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Commentary

COMMENTARY

# Why is there a paucity of clinical trials in Africa?

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**Summary:** Disproportionately few clinical trials are undertaken on the African continent, in part due to lingering neocolonial attitudes in the Global North which keep research activity primarily in developing countries, while being skeptical of the abilities of those in the Global South to undertake organized clinical studies. In the era of the COVID-19 pandemic, applicable research and clinical trials should be undertaken in relevant populations in order to extrapolate to a population level. This is all the more important in Africa, which has a rich genetic diversity. We suggest that a lack of organized research ethics committees across the continent and a deficiency of appropriate training are responsible in part for the reluctance of clinical trial organizers in the developed countries of the Global North to engage with medical leadership in Africa. We consider ways of alleviating this problem, including suggesting a pan-continental surveillance of ethics committee agendas and of training, either through the auspices of the African Union or the World Health Organization. In addition, medical leadership in African nations must be encouraged to take ownership of their medical ethics agendas to facilitate decent international clinical trial participation for the good of the continent as a whole.

We should like to discuss some of the reasons why international randomized controlled trials (RCTs) are not often conducted in Africa, outside South Africa or Egypt, despite the fact that Africa as a continent remains a major marketplace for medicines and medical devices from Big Pharma and from medical device companies from the Global North. In an era of globalization, it could be assumed that research, and particularly clinical trials, might be conducted equally around the world for the benefit of the international community, but a recent assessment of clinical trials on clinicaltrials.gov would suggest that of over 2.74 million studies, barely 7000 were conducted in Africa.[1] This has been brought into focus in the COVID-19 pandemic, where out of 157 clinical trials worldwide, only three are or have been conducted in Africa (in this case, Egypt).[2] However, without adequate representation in RCTs, trial findings cannot easily be extrapolated to large populations in Africa, given the continent's rich genetic diversity.

Although the colonial period has long since disappeared in Africa, what can be called *neocolonialism* still affects the social, political and economic standing of those living between Cairo and the Cape nowadays. The previous relationship of the colonial powers in the Global North to the ex-colonized nations of Africa has continued well beyond the colonial period, owing to sustained cultural and economic influence.[3]

Clinical trials that have been designed by medical researchers or Big Pharma in the Global North to be undertaken in Africa have until recently, frequently shown a paucity of ethical oversight. The expansion of research in African countries is frequently seen as a promising way of alleviating economic disparity and a means of addressing local health problems, but the applicability of some clinical trial designs to Africa has been at best tenuous. While it can be argued that participation in international RCTs brings about global medical benefit, it may be difficult to justify the ultimate societal value when the study objectives are not pressing health concerns to the developing nations of Africa. Glickman and colleagues[4] observed that many of the US-funded Phase III clinical trials in the Global South were for culturally irrelevant complaints, such as allergic

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rhinitis or overactive bladder, rather than pertinent health problems to the continent, such as malaria, TB and African neglected tropical diseases.

The issue of translating research outcome to clinical practice is complicated in Africa by poor infrastructure, lack of adequate human healthcare resources and a scarcity of research funding. Adequate planning must occur in study design and the applicability of research interventions should be paramount, thus placing more weight on conditions relevant to Africa, such as malnutrition, infectious diseases, genetic problems such as sickle cell diseases, non-communicable diseases, such as cardiovascular problems, hypertension and diabetes, and cultural malpractices, which have associated morbidity and mortality.

Given the marked rise in prevalence of non-communicable diseases in Africa, such as coronary heart disease, participation of African centers in international Phase III RCTs of medications and medically related devices is particularly important.[5] This is highlighted by the fact that African genetic differences can mean that responses to medications such as antihypertensives may be different in the continent, compared to those of participants from the Global North.[6] Furthermore, in the presence of a global pandemic, COVID-19 clinical trials of medicines and medical devices should also be undertaken in African countries to assess applicability of treatments and vaccine regimes to the continent.[2]

One of the issues that holds back African participation in clinical trials is the widespread presence of poorly structured ethical review committees in Africa, where the constituent members are either inadequately trained or non-independent. An assessment of research ethics committees in 33 African countries revealed that more than half of these were formed after the year 2000.[7] The study also highlighted that only a third of the ethics committees included individuals who had knowledge or training in medical ethics, and the study also found that most of those committees did not provide continued training for serving committee members.[7] In a different case study that looked at the composition of 12 African ethics committees, deep-seated problems with regularly timed meetings, committee member training, incompetent administration and financial transparency were highlighted.[8]

Solutions that address current Global North exclusion of many African research centers in RCT participation require an ethical system that is relevant to African countries, but equal to those of the developed world. Resolving North–South medical relationships in Africa requires each African country to adopt sensible medical leadership. We believe that the African Union (AU), the World Health Organization (WHO) or the World Health Assembly may need to provide initial guidance in setting up transparent and independent stewardship of clinical trials throughout the continent.

The major question of funding and of research training is not easy to surmount, even with international aid or sponsorship from Big Pharma. However, the need for African academic centers to build capacity in order to conduct reliable international RCTs could also be resolved through AU or WHO oversight. We have previously proposed the creation of an international RCT review board under the auspices of the WHO, perhaps in Addis Ababa, where independent representatives from a pan-continental African ethical body should attend to deter unethical trials from being approved and grant permission for those RCTs of continental importance (such as may be required in the COVID-19 pandemic).[9] Although this is a counsel of perfection, WHO or AU surveillance may smooth the progress of international RCTs in the continent and this would not be difficult to set up, given the number of related pan-African meetings that take place in the AU headquarters in Addis Ababa regularly. This approach should enhance the quality of research performed in Africa and negate worries in the Global North about the scientific interrelationships with Africa.

In conclusion, the *de facto* medical rift between the pharmaceutical bodies in the Global North and African countries is grounded in social and political factors that mirror neocolonial and postcolonial prejudices. However, we have highlighted some important areas that can be addressed to encourage ethical standards and future, more widespread international Phase III RCT involvement in Africa. Solutions dictate a wide international input, ranging from the WHO and AU to Big Pharma. Equally well, medical leadership in African nations must be encouraged to take ownership of their individual medical ethics agendas. We are hopeful that with a determined approach to this problem, strained North–South medical relationships can be resolved in Africa through true partnership, with decent RCT participation for the good of the continent as a whole.

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