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COVID-19 vaccines development in Africa: a review of current situation and existing challenges of vaccine production

Following the development of the coronavirus disease 2019 (COVID-19) vaccines and the launching of vaccination, the World Health Organization has reported that the African Continent is lagging in the race to vaccinate its population against the deadly virus. The Continent has received a limited number of vaccines, implying that vaccine production needs to be scaled up in Africa. In this review, we summarize the current situation concerning COVID-19 vaccine development in Africa, progress made, challenges faced in vaccine development over the years and potential strategies that will harness vaccine production success.

Keywords: COVID-19 vaccines, Development, Africa, Barriers

Introduction

The novel coronavirus 2019 (COVID-19) is the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [1]. First discovered in Wuhan in December 2019, it has spread to about 216 countries with more than 224 million confirmed cases and at least 4.6 million deaths globally as of September 2021 [2,3].

The disease poses an extraordinary threat to global health and public safety because of high human-to-human transmission on large scales, and preventive measures could not control the rapid spreading, unlike the SAR-CoV and MERS-CoV (Middle East respiratory syndrome coronavirus), which eventually petered out due to public health containment. With preventive measures or in the absence of an effective treatment regimen, vaccine development is the fastest and surest way of stopping the propagation of the virus, bringing the pandemic under control, and preventing associated mortalities. Vaccines for COVID-19 is an alternative approach to preventive medicine that will give the population adaptive immunity to the disease [4]. Vaccination remains one of the most cost-effective public health interventions for preventing any infectious diseases [5].

Effective SAR-COV-2 vaccines will limit person-to-person transmission and the severity of the disease, which are crucial for controlling the pandemic. Different vaccine developments platforms have emerged against the SAR-CoV-2, including the live attenuated virus, viral vectors, inactivated virus, subunit vaccines, recombinant DNA, and the proteins vaccines. In addition, several pharmaceutical companies have isolated the strain of the SAR-CoV-2, and the development of appropriate vaccines has already started and developed.

Five pharmaceutical companies identified the virus's genetic sequence, conducted the most extensive clinical trials, and produced the first vaccine dose administered to the public [6]. They were the Belgian Company Janssen Pharmaceutical with its vaccine candidature based on a non-replicating viral vector, the public-private partnership between the University of Oxford and the British Company AstraZeneca having a vaccine principle similar to Janssen, the inactive vaccines from Chinese company Sinopharma working with the Beijing and Wuhan Institute, the German Company BioNTech/Pfizer using a different approach called the RNA-based technology, and lastly American Company Novavax employing the protein subunit approach. In addition, other vaccines were approved in other part of the world.

As of March 3 March 3, 2021, a total of 413 million doses of the COVID-19 vaccines have been produced [7]. China leads the World, having produced the highest number (141.6 million doses), the United States has manufactured 103 million doses. Belgium, together with Germany, have churned out about 70.5 million while India has produced 42.4 million [7]. Although delayed in Africa, the pandemic is quickly picking up speed, with an increasing number of confirmed cases and deaths [8]. Therefore, local manufacturing and scientific experts in the Continent have a role in ensuring that Africa is not being left behind on the global vaccine. Furthermore, increasing the manufacturing capacity of the COVID-19 vaccines on the Continent will ensure that Africa will not rely on or beg for vaccines whenever there is a surge in the outbreak [9]. In this review, we summarized the current situation associated with the development of the COVID-19 vaccines in Africa, the progress made, challenges the Continent faces developing vaccines and the strategies that Africa must adopt to harness the production of vaccines Continent.

Current Situation of COVID-19 Vaccine Development and Progress Made

Vaccination rates in Africa are among the lowest in the World. While the United States has administered more than 136.7 million COVID-19 vaccines as of March ending 2021, only about 23.6 million doses have been administered in the entire Continent, according to the Africa Centre for Disease Control [10]. Access to the COVID-19 vaccines and their related challenges faced by African countries will be avoided if the vaccines are developed in Africa. The Continent is receiving a relatively small amount of doses often with unpredict-

able supplies and little warning about when they will arrive or what type of vaccines they will get [11].

There have been efforts to develop an effective and safe vaccine on the Continent [12]. Some African countries have geared up to manufacture the approved vaccine for the Continent. Currently, two countries are the hub for manufacturing the COVID-19 vaccines, namely South Africa and Egypt while other countries have made remarkable progress [12,13].

South African pharmaceutical firm Aspen signed an agreement with the US-based Johnson & Johnson in November 2020 for the technical transfer and commercial manufacture of their COVID-19 vaccine candidature (Ad26.COVS-2) [14]. In that aspect, Aspen Pharmacare performs formulation, filling, secondary packaging, and supply of the vaccine, which all take place at its Sterile Facility situated at Port Elizabeth, South Africa [14]. This facility, also known as SVP2, packages the vaccine product into vials, ampoules, and pre-filled syringes. At present, the facility has obtained accreditation from International Regulatory Authorities to supply lifesaving medicines to both the domestic and international markets. Aspen has been in the manufacturing system for a trusted period and is well known for developing generic antiretroviral drugs in Africa. This is the second contribution the Company has made to combat the coronavirus as it produces the generic anti-inflammatory drug dexamethasone (COVID-19 treatment).

At the time of writing, the technological transfer from Johnson & Johnson was successful and completed, with both parties now committed to produce and supply more than 300 million doses of the COVID-19 vaccines in Africa by the end of June 2020 [14]. When clinically evaluated, phase 3 trials showed that the vaccine was 66% effective in stopping moderate to severe COVID-19 and 85% effective in preventing the severe form of the disease 28 days after vaccination [15]. The vaccine has also proven effective against multiple virus variants, including the South African B.1.351 lineage [15]. Compared with other candidates, Moderna's COVID-19 vaccine reported 94.5% efficacy while Pfizer reported 95%. In comparison, Johnson & Johnson vaccines are based on primary endpoint prevention of moderate/severe cases, the latter target mild cases [15]. In a study undertaken by the Data and Safety Monitoring Board (and independent group of experts), there were no adverse safety concerns related to the vaccine. It was generally well tolerated [15]. The Johnson & Johnson vaccines have also received clearance and emergency authorization from the European Union and the United States. Cur-

rently, Aspen's vaccine is compatible with standard distribution channels. It has been estimated to remain stable for 2 years at -25°C to -15°C with a maximum of 3 months of routine refrigeration at a temperature of 2°C–8°C, enabling the vaccines to be delivered to remote areas of Africa [16]. The Company can presently manufacture 600 million doses of the vaccine, but the intention to produce such a large number has not been discussed between the two parties involved [17]. The number of doses that the Company can produce to supply the whole Continent depends on the negotiations between African governments and Johnson & Johnson. The South African government has signed another agreement with Johnson & Johnson to secure 11 million doses of the vaccine with 20 million doses more to follow [17]. At least half of the South African population will receive a vaccine manufactured in their own country [17]. Deliveries of doses destined to the 55 African Union member states are set to begin in the third quarter of the year 2021, and the availability of the vaccines will be subjected to approval by regulatory authorities of individual member states [16].

South Africa had led African vaccine production through its public-private partnership. Currently, the country has two COVID-19 vaccine production partnership agreements [18]. The first one is between Aspen Pharmacare and J & J and Biovac and US-based Immunity Bio Inc., which has been stipulated to commence in the second quarter of the year 2021 [18]. Biovac, together with Immunity Bio Inc., aims to build a pharmaceutical plant that makes active pharmaceutical ingredients and will start with COVID-19 shots. The two parties are now conducting phase 1 trials both in South Africa and the United States. The project may produce about 100 million doses of the COVID-19 vaccine per year [18]. Although not famous like those made by giant companies such as Johnson & Johnson and AstraZeneca, Immunity Bio's vaccine has peculiar advantages. The vaccine contains hAd5T cells that kill infected cells and could work effectively against different strains of the virus, according to Biovac [18].

The Egyptian government aimed to sign an agreement with China Sinovac Biotech to manufacture the COVID-19 vaccines in the country [19]. Egypt also hoped to become a center or manufacturing hub of the vaccine for domestic use or export to other African countries. The country has not received any Sinovac vaccine but has partnered with another Chinese vaccine developer called Sinopharm to acquire 650,000 doses [19]. Sinovac had previously provided 160 million doses of its COVID-19 vaccine to 18 countries already including China

[19]. The manufacturing process is set to be carried out inside the factories of the Egyptian Holding Company for Biological Products and Vaccines (VACSERA). Once it becomes operational, the facility would produce jabs under license from Sinovac for distribution worldwide, including in Africa and a portion of the Arab World [19]. To this end, the World Health Organization (WHO) has sent experts to assess the performance of VACSERA for possible manufacturing to kick off. Egypt's plan to become the manufacturing hub of Africa dates back to July 2020 after the country hosted and participated in clinical trials of the Chinese vaccine developer Sinapharm and was the first country on the Continent to receive supplies from this manufacturer [19].

On the 7th of April 2021, Algeria announced its intention to start the production of Russian's Sputnik V COVID-19 vaccines in September [12]. The partnership with Moscow aims to meet the vaccine challenge for African countries [12]. The Algerian state pharmaceutical products firm (Saidal) will produce the vaccine with the help and transfer of technology provided by the Russian side [12].

In a similar development within the North African Region, Morocco, under the auspices of H.M. King Mohammed VI, signed a memorandum of understanding with the Swedish Company "Recipharm" on the 5th of July 2021 to establish and scale up the manufacturing of COVID-19 jabs and other vaccines [20]. The initiative, which is expected to become functional by 2023, was purported to give Africa vaccine sovereignty and access to future bio-therapeutics [20].

Most recently (on the 10th of July 2021), the Senegalese government together, with the European Union, the United States, several European governments and other partners signed an accord to finance vaccine production at the Institut Pasteur of Dakar [21].

Challenges Faced by Africa in Developing Potential Vaccines and Strategies to Harness Production

Vaccination is one of the essential medical practices ever introduced; it has been vital to reduce mortality, improve life expectancy and economic growth [22]. Unfortunately, Africa is lagging in achieving the chances of reducing the burden of disease by vaccination. The Global Alliance for Vaccines and Immunization (GAVI) is aiding in COVID-19 vaccines becoming widely introduced [22]. Yet, the concern is how to sustain such vaccines and whether countries would afford new vac-

Table 1. Highlights current vaccine manufacturers across the African Continent

Country	Institution	Vaccine type
Senegal	IPD	WHO pre-qualified yellow fever vaccine
Egypt	VACSERA	DTP and some fill-finish
South Africa	Biovac	Fill-finish
Tunisia	IPT	Limited BCG and rabies
Ethiopia	EPHI	Starting up

From African Vaccine Manufacturing Initiative. Establishing sustainable vaccine development and manufacturing in Africa [Internet]. Cape Town: African Vaccine Manufacturing Initiative; 2017 [cited 2021 May 15]. Available from: https://dcvmn.net/IMG/pdf/26th_wiliam.pdf [24].

IPD, Institut Pasteur de Dakar; WHO, World Health Organization; VACSERA, Egyptian Holding Company for Biological Products and Vaccines; DTP, diphtheria–tetanus–pertussis; IPT, Institut Pasteur in Tunis; BCG, bacille Calmette–Guérin; EPHI, Ethiopian Public Health Institute.

cine introduction after graduation from GAVI [22]. Over the past decades, Africa has accounted for only a few projects that involve vaccine development. About 70%–80% of pharmaceuticals products used in the Continent are imported [10]. As a result, vaccine production in Africa has not yielded much success, and currently, African manufacturers produce less than 1% of vaccines utilized across the Continent [23]. Some manufacturers have ceased production due to the inability to compete with imported vaccines. Recently, fewer than 10 African vaccine manufacturers have been on the Continent (Table 1) [23,24]. Most African healthcare providers operate under tight budget constraints which they prefer to opt for imported vaccines [25]. African vaccine manufacturers find it challenging to be cost-competitive in the long run compared to their foreign counterparts [25]. They also depend largely on global supply chains which, are sometimes hampered by trade barriers, monopolized supply, and even export bans [25].

The slow progress goes beyond the question of wealth or capacity. Other middle-income countries like India and Vietnam are doing well in that direction, and all have vaccines in human clinical trials [26]. Middle-income countries in Africa such as Egypt, Morocco, Nigeria, and South Africa should have recorded the same happenings [26].

One of the challenges facing the capacity of the Continent to produce its vaccine, including the COVID-19 vaccine, is the dependability on external suppliers, which pose a severe problem to African's health resilience. African countries and their governments prefer ready-made vaccines that are imported. Consequently, they focus on securing deliveries of these vaccines than creating their own. This is because they

are able to secure funding or pool resources from foreign donors to facilitate payment and procurement of vaccines which is easier compared to the cost of vaccine development, pre-clinical testing and human trials in Africa [26].

This carries out funding projects for the development of any type of vaccine complex in Africa [26]. Above all, insufficient funds for medical scientists, research, and development and the undermining of African technological innovations to create a market for Western-led products are some root causes of the problems with vaccine development and distribution in Africa [26].

The African Union's vaccine development and access strategy have been limited to supporting clinical trials and accelerating post-trial product regulatory decisions [27]. The commission has already shipped 6 million doses of the Johnson & Johnson one-dose COVID-19 vaccines to be made available to its member countries through the African Vaccine Acquisition Trust [28].

Therefore, clinical trials done in Africa have been made possible through foreign companies such as Johnson & Johnson and AstraZeneca. Africa has the human resources, the know-how, and the intellectual capacity but still believes or has a strong preference to buy imported vaccines rather than developing one. African countries also like relying on donations from countries like China and the global vaccine sharing arrangement (COVAX), which has promised to get enough vaccines to cover 20% of its population. The African Union in January 2021 stated that it had secured 270 million COVID-19 vaccines to cater for 10%–15% of the Continent's population [26]. However, the COVAX program, which most African countries hope for, is like a drop in the ocean and will only vaccinate a small section of the population, leaving most countries behind.

For the COVID-19 vaccines to be produced successfully in Africa, it requires high upfront investment and funding, which aren't enough or very supportive on the Continent because of the preference for imported vaccines. It may be daunting to re-purpose facilities for large-scale production with this attitude. A study carried out by the African Vaccine Manufacturing Initiative (AVMI), the WHO, and United Nations Industrial Development Organization (UNIDO) showed that the cost of building a vaccine manufacturing plant in Africa will cost \$60–\$130 million dollars [29]. Recently, the Chief Executive Officer of Biovac estimated that the cost of producing up to 1 billion doses of vaccines in his facility would be between 200–336 million dollars [30]. African scientists also have

the expertise and the needed experience to deal with the pandemic. Therefore, African governments should fund initiatives like local vaccine production instead of relying solely on a vaccine made outside the Continent. Significant state-backed investments and grants to produce vaccines are available in wealthier countries, whereas African manufacturers face the high cost of production with little or no funding. Without commitment and support in this area, the COVID-19 vaccine or vaccine production in Africa will forever remain a difficult challenge. When African countries can finance these initiatives, there will be solid political leverage to access more vaccines. Investment in local innovation will be enhanced to solve health challenges in the Continent.

The sustainability of the COVID-19 vaccine industrial project in Africa subsequently requires patronage and purchasing support from African governments. There must be sufficient demand for the vaccine produced in Africa. African countries must commit to buying their manufactured vaccine to prepare the Continent to graduate gradually from receiving foreign assistance. Building on this current vaccine development, Africa also has the responsibility to deploy an integrative approach pulling together strategies, resources, and partnerships to sustain the initiative. There are technical partnership issues on the other side the Continent needs to focus on. The deal between Aspen and J & J to shift technology to the Continent for homegrown COVID-19 vaccines is an essential move offering a partial solution. However, the complexity of the manufacturing process (pre-requisite supplies, facilities, equipment, and high scientific expertise) is beyond the purview of Africa itself and requires both national and international partnerships.

It sometimes demands foreign pharmaceutical organizations to transfer the know-how and right for producing a vaccine to other companies, such as the case of AstraZeneca, allowing the Serum Institute of India and S.K. Bio in the republic of Korea to produce its COVID-19 vaccine [9]. Such cooperation must be supported and maintained by African governments, the private sector, global bodies, partners, and other stakeholders. According to UNIDO, long-term political support is vital for the strategic importance of local production to be effective demonstrable.

The recent signs of progress should be prioritized to create a favorable ecosystem on the Continent. Equally, Africa needs to strengthen further partnerships and connections with these foreign companies that have their vaccine patents can license them to African vaccine manufacturers and have the capacity

to fill and finish the manufacturing process.

Conclusion

African scientists have the expertise and experience to deal with fast-moving infectious diseases [31]. They have developed solutions to prior infectious disease outbreaks, if African governments were as agile as other countries, and had chosen to fund the creation or manufacturing of a local vaccine instead of solely relying on vaccines made elsewhere in the World and distributed to the Continent [26]. The successful development of COVID-19 vaccines in Africa would not only have given African countries more political leverage to access more vaccines, but it would have also encouraged more investment in local innovations and products for other diseases and healthcare challenges in the Continent [26]. In Africa, manufacturing and supply capacity must be addressed urgently to prevent this from happening again in a future pandemic, which is inevitable [23]. Increasing the manufacturing capacity for COVID-19 vaccines in Africa could help ensure that the Continent doesn't "have to beg for vaccines when there is an outbreak," said William Ampofo, chair of the AVMI [9]. However, Africa's lack of vaccine production capacity represents a severe lack of resilience that has significantly impacted African countries. This must be addressed urgently to prevent a repeat in future pandemics, which are inevitable [23].

Constrained global production disproportionately impacts Africa, as dependence on external suppliers subjects it to the consequences of vaccine nationalism and stockpiling and international supply-chain disturbances. In addition, delays and uncertainty around vaccine arrivals will result in adverse health and economic outcomes [23].

To achieve this goal, policymakers should put more focus on exploring financing options, assessing the viability of proposed manufacturing models, developing plans to strengthen the value chain, working with biotech businesses to assess the level of expertise required to drive local manufacture and working towards improving demand certainty for developing pan-African vaccine-manufacturing industry [23].

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