Breakthrough treatments for Ebola virus disease, but no access—what went wrong, and how can we do better?

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Three years since proving effective for Ebola virus disease in a clinical trial, two breakthrough treatments are registered and stockpiled in the USA but still not registered and generally available in the countries most affected by this deadly infection of epidemic potential. Analysing the reasons for this, we see a fragmentation of the research and development value chain, with different stakeholders taking on different steps of the research and development process, without the public health-focused leadership needed to ensure the end goal of equitable access in countries where Ebola virus disease is prevalent. Current financial incentives for companies to overcome market failures and engage in epidemic-prone diseases are geared towards registration and stockpiling in the USA, without responsibility to provide access where and when needed. Ebola virus disease is the case in point, but not unique—a situation seen again for mpox and likely to occur again for other epidemics primarily affecting disempowered communities. Stronger leadership in African countries will help drive drug development efforts for diseases that primarily affect their communities, and ensure all partners align with and commit to an end-to-end approach to pharmaceutical development and manufacturing that puts equitable access when and where needed at its core.

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See **Online** for appendix

Introduction

Three years have passed since a pivotal clinical trial in the Democratic Republic of the Congo showed that two Ebola virus disease experimental treatments, mAb114 and REGN-EB3, substantially reduce mortality of this deadly infection.[1] In 2020, both treatments were registered with the US Food and Drug Administration (FDA) and hailed as a global health and international collaboration success.[2] In August, 2022, WHO published treatment guidelines for treating laboratory-confirmed Ebola virus disease caused by Ebola virus (species *Zaire ebolavirus*), also calling for increased access to these drugs.[3] In fact, neither treatment is registered in any of the countries where Ebola virus disease is most prevalent or by the new African Medicine Agency (AMA), and neither is readily available for health-care providers when and where Ebola virus disease outbreaks occur.

What went wrong? And what does this teach us about rethinking the way we organise research and development efforts for epidemic diseases to ensure availability and access when and where needed most?

Ebola virus disease therapies: a formidable effort leaving an unfinished agenda

When in 2013 a long-feared major Ebola virus disease outbreak began that would devastate Guinea, Liberia, and Sierra Leone, killing more than 11 000 people, no treatment, diagnostic, or vaccine was available.[4] A surge in research activities ensued, thanks to an impressive mobilisation of public health institutions, governments, researchers, philanthropic organisations, pharmaceutical companies, and humanitarian actors that came together on an ad-hoc basis to try and move research and development forward.[5] As none of the tested drug candidates proved effective, treatment efforts extended into the 2018–20 outbreaks in the Democratic Republic of the Congo (figure).

In November, 2018, a broad consortium of partners under the aegis of WHO started the PALM[6] trial (NCT03719586) led by the US National Institutes of Health (NIH) and the Congolese Institut National de Recherche Biomédicale (INRB). The trial compared four treatment candidates that had meanwhile been brought forward (appendix p 1). The NIH financed the production of clinical trial batches of most drug candidates (ZMapp, mAb114, and REGN-EB3; Gilead Sciences [Foster City, CA] provided remdesivir), and also provided most trial funding. Despite the challenging operational realities of doing a randomised controlled phase 3 trial during an Ebola outbreak in the Democratic Republic of the Congo, the trial was successfully completed. By August, 2019, two experimental treatments, mAb114 and REGN-EB3, proved superior in reducing mortality caused by Ebola virus infection (from around half with the comparator drug ZMapp to around a third),[7] and the trial results were published rapidly.[6]

Then, relying on a business-as-usual approach to bring drugs to market once clinical safety and efficacy were shown, the remaining steps in the development of REGN-EB3 and mAb114 towards registration and availability were respectively left in the hands of Regeneron (Westchester County, NY) and Ridgeback Biotherapeutics (Miami, FL)—to which the Vaccine Research Centre (VRC, another department of NIH) that developed the mAb114 drug candidate had meanwhile licensed the rights.[8] NIH provided both companies with the relevant PALM trial data. As is customary for pharmaceuticals, a company that holds intellectual property rights over the technology and obtains marketing authorisation, even if based on trial data that were generated collectively, de-facto owns the product.

Questions raised by some partners throughout the trial preparation and conduct about data ownership and commitments by the companies to ensure availability, affordability, and access were largely left hanging on the presumption that all partners shared the same goals, and that it was either too early or too complicated to sort out

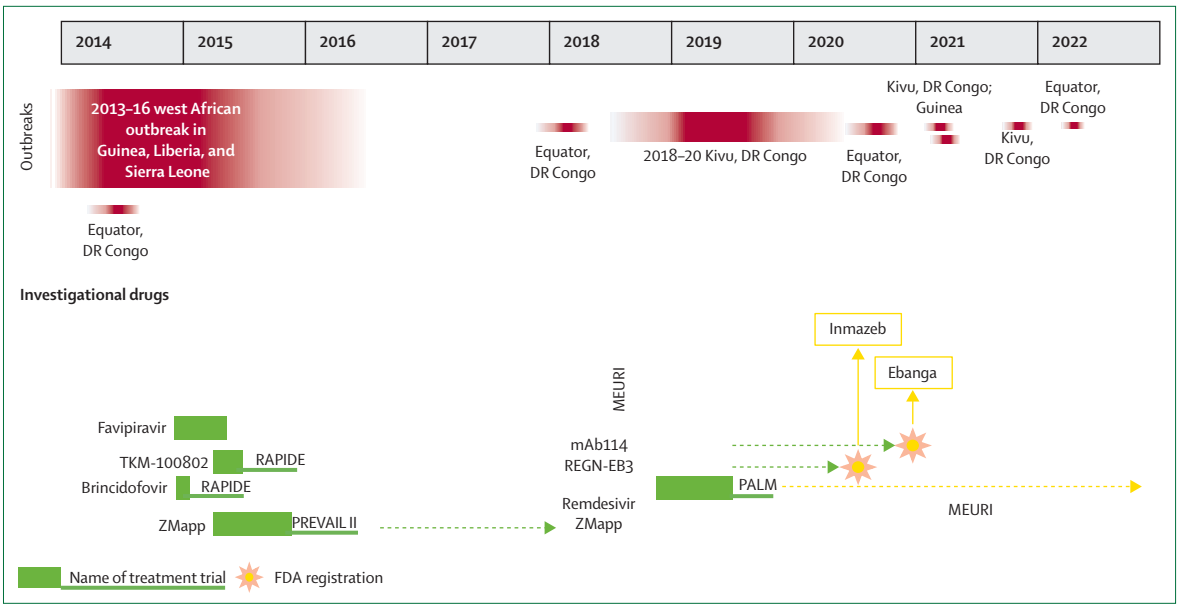

Figure: **Chronology of the research and development efforts with investigational Ebola drugs from January, 2014 to October, 2022**
MEURI is a framework established by WHO in 2014 for the ethical permissibility of use of unproven interventions outside clinical trials during public health emergencies. MEURI=Monitored Emergency Use of Unregistered and Investigational Interventions.

these issues in advance (Torreele E, unpublished). The terms of contractual agreements WHO, NIH, or INRB might have signed with Ridgeback Biotherapeutics and Regeneron about the use of the PALM[6] trial data are not shared publicly or with other trial partners. This also raises the broader question of the nature and governance of research partnerships between international and African research institutions in international collaborations, and with private companies, and the need for increased transparency and African ownership of research done in Africa, including data.[9]

Registration does not mean access

Using the data from the PALM[6] trial, Regeneron, a publicly traded US biotechnology company that had also received at least US$40 million from the US Government to develop REGN-EB3 as part of Project Bioshield,[10] obtained marketing authorisation from the FDA in October, 2020 (under the brand name Inmazeb; figure).[11] The US Government's Biomedical Advanced Research and Development Authority (BARDA) subsequently established a strategic stockpile of REGN-EB3 (quantity unknown) as part of its outbreak preparedness, for which it will pay Regeneron more than $300 million between 2021 and 2026.[12] Ridgeback Biotherapeutics, a privately owned US biotechnology company founded in 2016, obtained FDA marketing authorisation for mAb114 in December, 2020, (under the brand name Ebanga; figure). mAb114's registration dossier was based on a full package of preclinical and clinical data compiled over two decades by NIH's VRC, in addition to data from the pivotal PALM[6] trial in the Democratic Republic of the Congo.[13]

Upon registration with the US FDA, both companies were granted a Priority Review Voucher (PRV; appendix p 1), a highly coveted reward for registering drugs with the FDA for some categories of diseases representing a market failure. The market value of this tradable voucher is currently estimated at $80–100 million. Unfortunately, companies obtaining a PRV are under no obligation to ensure the drug is made available where needed.

To date, neither of the new Ebola treatments is registered outside the USA, not even in the Democratic Republic of the Congo where the pivotal PALM[6] trial was conducted. They do not seem to be produced or available for purchase, and no formal price has been announced. For REGN-EB3, informal rumours allege it might be in the range of $10 000 per treatment, which is out of reach for countries in the region or non-governmental organisations operating there. For mAb114, despite statements on Ridgeback Biotherapeutics' website that the drug is available free of charge for patients in countries affected by Ebola,[14] this is not the reality on the ground. Under its mandate to "promote the advanced development of medical countermeasures to protect Americans and respond to 21st century health security threats",[15] BARDA seems to be the only institution that holds stocks of these treatments.

When an Ebola virus disease outbreak caused by the Ebola virus (species *Z ebolavirus*) occurs, a small number of doses seem to get released. Mortality in 181 documented cases in five new outbreaks in the Democratic Republic of the Congo and Guinea since the PALM[6] trial concluded has been 46% (95% CI 39–54%)[16]—much higher than the expected 33–35% with these new therapies. This means

that the proportion of patients receiving REGN-EB3 and mAb114 is too small to see a notable health benefit, or they are not treated early enough, or both.

The steps that might have been taken by pharmaceutical companies or countries with a high prevalence of Ebola virus disease towards registration and procurement are unclear, but no stockpile of registered drugs seems readily available for use during outbreaks. Moreover, the absence of rapid point-of-care diagnostics that are sensitive enough and widely available generates delays in early diagnosis and treatment, with increased risk of fatal outcomes.

After the impressive collaborative effort led by public health organisations and financed in large part by the US Government, we collectively failed to make these new lifesaving treatments widely and readily available where and when needed, leaving local authorities to make do with a few sparse doses. This is not only an inefficient use of public resources (both financial and human), but also unethical towards the patients and communities that participated in the research. From the publicly available PALM trial protocol,[6] there is no indication about post-trial access or benefit-sharing commitments, and whether additional elements were presented to the NIH or the Democratic Republic of the Congo ethics committees that approved the protocol is unknown.

Furthermore, the scarcity of readily available treatments also precluded follow-on research to address outstanding questions—a missed opportunity to broaden the potential usefulness of these drug treatments. Critical research questions include: effectiveness for post-exposure prophylaxis or as presumptive treatment (without PCR-confirmed diagnosis); minimum effective dose; efficacy and safety in particular populations such as pregnant women; and possible use in combination with other antiviral drugs. Since the 2022 WHO recommendation is based on available evidence only, it ends up limiting these treatments for use under the restrictive conditions of the original clinical trial, for example, to PCR-confirmed cases only. Finally, although these treatments undoubtedly save lives, there clearly is room for improvement to further reduce mortality caused by Ebola virus disease, including other approaches, such as direct antivirals, which ideally would also be effective against the *Sudan Ebolavirus* species.

While Regeneron and Ridgeback Biotherapeutics benefited scientifically, economically, and reputationally from the collective research effort, including the financial reward provided by the PRV, none of it was channelled to ensure availability, access, and additional research, because of an absence of binding commitments at the start of the collaboration, especially around the use by the companies of collectively generated clinical trial data for registration. Meanwhile, the US Government has established a stockpile of at least one of the Ebola virus disease treatments for its national health security,[12] but has not engaged in ensuring registration, availability, and access in most prevalent countries to address their own health needs.

Fixing market failures requires a public health perspective and accountability

To foster medical innovations in areas of great medical need, but in areas that are considered market failures, such as Ebola virus disease, various market push-and-pull mechanisms have been designed to incentivise companies to bring drug candidates to market, often via research collaborations between the public and private partners and involving international researchers and local teams.[17,18] These collaborations include publicly funded research and clinical trials, the PRV, advance purchase commitments, and the prospect of health security stockpiles. However, such incentives tend to ignore the need for active engagement of national authorities to ensure the final outcome reaches the communities in need.

By focusing on fixing the market failure from a commercial perspective or focusing on national health security (of high-income countries), such incentives might, paradoxically, generate more global health challenges and inequalities,[19] as also illustrated by the case of Ebola virus disease treatments. Unless we adopt an end-to-end approach that fosters equity between collaborating partners, puts local communities at the core, and ensures the end goal of equitable access where needed to the novel products is met, we can bring products to market but we will not address the very public health challenge these products are destined for, possibly even worsening health inequity with nobody to hold accountable.

Mpox (formerly known as monkeypox) is another case in point.[20] Market incentives including a PRV[21] and US Government BARDA funding and stockpiling[22] have provided a good business case for Bavarian Nordic's development of a vaccine for the prevention of smallpox and mpox, MVA-BN, which was registered with the FDA in 2019.[23] Despite hundreds of reported cases annually, this vaccine was never available in countries in which mpox is historically endemic, such as the Democratic Republic of the Congo, Central African Republic, and Nigeria. Similarly, SIGA Technologies registered its smallpox drug tecovirimat with the US FDA in 2018, after a development process based on efficacy studies in animal models of mpox that was largely supported by various US Government departments.[24] However, people with mpox in endemic countries barely had an opportunity to benefit from this medical advance aside from a small compassionate-use programme piloted by the Ministry of Health of the Central African Republic, Institut Pasteur Bangui, Central African Republic, and Oxford University, Oxford, that started offering treatment to patients in January, 2022.[25] In sharp contrast, the 2022 mpox outbreak in Europe and other traditionally non-endemic countries is being met with rapid vaccine

and treatment roll-out, and governments from high-income countries once again scrambling to get hold of the supplies in priority, making pledges for pandemic solidarity sound disingenuous.[26] By leaving the ownership and control of the mpox vaccine and treatment to private companies, commercial interests get prioritised over public health.

The Ebola virus disease case also shows good intentions are not enough. Without a clearly articulated public health vision and political will from national governments, starting with the African authorities, and the necessary legal and financial influence that goes with it to structure and organise the research and development value chain (including equitable access) through binding agreements that spell out roles and responsibilities from start to end, we will keep coming up short of getting the job done.[27] As shown again by the inequity in access to COVID-19 vaccines and treatments, including in countries that participated in clinical trials, we continue to neglect equitable sharing of the benefits of medical research, especially with people in low-income countries.[28] The absence of transparency in governance arrangements and contracts enacted between the public and private sectors, seemingly abiding to business-as-usual confidentiality terms precludes accountability, for instance through community monitoring and civil society advocacy. Similarly, African authorities and ethics boards seem neither empowered, able, or willing to follow up on access commitments embedded in the clinical trials they approve.

PALM[6] trial leaders, in particular NIH and INRB, but also WHO (responsible for coordinating the trial governance), still have time to act and compel the pharmaceutical companies to invest part of the PRV proceeds towards making the products available in countries in which Ebola virus disease is most prevalent. At the same time, US Government agencies need to consider doing more to adopt and implement adequate post-trial access and benefit sharing commitments that ensure availability of these treatments for communities at risk. The African institutions (such as African Union, AMA, and Africa Centres for Disease Control and Prevention) that are committed to increased medical research and development in Africa to address the continent's health needs, and ethics committees from countries in which the trial took place, should advocate and ensure the right of their population to access the drugs that they helped to develop with their contribution.

Lessons learnt towards a different paradigm for epidemic preparedness and response

We must take a much bolder approach towards the governance of international research collaborations and public–private partnerships for epidemic preparedness and response.[29] Strong leadership from disease-endemic countries will be crucial, setting clear public health equity and access objectives for their communities as the overarching goal,[30] and civil society to hold them accountable.

Public health institutions and health authorities need to actively shape the way research and development projects are financed and governed such that they respond to health needs and deliver affordable health products to people who can benefit most.[31] A truly end-to-end approach to medical research and development is required, whereby product availability and access for the communities most affected by the disease—not marketing authorisation in high-income countries or national security stockpiles—is the end goal and ultimate measure of success for pharmaceutical product development for diseases such as Ebola virus disease.[32] This approach needs to be governed by transparent and binding agreements that commit the different stakeholders towards achieving the end goal of equitable access for people most in need.

The power of local public health leaders, researchers, and clinical trial capabilities can and must be used to mobilise adequate financing, combining international and local funding sources including the private sector, and shape the research and development response for access to people most afflicted first, in the interest of global public health. These aims are particularly important for diseases primarily affecting neglected populations in low-resource countries, which tend to be the focus or recipients of research, but not the beneficiaries. International research collaborations must be redesigned with more emphasis on local involvement in knowledge creation, financing, and control over research results,[33] and they must adopt an end-to-end approach to research and development focused on solving local health problems, with tools specifically designed for the local health context.

To create an effective preparedness-and-response ecosystem for epidemics, this approach should extend to all pharmaceutical developments intended for these diseases. For instance, we are now facing the welcome challenge of multiple clinical development candidates for Lassa fever. People engaging in Lassa fever drug development efforts should consider the end-to-end and public health-driven portfolio approach proposed by the West Africa Lassa Fever Consortium, whereby local clinical trial capacity and west African leadership become an asset to gain binding commitments by developers and financing bodies to attract research and development efforts in ways that ensure availability and access for the communities.[34]

Conclusion

Having effective diagnostics, treatments, and vaccines that can reduce mortality and help control outbreaks of life-threatening diseases such as Ebola virus disease is crucial for epidemic preparedness and response. Despite the many challenges of pharmaceutical research and development for such diseases, including mobilising the

needed finance to overcome market failures, the Ebola virus disease example shows that mobilising the different stakeholders involved in the research and development value chain to take new health technologies to marketing authorisation is possible. As outlined in this Personal View, two new Ebola treatments were successfully trialled during the 2018–20 outbreak in the Democratic Republic of the Congo, and subsequently received marketing approval from the FDA.

However, to be useful for the affected communities, effectively deal with outbreaks when and where they occur, and prevent spillover into a bigger epidemic or even pandemic, making these treatments readily available and accessible where needed is crucial, ideally accompanied with point-of-care diagnostic tests to quickly identify patients that can benefit from treatment. Attaining this end goal should be embraced by all research and development partners involved, from drug developers to clinical researchers, epidemic response teams, health-care providers, drug manufacturers, ethics committees, health and regulatory authorities, and funders—all carrying a collective responsibility for the end result. Designing an end-to-end value chain in which all actors work together towards the shared goal of equitable access to medical innovations for the communities and governance mechanisms that allow us to hold each other to account will be needed and will require developing new treatments as common goods for health, not commercial commodities.[35]

Learning from our mistakes, policy makers and public health institutions need to show a stronger political will and take the lead by designing fit-for-purpose policies and financial instruments to mobilise medical innovations focused on health needs to ensure equitable access, where and when needed. Patients, health-care workers, and civil society groups must push for more equitable research and development and hold decision makers accountable. International research institutions and funding bodies should design their funding mechanisms with clear conditionalities to ensure the development of appropriate health technologies, suitable to the local context, and enable availability where needed and equitable access. Through their research collaboration agreements, ethics committees, and other oversight mechanisms, researchers and institutions in Africa must ensure that the communities that have participated in the research and development through clinical trials are the first to benefit from the research products when epidemic outbreaks occur, affordably and equitably. Breakthrough treatments remaining out of reach for people whose lives could be saved is unacceptable.

Contributors

ET conceptualised the manuscript, led the analysis, and wrote and edited the original draft. YB took part in discussions, review, and editing. PO took part in discussions, the original draft, review, and editing. IA, FGBA, SHI, GH, and CO reviewed and commented on the paper.

Declaration of interests

We declare no competing interests.

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