The Urgent Need to Intensify Vaccine Development and Manufacturing in Africa:

Lessons from Emerging Pandemics

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Abstract

Over the years, the African continent has been severely plagued by disease outbreaks, most of which have resulted in devastating pandemics. Despite having the greatest burden and impact of these disease outbreaks, regional efforts to develop and manufacture vaccines in the continent have been inadequate, with a potential impact on pandemic preparedness and readiness efforts in the continent. Given that disease outbreaks are still likely to occur in the future, we discuss the urgent need to intensify vaccine development and manufacturing in Africa based on the lessons learnt from emerging pandemics.

An Overview of the Emergence of Pandemics in Africa in Recent Years

The last two decades have been characterized by a series of disease outbreaks that resulted in pandemics globally [1]. The African continent, which is home to a greater percentage (70%) of the least developed countries globally [2] and with illequipped health infrastructure and insufficient health workforce, has borne the greatest burden that these pandemics have had on countries [3, 4]. A recent study [5] revealed that the sudden rise of disease outbreaks -although most have been curtailed- is due to factors tied to evolving biological systems, human susceptibility to infection, and breakdown of public health measures, among others. Specifically, the chikungunya virus, monkeypox virus, rift valley virus, yellow fever virus, zika virus, etc. are some of the disease outbreaks that have plagued the African continent in recent years [5]. Cholera, which is amongst the most critical of these disease outbreaks, remains a significant cause of illnesses and deaths in many African countries compared to other continents of the world [6]. Globally, 4 million cases and 143000 deaths respectively due to cholera are reported annually, of which 54% occur in Africa [6]. Another critical disease outbreak in Africa worth highlighting is the Ebola virus which originated in the Democratic Republic of Congo and persisted from 2014 to 2016 with roughly 30,000 cases and 11,000 confirmed deaths in nine countries in West Africa [7]. The coronavirus-disease-2019 (COVID-19) which is the most critical of these disease outbreaks and was named the "greatest pandemic of the 21st century" [8] led to a global shutdown of economic and social activities in order to curtail the spread and transmission of the virus. As of the time of writing, reports from the World Health Organization (WHO) reveal that the COVID-19 pandemic has resulted in over 601 million confirmed cases and 6.5 million deaths globally [9].

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The Role That Vaccines Have Played in Mitigating the Spread of Pandemics

The development of safe and efficient vaccines against diseases that greatly increase morbidity and mortality has been one of the most significant scientific advancements of the twentieth century [10]. The recent advent of the COVID-19 pandemic further emphasized the need for and importance of vaccines in mitigating future pandemics [11]. This is demonstrated by over 217,000 deaths from the estimated 8.5 million COVID-19 infections that have occurred in the African continent [12]. With the development of COVID-19 vaccines, several success stories in vaccination coverage have been recorded mainly in highincome countries such as Australia and Europe with over 55% coverage, and Portugal and the UAE with a coverage rate of over 85% [12]. However, only 5% of African populations have received access to COVID-19 vaccines [13] despite the pledges of the COVID-19 Vaccines Global Access (COVAX) initiative to allocate sufficient vaccine doses to 47 countries in Africa with the motive of achieving at least 20% of vaccination coverage [14]. This indicates the limited progress in achieving herd immunity for COVID-19 and also reflects the disparities in ensuring equitable access to healthcare [15]. Recently, there have been an increased effort by the COVAX initiative and the African Vaccine Acquisition Trust (AVAT) to secure 720 million doses of COVID-19 vaccines for African countries in order to achieve 60% coverage in a bid to ensure equitable roll-out of COVID-19 vaccines by June 2022 [16]. Despite these efforts to attain equitable COVID-19 vaccine access in the region [17], there have been an increasing concern about the low vaccination uptake especially in sub-Saharan Africa [18]. Studies revealed that the low levels of vaccine uptake in the African continent are partly due to factors tied to high vaccine hesitancy, which has been reported in 33% of the total population in Mali [19], 50% in Zimbabwe [20], 85% in Cameroon [21], and in Ghana respectively [22]. This high rate of vaccine hesitancy is also attributed to perceived low risk and complacency, perceived low vaccine effectiveness and fear of side effects, anti-vaccine campaigns by some religious leaders [23], and misinformation and misconception about the COVID-19 vaccine [24].

Vaccines are a crucial part of a good health security system and as a result, they minimize mortality, increase life expectancy, and foster economic growth [25]. However, African countries are lagging behind in reducing the disease burden by vaccination -accounting for the high incidence of infectious disease mortality [11]. This is majorly attributed to the lack of equitable access to COVID-19 vaccines, which would otherwise have been averted if African countries had the required pharmaceutical manufacturing capacities to develop vaccines for regional use [26]. In light of this, African countries therefore, must focus on collaborative approaches to building capacity for vaccine development.

Current Progress and Efforts Towards Vaccine Development and Manufacturing in Africa: Evidence from South Africa and Egypt

Over the past decades, the African continent which is made up of 54 countries has been plagued by a myriad of infectious diseases, all of which underscored the need for vaccine manufacturing, supply, and distribution infrastructure in the continent [27]. The history of vaccine manufacturing in Africa can be traced back to the establishment of the Vacsera company in Egypt in 1881 [25]. However, vaccine manufacturing efforts in the continent are currently reported in 13 countries as seen in Table 1. The WHO has estimated that there are fewer than 10 African countries directly involved in vaccine development and manufacturing [28]. Most of the vaccine producing and manufacturing companies are situated in five countries: Egypt, Morocco, Senegal, South Africa, and Tunisia [28] with the rest of the local companies taking part in drug substance manufacturing (i.e. manufacture of active pharmaceutical ingredients), packaging, labeling, filling, and finishing steps.

Country	Vaccine manufacturing facilities	Date of Establishment	Manufacturing stage
Algeria	Saidal	1982	Drug substance manufacturing Import for distribution
Botswana	Botswana Baylor Children's Clinic	2026	Drug substance manufacturing
Egypt	VACSERA	1881	Fill & finish Pack and label
	Biogeneric Pharma	2005	Research
	Minapharm	1958	Research Fill and finish
Ethiopia	Ethiopian Public Health Institute	1995	Pack & label Import for distribution
Ghana	Ghana Health Ministry	2024	Drug substance manufacturing
Kenya	Afrigen	2022	Drug substance
Morocco	Sensyo Pharmatech	2024	Fill & finish
	Institut Pasteur Du Maroc	1929	Import for distribution
	Galenica	1978	Drug substance fill & finish Pack and label
	Sothema	1976	Pharmaceutical manufacturing
Nigeria	Innovative Biotech Ltd	2005	Research & development
	Biovaccines Nigeria Limited	2005	Research Pack and label
Rwanda	Rwanda Biomedical Center	2023	Drug substance manufacturing
Senegal	Institut Pasteur De Dakar	2009	Drug substance manufacturing Fill and finish Pack and label
	Aspen	1997	Fill & finish
South Africa	Biovac	2003	Research & development Drug substance manufacturing Fill & finish Pack & label Import for distribution
Tunisia	Institut Pasteur Tunis	1956	Drug substance manufacturing Fill and finish
Uganda	Dei Biopharma	2022	Drug substance manufacturing

Table 1. Showing vaccine manufacturing capacities in Africa

Source: <u>https://bit.ly/3AOwjcx</u> Disclaimer: For educational purposes only.

Africa has some of the lowest vaccination rates globally [29]. For context, while 68% of the total population in the United States has been fully vaccinated [30], recent reports from the Africa Centre for Disease Control reveal that only 21.2% of the total population in Africa has been fully vaccinated [31]. Equitable access to COVID-19 vaccines remains a significant challenge faced by African countries [32]. However, this challenge can be addressed if COVID-19 vaccines are developed in Africa, by Africa, and for use in Africa. Notably, country-specific efforts and initiatives to produce a safe and effective vaccine in Africa have been in pipeline with a number of successes recorded on multiple fronts [29]. Currently, South Africa and Egypt are the hubs for COVID-19 vaccine manufacturing in Africa [29] while other countries such as Algeria, Morocco, Rwanda, Senegal, Tunisia, etc. have made remarkable progress. It is, therefore, worth highlighting the current progress and steps being explored by South Africa and Egypt in order to provide evidence-based insights for other countries that may pursue similar offerings.

a. South Africa

In November 2020, South African pharmaceutical company, Aspen and US pharmaceutical company, Johnson & Johnson, agreed to the technology transfer and commercial manufacturing of their COVID-19 vaccine candidate [33]. As such, Aspen is responsible for the formulation, filling, secondary packaging, and distribution of the vaccine.

Currently, the company has been accredited by international regulatory agencies to export pharmaceutical products to both local and international markets [29]. Despite this momentous progress and success recorded as the first facility licensed to manufacture COVID-19 vaccines in Africa, it is particularly worrisome that the company has not received a single order or procurement from international agencies or countries, and plans to shut down its operations are currently at the forefront of the discussion [34]. Given this current scenario, it can be projected that a number of African countries would give up plans to explore the vaccine manufacturing prospect in the near future -which is a step back in the journey towards regional self-sufficiency and reliance.

b. Egypt

In early 2021, the Egyptian government signed an agreement with Chinese pharmaceutical company, Sinovac to manufacture the COVID-19 vaccines [35]. Additionally, Egypt aimed to establish itself as a hub for the manufacturing of the vaccine for domestic use or sale to other African nations. The manufacturing process has already begun operations with over 30 million COVID-19 vaccines manufactured already [36].

The current COVID-19 pandemic is indeed a wake-up call to the African continent as it brought to the limelight that existing efforts in the continent towards building capacity for vaccine manufacturing, supply, and distribution have been insufficient, compared to countries in other continents. This has resulted in the implementation of more innovative strategies such as technology and knowledge transfers, the setting up of more manufacturing plants in the continent, and the review of the Pharmaceutical Manufacturing Plan for Africa (PMPA) [37]. In 2012, the Assembly of Heads of State endorsed the PMPA business plan which consists of a package of technical solutions to some of the critical challenges confronting the African pharmaceutical industry [37]. While this initiative had its foreseeable impact on the state of pharmaceutical manufacturing in the region, the reality is that Africa did not witness the intended impact. It can be argued that the issue of scaling up pharmaceutical manufacturing in Africa was given little priority until about a decade later when the COVID-19 pandemic struck and disrupted drug importations into the region. Therefore, countries in the African continent must draw insights, consolidate lessons, and leverage the experiences gained during the COVID-19 pandemic to develop and manufacture vaccines.

The Deficit in Vaccine Development and Manufacturing in Africa: Lessons Learnt from the COVID-19 Pandemic

The COVID-19 pandemic revealed the acute lack of pharmaceutical manufacturing capacity that exists in many African countries which are evidenced by emerging reports from the Democratic Republic of Congo [38], Nigeria [39], Zimbabwe [40], and Sierra Leone [41]. During the COVID-19 pandemic, it was apparent that Africa has a long way to go in the manufacture of vaccines as countries in the continent were still struggling with the importation of active pharmaceutical ingredients (APIs), excipients, and other basic pharmaceutical commodities; whereas other countries were accelerating and intensifying their efforts towards producing a vaccine to curtail the spread and transmission of the virus. Furthermore, recall that wealthy nations and big pharmaceutical companies were unwilling to temporarily abolish their patents and intellectual property rights on COVID-19 vaccines, which would have made the COVID-19 vaccine manufacturing technology accessible to African pharmaceutical companies [42, 43]. Noteworthily, it has previously been established that pharmaceutical patents have significantly hindered access to medicines in sub-Saharan Africa [44] –as witnessed in the case of the COVID-19 vaccines. These occurred despite the fact that African countries paid twice as much for vaccines compared to these wealthy nations. The reality is that the African pharmaceutical industry is underdeveloped and is still in the process of building its capacity to fulfill the vaccine manufacturing needs and demands of the continent [45]. Lessons learnt from the COVID-19 pandemic reinforce the need for the continent to invest resources in the design, research, discovery, development, and distribution of vaccines, medicines, and diagnostics to meet present and future needs. The development of infrastructure and investment in capacity will be a key component of the response toward vaccine manufacturing in Africa, and it can lay the groundwork for quick and efficient responses to disease outbreaks that are likely to occur in the future.

While there has always been an emphasis on the need to intensify vaccine manufacturing in Africa, it is necessary to pay significant attention to the factors responsible for the low vaccine manufacturing capacity which exists across African countries. This would ensure a paradigm shift towards the development of a comprehensive, region-specific, and institutional response.

Factors Responsible for the Low Vaccine Development and Manufacturing Capacity in Africa

The manufacture of vaccines is considered to be complex and one that requires huge financing, and a firm regulatory system that will institute policies to ensure that the products and medicines are standard and safe [46]. Currently, only a little amount of the vaccines that have been administered in Africa were sourced from manufacturers in the continent [47]. As demonstrated in a report by the United Nations Economic Commission for Africa (UNECA), an extensive quota of Africa's vaccine needs is covered by importation, out of which Europe and India account for 51.5% and 19.3% respectively amongst others [48].

Africa's dependence on the importation of vaccines is a result of many interwoven factors impeding local manufacturing which include limited availability of finance, an unstable supply chain that makes access to raw materials difficult, and lack of a regulated environment to encourage manufacturing [49]. Consequently, the lack of upscale capacities involved in the packaging, labeling, and finishing of these products has contributed to a minimal level of vaccine manufacturing in Africa [46].

Lastly, vaccine manufacturing requires thoroughly trained staff with vast technical know-how, which might even be specific to a particular vaccine, whereas there are not enough training opportunities and facilities in Africa [50]. As of now, there are only a few available programs on vaccine manufacturing and these few focus mainly on clinical training. As a result, graduates of such programs are not sufficiently equipped with the knowledge and technicalities required for vaccine development and manufacturing [50]. Currently, about 3000 equipped personnel are employed full-time in Research and Development (R&D) organizations, whose primary focus is not even on vaccine manufacturing [50]. However, the manufacturing of vaccines in Africa will need huge consistent financing, as well as commitment from relevant stakeholders, to expand the capacity of research, and maintain regulatory standards [51]. Despite these factors, barriers, and setbacks which have hampered vaccine development and manufacturing in Africa, the continent has, however, recorded a number of successes and significant strides on multiple fronts.

Recommendations

The lessons learnt from the COVID-19 pandemic and other pandemics present an unprecedented global humanitarian and medical challenge and these have stimulated unparalleled progress in the development of vaccines and other therapeutics in many countries. These events highlighted the limited manufacturing capacity for vaccines and therapeutics in Africa necessitating the urgent need for the African continent to invest resources in the design, research, discovery, development, and distribution of vaccines, medicines, and diagnostics in order to mitigate future pandemics. Even though the continent has recorded a number of successes and significant strides on multiple fronts, African leaders and relevant stakeholders must not relent in their efforts to further build capacity for manufacturing vaccines, diagnostics, and therapeutics, as this could transform the continent. More so, this strategic investment could help Africa build a platform for producing vaccines against other diseases plaguing the continent.

Maintaining vaccines efficacy by ensuring an unbroken cold chain from production to patients is a major challenge for many African countries. For instance, of all the health institutions situated in Ethiopia, only about 48% have a dependable cold chain [52]. Therefore, there is a need to put in place measures to improve the stability and efficacy of vaccines outside the manufacturing plants.

Furthermore, the ongoing efforts to build and strengthen regional monitoring, regulatory and laboratory networks of the existing facilities in the continent are crucial as they can help to raise the overall standards and assist national reference centers and public health institutes. Organizations such as COVAX, UNICEF, or the Global Alliance for Vaccines and Immunization (GAVI) should be committed to procuring vaccines from local manufacturers in the African continent to sustain these nascent industries as this will ultimately facilitate their commitment to establishing sovereignty over health and medicines.

The reduction in vaccine hesitancy and more confidence in medical professionals in the continent will further increase the demand for vaccines. As such, governments and the media must intensify and continue with the awareness efforts on the importance and benefits of vaccines. More so, most African countries lack adequate training capacities and facilities as vaccine manufacturing and development requires expertise and technical know-how [52]. Adequate measures should, therefore, be put in place to ensure that the personnel involved in vaccine manufacturing are thoroughly trained in advanced vaccinology courses and provided the required facilities to further strengthen the capacity of the healthcare workforce in vaccinology.

Conclusion

African governments should work holistically to ensure the development of infrastructure and invest in capacities that will be a key component toward vaccine manufacturing in the continent. Significant and concerted efforts should also be directed to the factors responsible for the low vaccine manufacturing capacity which exists across African countries. This will ensure a paradigm shift towards the development of a comprehensive, region-specific, and institutional response that

will accelerate vaccine development and manufacturing efforts in the continent, whilst simultaneously strengthening our preparedness and readiness efforts in the event of another disease outbreak.

The opinions expressed in this paper are those of the authors.

Conflict of Interest: None

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