COVID-19, Clinical Trials Regulations: Making Sure Africa is Not an Unregulated Testing Ground

By:

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Recently, there has been discussion in the media, about vaccine trials for COVID-19 that may take place on the African continent. This discussion had been in the offing, mainly because Africa has sometimes been left out of vaccine trials. The discussions stirred more controversy when two top French scientists suggested that clinical trials should take place in Africa. Since the interview, The World Health Organisation (WHO) Director General (DG) Dr. Tedros Adhanom Ghebreyesus addressed the utterances to state categorically that this problematic colonial mindset was unacceptable. At the same time, the Democratic Republic of Congo has agreed to be one of the countries to test a COVID-19 vaccine, further 'muddying the waters.'

To fully appreciate the controversial nature of the topic, the Abdullahi v Pfizer cases (which concerned clinical Trials in Nigeria) brought against Pfizer in the United States are an essential reference point. The Pfizer cases were based on

allegations that Pfizer carried out clinical experiments on children in Nigeria knowingly and purposefully even though the participants had not given obtain informed consent to participate in the clinical trials. The cases were brought under the Alien Tort Statute (ATS), allowing for claims to be brought by individuals affected by actions of American companies outside of the United States of America (USA). The plaintiffs in these cases argued that there was an international customary law rule prohibiting medical experimentation on non-consenting human subjects. Exasperatingly, the matter was settled with an out of court settlement. The United States Appeal Court of Appeal for the Second Circuit (hereafter the US Court of Appeal) did, however, pronounce on several vital issues before remanding the case to the District Court, after which a settlement was reached. Notably, the US Court of Appeal affirmed the legal principles of the Nuremberg Code and the International Covenant on Civil and Political Rights (ICCPR). Those subjected to experimentation were therefore covered by the restriction on experimentation on non-consenting human beings. The Pfizer cases were of mutual concern to both the governments of the USA and Nigeria given that the violation of these ethical principles relating to clinical trials could foster distrust, reduce co-operation between nations and generate a substantial anti-American feeling in the region.

Against this background, it is important to note the immense power of pharmaceutical industry players during this pandemic. There are at least 15 transnational companies (TNC) in this sector (of which 8 of the top 15 TNCs are American). Although there are international legal norms and additional protection from the laws set by the home state of these pharmaceutical companies (Barnes and Wallace, 2018: 252-259), African countries need to be on the alert to avoid a repeat of the Pfizer cases.

Currently, COVID-19 is an urgent situation, requiring clinical trials for a cure or vaccines that can prevent COVID-19. Undoubtedly people from the African continent will be affected by COVID-19, as such, countries on the African continent could very well be part of the clinical trials to find a solution to this global pandemic. This unfolding reality creates anxieties, especially in light of the of very public failures by authorities in Nigeria and Uganda to protect human subjects from unethical clinical trials (Barnes and Wallace, 2018: 264). Further, it is a fact there are in the lack of protection for human subjects

currently in place in the majority of individual African countries (Barnes and Wallace, 2018: 249).

There is a need to rebalance to the power between pharmaceutical companies, on the one hand, and countries, doctors and patients, on the other. The rules that the Nuremberg trials and the ICCPR set out need to be modernized and set down for any clinical trials that will take place in African countries. Although there is a Pan African Clinical Trials Registry (PACTR) organization that keeps data on clinical trials, there are no clinical trials regulations on the African Continent. There is a need to introduce continent-wide regulation as the African Medical Agency is yet to be created after the requisite number of ratifications. With past experience as a prism to look through, a continental approach to regulation will be preferable instead of allowing countries to regulate on a country-to-country basis (Lema and others, 2009: 136).

Article 4 of the African Charter of Human and Peoples Rights (ACHPR) espouses the inviolable nature of human beings and upholds the respect of and individuals' life and bodily integrity. This position in the ACHPR is of vital importance during this pandemic because clinical trials, while being essential for innovation in medical research, have the potential to affect people adversely. Given this, African countries need to set up robust internal processes to avoid these potential adverse consequences of clinical trials. Having these internal processes on a continental level, basic though they may be, can set the minimum level of protection. From that point, individual countries can be encouraged to take up additional protections to safeguard their citizens. It is encouraging to see that on the African continent, there has been a movement towards such a scenario through the United Nations Economic Commission for Africa (UNECA) as well as through the development work on the Afroguide Clinical Trails. These developments together, with the PACTR - the hopefully soon to formed African Medical Agency - is a path to be taken.

I propose the focus of the emerging continental regulations should be on informed consent which emanates from the Nuremberg code and the Helsinki declaration. According to researchers, informed consent can only be achieved by ensuring five elements: voluntariness, capacity, disclosure, understanding and decision. Simply fulfilling the basic requirements of the template

information sheet and template consent form is woefully insufficient. True informed consent would require an understanding of culture and language as well as consider the actual and future needs that may impact informed consent. It is essential to keep at the forefront that informed consent is an ongoing process as the clinical trials progress. These regulations should ideally be administered at the African Union (AU) level with the African Medicines Agency taking a lead role.

In conclusion, I advocate for clinical trials taking place on the African continent as the global pandemic that we are all dealing with will not leave African countries unscathed. However, at all times clinical trial must only be allowed with proper precaution, under AU supervision (Already the African Union Centre for Disease Control has been very active) and ensuring that the balance of power remains with African countries.

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