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Africa's need for more COVID-19 clinical trials

Few treatments and vaccines are being tested in Africa, leaving a lack of data for the COVID-19 response. Munyaradzi Makoni reports from Cape Town, South Africa.

Experts are calling for more clinical trials of vaccines and therapies for COVID-19 to be done in Africa to ensure effective treatment and prevention for the continent. The pandemic has spurred unprecedented efforts in research and development globally, but, of the more than 3000 trials of interventions for COVID-19 that are underway, only 145 are taking place in Africa.

Only 2% of clinical trials took place in Africa before COVID-19, yet drugs now offered were mostly tested on non-Africans, says Bernhards Ogutu, chief research officer with the Kenya Medical Research Institute. As a result, there is concern over the lack of information on the efficacy of new drugs and vaccines in African populations.

Bartholomew Dicky Akanmori, regional adviser for vaccine research and regulation, WHO Regional Office for Africa, says that more studies are needed to assess the long-term safety and duration of protection of different COVID-19 vaccines in different population groups. "It is difficult to generalise clinical findings for an entire continent", he said.

"We have a huge population of 1.2 billion people, larger than North America and Europe combined", said Jenniffer Mabuka-Marua, from the African Academy of Sciences. "And this population also happens to be very genetically diverse and under unique environmental exposures that influence our body responses to drugs and vaccines." While there may be few clinical trials in Africa, WHO Africa says COVID-19 vaccines undergo rigorous testing in clinical trials to prove that they meet internationally agreed standards for safety and efficacy.

Some African countries also have high rates of comorbidities, such as HIV and tuberculosis, for which COVID-19 vaccines need to be tested for efficacy

and safety, says Akanmori. The lack of COVID-19 trials in Africa has been attributed to the uneven development of infrastructure and clinical facilities as well as the unpredictability of clinical regulatory timelines. But Akanmori emphasises the need for multiple vaccines that have been tested among

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different populations and with strategies for delivery in various geographical settings "if we are to protect as many people as possible".

More trials in Africa are also needed to assess the efficacy of existing COVID-19 vaccines against new variants of SARS-CoV-2. 501Y.V2, the rapidly spreading new variant that was discovered in South Africa last year, has since been detected in more than 20 African countries. B.1.525, which was first detected by genome sequencing in Nigeria, and B.1.617.2, a variant first identified in India late last year, are also contributing to cases and deaths.

A limited number of vaccine doses are reaching Africa and the rapid spread of new variants could threaten to reduce the efficacy of existing vaccines. This possibility is a major cause for concern for John Nkengasong, director of the Africa Centres for Disease Control and Prevention. 24 million people in Africa have received a first dose of COVID-19 vaccine, including 67% in Seychelles, 29% in Morocco, and 17% in Mauritius. However, 14 African countries have vaccinated less than 1% of their populations, and four countries have not yet begun vaccinations.

"Evaluating vaccine effectiveness in different real-life settings will be

critical to optimise the use of these vaccines and support the development of even more effective vaccines", said Akanmori. "Vaccines that are tested in African countries must ultimately be made available to the African populations that participated in their clinical evaluation", he told *The Lancet*.

There is a pressing need for COVID-19 treatments too. About 90% of mild-to-moderate cases of COVID-19 have occurred in Africa, says Ogutu, but there are no effective therapies for early stage disease. Discovering a treatment for patients with mild-to-moderate COVID-19 is a research priority in Africa, as elsewhere. "We need urgently to identify affordable and easy-to-administer treatments that can prevent the evolution to a severe form of the disease and slow the rate of infection", says Nkengasong.

ANTICOV, coordinated by the Drugs for Neglected Diseases initiative, is Africa's largest COVID-19 treatment trial and has begun in order to try to address these challenges. The study will test the efficacy of a potential new treatment combining the antiparasitic nitazoxanide and a corticosteroid, ciclesonide, for people with early mild-to-moderate COVID-19 in Burkina Faso, Cameroon, Côte d'Ivoire, Equatorial Guinea, Guinea, Ethiopia, Democratic Republic of the Congo, Ghana, Kenya, Mali, Mozambique, Sudan, and Uganda. 2000–3000 patients will be recruited in the coming weeks.

"It continues to be an important question to understand how we can treat people quickly and early to prevent transmission and reduce hospitalisations and this trial will be looking for solutions to these questions", says Mabuka-Marua. "We have a long way to go."

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