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Good Participatory Practice, Clinical Trials Awareness and COVID-19 Vaccine Acceptance in Sub-Sahara Africa

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Abstract The success stories regarding the availability of at least 4 coronavirus disease 2019 (COVID-19) vaccines showing efficacy rates of about 90%, barely 10 months after the sequence of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was made available by China and 8 months after the World Health Organization (WHO) declared the COVID-19 pandemic, is an incredible scientific and technological achievement. Clear and consistent communication by the pharmaceutical industry, national and regional medicinal agencies, and government officials is key to building public confidence in vaccine programs. In addition, community-based care with community health workers will increase efficacy. This includes clinical trials and regulatory process awareness campaign. Additionally, strategic campaigns should also address COVID-19 vaccine-related issues: Vaccine's level of efficacy, number of shots/doses needed, the time needed for protection, vaccine up-take, and herd immunity. Implementing the principles of good participatory practice and stakeholder engagement prior to market launch, is essential, to improve vaccine acceptance.

Keywords: *stakeholder engagement, COVID-19, clinical trials, vaccine acceptance*

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1. Introduction

The COVID-19 pandemic is expected to continue to impose enormous burdens of morbidity and mortality while severely disrupting societies and economies worldwide. Governments must be ready to ensure large-scale, equitable access and distribution of a COVID-19 vaccine when a safe and effective one becomes available. This will require sufficient health system capacity, as well as strategies to enhance trust in and acceptance of the vaccine and those who deliver it [1]. Currently, Several COVID-19 vaccines human clinical trials are on-going. Russia announced on the 11th of Aug 2020, as the first country in the world, the approval of a vaccine against SARS-CoV-2, with an efficacy of 92%. The vaccine (Sputnik V), developed by the Gamaleya National Center of Epidemiology and Microbiology (Moscow, Russia), is based on two adenovirus vectors [2]. In Nov.2020, BIONTECH/Pfizer [3], Moderna [4], and AstraZenecca/University of Oxford [5], all reported phase III data showing efficacy rates above 90%.

As of February 2021, several vaccines have gained approval for general population use, with more than 1 million doses distributed in countries including the United Kingdom, the United States, China and Russia. Countries such as Israel and the United Arab Emirates have started conducting immunization programs, making swift progress to vaccinate their citizens. However, majority of low and middle-income countries have either vaccinated only a small section of their population or are yet to implement vaccination distribution strategies [6].

According to a recent study, Israrel has observed a decline in the number of COVID-19 cases, since the vaccination campaign began in the country. A decline in the hospitalizations mainly among the elderly and high-risk populations is reported [7]. Doctors of France and Italy have reported few side effects after the Oxford-AstraZeneca vaccine was administered to healthcare providers. The medial staff has reported "high-intensity flu symptoms" after the first dose was administered. They were unable to perform their daily tasks, and had to stop work to recover [8]. Since January 18, Russia's Sputnik vaccine is being administered to its citizens. It's free and you do not have to schedule an appointment for it. There

are already two vaccines that have been registered with a third one on the way. Russia's vaccine Sputnik V is available in EU as well as non-EU countries, including Argentina and Serbia. A medical report mentioned that efficacy rate of Sputnik vaccine is 91% [9] whereas the Oxford/Astra Zeneca vaccine is as effective as 100% against more serious infection [10].

In U.S, few side effects have been mentioned by the Centers for Disease Control and Prevention (CDC) after Moderna and the Pfizer-BioNTech vaccines were made available to its population. These include fatigue, headache, chills, swelling, redness or a rash at the injection site, Muscle and joint pain and fever [11]. The UK vaccine roll-out has showed side effects that are in line with clinical trials. Reports of headaches, fever, dizziness, aching muscles, nausea and tiredness were the most common adverse events mentioned by majority of the population [12]. China has approved two COVID-19 vaccines that are available for public use namely, Sinovac Biotech and the other developed by a Beijing institute affiliated with state-owned China National Pharmaceutical Group (Sinopharm). China has administered more than 31 million doses under its vaccination program, providing protection to high-risk populations. CanSino Biologics, is working on a vaccine candidate that is currently administered only to military personnel. CoronaVac vaccine developed by Sinovac Life Sciences, has been granted emergency authorization by Indonesia, Turkey, Brazil, Chile, Colombia, Uruguay, and Laos. According to China's, Phase I and II trial this vaccine is safe and triggered immune response effectively among the older study participants. In addition, participants aged three to 17 are also vaccineinated with Sinovac's vaccine. Phase III clinical trials performed with Sinovac's vaccine are being conducted in several nations including Brazil, Turkey and Indonesia, where varied efficacy rates were released, however the data is not available publicly [13].

Currently, with the availability of the COVID-19 vaccines, and access and affordability guaranteed by the COVID-19 vaccine Global Access Facility (COVAX), Governments, public health officials and advocacy groups must be prepared to address hesitancy and build vaccine literacy so that the public will accept immunization when appropriate [1]. Anti-vaccination activists are already campaigning in multiple countries against the need for a vaccine, with some denying the existence of COVID-19 altogether. Misinformation is being spread through multiple channels could have a considerable effect on the acceptance of a COVID-19 vaccine [1].

COVID-19 vaccines' development is limited due to the relationships developed between the lead developers and the manufactures residing in high-income countries. In addition, majority of the vaccine's manufacturing capacity is located in developed nations resulting in highly concentrated state of production. Although, there are few COVID-19 vaccines developers that have collaborated with manufacturers of middle-income countries such as mAbxience Buenos Aires with Argentina, Johnson & Johnson collaborated with Aspen Pharmacare in South Africa, Novavax and AstraZeneca with the Serum Institute of India. However, it is difficult to assess how the terms of these partnerships are, including the guidelines as to which the licensed manufacturers can demand and negotiate their supply arrangements with these countries, is vague [14]. The accelerated pace of vaccine development has further heightened public anxieties, vaccine hesitancy, and could compromise acceptance [15,16,17]. COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization (WHO) – working in partnership with developed and developing country vaccine manufacturers. It is the only global initiative that is working with governments and manufacturers to ensure COVID-19 vaccines are available worldwide to both higher-income and lower-income countries. Whereby, 92 low- and middle-income economies that are eligible to be supported by the COVAX Advance Market Commitment (AMC) [18,19].

According to a recent report, more than 39 million doses of vaccine had been administered in 49 richer states and surprisingly, only 25 doses were given to one poor nation [20]. Developed nations are placing large volumes of pre-orders, making it challenging for low-income countries to achieve a timely and sufficient supply of COVID-19 vaccines. If this continues, it is expected that billions of people all over the world will not be vaccinated in 2012. This will eventually prolong the pandemic and increase the risk of mutation of the virus, possibly compromising the efficacy of the existing vaccines. Several countries with their own national procurement strategies might affect COVAX vaccine's supply adversely [21]. Many high-income countries are making purchase agreements directly with lead developers instead of purchasing their vaccines via COVAX to secure abundant supply of COVID-19 for its people. This will impose a greater threat to equitable allocation, by leaving behind the high-risk populations and the healthcare providers of the low-income countries [22].

According to The Economist Intelligence Unit, Africa is facing a surge in COVID-19 transmission which is believed to have severe consequences in terms of public health outcomes as compared to the one experienced during 2020. Majority of the African countries do not have sufficient supply or access to COVID-19 vaccines, creating a more vulnerable position for its people. High-income countries with their immense resources, strong logistics and well-supplied manufacturing capacity will easily access vaccines through the COVAX Facility. Countries like South- Africa and other low-income nations are depending upon the goodwill of the international community. Lack of adequate transport, storage and distribution facilities is another challenge compromising delivery of vaccine across Africa. This will result in implementation of a slow-starting and slow-progressing vaccination program, preventing most of the Africans unvaccinated by the end of 2021 [23].

This article intends to address the importance of stakeholder engagement both for clinical trials and vaccine acceptance. It is necessary to ensure an equitable distribution of vaccines to achieve global vaccine immunity, highlighting important factors that need to be considered while developing and implementing vaccination programmes. As discussed by Folayan et al. [24], stakeholder engagement in the design and

implementation of trials during epidemics is an ethical imperative; the urgency to respond to emergencies and the nature of these emergencies should not preclude engaging stakeholders in the design, implementation, and monitoring of clinical trials [24].

2. COVID-19 Vaccine Trials in Africa

The critical need for competency to conduct clinical trials in sub-Saharan Africa because the biological, economic, and sociopolitical factors associated with the emergence of diseases, epidemics, and pandemics are over-represented in many countries of the region, cannot be over-emphasized. Diversity, equity, and inclusion are important for clinical research and to guarantee quality measures of effectiveness across ethnic lines. Any significant lack of diversity (, age, gender, ethnicity/race, socioeconomic status, residential/occupational status and comorbid medical conditions.) in the clinical trial process can result in efficacy and safety outcomes that may be flawed and distorted; and when diverse populations are knowingly excluded from vaccine trials there is a real risk of making assumptions about drug safety and effectiveness that may not be accurate at all [25,26].

In July 2020, the African Union (AU) in an effort to provide appropriate vaccines to African people created a new Consortium with the global vaccine developers, international pharmaceutical companies, policy makers and organizations that conduct clinical trials in Africa: The Africa Centers for Disease Control and Prevention (CDC) Consortium for COVID-19 Vaccine Clinical Trial (CONCVACT) which has been assigned the role to assess all the possible outcomes, safety and efficacy measures of vaccines candidate tested within the African populations [27]. Based on the previous reports, the AAS clinical trials community highlighted that including the African nations and the WHO Africa Regions, only 2% of the clinical trials happens there for all kinds of vaccines. As African population contributes to a large section of the world's population the vaccines should be tested on a much larger scale. The WHO (August 2020) reported that out of the 33 COVID-19 vaccine candidates under clinical evaluation, two are in Africa [28]. This number has since increased, alas, minimally. South Africa is championing clinical trials with COVID-19 vaccine in the continent, with 3 vaccine candidates: (1) Ox1Cov-19 (Oxford University) (2) NVX-CoV2373 (Novavax, USA) (3) Ad26.COV2-S (Johnson & Johnson) [29,30]. Furthermore, 2 other trials being planned in East Africa: Kenya, in collaboration with Oxford University, and Uganda, in collaboration with the Imperial College London [28], with Uganda adjusting law on Informed Consent [31]. The reactions on the comment section of TrialsiteNews website discussing an interview with by Professor Pontiano Kaleebu on the planned trials in Uganda is a testimony on the necessity for clinical trials awareness and literacy campaigns [32]:

- Commentatory1: Why they want to test medicine in Uganda when their own people are dying more with Uganda having less deaths and cases. We are not lab rats!!!
- Commentatory2: Why are the trials on Uganda. Are we one of the countries having high numbers of deaths and infections? Why aren't they trying it on the US or Brazil or even Mexico or Nigeria? Why us? We are tired of being guinea pigs for the Western world science.
- Commentatory3: Someone clarify why a country like UK with registered deaths in tens of thousands would prefer to do trials in Uganda with infections under 2000 both deaths and active cases. Are we guinea pigs? Save us the pain and try it on your citizens, when it works u sell to us after all you have always robbed us since time immemorial.

Since the Oxford/AstraZeneca vaccine was administered in South Africa, any further rollout of the vaccine has been stopped from February onwards. The Oxford-AstraZeneca vaccine has offered a minimal protection of only 10% against the first ever variant seen there. Based on a small-scale clinical trial, the researchers mentioned that the vaccine has not showed sufficient efficacy against mild to moderate infection, though it is believed that it will offer adequate protection against more serious infection [33]. The vaccines prepared by Johnson & Johnson (J&J) and Novavax have also demonstrated ineffective response in providing protection against B.1.351, the SARS-CoV-2 variant responsible for causing majority of the infections in South Africa as compared to the older variant. The vaccines' efficacy was 57% for J&J and 49% for Novavax against mild infections, significantly lower than that observed in any other country. Currently, the Oxford team is making an effort to design a second-generation candidate that is effective against B.1.351 variant. This new vaccine might be given as a booster dose in addition to the existing one [35].

There is need for formative research by the research team for formal collection of information on the sociocultural norms, practices, and perceptions of clinical trials. The fears, myths, and misconceptions about COVID-19 make the conduct of formative research an important pre-requisite for the planning and implementation of clinical trials [24]. Understanding the concept, processes, procedures, and importance of clinical trials (with ethnic diversity), will also improve on vaccine acceptance. On its November 21st, 2020 Editorial, The Lancet highlighted the many open questions that are still to be addressed and why transparency in communication is vital [34].

2.1. Good Participatory Practice and Clinical Trials Awareness

The Good Participatory Practice Guidelines for Emerging Pathogens (GPP-EP) provides guidance for developing systems that can guide stakeholder engagement in the design, financing, and implementation of prevention and treatment trials during health emergencies. The guidelines recognize that stakeholder engagement in the clinical trials could strengthen the epidemic response, and stakeholder engagement in research conducted during epidemics is an ethical imperative [35]. On the 23rd of April 2020, WHO published a Good Participatory Practice for COVID-19 clinical trials toolbox, reemphasizing the above-mentioned guidelines [36]. Clinical trials are research studies performed in people that are aimed at evaluating a medical,

surgical, or behavioural intervention. Clinical trials are necessary to establish safety and efficacy a new treatment, like a new drug or vaccine or diet or medical device is safe and effective in people. People participate in clinical trials for various reasons: Play a more active role in their own healthcare. Assist in the research about certain health/medical conditions. Having access to better clinical care services, etc [37]. African Vaccine Regulatory Forum (AVAREF) has been in existence since 2006, created by the World Health Organization (WHO) to serve as an informal capacity-building platform aimed at improving the regulatory oversight of interventional clinical trials being conducted in Africa [38], should champion strategic communications regarding vaccine trials in the continent. Emphasis should be made on: Value of clinical research, participation in trials, ethical standards, quality control mechanisms, etc. Clinical trial performed within target regions and with the participation of local stakeholders, will enable informed decision making when advocating for the adoption of such vaccine candidate or other COVID-19 vaccines.

In addition, many poor nations are unable to train and prepare their regional, and local healthcare professionals to successfully implement COVID-19 vaccination programmes. It is believed that many low-income and middle-income countries will face logistical and administrative challenges in administering COVID-19 vaccines to their entire adult population such as involving majority of their population to undergo two-dose vaccination schedules and maintain cold or ultra-cold supply chains [39]. It is necessary to plan country level monitoring system to regulate the storage, delivery and other logistical barriers in resource-poor countries.

2.2. Vaccine Hesitancy

Vaccine hesitancy is not a new phenomenon, proliferation of anti-vaccination misinformation through social media has however, given it new urgency, especially in light of the coronavirus pandemic and hopes for rapid development and deployment of a vaccine [40]. The concept of vaccine hesitancy came into existence after the Strategic Advisory Group of Experts in Immunization (SAGE), a selected group of people working for WHO examined the rising trends associated with the vaccination process [41]. The WHO has mentioned three factors (the three C's) that play a critical role when it comes to vaccine hesitancy [42]: (1) Complacency refers to the perception of risks, complications and value related to vaccines. (2) Convenience refers to the affordability, accessibility and availability of the vaccine and how different factors are associated with it. (3) Confidence refers to the effectiveness and safety of vaccines, a trust on the government and the sectors that provide the vaccines. It implies that individuals perceive the benefits of the vaccines and have faith in the health services and health professionals [43]. WHO has emphasized that the attitude what leads to vaccine hesitancy is context specific. It is observed that individuals can refuse one specific vaccine whereas continue to receive others [44]. According to SAGE working group, the vaccine hesitancy depends on few specific factors such as: Cultural background, ethnicity, racial history, economic condition, individual's attitude and beliefs, family's perception, environmental, and political factors, personal experience, and vaccine specific issues. A broader understanding is required to evaluate the social, historical, and cultural impact that gives rise to hesitancy [45,46]. Social media analysis by Wilson and Wiysonge demonstrates clearly, an alarming footprint of vaccine hesitant groups, with studies from the early 2000s to the present showing that large proportions of the content about vaccines on popular social media sites are anti-vaccination messages, They could show that, there is a significant relationship between social media and public doubts of vaccine safety, whereby substantial relationship between foreign disinformation campaigns and declining vaccination coverage exist [40].

3. Discussion

Clinical research literacy and clinical trials awareness campaigns are two education interventions targeting health care professionals and the local populations respectively, that must be invested upon. The creation of forums or consortiums like AVAREF and CONCVACT are not enough if their activities are not visible to a broader audience. Folayan et al. succinctly analyzed the nine essential stakeholder engagement practices enumerated in the GPP-EP are applicable to the planning and conduct of COVID-19-related clinical trials in sub-Saharan Africa, also stating the need of adapting the practices depending on the culture of the societies in the region while in the field [24]. Essential stakeholder engagement practices include: 1) Formative research, relevant for formal collection of information on the sociocultural norms, practices, perceptions, traditions, and local history of research that may influence the recruitment and retention of community members as study participants [47]. 2) Stakeholder engagement plan and a communications and issues management plan based on the findings of the formative research. 3) Protocol development, i.e. rationale, objectives, design, methodology, statistical considerations, ethical considerations, and implementation of the trial shaped by the findings from formative research with stakeholders [18]. 4) Informed consent, a key consideration in the informed consent process in sub-Saharan Africa, is the engagement of third parties, who are important in the decision-making processes of individuals – relatives, and community leaders [48]. 5) Standard of disease prevention for vaccine research and standard of care for treatment research are critical to ensure that study participants have equal access to the best‐proven standard [24]. 6) Policies on trial ‐ related physical, psychological, financial, and/or social harms should be negotiated with attention paid to individuals or groups who may be vulnerable, marginalized, and/or stigmatized [35]. The joint effort of all the countries will surely lead to first COVID-19 vaccine broad immunization action in the coming months. It is the people's perspective, attitude, that will determine the success of the vaccines. Addressing issues around vaccine hesitancy following the WHO SAGE guidelines is critical, to attending vaccine uptake levels needed for herd immunity [44].

4. Conclusion

"We still know the basics of what we must do to bring this epidemic under control, and that also includes preparing people for a vaccine, there is a lot of mistrust, a lot of miscommunication that needs to be cleared up. Some of this will last well into the coming year, but there is a good chance that we can prepare communities for, and enlist the support of communities, in rolling out this vaccine" Paul Farmer [49].

Context-dependent strategic communication and stakeholder engagement are relevant for both clinical trials awareness and vaccine acceptance campaigns. Engaging stakeholders in the designing, implementing, monitoring, and disseminating COVID-19 vaccine clinical trials is crucial both for awareness and acceptance of not just the clinical trials, but ultimately, the successful vaccine candidates in sub-Saharan Africa. AVAREF, CONCVACT and other relevant regional clinical trial regulators, should promote and monitor stakeholder engagement following the GPP-EP guidelines. Efforts directed towards COVID-19 vaccine acceptance should be planned strategically before the vaccine is commercialized and distributed.

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