

global coordination to address logistical challenges of product access, distribution, and administration that often arise in low-resource settings.

During the 2018–20 Ebola virus disease outbreak in the Democratic Republic of Congo, the second largest known outbreak, the Pamoja Tulinde Maisha (Swahili for Together, Save Lives; PALM) collaboration, a multisector partnership with joint Democratic Republic of Congo and USA sponsorship, launched a randomised clinical trial to assess the efficacy of four different medical countermeasures against Ebola virus disease on Nov 20, 2018.³ On Aug 9, 2019, the Data and Safety Monitoring Board for the PALM trial recommended study closure because of clear evidence of efficacy of mAb-114 and REGN-EB3 against Ebola virus disease. That day, the study team immediately informed operating Ebola treatment centres, to ensure that all patients would receive benefit from the drugs. Since that time, the PALM team has dedicated efforts to providing these monoclonal antibodies for treatment during Ebola virus outbreaks within and outside of the Democratic Republic of Congo.

Contrary to what was stated in the article,¹ at the time of subsequent Ebola virus outbreaks in the Democratic Republic of Congo, products were in country and available for use. The challenges were overcoming logistical barriers, including getting treatments and supplies to difficult remote sites, and identifying adequate treatment centres and staff able to manage and administer products.⁴ The PALM team worked with the Democratic Republic of Congo Ministry of Health officials and international partners to address these challenges and get products to those who might benefit. During the Nzérékoré outbreak in Guinea in 2021, the PALM team worked with local Guinean officials to provide training support to strengthen local teams in the

administration of products. A further point is worth making. Historically, high mortality rates observed during Ebola virus outbreaks would be reduced by treatment dissemination if outbreaks were identified early. Late identification results in a high number of cases not receiving treatment. Hence, expanded training of local clinicians to recognise Ebola virus disease clusters is crucial, along with improved access to diagnostic testing.

Our experiences have shown that the main barrier to providing proven treatments for Ebola virus disease is neither the scarcity of availability of product, absence of commitment by the study team, nor local regulators, but rather improving the ability to identify Ebola virus disease cases early, overcoming challenges of moving products and supplies, and training the professionals in the remote locations where outbreaks occur.

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Authors' reply

Effective outbreak preparedness and response requires products available in sufficient quantities and delivered where and when needed. Clearly, providing prompt diagnosis and health care is challenging in the Democratic Republic of the Congo and other Ebola virus disease-epidemic countries, as stated by Olivier Mbaya and colleagues; less than a third of the 181 people who had Ebola virus disease during 2020–22 had received mAb-114 or REGN-EB3.¹ But, despite the commitment of leading research organisations such as the Congolese Institut National de Recherche Biomédicale and the US National Institutes of Health, relying on remaining drugs from trial batches under expanded access use, without formal regulatory authorisation and with limited supply channels falls short of being a satisfactory, sustainable solution, for the Democratic Republic of the Congo and more broadly, patients with Ebola virus disease in all at-risk countries.

Should a major outbreak happen tomorrow in Africa, there will be no readily available stocks of either products with regulatory approval by local or regional health authorities to roll out swiftly. There is also no clear pathway for local authorities or emergency first responders such as WHO and Médecins Sans Frontières to purchase and deliver these treatments where needed. As documented in our Personal View,² safety and efficacy evidence obtained collectively through the PALM clinical trial³ was handed over to the pharmaceutical companies Ridgeback and Regeneron, which then registered these treatments with the US Food and Drug Administration

in 2020, and also enjoyed a lucrative priority review voucher. However, these companies did not do their part to enable affordable access, nor did any of the organisations in charge of the PALM trial set in place the right conditions for these research and licencing collaborations to guarantee timely availability and access.

Ridgeback is understood to have no capacity to produce mAb-114 before 2024 at the earliest, and Regeneron's REGN-EB3 is stockpiled by the US government.⁴

This situation epitomises the limitations of relying on goodwill and charity approaches for epidemic preparedness, and the need for an enforceable end-to-end approach that includes access from start.² When issuing its Ebola virus disease treatment guidelines in August, 2022, WHO expressed concerns that access to these therapeutics is challenging and pricing and future supply remain unknown, and even warned that this strong recommendation could exacerbate health inequity.⁵ It is time for the international community and for national authorities of the affected countries to step up efforts to complete the unfinished agenda, and ensure equitable access to Ebola treatments where and when needed, reflecting the collective effort many organisations have put into their development, including setting up and conducting a very challenging clinical trial. Building on lessons learnt from COVID-19, these efforts should include exploring technology transfer and local production of these life-saving health technologies, for greater autonomy and resilience in the region.

We declare no competing interests.

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