Research Article

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The Politics of the Second Vaccine: Debates Surrounding Ebola Vaccine Trials in Eastern Democratic Republic of the Congo

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Abstract

Two experimental Ebola vaccines were deployed during the tenth Ebola epidemic (2018–20) in the Democratic Republic of the Congo (DRC). The first, the Ervebo vaccine manufactured by Merck, was used as part of a ring vaccination in the epicentre of the epidemic in North Kivu. In 2019, the prime- (Ad26.ZEBOV) and boost- (MVA-BN-Filo) vaccine manufactured by Johnson & Johnson (J&J) became the second vaccine against Ebola, deployed by the DRC-EB-001 vaccine trial in Goma, North Kivu. There was international debate as to the value and ethics of testing a second vaccine in an epidemic context. This article examines how this debate unfolded among actual and potential DRC-EB-001 trial participants in Goma. Drawing on ethnographic observation, interviews and focus groups, it explores how the trial was perceived and contested on the ground and situated in broader debates about the ethics of clinical trials, especially during the COVID-19 pandemic. We illustrate how debates around the ethics of clinical research are not simply centred on bioethical principles but are inseparable from local political dynamics and broader contests about governance, inequality and exclusion.

Keywords: Ebola; DRC; vaccines; clinical trials; global health emergency

Introduction

The labelling of a crisis makes new types of action and intervention possible. In her analysis of the West African Ebola epidemic (2014–16), Kelly (2018) describes the 'epistemic shift' which followed the declaration of a Public Health Emergency of International Concern (PHEIC), making it possible to fast-track clinical research in new ways. During the epidemic, the World Health Organization (WHO) concluded that, in a context of exceptional emergency, it was acceptable 'on both ethical and evidential grounds' to test vaccines which had promising results in laboratory and animal models (Kelly, 2018: 148). Debate followed among global health institutions about the best design for such experimental interventions. Some held that only randomised, placebo-controlled trials could produce robust evidence of efficacy; others argued that withholding potentially effective treatment from patients was ethically unacceptable. In the end, a trial of the new Merck vaccine in Guinea produced compelling results using a new experimental ring-vaccination strategy. By recruiting those at highest risk of infection, it balanced both 'robust science and humanitarian demands' (Kelly, 2018: 151). Although effective, the Merck vaccine did have potential weaknesses compared to other vaccines in development: the stringent cold-chain requirements and the fact it was only effective against the Zaire strain

Journal of Humanitarian Affairs Volume 3, No. 3 (2021), 4–13 © The authors
http://dx.doi.org/10.7227/JHA.069

(Kelly, 2018: 152). However, as Kelly (2018: 152) predicted, the consequence of the success of the ring-vaccine trial was that launching new trials in the future 'would be considered unethical' given that a vaccine had already been proven effective, and 'to generate conclusive results would require an outbreak of a size that is unlikely to occur again' (Kelly, 2018: 152).

In 2018, the Merck vaccine was deployed in North Kivu, a province in eastern DRC, which was in the midst of the country's tenth Ebola outbreak, the second largest globally recorded. It was given to healthcare workers and contacts of individuals diagnosed with Ebola in the north of the province. But when cases continued to rise, the WHO urged that other vaccines be introduced in order to increase the number of people vaccinated and stop transmission of the virus (SAGE, 2019). In 2019, a second trial (the DRC-EB-001 trial) was set up to test a second vaccine, manufactured by Johnson & Johnson (J&J), to create a protective 'curtain' for people near but outside the outbreak zone (Arie, 2019). It was to be made available in two health areas of the provincial capital, Goma. But the start of the trial was delayed amid debate about introducing a second experimental vaccine in an epidemic context (Kupferschmidt, 2019; Mahamba, 2019; Monrad, 2020). While proponents of a second vaccine highlighted the ethical need to protect as many people as possible (SAGE, 2019; MSF, 2019a, 2019b; Arie, 2019), the Congolese Minister of Health, Oly Ilunga Kalenga, opposed a second vaccine, arguing that it would confuse people in the outbreak zone: 'We have an effective weapon … Let's focus on that' (Branswell, 2019). This debate has since been discussed in the medical ethics literature, where it has been argued that a second trial is problematic because an existing effective treatment should not be withheld, but at the same time, a second vaccine might have certain advantages compared to an existing product, especially in the context of logistical or supply concerns (Monrad, 2020).

But how was the DRC-EB-001 trial perceived among those who did, and did not, choose to participate in Goma? The aim of this article is not to judge the ethical procedures of the trial, but to examine how debates about the second vaccine unfolded among actual and potential trial participants. Research participants are rarely involved in ethical debates in which they are so centrally implicated: but to understand the complexity of medical research, it is crucial to 'recognise its study subjects as interlocutors in ongoing global ethics debates, not as mere objects of ethical responsibility' (Geissler and Pool, 2006: 975). We adopt an anthropological approach which examines the lived experience of 'postcolonial techno-science' (Fairhead *et al.*, 2006). While bioethical frameworks centre on standardised protocols, ethnographic studies have examined how clinical research is interpreted by its participants, and the political and historical factors influencing these understandings (Enria and Lees, 2018). This literature has highlighted the importance of placing bioethics in their political and economic context, exposing the limits to bioethical discourses and the complexities of voluntariness amid profound inequalities (Fairhead *et al.*, 2006; Molyneux and Bull, 2013). Much of this literature situates itself outside bioethical framings to focus on medical research's 'imperial origins as well as asymmetrical topography of power and resources' (Geissler, 2011: 1). It calls for reflections which move beyond bioethics to focus on the politics of poverty and inequality (Molyneux and Geissler, 2008). In this article, we argue that debates around the ethics of clinical research should not simply concern bioethical principles but are inseparable both from local political dynamics and long-standing contests about governance, situated against a background of imperial medical exploitation and contemporary geopolitical inequalities.

Methods

The article is based on ethnographic research carried out between October 2020 and March 2021 in Goma, when the DRC-EB-001 vaccine trial was restarted after a five-month suspension caused by the COVID-19 pandemic. We established a social science team which worked in collaboration with the trial to explore local experiences of the trial. The aim was to produce academic research that could help inform the intervention, while also providing critique and maintaining academic independence. This required a delicate balance: the social science study remained distinct from the community engagement activities of the trial, and we established systems to maintain the confidentiality of our data. Methods included ethnographic observation at vaccine clinics, thirty-one in-depth interviews with trial participants, fifteen interviews at the exits of vaccine clinics, as well as eight in-depth interviews with politicians, traditional medical practitioners, civil society activists and health authorities. The article also draws from five focus group discussions with trial participants and three with political and health authorities and people who did not participate in the trial. Interviews and discussions were carried out in Swahili or French. All participants are anonymised, and English translations are the authors' own. Ethics was provided by the London School of Hygiene and Tropical Medicine (LSHTM) ethics committee, the Médecins Sans Frontières (MSF) Ethics Review Board, the *Avis du Comité National d'Ethique de la Santé* and the *Comité d'Ethique, Université de Kinshasa.* The research was supported by the Coalition for Epidemic Preparedness Innovations (CEPI) and Ebola Vaccine Deployment, Acceptance and Compliance (EBODAC).

To begin, the article describes the political context during the Ebola epidemic in DRC and the two vaccines

in North Kivu. This lays the foundation for analysis of how debates surrounding vaccine trials were shaped by the political and historical context of the region as well as the recent epidemic response. We then examine three local debates surrounding the DRC-EB-001 trial: the fact it was a second vaccine; its selected locations; and the experimental nature of the vaccine itself. In the third section, the article examines how local debates surrounding the DRC-EB-001 trial were situated in concerns about inequality and exclusion in a tense political environment, as well as questions of power and priorities in local as well as international health governance. We conclude that bioethics cannot be disentangled from political histories and contemporary contests and consider the implications for how to think about clinical trial ethics.

Setting the Scene: The Politics of Ebola in Eastern DRC

Between August 2018 and June 2020, the world's second largest recorded Ebola epidemic took place in eastern DRC and resulted in 2,287 deaths. The epidemic began in the Grand Nord territories of North Kivu province. There was local opposition to the emergency response, including attacks on treatment centres and healthcare workers. These dynamics must be situated in historical and political context. As recent research in the Grand Nord has illustrated, the epidemic exposed and exacerbated a profound sense of distrust in the central government and foreign intervention, which was linked to the region's history of political marginalisation as well as contemporary political upheaval and violence (GEC, 2020; Nyenyezi Bisoka *et al.*, 2021; Crawford *et al.*, 2021). The Grand Nord has a long history of violent conflict and rebellion. Most recently, the Allied Democratic Forces rebel group has increased attacks against the population, leading to local discontent at the inability of the government forces or the UN's largest and most expensive peacekeeping mission to provide security (Nyenyezi Bisoka *et al.*, 2021; GEC, 2020). The introduction of a well-funded Ebola response (approximately $1.2 billion) into an area where basic services are underfunded gave the impression that the response aimed to benefit responders rather than local communities (Crawford *et al.*, 2021: 41). In addition, the response created a parallel system, bringing staff from Kinshasa and abroad who were paid more than locals (GEC, 2020). Inflated salaries and instances of corruption gave the impression that responders had incentives to prolong the outbreak, or even invent Ebola altogether as a business to enrich Kinshasa elites and the international non-governmental organisations competing for donor money (GEC, 2020). The epidemic also unfolded in a turbulent political environment: President Joseph Kabila postponed elections from 2016 until December 2018 in an attempt to hold onto power. In the east, there was significant support for the opposition candidate, Martin Fayulu. When Ebola was used as a pretext to postpone elections in affected regions the virus came to be seen as a political invention to suppress the opposition stronghold (Nyenyezi Bisoka *et al.*, 2021).

Within two weeks of the declaration of the epidemic, the Congolese Ministry of Health and the WHO began administering the experimental vaccine manufactured by Merck (rVSV-ZEBOV), which had not yet been licensed but had been shown to be protective in trials in West Africa. It was used under a 'compassionate use' protocol which allows for unlicensed treatments to be administered when there is no better alternative (Kelly, 2018). The trial adopted a ring-vaccination strategy, vaccinating healthcare workers and close contacts of someone diagnosed with Ebola. The reaction to the Merck vaccine in North Kivu was complex. Ethnographic research in the region illustrates how the widely reported flu-like side-effects produced fear, while rumours spread that the vaccine was a government scheme to exterminate the population, or a business opportunity for pharmaceutical companies (Nyenyezi Bisoka *et al.*, 2021; MSF, 2019a, 2019b). At the same time, people also described wanting to be vaccinated and finding themselves ineligible.[1] A senior MSF worker concluded that 'we need to stop blaming communities for their own deaths and make sure more people have access to treatments and vaccines' (MSF, 2019b).

By May 2019, the WHO vaccine committee recommended that another vaccine be introduced in order to vaccinate more people and break transmission of the virus (SAGE, 2019). Despite the ring vaccination, the number of cases continued to rise, and the WHO estimated that around 10 per cent of contacts were not traced (Arie, 2019). With an estimated 500,000 doses available at the time, the WHO expressed concern about 'potential shortages' of Merck if the epidemic continued and decided to adjust the recommended dosing by half in order to preserve existing supplies (SAGE, 2019; Branswell, 2019). Meanwhile, MSF criticised the opaque eligibility requirements and rationing of doses on the ground: 'It's like giving firefighters a bucket of water to put out a fire, but only allowing them to use one cup of water a day' (MSF, 2019b). MSF highlighted the difficulties of tracing contacts as well as the likely shortages of the Merck vaccine in the face of increasing cases (MSF, 2019a). As the slow pace of vaccination continued, MSF called for an independent evaluation of vaccine strategy and concluded that the ring strategy was not enough to stop Ebola transmission (MSF, 2019a, 2019b). The International President of MSF explained

that 'a largescale approach is needed for prevention, this means better access to vaccination for the population to reduce transmission' (Arie, 2019).

In July, the WHO declared the epidemic a PHEIC, and global health institutions urged for the adoption of a second vaccine to ensure more people could be vaccinated (Arie, 2019). Three candidates emerged: Ad5-EBOV (Chinese), the rVSV/Ad5 vectored vaccine (Russian) and the prime- (Ad26.ZEBOV) and boost- (MVA-BN-Filo) vaccine manufactured by J&J. The J&J vaccine was available in large quantities and the pharmaceutical company committed to donating doses to the outbreak area (Branswell, 2019). A coalition of the DRC's *Institut National de Recherche Biomedicale* (INRB), the LSHTM, MSF, CEPI and the Wellcome Trust backed the deployment of the J&J vaccine to ensure more people could be vaccinated (Rolley, 2019; Arie, 2019). The J&J vaccine had been tested on more than 6,000 volunteers, confirming its ability to generate immune response, but had not been tested in outbreaks to demonstrate its efficacy (Mahamba *et al.*, 2019). The Wellcome Trust concluded that there was a 'pressing need to introduce a second vaccine, by Johnson and Johnson, in the DRC – to protect communities outside of the current outbreak zone who are likely to be affected next', while the director of LSHTM concluded: '[W]e must use all the tools and approaches at our disposal, including the coordinated use of both the Merck and Johnson and Johnson vaccines. WHO has sounded the global alarm. Now, it is up to the world to act' (Arie, 2019).

Discussion about a possible second vaccine took place in a turbulent political context in Kinshasa amid tensions between allies of the former president, Kabila, and the incumbent president, Félix Tshisekedi, as well as the Ministry of Health and INRB. In January 2019, after long-delayed elections, Tshisekedi took over from Kabila. This was the first peaceful transition since independence in 1960 but hinged on an uneasy coalition with pro-Kabila allies. After the transition, the position of ministers appointed by Kabila, such as the Minister of Health Oly Ilunga, was uncertain. In July 2019, Ilunga resigned after his mandate was curtailed by Tshisekedi to only non-Ebola matters (Mahamba, 2019). Tshisekedi subsequently named Jean-Jacques Muyembe – the co-discoverer of Ebola and head of the INRB – the new head of the response. In his resignation letter, Ilunga attacked backers of the J&J trial who, he argued, 'have shown a clear lack of ethics by intentionally hiding important information from the health authorities' (Ilunga, 2019). 'Congolese have the right to have the gold standard, the best vaccine, they don't need to be the subject of experimentation', Ilunga stated, and accused 'an opaque consortium' of vaccine producers and university researchers of 'malicious lobbying' (Mahamba *et al.*, 2019). In September, Ilunga was arrested for alleged misuse of Ebola funds and in November, the DRC-EB-001 trial began with Muyembe as the Principal Investigator.

The DRC-EB-001 vaccine trial began in Goma on 14 November 2019 and ended on 9 February 2021. The trial was funded by CEPI, and comprised a non-randomised, single-arm evaluation of the effectiveness, safety and immunogenicity of a heterologous two-dose preventative Ebola vaccine. Phase 1 was conducted at six vaccination sites in two health areas of Goma, Majengo and Kahembe, which were selected because they were 'crossroads': Majengo is a 'northern port' of the city with links to the Grand Nord territories which were the epicentre of the epidemic, while Kahembe is a trading centre on the Rwandan border. The two doses were to be administered 56 days apart. However, on 9 April 2020, vaccination was suspended for five months to prevent potential COVID-19 transmission. At this point, only 9,560 of the 20,000 participants had received their second dose. During the suspension, the Ebola epidemic ended. As a result, Phase 2 of vaccination intended for the epicentre of the epidemic in the Grand Nord was cancelled. Vaccination restarted in Goma on the 23 September. The trial provided participants with access to free medical care for one month following vaccination and pregnant women with free health care until delivery.

Three Local Debates Surrounding the Trial

Another Trial: Business or Access?

The first point of debate among people in Goma was the fact that J&J was the second unlicensed Ebola vaccine in the province, especially given its prominence in recent political debates. As a musician in Goma asked in a focus group, 'Why did they change the vaccine? What does the second bring in contrast to the first?'[2] After the high-profile resignation of Ilunga, people questioned whose interests a second vaccine served, and how J&J had been chosen. Some concluded that the trial was an extension of 'Ebola business'. For example, the prodemocracy group, *Lutte pour le Changement* (LUCHA), came out in support of Ilunga and published an article entitled 'Ebola: vaccines or business?' It questioned the ethics behind testing a second vaccine that takes more time than an existing vaccine to give immunity, challenged the claim that there was a shortage of Merck and criticised the trial's $80 million budget: 'Is the priority for donors to quickly stem the current epidemic or to take advantage of the long duration of the epidemic to conduct all kinds of experimental tests on a wounded Congolese population?' (LUCHA, 2019). In an interview,

a member of LUCHA concluded that the 'do no harm principal was not respected, especially if the vaccine is not proved efficient … that would mean they were in the process of sacrificing peoples' lives when they could have helped them.'[3] Civil society groups were also uneasy about introducing another trial with potential risks when a vaccine already existed. One activist asked during an interview: Was it not the responsibility of the donor or pharmaceutical company to ensure that there was enough of the first vaccine?[4]

The fact that the trial went ahead after Ilunga's concerns was described as a breach of Congolese sovereignty by pharmaceutical companies. A member of LUCHA explained in an interview that 'the thing that worried [them was] that there was already a vaccine', but then there was the 'strong pressure' to 'accept' a second trial. LUCHA criticised the 'opacity' behind the decision to approve a DRC-EB-001 trial, made by pharmaceutical companies 'in collusion' with the INRB. Muyembe, they argued, had a 'conflict of interest' given his dual role as the new head of the response and DRC-EB-001 Principal Investigator. 'The urgency is to stop the spread of the epidemic and not to experiment with all kinds of drugs and vaccines developed by certain multinationals that you represent', LUCHA tweeted to his account.[5] During a heated focus group discussion, a doctor from Goma concluded: 'We are not guinea pigs on which they can do lots of trials. We don't know why they approved that vaccine [J&J], perhaps some authorities had specific interests in that. Because of their interests, they sacrifice the population.'[6]

For citizens in Majengo and Kahembe who chose *not* to participate, the second vaccine was described as further indication of the international and government focus on Ebola, rather than security for citizens. A young man from Majengo working as a security guard for an NGO summarised local sentiment in responding to a question about health priorities in the region:

> The disease which has made us suffer the most is insecurity. The population is already traumatized by our history which means that the image of foreigners is not good. People think everything that comes here is to make us suffer. For example, look at how the whole republic and the whole world mobilised for the Ebola response, but when you come back to the massacres that are happening here, you see that no one is interested … So, when they bring another vaccine here, the rumours are more believable than the truth.[7]

Meanwhile, other political and health authorities in Goma were conflicted: they highlighted the potential advantages of the J&J vaccine, but the difficulties of a second trial. A senior health official working in vaccination talked about the concerns about potential Merck shortages, the hopes that J&J might cover more variants and the impression that the J&J cold chain was more manageable. However, he criticised the 'closed manner' in which trials are conducted: 'If you work without me, you work against me,' he explained. 'People are hesitant because they weren't sufficiently involved in decisions.'[8] The head of a local civil society agreed that the J&J vaccine had potential advantages, but pointed out that the trial shared some of the same problems as the broader Ebola response: it involved bringing expensive infrastructures and well-paid outsiders to areas where people feel abandoned by the ruling class.[9] The head of a local peace organisation discussed the potential advantages of J&J, but described the 'intoxication' of the population as a strategy by self-interested politicians: 'They ask what do the population want? Okay, they don't want vaccine trials, so I am going to support rumours about the vaccine being sent by whites to exterminate Africans.'[10] As a senior medical authority in Goma concluded: 'We are medical professionals, the medical world has its way of seeing things, we focus on results, while the population see vaccination as business. So, marrying these two visions, the one who sees the business, the one who sees the public interest, that's the challenge.'[11]

Yet, 20,000 people in Goma did volunteer to participate. So, how was a second vaccine perceived by the participants themselves? In fact, the majority of the participants we interviewed said that they did not know that there was another Ebola vaccine. Instead, it was participants with close family links to the Grand Nord who had detailed knowledge of the Merck vaccine. Rather than being confused by two trials, these participants carefully considered the differences between the two: they explained that J&J was two doses rather than one, that its eligibility requirements were different[12] and, according to them, that it *appeared* to have fewer side-effects.[13] Many of these participants had spent time in the Grand Nord during the epidemic and no longer believed that Ebola was just a 'business'. One young woman described how she had been identified as a suspected case in Butembo. However, after testing negative at a treatment centre, she decided that Ebola was real: if it was just a business, the clinic would have declared her as a positive case. She explained: 'I then saw people die in Butembo, I was scared. There was a vaccine called Merck but it was not available to everyone.' Like other participants, when she heard that a new vaccine was available in a trial with different eligibility requirements, she decided to volunteer. 'I was not even in the zone of Majengo, but I heard on the radio that the J&J vaccine was being given in Majengo even for those who lived elsewhere in Goma, so that is why I came to take the vaccine because I know that it is going to be protective when the epidemic arrives,' she explained.[14]

Another participant from Majengo explained that 'there seemed to be fewer side-effects than with the other vaccine, so I noticed that there had been an evolution, this was one of the factors which motivated me to be vaccinated.'[15] The second vaccine, then, was described as a means of accessing potential protection which had previously been inaccessible.

Locating Participants

The second source of debate was the locations selected for the vaccination sites: two *aires de santé* in Goma – Majengo and Kahembe. Whereas the Merck vaccine was restricted to contacts and healthcare workers, J&J was open to volunteers. In an interview, a traditional medical practitioner summarised: 'Yet another trial, and only in certain neighbourhoods. *Bon!* We ask ourselves why they have only chosen certain neighbourhoods and left the others.'[16] The explanation that these areas were selected because they have frequent travel and trade links to the Grand Nord, as well as Rwanda, was challenged by participants of the trial. James, a teacher from Majengo, summarised:

> It's not only people in Kahembe who frequently travel to Rwanda for trade. If you choose Kahembe, why not Birere where people also live close to Rwanda? And Majengo, there are others who live in Sake who travel north frequently. So, the logic is not clear! That led to rumours, the big fear was that this [choice] was political.[17]

Indeed, a rumour circulated that Majengo had been selected because it was predominantly inhabited by the Nande population from the Grand Nord. After the failure of the central government to provide security for civilians in the Grand Nord, the Ebola epidemic and then the election postponement, people in Majengo concluded that the government was now using the DRC-EB-001 trial as another tool to exterminate Nande. James summarised: 'People say, why have you only chosen here? Because there are 70–80 per cent Nande. See how they first banned us from voting … And now they are targeting us here with the undesirable consequences of the trial. If we are exterminated, so much the better. People here feel persecuted.'[18]

In addition, there was concern in Goma about how the trial interacted with existing inequalities. There was concern over the fact that the trial was only based in '*quartiers populaires*' on the periphery of the city rather than the affluent city centre, where potential participants might ask more questions or be less interested in the free health care provided by the trial. A nurse from Majengo who did not participate in the trial explained:

> They only bring the trial to Kahembe and Majengo. Why don't they take the vaccine to the centre of the city, in town where there are the big bosses? How is it that they do not put this vaccination in the city but bring it here in the bush? It suggests it's something to exterminate us.[19]

Participants of the trial voiced similar concerns: 'Why not take the vaccine to people who live in the centre of the city too? That question pushed people to refuse participating here', one participant in Majengo summarised.[20] A young man working in rural development in Majengo explained that he did not participate in the trial, and among those who did 'it was because of poverty':

> For example, for pregnant women they guarantee free health care and the costs of delivery; so those who did not have the means went to be vaccinated, but it wasn't of their own will.[21]

The trial's location in eastern DRC was also read in relation to the strained relationship with the central state. One representative of the faculty of medicine at the University of Goma described: 'I believe there is politics behind the choice [in the location of Goma], Kinshasa is also a highly populated city, people there travel a lot. Why not give the vaccine to Kinois also? Why only here in the east again?'[22]

Finally, people we talked to questioned the trial's presence only in two neighbourhoods in Goma, a city where there had been only a few cases of Ebola. One healthcare worker who did not take part in the trial asked, 'Why don't we take the vaccine to where the epidemic is raging? Here we have never seen a case.'[23] Participants of the trial also found this troubling: 'Why only us? Is it only us who might contract Ebola in the future?'[24] In Kahembe, a participant concluded: 'The objective is to produce a vaccine which is available to prevent Ebola. So, I was wondering why they only chose Kahembe and Majengo. I would like that it was all of Congo vaccinated.'[25]

'We Are Not Guinea Pigs'

The third subject of debate was the experimental nature of the trial, especially given that another vaccine had already been developed. While there was widespread trust in routine vaccinations, there was unease at the presence of trials conducted by foreign institutions and pharmaceutical companies. 'When people see the word experimental, they think, is it because they [foreigners] see us as animals that they can do their vaccine trials on, or what?,' a leader in Majengo explained.[26] The term *essai*, or trial, caused anxiety among participants who were concerned about the potential long-term side-effects of the vaccine. Some participants criticised the trial for only providing free medical coverage for a month after vaccination, while others asked how the trial would feedback results to those who had volunteered so

that they might know if they had a degree of protection in the future, or whether there were emerging side-effects.[27]

In 2020, the possibility of COVID-19 vaccination trials in Africa reignited criticism of contemporary Western-led clinical research on the continent. In April, two French doctors suggested on television that a possible COVID-19 treatment should first be tested on Africans, where 'there are no masks, no treatment or intensive care … we know that they are highly exposed and don't protect themselves.' The football player Didier Drogba summarised the widespread public criticism in a tweet: 'Africa isn't a testing lab' (BBC, 2020). This debate began in the DRC when Professor Muyembe – the head of INRB and the DRC-EB-001 trial – was initially quoted saying that DRC was a 'candidate' for COVID-19 trials. After public outcry, he clarified his position and reassured his fellow citizens that they would not be used as 'guinea pigs' (TV5, 2020). The controversy reignited political controversy around the DRC-EB-001 trial. A committee in support of Ilunga released a communique which stated that Muyembe's comments were not simply a 'problem of communication' but raised questions about who can authorise pharmaceutical companies to test vaccines in DRC. It asserted that in the case of the DRC-EB-001 trial, a 'foreign pharmaceutical company used its privileged relationship with a national laboratory to launch vaccine trials while ignoring the recommendations of the government' (Comité de soutien au Dr Oly Ilunga Kalenga, 2020).

After two Ebola experimental vaccines in North Kivu, the suggestion of a possible COVID-19 trial was a particularly sensitive subject, reinforcing the *perception* that citizens were being used disproportionately as guinea pigs. When responding to questions about the DRC-EB-001 trial, people we interviewed referred interchangeably to COVID and Ebola trials. COVID-19 was Europe's priority, they argued, and therefore it was Europe's turn to test vaccines at home. A young man working in development from Majengo explained:

> When it comes to trials, why is it always in Africa or Congo that they want to do trials? And especially when they want to introduce a COVID trial in Congo, why? COVID-19 isn't tangible yet here, people don't believe it. Then when we hear that a COVID trial will be done here, when it should be done there *chez eux* [in Europe]! By saying they want to do it again in Congo, people think there is something hidden, or that it's a plan to exterminate blacks.[28]

Participants of the trial asked similar questions. A young woman who participated in the trial in Kahembe summarised: 'Why in DRC again when the disease comes from their [les blancs] home? Better that they start at home with trials and bring the vaccine here once it is licensed.'[29] In a context of relatively few COVID-19 cases, the proposition of vaccine trials was considered evidence that clinical research served the interests of outsiders, at the risk of Congolese lives.

The controversy was exacerbated by the impact of the pandemic on the DRC-EB-001 trial itself. The five-month suspension of the Ebola trial in order to prevent COVID-19 transmission meant that almost half of the participants did not receive their second dose 56 days later as planned. After the emphasis placed on the importance of the 56-day window in community engagement, this led to anxiety: Would the vaccine still be effective after a delayed second dose? Was there any potential danger in the delay? In addition, during the five-month suspension, the Ebola epidemic ended. This led to some questioning among people in Goma as to whether the trial should restart at all. When the trial did restart, people started to look for hidden agendas. In a context of global debate about COVID-19 trials, a rumour circulated that the second dose of the Ebola vaccine had been replaced with an experimental COVID-19 vaccine: Europe needed a vaccine but did not want to risk its own citizens, so pharmaceutical companies were clandestinely testing COVID-19 vaccines on Africans. Participants in the DRC-EB-001 trial were concerned and asked for reassurances that the second dose was indeed the Ebola vaccine.[30] These anxieties became situated within global rumours about COVID-19 vaccines: rumours in Goma circulated that the DRC-EB-001 trial was administering COVID-19 vaccines to exterminate the population so that white people could steal DRC's riches, or that the vaccine inserted microchips to enable white people to telecommand African populations.[31] 'We tried and tried to explain J&J was different from COVID vaccines, but COVID has disturbed everything! Everything, everything, everything!' one health authority in Goma concluded in exasperation.[32]

Unpacking the Politics of Medical Research

Much of the debate about medical research ethics situates itself within bioethics and the good clinical practice principles which regulate trials. Bioethical debates focus on the danger of 'misconceptions' among potential participants which need correcting by better trial communication (Emanuel *et al.*, 2004: 930). Yet, this focus on individual consent and standardised principles obscures the broader politics of inequality in which medical research is situated, and the political and economic struggles that it involves (Geissler, 2011: 5). The focus on the 'demystification of science' overlooks the 'very real political economy of the global medical

research industry' (Fairhead *et al.*, 2006: 1119). By examining three local debates surrounding a trial in eastern DRC, this article describes how the ethics of clinical research are not simply discussed in relation to bioethical principles but are inseparable from political conversations about state and humanitarian governance, against a backdrop of profound inequalities.

The DRC-EB-001 trial unfolded in a context of historical conflict and tension with the central state, insecurity, as well as a contentious Ebola response which accentuated existing distrust toward foreign intervenors. These complex state–society relations and the contentious political economy of aid were central to shaping debates about the trial. Local discussions centred on the location of the DRC-EB-001 trial – locally in Goma, regionally in eastern DRC and internationally in Africa – because it was seen as an indication of whose lives mattered at the local, national and international scale. In Goma, the trial was seen as benefitting from existing inequalities, exposing a government-endorsed politics of life in which the lives of poorer citizens in the city's peripheries were worth less. Rumours about the extermination of Nande reflected the regional histories of distrust toward the central government, in a context of the recent cancellation of elections and massacres of civilians. Regionally, the location of two vaccine trials in North Kivu was seen as another indication that Kinshasa considered lives in the east of the country expendable. These reactions, then, were not only specific critiques of the trial but part of a broader expression of frustration with governance in DRC.

This second Ebola trial also sparked debate about whose interests were behind vaccine trials. In 2019, the political context in Kinshasa and controversies surrounding the Ebola response were central to debates about the trial. In 2020, however, global controversy about COVID-19 vaccines reignited critiques of profit-making in global health and exploitation of Africans as 'guinea pigs'. The rumour that the second dose of the J&J vaccine had been replaced with a COVID-19 vaccine communicated deeper anxieties that trials were a business opportunity for pharmaceutical companies, a shadowy elite and former colonisers to test new treatments on African bodies. In reality, as political scientist Fred Eboko (2020) stressed, Africa is in fact the 'least sought out' location for clinical trials: in 2017, 57 per cent of clinical trials were conducted in North America, while only 7 per cent were conducted in the Africa and the Middle East. However, situated against a history of imperial medical experimentation as well as more recent exploitative practices (Tilley, 2011; White, 2000; Lachenal, 2014), opposing vaccine trials in the COVID-19 era became a means for people to contest geopolitical power inequalities and the fact that their lives mattered less internationally (Tilley, 2020). Discussions about the ethics of a second trial were not just a way to communicate concerns about unknown side-effects, but also to critique continued governance by outsiders 'who set intellectual priorities, defined peoples' needs … and turned them from agents to objects of knowledge' (Tilley, 2020: 166). Rumours about the trial then were not just sources of misinformation, but 'debates about ethical practice in a context in which experiences of alienation and exploitation form the background of medical research' (Geissler and Pool, 2006: 980). In this way, questioning medical research ethics became a means of expressing 'wider concerns with political economy and justice' (Fairhead *et al.*, 2006: 1119): a way to debate 'the local within the global, and the present within its history' (Geissler and Pool, 2006: 978).

As Congolese political scientist Aymar Nyenyezi Bisoka and colleagues (2021) have argued, the Ebola epidemic therefore became a space for people in eastern DRC to protest the central state's ineffective governance as well as the protracted presence of foreign actors: 'resistance' toward the response became a form of political activism. Narratives surrounding Ebola business were a political commentary about the epidemic political economy, the forms of exclusion and inequality it reproduced, as well as the continued neglect of priorities such as security, basic services or other deadly diseases. A second vaccine was seen as the epitome of this focus on Ebola rather than local insecurity, and another (more explicit) business – while humanitarians did not purport to profit from interventions, pharmaceutical companies are for-profit. The critique of the 'business' of trials became a part of a broader criticism of profit-making in crisis.

But perceptions of the DRC-EB-001 trial were far from homogenous: 20,000 people in Goma volunteered to be vaccinated. Contrary to initial concerns, our research shows that trial participants were not confused by two trials – in fact, many participants of the DRC-EB-001 trial did not know that another Ebola vaccine already existed. This illustrates the considerable gap between international bioethical debates and the considerations among people deciding whether to volunteer. For those who were already well informed about the Merck vaccine, personal experiences of the epidemic shifted their perceptions: participants who had seen Ebola for themselves described the second trial as an opportunity to access potential protection after they had found themselves ineligible for Merck. These participants were instead concerned about access: If the vaccine was potentially protective, why was it only implemented in two neighbourhoods in Goma? This raises broader ethical questions about why some vaccines are available in some areas and others are not, and who has the power to control this in an epidemic context. Close examination

of how the ethics of vaccine trials is discussed in the everyday reveals how such debates cannot be separated from political histories, global inequalities and personal lived experiences.

Conclusion

The introduction of a second experimental Ebola vaccine in North Kivu sparked debate about the ethics of clinical research in epidemic contexts. Examination of how this debate unfolded among actual and potential participants in Goma reveals how bioethics cannot be disentangled from political histories and contests. The political dimensions of bioethical debates are multifaceted. In eastern DRC, people articulated specific critiques of the trial itself, but the trial also became a space for broader political discussions: a site where citizens articulated long-standing grievances about governance, political economy and social justice, as well the continued influence of outsiders and their priorities. As Enria and Lees (2018: 49) describe, the arrival of a new biomedical technology can 'create a space for conversations that transcend the encounter' between trial and participant, becoming a part of citizens' everyday struggles for recognition. Biomedical interventions are not only entangled with political dynamics and understood in relation to them, but they also become new sites for articulating wider concerns about power, inequality and exclusion.

These insights have important implications for how to think about clinical trial ethics, and global health interventions more generally. While White (2011) argues that medical research is not primarily an ethical issue but must be viewed as a site of political contest, we argue that the two are inseparable. To understand experiences of biomedical interventions and debates surrounding their ethics, it is necessary to move beyond analyses of 'local acceptability' of medical procedures, to instead focus on political questions of governance and political economy. Global health and humanitarian institutions must recognise the political significance of local popular critiques of international interventions, situating them in legacies of colonialism and postcolonial political and economic inequality. Fine-grained, contextual research on the everyday politics of biomedical ethics is crucial and timely, not only in DRC where cyclical Ebola epidemics continue, but worldwide in an era of debate surrounding COVID-19 vaccine roll-out.

Acknowledgements

We would like to acknowledge the excellent research assistance provided by Benjamin Shukuru Kasiwa, Janvier Koko Kirusha, Paluku Kahehero Joël, Omega Thige Frédéric, Karenzi Lina, Barhuze-a-Bankulikire Bakulikira Siloé and Ferdinand Ntabala. The research was made possible thanks to financial support from CEPI and EBODAC. We want to thank everyone in Goma who took the time to talk to us. Any errors remain our own.

Notes

1 Interviews with participants of DRC-EB-001 trial, September–December 2020.
2 Focus group, 12 November 2020.
3 Interview, 23 October 2020.
4 Interview, 29 October 2020.
5 Tweet, 1 August 2019: https://twitter.com/luchaRDC/status/1156968356458696704?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1156968356458696704%7Ctwgr%5E%7Ctwcon%5Es1_&ref_url=https%3A%2F%2Fwww.rfi.fr%2Ffr%2Fafrique%2F20190802-ebola-rdc-croire-polemique-deuxieme-vaccin.
6 Focus group, 12 November 2020.
7 Focus group, 12 November 2020.
8 Interview, 17 October 2020.
9 Interview, 29 October 2020.
10 Interview, 2 November 2020.
11 Interview, 20 October 2020.
12 Male participant, Kahembe, 3 November 2020.
13 Male participant, Majengo, 15 October 2010.
14 Female participant, Majengo, 23 October 2020.
15 Male participant, Majengo, 15 October 2020.
16 Focus group, 6 November 2020.
17 Male participant, Majengo, 15 October 2020.
18 Male participant, Majengo, 15 October 2020.
19 Focus group, 5 November 2020.
20 Male participant, Majengo, 23 October 2020.
21 Male participant, Majengo, 23 October 2020.
22 Focus group, 12 November 2020.
23 Focus group, 5 November 2020.
24 Male participant, Majengo, 27 October 2020.
25 Male participant, Kahembe, 16 October 2020.
26 Focus group, 5 November 2020.
27 Focus groups, Majengo, 22, 23 and 28 October 2020.
28 Focus group, 12 November 2020.
29 Female participant, Kahembe, 3 November 2020.
30 This was mentioned in almost every interview.
31 Female participant, Majengo, 30 October 2020.
32 Interview, 20 October 2020.

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