

The Case for Why Africa Should Host COVID-19 Candidate Vaccine Trials

Jerome Amir Singh^o

Centre for the AIDS Programme of Research in South Africa, Durban, South Africa

In response to provocative comments by 2 European clinicians and scientists, the World Health Organization Director General has declared that Africa will not host COVID-19 vaccine trials. Such a stance risks stigmatizing COVID-19 vaccine trials in Africa and depriving Africa of critical research. To the contrary, there is a critical need for Africa to host COVID-19 vaccine trials on public health, scientific, and ethics grounds.

Keywords. COVID-19; vaccine trials; ethics; public health; global health.

In early April 2020, during a debate on vaccine trials on French television, a senior French clinician suggested that a vaccine trial testing the efficacy of a decades-old tuberculosis vaccine, bacille Calmette-Guérin (BCG), against COVID-19, should be conducted in Africa. His rationale was simple: “. . . there are no masks, no treatment, no intensive care, a bit like it is done in some studies on AIDS or among prostitutes. We try things because we know they [sex workers] are highly exposed and they don't protect themselves.” [1] A senior French scientist also being interviewed, concurred. While the scientists, were not, in fact, referring to the testing of a novel COVID-19 candidate vaccine in Africa [1], the damage was done. The remarks provoked global outrage [2, 3]. In his response to the ensuing controversy, the World Health Organization (WHO) Director General, who hails from Africa, was emphatic. Categorizing the remarks as appalling, disgraceful, and racist, the WHO Director General declared: “Africa

cannot and will not be a testing ground for any [COVID-19] vaccine.” Further, that “the hangover from a colonial mentality has to stop. We assure you that this will not happen in Africa.” [4] While the WHO Director General may not have intended his comments to mean that Africa was barred from participating in such trials and, further, while the WHO has no authority under international law to block such trials in Africa, the ensuing negative publicity has fueled suspicion about biomedical research and quickly turned public sentiment against COVID-19 vaccine trials across the African continent [5–7]. This is an unfortunate development. To the contrary, because of its particular vulnerabilities, Africa critically needs to host studies trialing novel COVID-19 vaccine candidates, from the outset of the COVID-19 pandemic.

THE PUBLIC HEALTH IMPERATIVE TO TEST NOVEL COVID-19 CANDIDATE VACCINES ON AFRICAN POPULATIONS

While African countries have relatively low numbers of COVID-19 cases compared to settings elsewhere, this is not necessarily indicative of low prevalence or successful containment, but low surveillance. By 21 May 2020, South Africa, which has a population of approximately 59.5 million, had conducted 525 433 polymerase chain reaction (PCR) tests, including 18 572 tests in the previous

24 hours [8]. By 20 May 2020, Kenya, which has a population of approximately 52 million, had conducted 49 405 tests, including 2621 tests in the previous 24 hours [9]. By 20 May 2020, Nigeria, which has an estimated population in excess of 200 million, had conducted 37 043 tests, including 1812 tests in the previous 24 hours [10]. These statistics speak to the low level of surveillance on the continent and almost certainly mask much higher prevalence in these countries. These settings typify the situation elsewhere on the continent. The low number of documented cases on the continent may also be due to the possibility that the virus is not yet as prevalent in many parts of Africa. However, there is no reason to believe the disease will not eventually spread just as widely as has been the case elsewhere in the world.

Africa is particularly susceptible to COVID-19 because 56% of its urban population is concentrated in overcrowded and poorly serviced slum dwellings [11], and only 34% of households on the continent have access to basic hand washing facilities [12]. Africa also shoulders a disproportionate burden of major diseases, such as HIV/AIDS, tuberculosis, and malaria [13]. With lower ratios of hospital beds and health professionals to its population than other regions [14], and high dependency on imports for its medicinal and pharmaceutical products [15], the United Nations Economic

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Correspondence: Jerome Amir Singh, PhD, MHSc, LL.M., Centre for the AIDS Programme of Research in South Africa (CAPRISA), Durban, South Africa (singhj9@ukzn.ac.za).

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Commission for Africa has warned that between 300 000 and 3.3 million Africans could lose their lives as a direct result of COVID-19, depending on the intervention measures taken to stop the spread [16]. As is the case with other infectious diseases, such as polio and measles, the world relies on universal immunization for disease control. Gaps in coverage for polio and measles vaccinations continue to lead to outbreaks globally and highlight the public health utility of vaccination campaigns. This factor, along with Africa's lack of health care infrastructure, and the possibility that the virus may only just be making its presence known in the continent, make vaccine trials in Africa even more compelling. Given these factors, Africa can ill afford to be omitted from COVID-19 candidate vaccine trials.

THE SCIENTIFIC RATIONALE TO TEST NOVEL COVID-19 CANDIDATE VACCINES ON AFRICAN POPULATIONS

As of 20 April 2020, there were 5 candidate vaccines in clinical evaluation and a further 71 candidate vaccines in preclinical evaluation [17]. These candidates are being trialed in Asia, North America, and Europe. If novel candidate vaccines are not tested in African settings, the continent has to bank on efficacious vaccines developed and tested elsewhere being effective in African populations. This may turn out not to be the case. Host genomics play a key role in viral susceptibility, disease progression, and clinical outcome after viral exposure [18, 19]. In this regard, the immune response in Africans and Europeans differ, especially in the case of genes involved in inflammatory and antiviral responses [20]. This is significant as interactions between the innate and adaptive immune responses in COVID-19 have implications for viral pathogenesis [21]. Accordingly, controlling current rates of SARS-CoV-2 infection and designing an immune intervention or preventive vaccine for COVID-19 requires a better understanding the underlying genomic

susceptibility and resistance to COVID-19 [22], including host-pathogen interaction, host immune responses, and the pathogen immune evasion strategies.

Race and ethnicity/geographic ancestry have also been shown to affect vaccine responsiveness [23–26]. For instance, rotavirus vaccine efficacy is considerably lower in Africa as compared to Europe and North America, and has been attributed to host genomics, particularly mutations in genes involved in the immune response, or to the receptor/ligand [27]. Given these factors, it cannot be taken for granted that a vaccine which demonstrates efficacy in Asian or Caucasian populations will demonstrate equivalent efficacy in African populations, or in all African settings. As such, it is crucial for Africans across the continent to participate in COVID-19 vaccine trials, from their outset.

THE ETHICAL IMPERATIVE TO TEST NOVEL COVID-19 VACCINE CANDIDATES ON AFRICAN POPULATIONS

The exclusion of African populations in COVID-19 vaccine trials testing novel vaccine candidates could translate to African countries losing precious time in protecting their populations if efficacious vaccines developed elsewhere are later found not to confer protection on African populations. Accordingly, the conduct of COVID-19 vaccine trials in Africa has considerable *social value* as such research is responsive to the urgent health needs and priorities of African people and will yield critical information towards those ends. It has been argued that inclusion in clinical trials is a moral right and a benefit [28], and the US National Institutes of Health has even made inclusivity a review criterion [29]. *Equity* speaks to social justice or fairness [30]. As the inclusion of disadvantaged and marginalized groups in research can help global health research advance equity [31], sponsors, scientists, and regulators contemplating host sites for candidate COVID-19 vaccines should consider that the health and well-being of

African populations can best be assured by their inclusion in COVID-19 vaccine research. Such inclusion also realizes the notions of *solidarity*—which requires us to think about how we might stand together to defend the interests of vulnerable groups—and *common good*—which requires us to share benefits and burdens, and sacrifice for one another, as it will benefit everyone if we do so. Dozens of concurrent COVID-19 vaccine trials testing novel candidates will require the accrual of thousands of participants to meet sample size targets. This need will be expeditiously met if dozens of host sites across multiple regions accrue such numbers concurrently. Africa can play a crucial role in helping to meet such targets in a timely manner.

Africa has a long history of, and considerable experience in, hosting and conducting vaccine trials [32], including phase 1 vaccine trials on a range of major diseases across the continent [33–37]. African scientists are also making valuable contributions to COVID-19 vaccine development [38–41]. Accordingly, the inclusion of suitable African host countries in vaccine trials will honor the principle of *collaborative partnership*. South Africa is currently the only African country to participate in the SOLIDARITY trial, which aims to assess the efficacy of multiple candidate COVID-19 therapeutics [42]. African countries can play a similar participatory role in novel COVID-19 vaccine trials. The inclusion of African populations in COVID-19 vaccine research could also facilitate their timely post-trial access to efficacious experimental intervention [43, 44], arguably faster than if those settings were not participating in COVID-19 vaccine trials.

Lastly, it would be remiss not to acknowledge that the WHO Director General's strongly expressed sentiments against the testing of vaccines on the African continent may be premised on the belief that Africans could be exploited if they participate in COVID-19 vaccine trials. As is the case with other research conducted in

Africa, including COVID-19 therapeutic trials [42], COVID-19 vaccine trials must be conducted in accordance with local and international ethics guidelines [43, 44], and applicable local regulations. Such an approach is supported by the WHO Director General, who has noted: “We [the WHO] would follow all the rules to test any vaccine or therapeutics all over the world using exactly the same rule, whether it’s in Europe, Africa or wherever.” [1]. Furthermore, COVID-19 vaccine research should involve local investigators and must be underpinned by meaningful stakeholder and community engagement initiatives.

CONCLUSION

The COVID-19 pandemic presents the greatest public health threat to the world since the 1918 H1N1 pandemic. As COVID-19 is now truly a global pandemic, all of humanity shares a common fate. As dozens of COVID-19 vaccine trials commence in the weeks and months ahead, African sites should be central to COVID-19 vaccine trial site mapping. Such an approach is in the interests of public health, scientifically responsible, and realizes key ethics values. Without such an approach, Africa risks being left behind in our response to the COVID-19 pandemic. This would be unconscionable.

Notes

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