior to that, global head of clinical research clusters for Novartis Vaccines and Diagnostics. She says of Gates MRI's first project, testing whether a booster shot of Bacillus Calmette–Guérin (BCG) vaccine in adolescents can increase their resistance to tuberculosis, "These studies need to be done, but this is a very inexpensive vaccine, and there's not a big market—there would be no incentive for a private partner to take on a study of this nature."

"This [right-to-try] law intends to diminish the FDA's power over people's lives, not increase it." Senator Ron Johnson (R-WI) admits his true intentions in crafting the right-to-try law in a letter to Commissioner Scott Gottlieb. (*STAT*, 31 May 2018)

"What she went through and the hope she gave people was just fantastic and I think she deserves everything." Louise Brown, the first test tube baby, reflects on her mother's pioneering role, on the event of her 40th birthday. (*YouTube,* 10 June 2018)

"Ten new tests a day—no one can be expected to master that." Diane Hauser, a senior associate at the Institute for Family Health, comments on a new study in the journal *Health Affairs* that reports on the explosion of genetic tests over the past four years, whereby about ten tests entered the market each day. (*The Washington Post*, 7 May 2018)