cTAP

COVID-19 TRANSPARENCY & ACCOUNTABILITY IN AFRICA

Vaccine Equity In Africa

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List of Acronyms

UN	United Nations
AU	African Union
WHO	World Health Organization
COVAX	COVID-19 Vaccines Global Access
SARS	Severe Acute Respiratory Syndrome
SARS CoV	SARS-associated Coronavirus
SARS CoV2	Severe Acute Respiratory Syndrome Coronavirus 2
MERS CoV	Middle East Respiratory Syndrome Coronavirus
HIV	Human Immunodeficiency Virus
ART	Antiretroviral Therapy
PrEP	Pre-exposure Prophylaxis
PEP	Post-exposure prophylaxis
ICU	Intensive Care Unit
DNA	Deoxyribonucleic acid
RNA	Ribonucleic acid
HICs	High Income Countries
LMICs	Low and Middle Income Countries
ICESR	International Covenant on Economic Social and Cultural Rights
OECD	Organisation for Economic Co-operation and Development
EPI	Expanded Programme on Immunisation
ACT Accelerator:	Access to COVID-19 Tools (ACT) Accelerator
AVAT	African Union's African Vaccine Acquisition Trust
R&D	Research and Development

Executive Summary

Pandemics and other public health emergencies have claimed hundreds of millions of lives in world history, with varying degrees of impacts on past civilisations and countries' economies in recent times. In 2019, COVID-19 joined the list of recent public health emergencies with a global devastation that crippled health systems and national economies across all regions. According to DEVEX's Inside Development (Jenny Lei Ravelo, n.d.), global cumulative cases, as at the time of this report, is close to 500 million with more than 6 million cumulative deaths.[1] Europe and the Americas have the highest cumulative cases and deaths while Africa—with about 9 million cumulative cases and 200,000 deaths—has the least.

Being the most successful and cost-effective public health interventions available, vaccines have contributed to the prevention and responses to disease outbreaks and public health emergencies. Sadly, despite the high incidence of mortality caused by infectious diseases, Africa remarkably does not have the capacity to manufacture vaccines essential to reduce mortality, improve life expectancy, and promote economic growth (Makenga G B. S., 2019). The continent has depended largely on vaccines manufactured from other climes for its vaccination needs. This became a huge challenge for its vaccine response to COVID-19, leading to inadequate and inequitable vaccine distribution to the African population.

The outstanding achievement of the timely development and manufacture of COVID-19 vaccines within a short period became threatened as countries with vaccine manufacturing capacities as well as other wealthier ones cornered available stocks for their population—vaccine nationalism. This has left other nations, including all countries in Africa at the last rung of the ladder to access the vaccines. In anticipation of this challenge and its impacts, on the 24th of April, 2020 the World Health Organization (WHO) hosted the launch of the Access to COVID-19 Tools (ACT) Accelerator.

The ACT Accelerator is a global collaboration to accelerate the development, production, and equitable access to COVID-19 diagnostics, therapeutics, and vaccines with a COVID-19 Vaccines Global Access

1. COVID-19 — a timeline of the coronavirus outbreak | Devex

(COVAX) Facility effectively functioning as the vaccine pillar of the Accelerator.

Currently, COVAX has shipped about 700 million COVID-19 vaccine doses to 54 countries in Africa, however, this is far below the needed doses to fully vaccinate 70% of the continent's population. This was at a time fully vaccinated countries were administering booster doses. With the inadequacy of vaccine supply to Africa, as a result of other factors like inadequate storage and logistics capacity, a huge portion of the supplied doses still were not utilised, further contributing to inequitable vaccination in the region. The lack of Research and Development (R&D) infrastructure and personnel, technology transfer and regulatory capacity, medical technology patenting as well as other internal factors, particularly the weak health system further contributed to inequitable access to the COVID-19 vaccine and vaccination in Africa. Vaccine inequity portends serious threats to COVID-19 response and has implications to global health. Some of these, highlighted in this report, include the risk of new viral variants which has continued to weaken vaccine response to the COVID-19; risk of greater inequality and reduced global resilience to existential threats and risk of a weakened global economy. The low vaccination rates also have implications on vulnerable groups in Africa, since the prolonged pandemic may result to longer shutdowns and stricter non-pharmaceutical response measures. These have led to disruption of maternal and neonatal health as well as education services causing a marked increase in gender-based violence and undermined global progress towards gender equity and equality as well as increased risk of child marriage and forced labor.

To effectively respond to the ongoing pandemic and prevent inequity of this scale when another pandemic arrives, equity and equality of the global public health system must be considered. The interests of the whole world, not just the interests of wealthier countries, must be prioritised. To achieve this, especially in Africa, in the short term, the commitments made by wealthy nations to donate COVID-19 doses must be fulfilled. Furthermore, vaccine uptake platforms and facilities like COVAX and AVAT must be prioritised while supply queues by world's wealthy countries for COVID-19 vaccines must reduce. On the medium and long terms, African nations must strengthen their health systems for effective vaccine rollout and crisis response. Africa must also implement strategies to ramp up vaccine R&D, vaccine manufacture and development on the continent.

Introduction

COVID-19 has become one of many devastating public health emergencies in the world history. Its outbreak since 2019 has wreaked havoc, with hundreds of million reported cases and millions of fatalities, not forgetting the socio-economic impacts across every country and regions of the world. Its outbreak and impact have shown similar trends with past global outbreaks, some of which also reported enormous fatalities. More travels and globalisation have contributed to the advanced mobility of pathogens, thereby increasing the rate of emergence of infectious diseases or disease outbreaks. Repeated outbreaks of infectious diseases with epidemic and pandemic potential have devastating effects on health systems, quickly eroding any progress made towards Universal Health Coverage. For instance, many countries abandoned various disease programmes and health services to respond to the COVID-19 pandemic (World Health Organization, 2020). [2] This has specifically led to increased disease burden and setbacks.

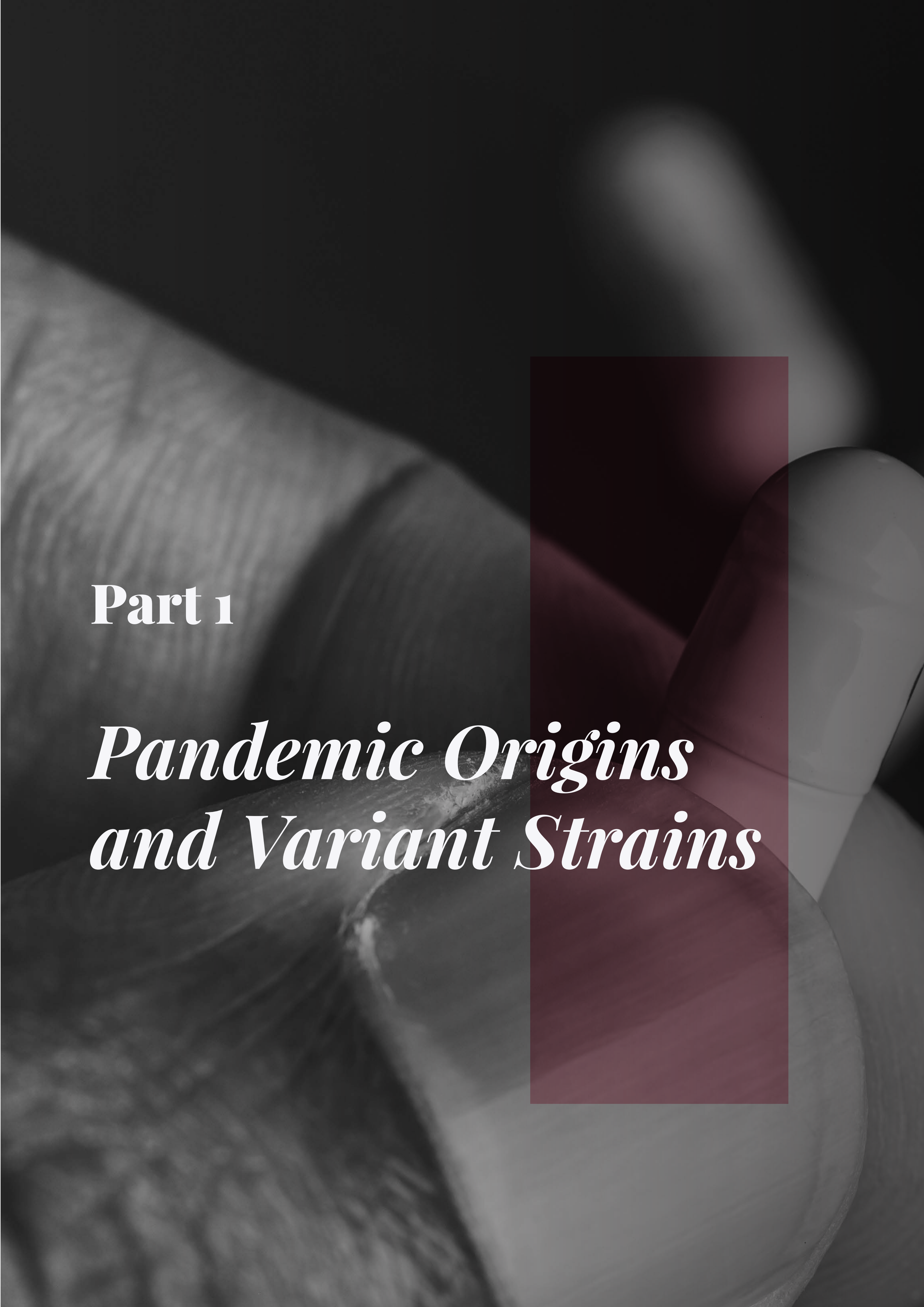
During the 20th century, improved sanitation, nutrition, and the widespread use of antibiotics as well as vaccines reduced the spread of diseases and associated mortality. Vaccination was one of the public health measures with the greatest impact on the reduction of the burden from infectious diseases and associated mortality, especially in children (World Health Organization – Media Center, 2011). Unarguably, vaccination has proven to be one of the most successful cost-effective public health interventions saving millions of people from illness, disability and death each year. It has therefore become an important strategy to prevent, and respond to, disease outbreaks.

2. COVID-19 significantly impacts health services for noncommunicable diseases (who.int)

Vaccine development and manufacture takes a long time, involving series of complex procedures from research to manufacture, then, approval and licensure. It was therefore an outstanding achievement for the development and manufacture of COVID-19 vaccines within a year that the causative organism was linked to the diseases. This was owing to advancement in research and technology, and several other considerations including strong political will. Yet, as with most other vaccines for past disease outbreaks, equitable distribution, supply and access have become serious issues. Many poor and low-income countries, including those in Africa cannot afford the vaccines, as such cannot effectively vaccinate their populations due to limited access to the vaccines, as well as their characteristic poor health systems, leading to vaccine inequity.

Many wealthier nations began stock-piling vaccines through purchase contracts, even when the vaccines were in the development and production stages, leaving poorer countries at the end of the queue. In fact, by the time the vaccines were approved for use, some of these wealthy countries had already purchased doses that were enough to vaccinate their populations two times over. This trend, called vaccine nationalism, has contributed largely to the current spate of vaccine inequity in Africa and subsequent low vaccine uptake on the continent. While the affected countries and their populations may bear the brunt of this problem, the whole world continues to be at risk. For instance, there is the risk of new variants which may be resistant to available vaccines, thereby undoing progresses made in scientific, healthcare and public health interventions. The global economy will continue to be affected, while global resilience will also be at risk. Due to the resultant instability in the affected regions, there will be increased migration, putting pressure on the resources of other regions. as well as many other direct and indirect consequences globally.
Apart from vaccine nationalism, which is a major external factor contributing to vaccine inequality in Africa (Allen, 2022), other factors can be traced to inadequate Research and Development (R&D) and low capacity to develop and manufacture vaccines on the continent.

Other internal drivers within the continent including member countries' weak health systems and inadequate governance structures, may also be contributing to low vaccine uptake and inequity in general. Addressing these drivers and other identified gaps require strategies with varying timelines and actions from different actors, including multilateral platforms like the United Nations (UN) and the World Health Organisation (WHO), as well as vaccine uptake platforms like COVAX and governments of member countries. However, it is clear that the menace of vaccine inequity must be addressed in order to accelerate progress towards winning the war against COVID-19 globally.



Part 1

Pandemic Origins and Variant Strains

Global Figures

According to the WHO Regional Office for the Mediterranean, a disease outbreak is the occurrence of cases of a disease more than what would normally be expected in a defined community, geographical area or season (WHO Regional Office of the Eastern Mediterranean, n.d.). Outbreaks of infectious diseases are caused by the spread of infectious agents from one person to another when there is an exposure to the animal reservoirs or environmental sources of such agents.

Human behaviours such as hygiene and sanitation can also impact greatly on outbreak and spread of diseases; hence, the non-pharmaceutical responses to disease outbreaks which targets human behaviours that can help to curb or limit their spread. These outbreaks especially those having epidemic potentials or proportions have become one of the greatest threats to public health security with potentials to disrupt the socio-economic lives of people globally.

Disease Outbreaks: Epidemics & Pandemics

Though there are no specific widely acceptable set of standards for determining what constitutes an epidemic versus a pandemic, however, epidemics become pandemics when a disease spreads across several countries or continents and affects a large number of people (Tulane University School of Public Health and Tropical Medicine, 2020). The pandemic label to a disease outbreak is not in any way suggesting its virulence—the ability of the disease to destroy the body's resistances or fortifications against diseases—or lethality. A key attribute of epidemics with pandemic potentials is their potential to spread across large territories.
For instance, the School of Public Health and Tropical Medicine (SPHTM), Tulane University, illustrated distinctions between epidemics and pandemics by examining two disease outbreaks—SARS in 2003 and COVID-19 in 2019, both caused by coronaviruses (Tulane University School of Public Health and Tropical Medicine, 2020). According to the school's publication exploring disease outbreak response, key similarities of coronavirus diseases are:

• Common in animals, but in rare cases they infect humans;

• Of different kinds and all cause symptoms ranging from mild respiratory illnesses to acute respiratory syndromes;

Epidemics become pandemics when a disease spreads across several countries or continents and affects a large number of people

• Named for their appearance; viewed under a microscope they look to be covered in pointed structures that surround them like a crown, or corona;

• Responsible for both the 2003 Severe Acute Respiratory Syndrome (SARS) epidemic and the COVID-19 pandemic.

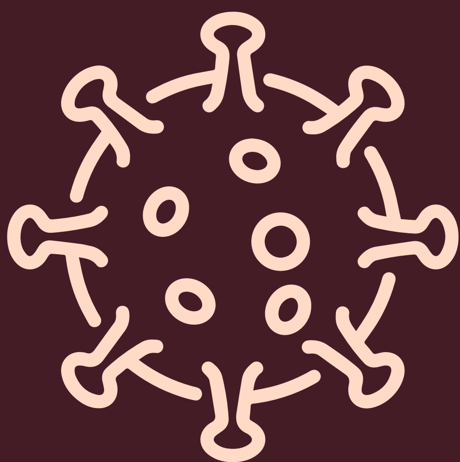
However, despite having the same causative organisms, SARS was classified as an epidemic while COVID-19 was declared a pandemic according to SPHTM's publication (Tulane University School of Public Health and Tropical Medicine, 2020) for the following reasons:

• For about six months of its outbreak in Asia from February 2003, SARS-associated coronavirus (SARS-CoV) spread only across Asia, Europe and the Americas with presence in only about two dozen countries. According to the WHO,[3] only about 8,000 people fell sick and just about 774 died from the disease. Despite being highly dangerous, its outbreak was contained within months.

• SARS-CoV-2 responsible for the coronavirus disease (COVID-19) which is less deadly than SARS on an individual case basis, but is highly contagious was first detected in Wuhan, China, in December 2019. Its symptoms—including fever, fatigue, and dry cough—ranged from mild to severe. By March 2020, the WHO had reported more than 118,000 cases in 114 countries and 4,291 deaths, and declared COVID-19 a pandemic.

Factors Affecting Disease Spread

Over time, mobility and global/geographical connectivity through trade, tourism, war and other forms of interactions have been major driving forces behind disease outbreaks and consequent spread across countries and continents. Recently, urbanisation in the developing world is likewise playing critical roles, bringing more rural residents into denser neighbourhoods even as population increase puts greater pressure on the environment and public health systems. Increased passenger air traffic has also contributed to increased disease spread.



3. Disease Outbreak: Public Health Responses and Challenge (tulane.edu)

Pandemics: Causes and Transmission

Many infectious diseases leading to pandemics are caused by zoonotic pathogens transmitted to humans due to increased contacts with animals through breeding, hunting and global trade activities (Piret J, 2021). By understanding the pathogen transmission mechanisms in humans, infection prevention and control mechanisms have been developed.

In recent centuries, public health measures such as quarantine, isolation and border control have helped prevent the spread of infectious diseases and preserved social structures. In the absence of pharmacological solutions these control methods have been used to control the COVID-19 pandemic as well as several other fairly recent disease outbreaks. A comprehensive control program for the spread of aquatic pathogens and zoonoses at the animal-human interface can be used to detect the risk of infection.

According to (Piret J, 2021) transmission of pathogens involves five stages:

1. The pathogen exclusively infects animals under natural conditions;

2. The pathogen evolves so it can be transmitted to humans but without sustained human-to-human transmission;

3. The pathogen undergoes only a few cycles of secondary transmission between humans;

4. The disease exists in animals but long sequences of secondary human-to-human transmission occur without the involvement of animal hosts; and

5. The disease occurs exclusively in humans.

According to (El-Sayed A., 2020), the animal species that harbour the pathogen, the nature of human interaction with that animal and the frequency of these interactions accentuates the risk of zoonotic transmission. Furthermore, land use and climate changes are also now being suggested to play important roles in the transmission of pathogens from wildlife to humans.

Epidemics become pandemics when a disease spreads across several countries or continents and affects a large number of people

Major Pandemics: A Review

Plague

Plague is caused by the flea-borne bacteria Yersinia pestis, responsible for at least three human plague pandemics: the plague of Justinian, the Black Death and the Third Plague (Piret J, 2021). Y. pestis is a gram-negative, rod-shaped, coccobacillus bacteria. It is a facultative anaerobic bacterium transmitted by fleas associated mainly to rodents and other mammalian hosts (Perry R. D., 1997). Fleas acquire the bacteria by sucking blood from an infected rodent which quickly multiplies and block the alimentary canal in the gut of the fleas (Bacot A. W., 1914). The fleas continue to transmit the bacteria to new rodent hosts as it bites and sucks blood from them.

Plague manifests in three forms—bubonic, septicemic and pneumonic—depending on infection route (R., 2018). Also, according to(Piret J, 2021) , the bubonic form is the most common and results from the bite of an infected flea. Clinical manifestations include flu-like symptoms such as fever, chills, headache, body pains, weakness, vomiting and nausea followed by painful swollen lymph nodes. Septicemic plague is also life-threatening, involving infection of the blood and like the bubonic form also spread by bites from infected fleas. Pneumonic plague on the other hand is a severe lung infection that may result into headache, coughing, fever, chest pain and shortness of breath. It can cause intravascular coagulation. Pandemics from plagues alone may have led to about 300 million deaths in human history.Cholera

Cholera

Cholera is an acute, often fatal disease, of the gastrointestinal tract caused by Vibrio cholerae (Faruque S. M., 1998). V. cholerae, gram-negative and coma-shaped bacteria, is a facultative anaerobe with a flagellum at one cell pole as well as pili. The bacteria colonises the small intestine and produces the cholera toxin responsible for a rapid and massive loss of body fluids leading to dehydration, hypovolaemic shock and death. Cholera is one of the leading and most frequent epidemics sometimes leading to pandemics.

Influenza

Influenza viruses, divided into A, B, C and D types, belong to the Orthomyxoviridae family. Usually single-stranded ribo-nucleic acid (RNA) viruses (Wright P. W., 2001), they are enveloped and negative-sensed. Their genes contain at least 10 structural proteins encoded by at least 7 or 8 RNAs segments. The protein structure is made up of Hemagglutinin (HA), a neuraminidase (NA), two matrix proteins and a nucleoprotein. In a typical seasonal epidemic, influenza virus causes about 5 million cases of severe illness and approximately 500,000 deaths worldwide (Iuliano A. D., 2018). Most typical seasonal influenza infections are asymptomatic or cause only mild or classical influenza illness characterised by about five days of fever, cough, chills, headache, muscle pain, weakness and sometimes upper respiratory tract symptoms (Zambon, 2001). However, for people with underlying medical conditions such as diabetes mellitus and cardiac/pulmonary diseases, as well as infants and older people, the influenza infection may result in serious health complications. Pandemics from influenzas may have resulted to the death of over 100million people.

HIV/AIDS

Human Immunodeficiency Virus (HIV) attacks cells that help the body fight infections. Its effect on these cells makes the body more susceptible to infections and other diseases. The virus is transmitted through contact with an infected person during unprotected inter-course— sex without condom—and by sharing sharp objects including injection and medical equipment that cut through the skin and come into contact with blood. If left untreated HIV can lead to Acquired Immune Deficiency Syndrome (AIDS). It is impossible to rid the body of the virus once infection occurs, and there is currently no effective treatment for HIV.

By taking the Anti-Retroviral Therapy or ART drugs however, people living with HIV can live longer and healthier lives. They are also able to prevent the spread of HIV to their sexual partners. Since it was first identified in 1981, HIV has become the cause of one of humanity's deadliest and most persistent pandemics, killing more than 30 million people worldwide.

Coronaviruses

According to Masters and Perlman (2013) coronaviruses belong to the Coronaviridae family and include four genera, alpha-, beta-, gamma-, and delta-coronaviruses. Coronaviruses are enveloped, positive-sense, single-stranded, RNA viruses that infect a wide range of animals and humans (Masters P. S., 2013). Their genome encodes non-structural proteins and four structural proteins including the membrane, spike, envelope and nucleocapsid proteins. Human coronaviruses (HCoVs) cause seasonal respiratory diseases, and to a lesser extent, gastroenteritis. HCoV-229E and HCoV-OC43, belonging to the alpha-coronavirus genus, are the causative agents of common cold (Kahn J. S., 2005). HCoV-NL63 and HCoV-HKU1, members of the beta-coronavirus genus, cause more severe, although rarely fatal, infections of the upper and lower respiratory tracts (Kahn J. S., 2005). Furthermore, beta-coronaviruses also include three highly pathogenic viruses such as Severe Acute Respiratory Syndrome coronavirus (SARS-CoV), Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and SARS-CoV-2 [the etiological agent of corinduce severe pneumonia in humans.

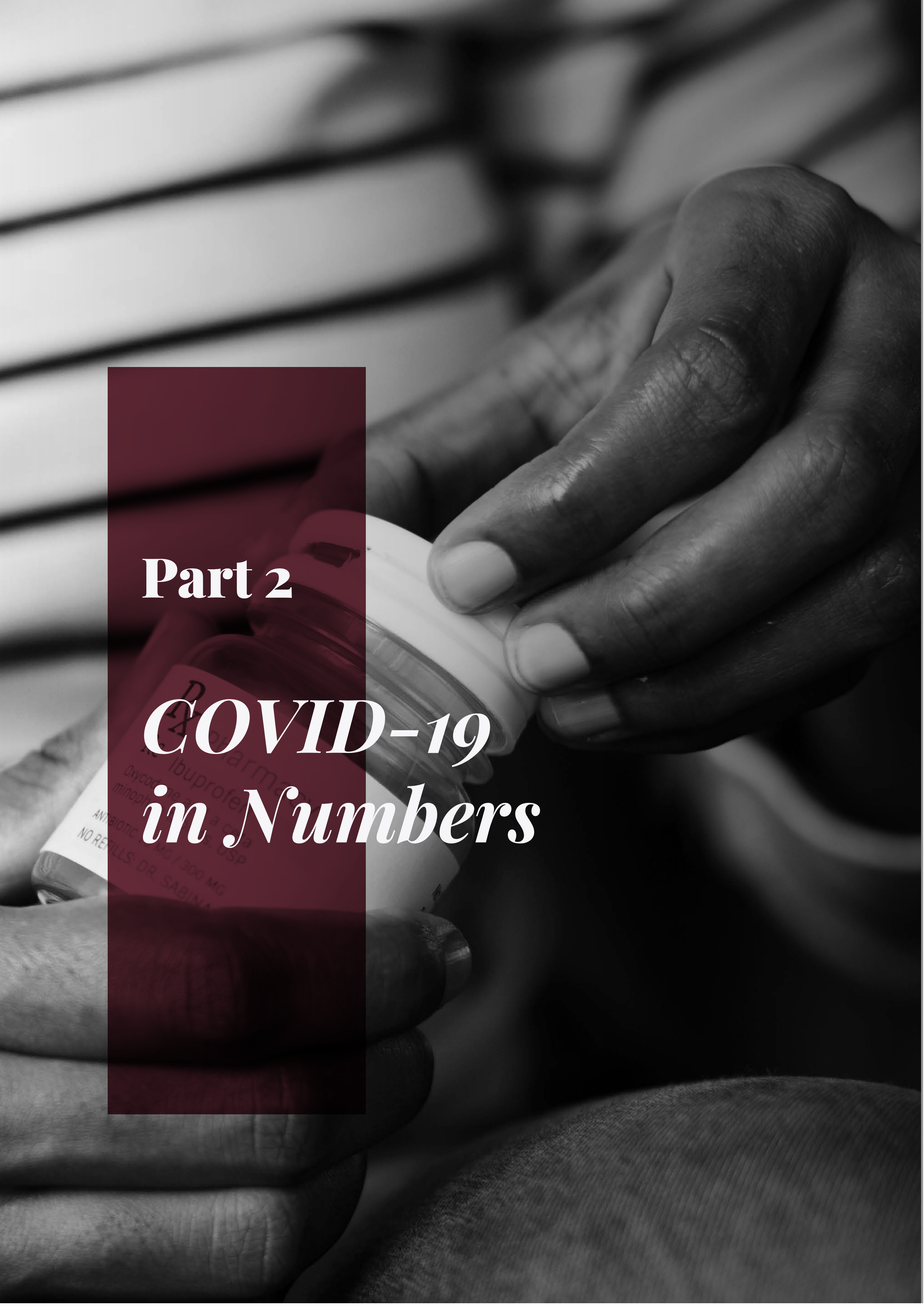
In their article in the Frontiers in Microbiology Journal, Jocelyne Pire and Guy Boivin attempted a classification of coronavirus outbreaks based on their causative organisms. Excerpts of their classification is presented in Box 1.

1. SARS-CoV Epidemic: SARS-CoV originated in Guangdong province (China) in 2003. Bats are likely the possible natural reservoir of SARS-CoV and palm civets could be intermediary hosts before dissemination to humans. The causative agent was identified within a few weeks. During the 2002-2003 outbreak, SARS-CoV infection was reported in 29 countries in North America, South America, Europe and Asia. Overall, the WHO reported about 8,437 probable cases with 813 SARS-related fatalities. SARS-CoV infection typically causes an influenza-like syndrome with rigours, fatigue and high fever. Less common symptoms include nausea, vomiting and diarrhoea. In 20-30% of infected patients, the disease progressed to an atypical pneumonia, with shortness of breath and poor oxygen exchange in the alveoli, requiring management in Intensive Care Unit (ICU) or mechanical ventilation. Many of these patients also developed diarrhoea with active virus shedding. Respiratory failure was the most common cause of death among patients infected with SARS-CoV. The major routes of SARS-CoV transmission were droplets, aerosols and fomites.

2. MERS-CoV Epidemic: Ten years after the first emergence of SARS-CoV, MERS-CoV was reported in Jeddah, Saudi Arabia. The potential animal reservoirs of MERS-CoV are bats and dromedary camels have been suggested as the intermediary hosts. Infection with MERS-CoV causes acute, highly lethal pneumonia and renal dysfunction with various clinical symptoms including fever, chills, rigours, headache, a non-productive cough, sore throat, arthralgia and myalgia. Other symptoms include nausea, vomiting, diarrhoea and abdominal pain. It is estimated that 50-89% of patients with progression to respiratory and/or renal failure require ICU admission.

3. SARS-CoV-2 Pandemic: In early December 2019, atypical pneumonia was reported in a cluster of patients in Wuhan, China and was shown to be caused by a new coronavirus, called SARS-CoV-2 whereas the disease is referred to as COVID-19. The animal reservoirs are likely bats. Pangolins were proposed as animal hosts that transmitted the virus to humans but the intermediary host, if any, remains unidentified. SARS-CoV-2 infection may be asymptomatic (up to 40% of cases) or causes a wide spectrum of illness from mild symptoms to life-threatening diseases. Infected individuals most commonly present with fever, dry cough, shortness of breath, fatigue, myalgia, nausea/vomiting or diarrhoea, headache, weakness, rhinorrhea, anosmia and ageusia. Common complications among hospitalised patients include pneumonia, Acute Respiratory Distress Distress (ARDS), acute liver injury, cardiac injury, prothrombotic coagulopathy, acute kidney injury and neurologic manifestations. Critically ill patients could also develop a cytokine storm and a macrophage activation syndrome. Co-morbidities such as hypertension, diabetes, cardiovascular disease, chronic pulmonary disease, chronic kidney disease, malignancy and chronic liver disease have been present in 60-90% of hospitalised patients.

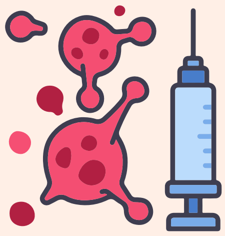
Box 1: Classification of disease outbreaks caused by coronaviruses (Piret J, 2021)



Part 2

COVID-19 in Numbers

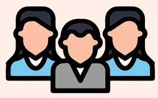
Global Figures



In terms of vaccination globally, a total of

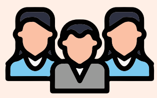
144.34

doses of COVID-19 have been administered per 100 population



58.21

per 100 persons have been fully vaccinated with, the last dose of primary series while



20.03

persons per 100 population have received boosters.

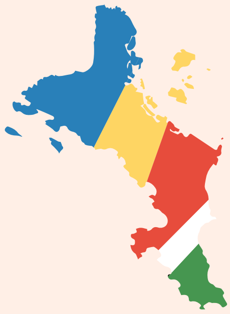
With over six million cumulative deaths reported globally (Jenny Lei Ravelo, n.d.), COVID-19 pandemic has spread to every continent and region of the world; its devastation and socio-economic impacts felt in all countries of the world including those with the most advanced health systems.

As of April 2022, according to the WHO Situation Report, there has been a total of 497,057,239 and 6,969,684 global cumulative cases and deaths respectively. Most of these came from the Americas and Europe with 207,759,697 and 151,489,694 cumulative cases as well as 3,453,464 and 500,941 cumulative deaths respectively (see table below). Africa and Eastern Mediterranean WHO regions contribute the least to these global figures with 8,613,169 and 21,638,314 cumulative reported cases as well as 22,498 and 42,370 cumulative reported deaths respectively (see table 2 below).

Name	Cumulative Cases	Cases newly reported in the last 7 days	Deaths – cumulative	Deaths – newly reported in the last 7 days	Total vaccine doses administered per 100 population	Persons fully vaccinated with the last dose of primary series	Persons boosted per 100 population
Global	**497,057,239**	**6,969,684**	**6,179,104**	**21,651**	**144.34**	**58.21 (out of 100)**	**20.03**
Europe	207,759,697	3,453,464	1,958,076	9,380	165.08	586,052,546	27.36
Americas	151,489,694	500,941	2,709,531	5,898	170.93	682,503,844	29.93
South-East Asia	57,425,623	201,476	780,995	1,344	136.11	1,218,038,701	4.66
Western Pacific	50,129,978	2,748,935	217,859	4,402	215.07	1,612,376,081	42.65
Eastern Mediterranean	21,638,314	42,370	341,411	550	94.5	295,847,543	7.98
Africa	8,613,169	22,498	171,219	77	26.3	143,253,334	0.8

Table 2: COVID Situation of WHO Region as of 12th of April 2022 (World Health Organization, n.d.)

Africa Figures: A Breakdown



Seychelles is one of the countries with the most impressive figures, particularly in terms of vaccination rates.

41,147
cases

163
deaths

In Africa, Seychelles is one of the countries with the most impressive figures, particularly in terms of vaccination rates. The cumulative cases reported are 41,147 with only 163 deaths; and with 203.21 total vaccine doses administered per 100 population, 81.5 persons are fully vaccinated with the last dose of primary series and 35.9 persons out of 100 population have received a booster. South Africa has the highest cumulative reported cases at 3,732,075 with more than 100,000 cumulative reported deaths. Ethiopia is at a distant second, with 470,050 cumulative cases and 7,509 deaths.

In West Africa, Nigeria has reported 255,606 cumulative COVID-19 cases and 3,142 deaths. In terms of vaccination, the country has only administered 15.23 doses per 100 population; with only 4.64 person in a 100 population fully vaccinated, and just 0.38 persons per 100 population receiving a booster dose of COVID-19 vaccine. Ghana has 161,048 reported cases and 1,445 deaths, with 41.99 out of a 100 population vaccinated. Cameroon's vaccination figures, just like Nigeria's are not also promising, with 119,544 cumulative cases and 1,927 deaths reported and with just above 5 doses per 100 population. Rwanda and Malawi each has 129,757 and 85,703 cases reported respectively, 1,459 and 2,628 deaths respectively. While Rwanda shows very promising vaccination figures with more than 150 total vaccine doses per 100 population administered, Malawi's figures are not so promising.

Kenya in East Africa has reported 323,541 cumulative cases with 5,648 fatalities. It has administered 32.43 total vaccine doses per 100 population; just about 15 persons out of 100 population have been fully vaccinated and only 0.5 persons out of a hundred have received a booster.

Name	Cumulative Cases	Cases newly reported in the last 7 days	Deaths – cumulative	Deaths – newly reported in the last 7 days	Total vaccine doses administered per 100 population	Persons fully vaccinated with the last dose of primary series	Persons boosted per 100 population
Global	**497,057,239**	**6,969,684**	**6,179,104**	**21,651**	**144.34**	**58.21 (out of 100)**	**20.03**
Africa	**8,613,169**	**22,498**	**171,219**	**77**	**26.3**	**143,253,334**	**0.8**
South Africa	3,737,075	9,121	100,096	46	56.33	31.37	3.5
Ethiopia	470,050	231	7,509	5	25.55	18.23	0.3
Kenya	323,541	87	5,648		32.43	15.2	0.5
Zambia	317,483	373	3,967		18.41	11.64	0.32
Botswana	263,950		2619		107.04	54.96	10.37
Nigeria	255,606	90	3,142		15.23	4.64	0.38
Zimbabwe	246,973	448	5,457	11	56.29	23.27	1.39
Uganda	163,932	45	3,596		38.49	17.52	0.06
Ghana	161,048		1,445		41.99	16.32	0.51
Rwanda	129,757	26	1,459		153.37	62.53	22.07
Cameroon	119,544		1,927		5.87	3.95	0.11
Senegal	85,950	31	1,965		14.91	6.21	0.02
Malawi	85,703	39	2,628	2	10.42	4.5	
Seychelles	41,147	348	163		203.21	81.5	35.9
Sierra Leone	7,675	1	125		35.97	14.11	0.04
Liberia	7,402		294		22.39	20.08	0.03

Table 3: COVID Situation of Select African Countries in WHO Africa Region as of 12th of April 2022 (World Health Organization, n.d.)

Undercounting and Asymptomatic Cases

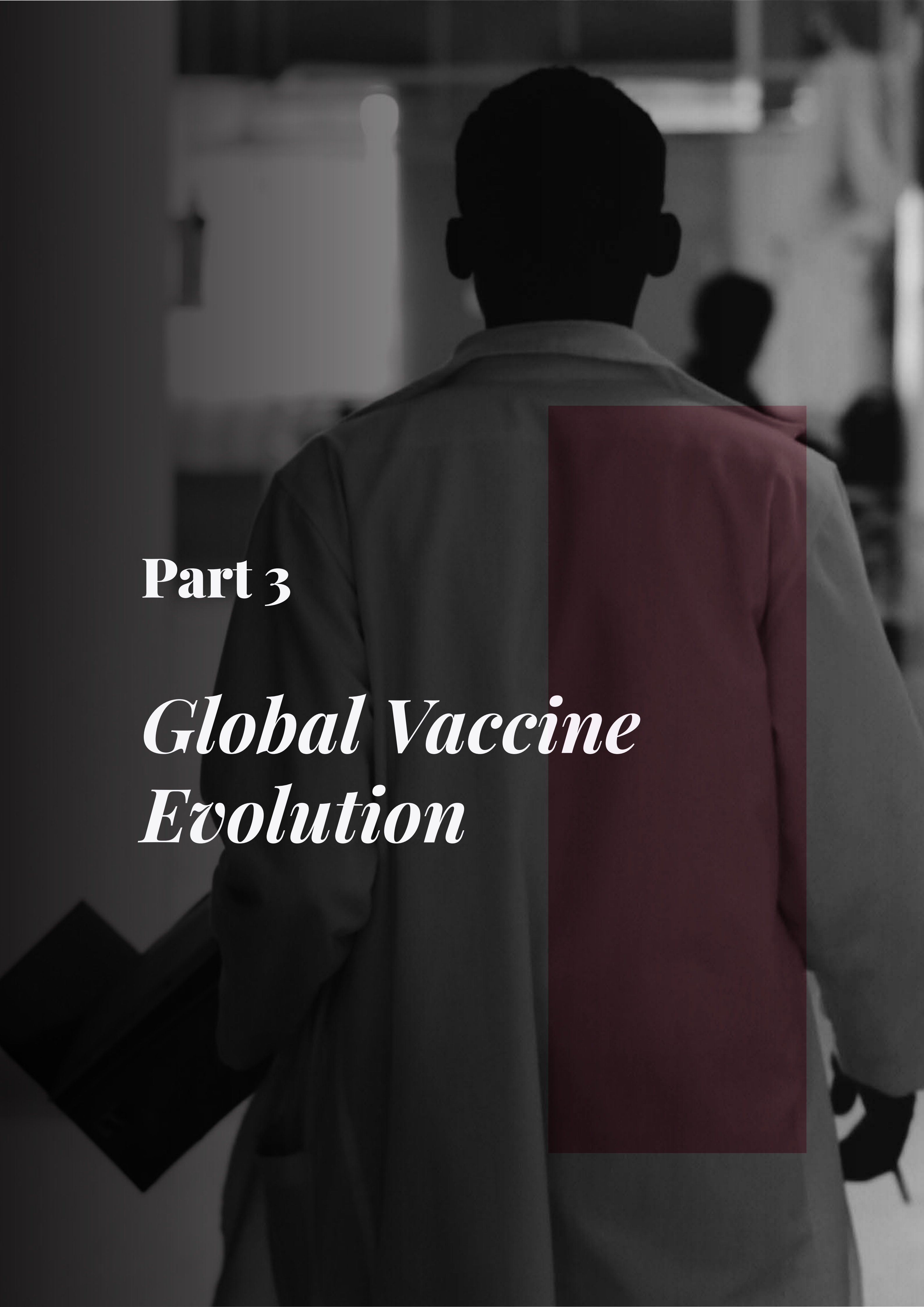
Evidence from reported global COVID-19 cases and other parameters demonstrates that Africa has milder COVID-19 cases compared with other parts of the world because there is a comparatively smaller fraction of people with risk factors such as diabetes, hypertension and other chronic diseases associated with more severe cases and deaths. Africa's youthful population is also a protective factor. With 200 million people
aged between 15 and 24 (the youth bracket), Africa has the youngest population in the world, this is according to a UN statement (Ighobor, 2013). However, other studies have shown that up to 65% of Africans have been infected with the COVID-19 virus (World Health Organization, 2022).

According to a release by the WHO (World Health Organization, 2022) an analysis conducted in Africa, synthesised 151 studies published on seroprevalence in Africa between January 2020 and December 2021. It found that exposure to SARS-CoV-2 skyrocketed from 3% (1.0-9.2% range) in June of 2020 to 65% (56.3-73% range) by September 2021, or 800 million infections compared with 8.2 million cases reported at that time. The study showed that exposure to the virus rose sharply following the emergence of the Beta and the Delta variants.

The analysis also revealed that the number of actual infections may be 97 times higher than the number of confirmed recorded cases. This is relatively higher compared to the global average where true infection figures is only 16 times higher than the recorded cases. However, seroprevalence varies widely in African countries. It appears higher in denser urban areas than in less populated rural areas—and between age groups, with children aged 0-9 years having fewer infections compared with adults. Exposure to the virus also varied between countries and Africa's sub-regions.

The analysis further proposed that more than two-thirds of all Africans may have been exposed to the COVID-19 virus. ***Asides Africa, the seroprevalence studies also observed a significant under-counting of cases across the globe. The study estimated that 45.2% of the world's population may have been infected with the virus by September 2021.***

Since the studies were carried out across other regions at varying times, it was difficult to compare Africa's figures with those of the other regions of the world. However, a striking distinction from the analysis and its result in Africa is the high number of asymptomatic cases, with 67% of cases having no symptoms contributing to the under-counting of COVID cases on the continent. These kinds of studies during periods of outbreaks are critical as they can provide important sources of data less reported and symptomatic cases. These kinds of cases are usually missed by routine diagnostic testing typical of African countries focused on travellers and people who voluntarily come to the health facilities with the symptoms of the infection.



Part 3

Global Vaccine Evolution

It is often said that vaccines, aside from the introduction of clean water and sanitation among many human inventions and interventions available, have made the biggest contributions to global health. Vaccines have significantly reduced the burden of childhood disease and saved millions of lives worldwide. Polio for example is currently at the brink of extinction worldwide due to intensive immunisation. More children today are living healthier lives without vaccine-preventable diseases. ***The impact of vaccines extends beyond public health; but also, to children's educational performance, increases in household incomes and, ultimately, greater national economic growth (World Health Organization, 2016).*** Vaccine development as well as vaccination are undoubtedly important and could pass as part of the most successful and cost-effective public health interventions within global use.

Variolation might possibly be the first modern method of vaccination method used before the work of Edward Jenner in 1796. In the vaccination of individuals against smallpox, variolation was the then known method for inoculation—the act of immunising someone against a disease by introducing infective material, microorganisms, or vaccine into the body. The method was fairly successful but with high risk of serious illnesses and even death. Exchanging the smallpox material used for the procedure with fluids extracted from a cowpox lesion, Edward Jenner significantly reduced these risks. Although the cowpox virus may cause only a mild infection, it triggered an immune response which provided cross-protection against smallpox infection (Greenwood, 2014).

According to Fleming, 2020,[4] Jenner's principle underpinned the development of subsequent vaccines based on attenuated organisms. Also, according to Fleming, the introduction of smallpox vaccine in England alone reduced smallpox deaths from more than 3,000 per million inhabitants in the 1700s to less than 10 by the end of 1800s. This disease which had existed for thousands of years, killed millions, fatal in up to 30% cases, has now been eradicated because of vaccine technology (Fleming, 2020). The last known natural case of smallpox was in Somalia in 1977.

Table 4: Average number of annual smallpox deaths per million inhabitants in England during the various stages of vaccination implementation between 1700 and 1898 (O'Neill, 2022)

Time Period	1889-1898 (Vaccination enforced)	1857-1866 (Vaccination compulsory)	1857-1866 (Vaccination optional)	1700-1797 (No Vaccination)
Deaths per million Inhabitants	10	214	417	3000

4. Sean Fleming, 2020. https://www.weforum.org/agenda/2020/04/how-smallpox-successfully-eradicated-covid/

In 1885, Louis Pasteur's rabies vaccine followed as the vaccine with greater impact on public health. During that period which was considered as the early days of bacteriology, developments followed rapidly. Various kinds of vaccines and antitoxins were developed to prevent diphtheria, tetanus, anthrax, cholera, plague, typhoid, tuberculosis, from then through the 1930s.

After this period, specifically the middle of the 20th century, there was a period of active vaccine research and development. For instance, polio vaccines were developed using methods designed to grow viruses in the lab. These methods also led to rapid discoveries and innovations. Scientists targeted other common childhood illnesses such as measles and rubella. During this period, vaccines contributed significantly to reduce the burden of illnesses. Currently, innovative technologies in medicine and global health have taken vaccine research into new dimensions such as recombinant DNA technology and new vaccine delivery technologies. Several vaccine studies with increasing disease targets are beginning to focus on non-communicable diseases, drug addiction and allergies (OpenLab at City Tech, n.d.).

Some of human diseases against which there are effective vaccines are :[5]

1. Cholera
2. Chickenpox
3. Dengue fever
4. Diphtheria
5. Ebola
6. Haemophilus influenzae type b
7. Hepatitis A
8. Hepatitis B
9. Hepatitis E
10. Human papilloma-virus
11. Influenza
12. Japanese encephalitis
13. Malaria
14. Measles
15. Meningococcal disease
16. Mumps
17. Pneumococcal disease
18. Pertussis
19. Poliomyelitis
20. Rabies
21. Rotavirus gastroenteritis
22. Rubella
23. Tetanus
24. Tick-borne encephalitis
25. Tuberculosis
26. Typhoid fever
27. Varicella
28. Yellow fever
29. Shingles (Herpes Zoster)
30. Smallpox
31. Zika virus
32. COVID-19

5. See https://en.wikipedia.org/wiki/Vaccine-preventable_diseases and https://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/

For some of these diseases, the time between the discovery of the source of infection and the development of the vaccine was relatively short. Measles had the fastest vaccine development period before. It took about 10 years between the time the causative agent was linked to the disease to the time the vaccine was licensed in the US (1953–1963). That record was broken in 2020. In a single year several vaccines were developed to fight the coronavirus infection. The table below adapted from Our World Data (Samantha Vanderslott, 2013) shows some diseases, their causative organisms, the year their causative agents were linked to the diseases and the license year for the vaccine in the US.

Disease	Causative Agent	Year the agent was linked	Vaccine(s)	Year of vaccine license in the US
Malaria	Plasmodium spp.	1880	RTS,S	None yet licensed
Tuberculosis	Mycobacterium tuberculosis	1882	Bacille Calmette-Guerin (BCG)	None yet licensed
Typhoid fever	Salmonella Typhi	1884	Ty21a (Vivotif, Emergent BioSolutions) ViCPS (Typhim Vi, Sanofi Pasteur)	1989
Meningitis	Haemophilus influenza	1889	Meningococcal Vaccines	1981
Whooping cough	Bordetella pertussis	1906	Pertussis Vaccine	1948
Dengue fever	Dengue virus	1907	Dengvaxia	2019
Polio	Poliovirus	1908	IPV and OPV	1955
Zika fever	Zika virus	1947	-	None yet licensed
Chickenpox	Varicella zoster virus	1953	Varicella	1996
Measles	Measles virus	1953	MMR Vaccine	1963
Mononucleosis (Birth defect)	Human cytomegalovirus	1960	-	None yet licensed
Hepatitis	Hepatitis B virus	1965	Hepatitis B Vaccine	1981
Diarrheal disease	Rotavirus	1973	Rotateq (RV5) and Rotarix (RV1)	2006
Ebola	Ebola virus	1976	rVSV-ZEBOV	2019
Cervical cancer	Human papillomavirus	1981	HPV	2006
AIDS	HIV	1983	-	None yet licensed
COVID-19	SARS-CoV-2	2020	Pfizer-BioNtech, Moderna- Spikevax and Johnson&Johnson	2020

Table 5: Some diseases, their causative organisms and other parameters

Contributions of Vaccines to Global Health

Through vaccine interventions, an estimated 2.5 million deaths from various diseases such as measles, tetanus, diphtheria and pertussis (whooping cough) are avoided every year, contributing to reductions in the global disease burden (UN Office for the Coordination of Humanitaria Affairs, 2018). According to a statement by UNICEF (UNICEF, n.d.), it was estimated that vaccines may be saving about 5 lives every minute. Since the discovery of the smallpox vaccine, the spread of the disease worldwide has greatly reduced. Vaccines have also been instrumental to reducing the burden of many diseases including smallpox and polio which once were thought to be deadly. Most importantly, vaccines have contributed to reducing child and infant mortality.

Global Vaccine Uptake Programmes

The Expanded Programme on Immunisation (EPI)

The World Health Organization (WHO) launched the Extended Immunization Program (EPI) in May 1974 with the overall aim of vaccinating all children all over the world with the available disease preventing vaccines. Each UN member state government developed and implemented an immunisation programme policy based on the EPI guidelines.

Establishing an effective immunisation programme or policy is multifaceted and contains complex components including a reliable cold chain system, transport for vaccine delivery, maintenance of vaccine stocks, training and monitoring of health workers, outreach programmes for public awareness, and a means of documenting which child receives which vaccines.[6] The EPI in many countries for example Nigeria, has evolved into National Programmes on Immunisation (NPI).

According to reports from several countries, the EPI has contributed to the reduction of country disease burdens, under-5 mortality and accelerated immunization oucomes across countries. For example, a statement on the UNCEF Ghana website, stated that “In Ghana, the Expanded Programme of Immunisation (EPI) has helped reduce infant mortality. There has also been a significant fall in morbidity rates of vaccine-preventable diseases such as measles and poliomyelitis. For example, since 2003, there has been no death caused by measles, while in 2011, Ghana was certified as having attained elimination status for maternal and neonatal tetanus” (UNICEF, Ghana, n.d.). EPI in Philipines and Democratic People’s Republic of Korea also impacted on several health indices of both

6. Expanded Program on Immunization – Wikipedia. See: https://en.wikipedia.org/wiki/Expanded_Program_on_Immunization

countries (Republic of the Philippines, Department of Health, n.d.) and (World Health Organization Regional Office for South-East Asia, n.d.)

Gavi, the Vaccine Alliance (Previously Global Alliance for Vaccines and Immunization–GAVI)

With the aim of extending the EPI's reach to poorer countries, the Global Alliance for Vaccines and Immunization (GAVI) was created in 1999, with a target of improving child health in those countries. It effectively succeeded the Children's Vaccine Initiative, launched in 1990. Unlike the EPI, GAVI is a global health partnership platform, consisting of public and private sector organisations including the UN agencies and institutions (WHO, UNICEF, the World Bank), public health institutes, donor and implementing countries, the Bill and Melinda Gates Foundation and The Rockefeller Foundation, the vaccine industry, non-governmental organisations (NGOs), and many more. Gavi provides these stakeholders with a unique opportunity to promote consensus on policy strategies and priorities and to recommend implementation responsibilities to advance vaccination against diseases.

Gavi has made important contributions to achieving the United Nations' Sustainable Development Goals by focusing on performance, outcomes and results. It has become the largest vaccine funder in low- and middle-income countries, as its partners provide funding for vaccines and intellectual resources for healthcare advancement. Gavi also help strengthen the health systems ability to provide immunisations and other health services in a sustainable way. Gavi runs in five-year funding cycles which enables it to negotiate long-term deals with manufacturers, secured in the knowledge that funding will be ava***ilable (Gavi The Vaccine Alliance, n.d.). According to a CNBC report,7 following the latest Global Vaccine Summit in June 2020 in the UK, $8.8 billion was raised for the 2021-2025 funding cycle, exceeding the $7.4 billion target (Taylor, 2020). This included $2 billion from the UK, $1.6 billion from the Gates Foundation and $1 billion from Norway.***

The UK government according to Gov.uk[8] stated that this funding round would mean that 300 million more children in lower-income countries are immunised against diseases including measles, polio and diphtheria by the end of 2025 (British High Commission Nairobi, 2020). It also pointed out that the funding will support health systems to withstand the impact of coronavirus and maintain the infrastructure necessary to roll out a future COVID-19 vaccine on a global scale (Wikipedia, n.d.) .

7. https://www.cnbc.com/2020/06/04/bill-gates-backed-vaccine-alliance-looks-to-raise-7point4-billion.html
8. The Global Vaccine Summit, hosted by the UK, raises US$ 8.8 billion for immunisation - GOV.UK (www.gov.uk)

Global Vaccine Action Plan (GVAP)

The Global Vaccine Action Plan (GVAP) is ndna global vaccine policy developed and endorsed by the member states of the World Health Assembly in May 2012 to support the achievement of the objectives of the Decade of Vaccines (DoV) that all individuals and communities enjoy lives free from vaccine preventable death. Like the Gavi, it also brought together a wide range of stakeholders across various sectors who committed to achieving the ambitious goals of the GVAP. It is a framework to prevent millions of deaths by 2020 through more equitable access to existing vaccines for people in all communities. Through the GVAP, some progresses were also recorded in global immunisation targets (World Health Organization, n.d.).

According to a Lancet report (The Lancet, 2018) which highlighted some of the impacts GVAP has made on global immunisation objectives, between 2011 and 2017, an additional 20 million children were vaccinated. The report further revealed that by 2017, 123 countries reached at least 90% national coverage of the three-dose diphtheria–tetanus–pertussis vaccine (DTP3). Although coverage in Africa has plateaued at 72%, maintenance at this level since 2010 is seen as an achievement considering the rapid population growth in the region.

Though at the close of the policy, gaps still existed, for instance, globally, 19·9 million children remain unprotected by DTP3, with major local disparities: 60% of these children live in just ten countries, a third of whom live in Nigeria where DTP3 coverage is only 42%. In the past 8 years, coverage of first dose measles-containing vaccine has stagnated at around 85% globally, with major local discrepancies in coverage. However, coverage with the second dose of this vaccine has risen from 39% in 2010 to 67% in 2017. A report of the GVAP done by the Strategic Advisory Group of Experts (SAGE)[9] on Immunisation provided an overall assessment of GVAP's successes and challenges. It also proposed 15 recommendations for the development, content and implementation of the next decade's global immunisation strategy.

Access to COVID-19 Tools (ACTS) Accelerator .[10]

The Access to COVID-19 Tools (ACT) Accelerator was inaugurated in April 2020 at an event co-hosted by the Director-General of the WHO, the President of France, the President of the European Commission and the Bill and Melinda Gates Foundation. It is an innovative global collaboration to accelerate the production and development of COVID-19 vaccine and promote equitable access to tests,

9.https://www.who.int/publications-detail-redirect/the-global-vaccine-action-plan-2011-2020-review-and-lessons-learned-strategic-advisory-group-of-experts-on-immunization

10. What is the ACT Accelerator (who.int). See: https://www.who.int/initiatives/act-accelerator/about

treatments and vaccines. ACT Accelerator brought together governments, scientists, businesses, civil society, and philanthropists and global health organisations like the Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, The Global Fund, International Drug Purchasing Facility (UNITAID), the WHO, as well as the World Bank.

These organisations are working together to accelerate the eradication of epidemics by supporting the development and equal distribution of trial treatments and vaccines that the world needs to reduce mortality and disease prevalence, rebuild global socioeconomic activities in the short term. In the medium term, the ACT Accelerator committed to promoting high level of COVID-19 control. Effectively, the ACT Accelerator is made up of four pillars including diagnostics, treatment, vaccines and health system strengthening; with each of the pillars contributing to the overall objectives by leveraging on innovation and collaboration.

As of March 18, 2022, pledges towards the 2021-22 funding target totalled US$ 1.6 billion, counting towards the US$ 16.8 billion grant financing ask, bringing the 2021-22 funding gap to US$ 15.2 billion (World Health Organization, 2022).
Seeing that global equitable access to a vaccine is the only way to mitigate the public

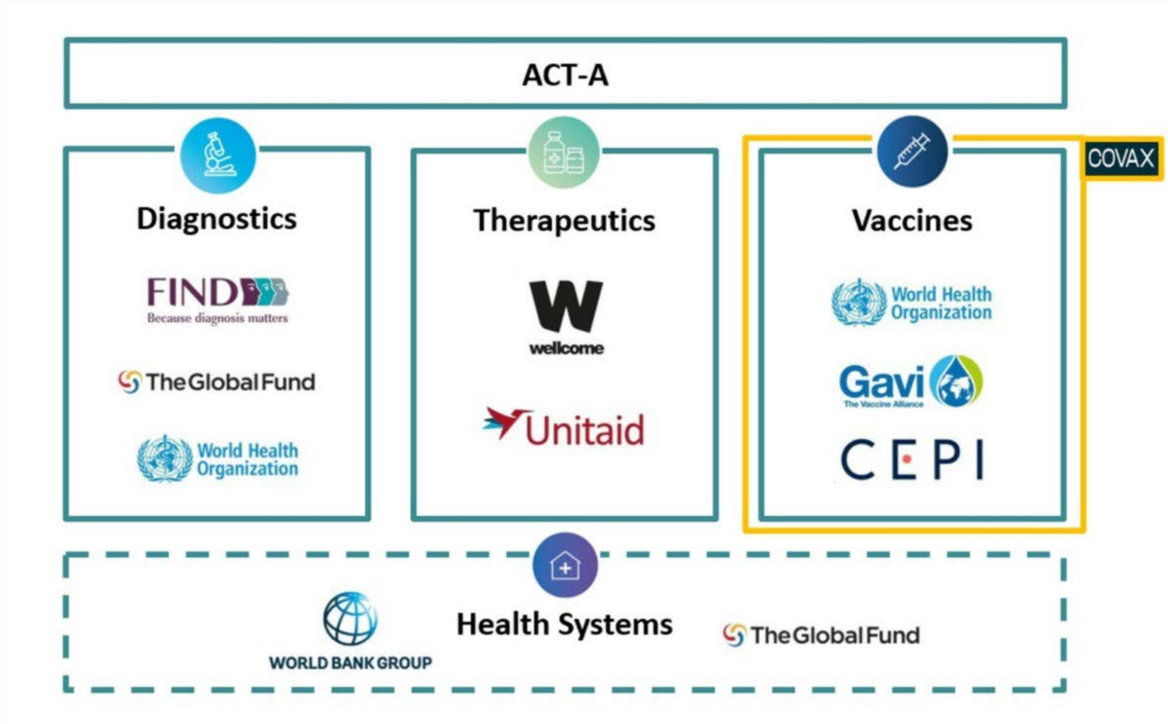


Fig 3: ACT Accelerator Showing COVAX Pillars (Katerini Tagmatarchi Storeng, 2021)

health and economic impact of the COVID-19 pandemic, COVAX was created to maximise the chances of successfully developing COVID-19 vaccines and to produce them in the quantities needed to end the pandemic, while ensuring that income level does not become a barrier.

COVAX organises international resources to provide low-and middle-income countries with equal access to COVID-19 tests, treatments and vaccines. Like other uptake programmes, it is also a global initiative aimed at equal access to the CoVID-19 vaccine. It is led by the Gavi, the vaccine alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO; alongside key delivery partner, UNICEF. It is one of the pillars of the Access to COVID-19 Tools Accelerator (ACT-A) (see Fig 4). It leverages UNICEF's experience as a key partner as the world's largest buyer of vaccines to implement procurement of COVID-19 vaccine doses, as well as logistics, country readiness and in-country delivery. (Katerini Tagmatarchi Storeng, 2021) provided some insights into the structure of COVAX in a research report published on Global Public Health Journal. See Box 4.

COVAX has three main work-streams (see Fig 5), each overseen by a co-lead organisation and with both direct and indirect ties to the pharmaceutical industry. CEPI oversees the 'development and manufacturing' work-stream that decides which vaccine candidates are worthy of financial support and subsequent procurement. This work-stream is led by CEPI's Melanie Saville, who previously worked for the UK's National Health Service and various pharmaceutical companies. Voting members in this work-stream's main decision-making body, called the 'Research and Development and Manufacturing Investment Committee', include representatives of Gavi, CEPI, the Gates Foundation and the Africa CDC, as well as five individuals who are venture capitalists and current and former pharmaceutical company executives.

Gavi leads COVAX's second work-stream for vaccine 'procurement and delivery at scale' with Aurélia Nguyen, a former pharmaceutical executive and subsequent Gavi employee as managing director. It is based within the Gavi Secretariat and the Gavi Board has ultimate responsibility for this work-stream's decisions and implementation.

The final work-stream, which focuses on vaccine 'policy and allocation', is led by WHO's Strategic Advisory Group of Experts (SAGE) on Immunisation. The work-stream advises other work-streams, as well as the WHO and its member states on vaccine science and ethics. It consists of members of universities, public health bodies, UN organisations, CEPI, Gavi, the Gates Foundation and NGOs. COVAX's three work-streams are further divided into 31 sub-committees or working groups. The top five institutions represented as chairs of these committees are WHO, CEPI, Gavi, UNICEF and the Gates Foundation.

Box 4: COVAX work-stream. Adapted from COVAX and the rise of the 'super public private partnership' for global health (Katerini Tagmatarchi Storeng, 2021)

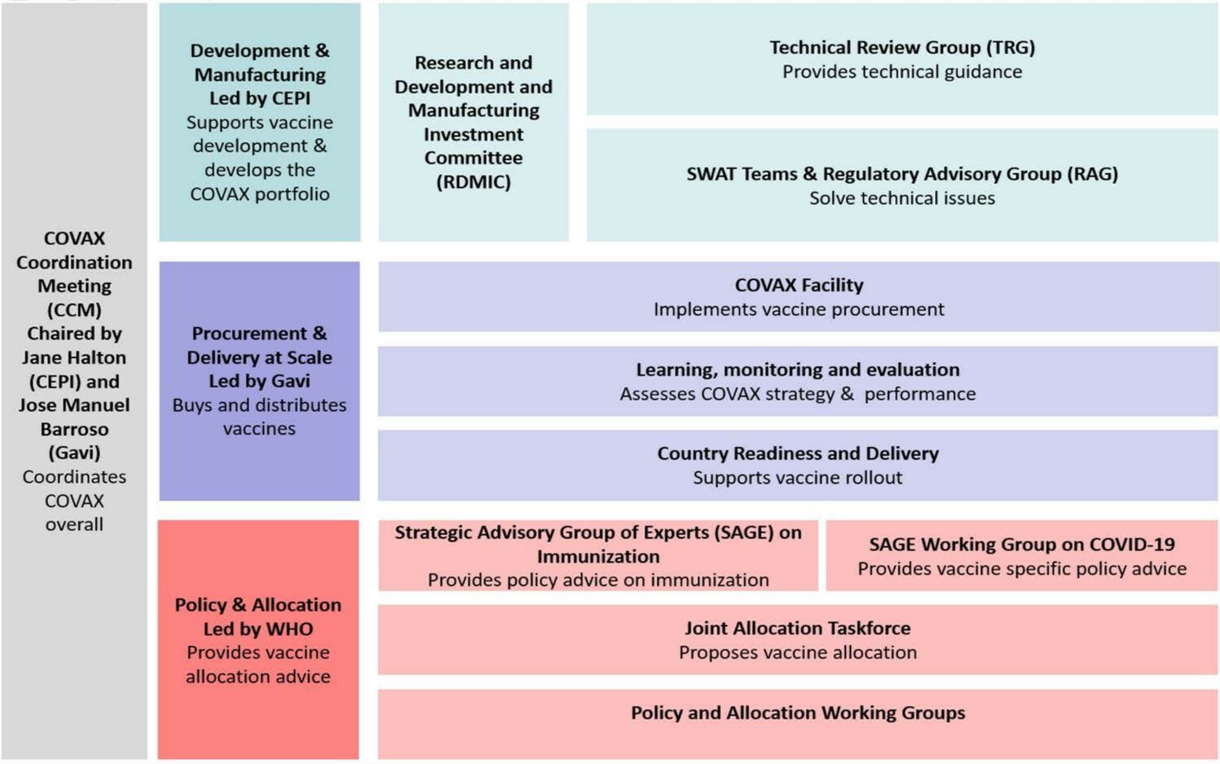


Fig 4. COVAX's three work-streams (simplified and subject to change due to COVAX's evolving nature). Source: Gavi (2021b) (COVAX, 2021)

According to Gavi (COVAX, 2021) a document containing the structures and principles of the COVAX Facility, COVAX has 464 individuals as part of COVAX's governance structure. Only 63 (14%) of these represent governments. Remarkably, an overwhelming majority of country representatives (81%) are from self-financing countries. Industry representatives account for 6% of COVAX listed participants, and only 16 individuals (3.4%) represent NGOs or civil society. However, the document didn't give any information about how committee members are selected. Also, several sub-committees have been established on paper only, as their membership is yet 'to be determined'.

As of 19 October 2020, 184 countries had joined COVAX (Telesur, 2020). COVAX began distributing vaccines in February 2021. Though COVAX promised 100 million doses by the end of March 2021, this goal was not reached until 6 July (Gleeson, The best hope for fairly distributing COVID-19 vaccines globally is at risk of failing. Here's how to save it, 2021). ***By mid-August 2021, COVAX delivered 200 million vaccine doses to nearly 140 countries instead of the 600 million doses initially projected .11***

Despite COVAX's good intentions, achieving its aims has proven to be a mammoth effort due to a number of variables, including vaccine diplomacy

11. COVAX – Wikipedia. See: https://en.wikipedia.org/wiki/COVAX

and corporate interests. However, the facility has made a significant contribution to the current wave of vaccination supplies to under-developed and Lower-Middle Income Countries (LMIC) nations worldwide.

On 24 February 2021, Ghana became the first country in the world to receive vaccines through COVAX when 600,000 doses of the Oxford–AstraZeneca vaccine were delivered to Accra (Steinhauser, 2021). On 2 March, COVID-19 vaccines were distributed in Ghana with Zipline drones reaching remote areas usually underserved by traditional logistics (Prabhu, 2021). Ducharme Jarmie[12] reported that on the 1st of March 2021, frontline workers and public officials from the Ivory Coast became the first persons to be inoculated with COVID-19 vaccines shipped from the COVAX Facility (DUCHARME, 2021). He also reported that more than 500,000 doses of the Oxford–AstraZeneca COVID-19 vaccine manufactured by the Serum Institute of India were shipped to Abidjan the week before. The vaccines were flown in by UNICEF from Mumbai.

One year since the COVAX Facility delivered the first COVID-19 vaccines to Africa, around 400 million doses have been administered—the region's largest ever vaccine rollout in a single year. However, COVID-19 vaccination rates in the continent remain the lowest in the world. As of January 2022, COVAX has shipped over 1 billion COVID-19 vaccines to 144 participants (Gavi The Vaccine Alliance, 2022).

The African Vaccine Acquisition Trust (AVAT)

To achieve Africa's COVID-19 vaccination policy, which calls for immunising at least 60% of the continent's population via a pan-African approach, the African Vaccine Acquisition Trust (AVAT) was established and operates as a centralised buying agent on behalf of the African Union (AU) member states. It is a special purpose vehicle established in November 2020 by the COVID-19 African Vaccine Acquisition Task Team, which was set up by President Cyril Ramaphosa of the Republic of South Africa in his capacity as the AU chairman. It was supposed to be a support component to the COVID-19 immunisation strategy that was endorsed by the AU Bureau of Heads of State and Government in August 2020. AVAT's main partner institutions are the African Union's Africa Centres for Disease Control and Prevention (Africa CDC), the African Export-Import Bank (Afreximbank) and the United Nations Economic Commission for Africa (UNECA) (African Union, 2021).

12. https://time.com/5942715/ivory-coast-covax-first-shots/

Part 4

Africa and Access to Vaccines

The scarcity of resources is a significant factor in Africa's low vaccination rate. Less than 1% of the vaccines used on the continent are produced in Africa. The UN-backed vaccine system and vaccine uptake facilities and platforms have battled with limited funding, production challenges, and delivery delays as a result of manufacturers giving preference to wealthier countries' purchasing agreements. There aren't many possibilities for nations looking to negotiate bilateral finance agreements. On the African continent, efforts are being made to increase COVID-19 vaccine production. At least twelve COVID-19 production facilities have been established or are in the planning stages throughout six African countries as of September 2021. (see figure 7). African COVID-19 vaccine production in the upcoming years may include Pfizer-BioNTech, Johnson & Johnson, and Russia's Sputnik V and China's Sinovac vaccines (ZAINAB USMAN, 2021).

Vaccine R&D and Manufacturing Landscape in Africa

A 600-million-euro ($710 million) finance plan for Aspen Pharmacare was announced for South Africa by the US International Development Finance Corporation and European partners. It is possible that by the end of 2022, Aspen's factory will "fill-and-finish" (i.e., package imported vaccine material) about 500 million Johnson & Johnson doses. Additionally, Cape Town's Pfizer vaccine manufacturing will be accelerated beginning in 2022 thanks to an agreement with South Africa's Biovac Institute. The government of Senegal is constructing a $200 million COVID-19 vaccine manufacturing plant with the Fondation Institut Pasteur de Dakar, with assistance from the United States and Europe. This plant would be the first on the continent to produce vaccine ingredients concurrently with fill-and-finish (Zainab Usman, 2021).

This kind of progress is also highlighted for the Vacsera vaccine facility south of Cairo in Egypt, with a targeted capacity of 1 billion vaccines yearly. There also plans for collaboration between Egypt and Senegal in lowering Africa's reliance on vaccine imports thanks to two agreements for drug substance manufacture and fill-and-finish for Russia's Sputnik V vaccine (ZAINAB USMAN, 2021).

Africa has to scale up domestic vaccine manufacturing for the long term as a result of the difficulties in obtaining adequate vaccine supplies for COVID-19. The African Union said in April 2021 that it will speed up domestic vaccine manufacturing in order to cover 60 per cent of Africa's demand for routine vaccinations by 2040. The African Development Bank agreed to establishing two vaccine technology transfer platforms (Irwin, 2021) at the same time that the World Health Organization launched an mRNA vaccine technology transfer hub (World Health Organization, 2021). There are more signs of additional international agreements to increase vaccine production in Africa. These however have to met with the requisite political will of African governments and leaders.

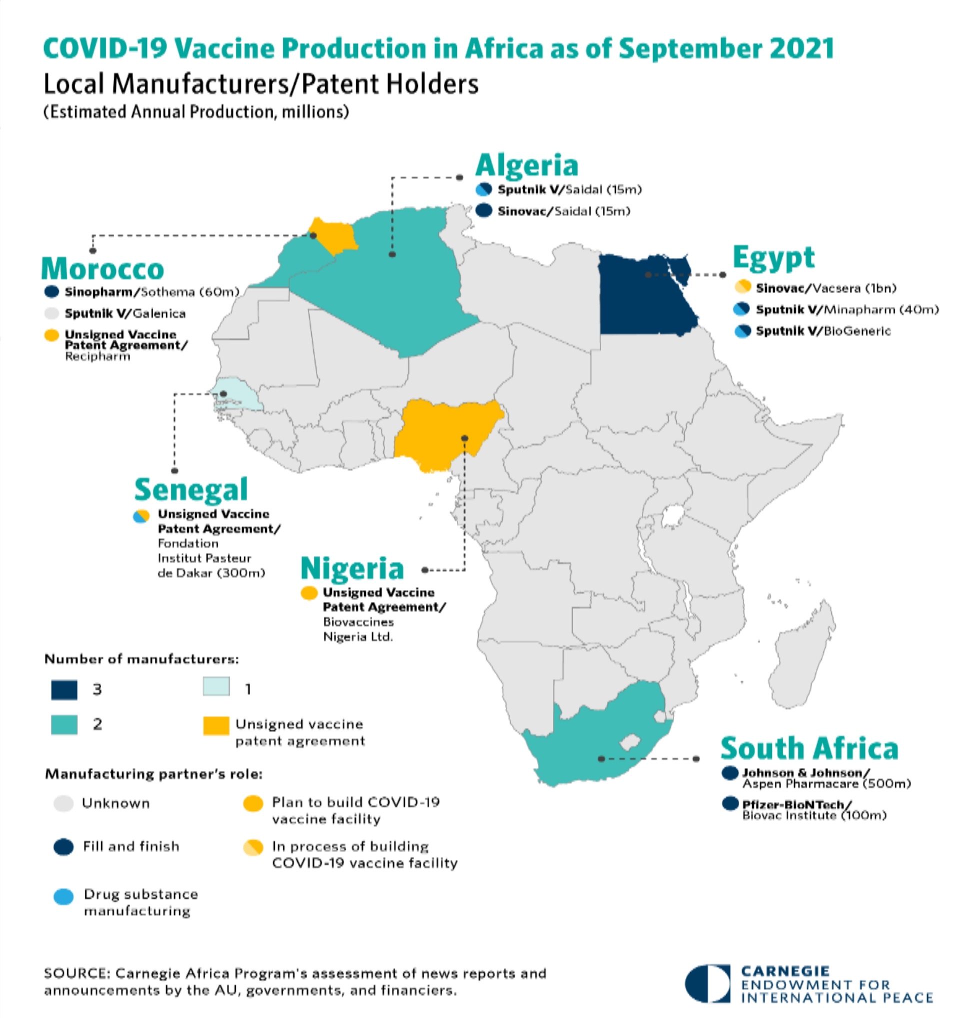


Fig 7: Vaccine production landscape in Africa as of September 2021 (ZAINAB USMAN, 2021)

Africa's Dependence on Developed Countries for Vaccine Access

African governments may actually be interested in the idea of establishing vaccine production facilities within their countries but usually show less political and financial enthusiasm to pull the process through (Makenga G B. S., 2019). They would rather require external support for the investment or provide incentives to investors who want to invest; however, global stakeholders are only willing to render technical support, but investing in local production is not their preference. Also, the National Regulatory Authorities (NRAs) in Africa are still weak, most only perform oversight of pharmaceuticals and not yet biopharmaceuticals that manufacture vaccines. The availability of knowledge, raw materials, consumables, equipment, market access, the countries' import regulations, flaws in research and development, and the lengthy wait times for dossier evaluation and approval, are additional difficulties. Construction of infrastructure, the purchase of technology, and the rules and incentives of the international community are additional critical elements (Makenga G B. S., 2019). These factors have significantly weakened the domestic production capacity and increased Africa's reliance on foreign suppliers for its vaccine and vaccination needs. Interestingly, there are now eight vaccine production companies in Africa with active or potential vaccine production capacities (See Fig 7).

Only one of these companies—Pasteur Institute in Dakar, Senegal—exports a WHO certified vaccine for yellow fever. To provide vaccinations that cover both upstream and downstream processes, two more facilities (Pasteur Institute in Tunis, Tunisia, and Egyvac-Vascera in Egypt) with locally produced and marketed products can supply vaccines that include all upstream and downstream processes. Another facility, Biovac in South Africa, is only involved in the last stages of developing and manufacturing vaccines. Four companies (Pasteur Institute, Algeria, Pasteur Institute in Morocco, EPHI in Ethiopia and Biovaccines in Nigeria) are considered at the preliminary planning phase of vaccine development and production, three of which have had past experience producing some basic vaccines (UNIDO, AVMI & WHO, 2017).

Investment in Local Vaccine Production in Africa

According to WHO estimates , the cost of building a vaccine manufacturing plant with a 20 million dosage capacity can range from USD60 million to USD130 million, depending on the vaccine technology and formulation (Syarifah Liza Munira, 2017)[13].

Over 60% of all costs are related to capital expenditure, and a highly specialised staff is a significant driver of operational costs. Investment costs, account for an estimated 60% of total manufacturing costs, R&D costs, fixed costs (including labour), variable costs, indirect operational expenditure costs, administrative and manufacturing overheads, spare parts and maintenance costs, and costs associated with quality management systems are all equally significant expenses.

Vaccine Manufacturing Cost in Africa: Actors and Drivers

An analytical assessment of vaccine manufacturing capacity and procurement mechanisms for establishing sustainable vaccine manufacturing capacity in Africa commissioned by African Vaccine Manufacturing Initiative (AVMI)[14] identified key vaccine manufacturing cost drivers in Africa (UNIDO, AVMI & WHO, 2017). These are highlighted in Box according to the report of the assessment.

13. Syarifah Liza Munira: Viability of local vaccine production in developing countries: An economic analysis of cost structures, market shares and vaccine prices, Department of Global Health, Australian National University

14. VMPA-Study-e-book.pdf (avmi-africa.org)

- **Human Resources and Education:** with few African educational institutions in the field of vaccinology, microbiology and vaccine or biotech manufacturing, highly qualified personnel are scarce, leading to higher costs in attracting and retaining staff.

- **Maintenance & Calibration:** with no significant vaccine manufacturing industry in Africa, there is a resultant lack of support infrastructure for maintenance of manufacturing facilities. While maintenance is required regularly and quickly, there may be long delays in service personnel and expert from coming from abroad to remedy issues, and of the increased cost of their travel. Cost of maintenance and calibration is also higher typically, as compared to other Developing Countries Vaccine Manufacturers (DCVMs) due to an underdeveloped vaccine manufacturing ecosystem and lack of infrastructure.

- **Pricing and Price Independence:** Vaccines, being public sector goods with the government and UN agencies as major partners, experience a strong downward pressure on the price, limiting independence and volume linked elasticity. Pricing policy of governments in Africa (e.g. Egypt) is stringent and distant from free market prices. Further, lack of a domestic private market and inaccessible foreign public and private markets restrict revenue generation possibilities, opportunity to cross-subsidise profits, and access to tiered pricing benefits.

- **Incentives:** In some cases, incentives to procure raw materials are being offered to subsidise manufacturing from African countries.

- **Utilities:** Availability and (increased) cost of sustainable and reliable utilities (water, electricity, generators) lead to additional spending on water plants and purification units, back-up UPSs, generators and waste disposal systems.

- **Demand Dynamics and Stability:** It is riskier to establish demand stability with a very large single buyer with huge bargaining power coupled with stringent WHO PQ requirements.

- **Functional Local NRA:** Factors outside the control of the manufacturer, but directly affecting its ability to generate profits, include the need for functional (as assessed by the WHO) NRAs. This restricts the manufacturers' ability to access export markets, public and private, essential for profitability in terms of sales volumes, and tiered pricing.

- **Competition:** Finally, heightened competition from multinational companies and developing country manufacturers could make procurement cheaper than manufacturing.

Box 8: Drivers of Vaccine Manufacturing Cost in Africa

Vaccine Manufacturing Financing in Africa

Government budgets (public funding) have been the primary funding source for the current opportunities for local vaccine manufacturing, with fee income and grants serving as supplements. Since their inception, the majority of vaccine producers in Africa have received funding and subsidies, and they still do today, along with income from ongoing operations. Additionally, donor development banks with ties to the area, such as the Africa Development Bank (AFD) and Islamic Development Bank, offer loan financing on a bilateral basis. Given the absence of interest from alternative financial sources, it may be assumed that government money predominates.

A few others adopt the financing strategy known as a public-private partnership. ***An example, is the Biovac Consortium in South Africa, jointly owned by the government (47.5%) and the private sector (52.5 %). Additionally, Biovaccine in Nigeria has a similar system.*** This funding structure combines an initial equity investment by the parties involved, a set handling fee, loans from local development banks, bilateral grants and technical assistance, and grants from the Departments of Trade and Industry to promote local production.

Investment in Health Research at Public and Private Sector Levels

A crucial step in the production of vaccines is research and development (R&D). There aren't enough R&D pipelines for diseases that disproportionately affect African nations and take care of the continent's unmet health requirements (Nwaka S, 2010). There is work to be done. This entails maximising funding and providing resources for health R&D in Africa. Africa contributes 25% of the world's disease burden and 17% of the world's population, yet it only contributes 1.1% (US$22.3 billion) of the world's R&D funding (R&D Magazine, 2016), with Egypt, Nigeria, and South Africa accounting for 65.7 percent (US$14.66 billion) of Africa's overall R&D expenditure (R&D Magazine, 2016).

Only a few African nations have been able to come close to investing the required 1% of GDP in R&D, despite commitments to do so. By comparison, most of the world's largest developed economies have overall levels of R&D expenditure exceeding 2% of GDP.

Large capital resources are needed for public investments in enhancing research capacity. However, rates of return are frequently erratic, and it is challenging to balance spending with urgent government objectives in infrastructure, security, health, and education. The business sector is often the major source of funding for research and development (R&D) in Organization for Economic Co-operative and Development

(OECD) member nations. Historically, public funding has provided the majority of R&D funding in Africa, with significant funding coming from foreign sources in several of the continent's nations. For example, foreign funding played a considerable role in the 2015 R&D expenditures in Ghana (31%), Senegal (41%), and Burkina Faso (60%) (UNESCO, 2014). According to the UNESCO Institute of Statistics (UNESCO Institute for statistics, 2017), in 2014, Africa had an estimated 198 researchers per million people, across all fields. In contrast, there were 428 in Chile and over 4,000 in the UK and USA. The problem is made worse by the continuous "brain drain" of highly qualified scholars who leave Africa for a variety of reasons. Graduates from sub-Saharan African countries emigrate in excess of 10%; the percentage is significantly greater in the health workforce (UNESCO Science Report, 2021). Education quality is also a significant problem that has an impact on research in Africa. Out of 890 universities worldwide that featured in the Times Higher Education 2016-2017 rankings, only 26 were in Africa (Times Higher Education, n.d.).

Current State of Vaccination and Vaccination Targets in Africa

Between January and February 2022, Africa saw a 15% increase in the uptake of the COVID-19 vaccine as numerous nations launched mass vaccination campaigns to increase coverage and protect populations from the virus' harmful health effects (WHO Africa, 2022). In February 2022, 62 million doses were given across the continent, up from 54 million in January. Vaccination programmes in large nations like the Democratic Republic of the Congo, Ethiopia, Kenya, and Nigeria were a major factor in the uptake. The World Health Organization (WHO), UNICEF, Gavi, the Vaccine Alliance, and partners also supported mass vaccination programmes in at least 10 priority countries to reach 100 million people by the end of April 2022 in an effort to increase COVID-19 vaccine uptake in Africa (WHO Africa, 2022).

Although, Africa needs at least 1,874,357,227 doses to vaccinate 70% of its population, to date, the continent has received 772,005,230 doses (41% of doses required to reach 70% of population fully vaccinated), leaving a gap of 1,095,921,765 doses. The continent has out of these has administered 493,962,925 (64% of doses received). So far, only about 17% of the adult population are fully vaccinated (230,704,828) while only about 23% (305,382,198) have received at least a dose of COVID-19, as of 3rd of May, 2022. Twenty-one countries including Eritrea, Burundi, DRC, Madagascar, Cameroon, Malawi, Mali, South Sudan, Tanzania, Senegal, Niger, Nigeria, Burkina Faso, Sudan, Somalia, Gabon, Djibouti, DRC, Zambia, Chad, Gambia, Algeria and Equatorial Guinea are yet to fully vaccinate 15% of their population. Only seven countries have fully vaccinated more than 50% of their population. This group is led by Seychelles at 82%. Rwanda has done 65% while Tunisia, the least in the group has done 54%. In Africa, only Seychelles and Mauritius have surpassed 70% vaccination coverage (WHO Regional Office for Africa, n.d.).

Key Indicators Summary

Country	Doses received	Estimated doses needed to vaccinate 70% of population	% doses received over needed to reach 70% of population fully vaccinated	Additional doses needed to vaccinate 70% of Population	Total Doses Administered	% doses administered over received	Vaccinated 1 dose	% Population received at least 1 dose	Fully vaccinated	% Population fully vaccinated
Seychelles	612,000	137,676	445%	0	201,121	33%	84,679	86%	80,457	82%
Mauritius	3,703,980	1,780,474	208%	0	2,698,115	73%	1,000,474	79%	963,452	76%
Rwanda	26,963,370	18,133,093	149%	0	20,141,669	75%	8,995,787	69%	8,380,667	65%
Morocco	59,817,252	51,674,781	116%	0	54,525,296	91%	24,901,908	67%	23,380,122	63%
Botswana	2,854,400	3,292,275	87%	432,525	1,919,965	67%	1,475,516	63%	1,333,463	57%
Cabo Verde	1,045,840	778,383	134%	0	752,194	72%	354,802	64%	307,019	55%
Tunisia	18,180,598	16,546,065	110%	0	14,747,149	81%	7,189,498	61%	6,366,918	54%
Mozambique	32,989,920	43,757,609	75%	10,767,689	31,616,078	96%	14,816,217	47%	13,891,137	44%
Sao Tome and Principe	431,020	306,825	140%	0	208,657	48%	113,708	52%	86,914	40%
Comoros	3,159,996	1,217,433	260%	0	642,320	20%	399,949	46%	301,218	35%
Lesotho	1,776,610	2,999,153	59%	1,095,343	933,825	53%	933,825	44%	735,610	34%
Egypt	93,666,770	143,268,164	65%	49,601,394	82,802,769	88%	46,221,961	45%	34,130,697	33%
South Africa	38,199,682	83,032,166	46%	44,832,484	34,881,319	91%	21,674,770	37%	19,354,014	33%
Eswatini	830,880	1,624,230	51%	687,942	535,393	64%	387,509	33%	336,066	29%
Liberia	5,624,030	7,080,748	79%	1,429,718	1,837,296	33%	1,751,520	35%	1,438,154	28%
Zimbabwe	22,397,800	20,808,098	108%	0	9,983,503	45%	5,799,542	39%	3,616,013	24%
Mauritania	6,279,311	6,509,524	96%	181,827	2,650,797	42%	1,567,041	34%	1,068,149	23%
Uganda	46,147,430	64,037,400	72%	17,389,970	20,223,978	44%	15,409,049	34%	10,250,742	22%
Benin	6,541,590	16,972,477	39%	10,196,397	3,333,450	51%	3,154,360	26%	2,621,821	22%
Côte d'Ivoire	21,012,120	36,929,585	57%	15,910,315	11,982,186	57%	7,952,458	30%	5,437,294	21%
Central African Republic	2,568,280	6,761,670	38%	4,184,810	1,037,580	40%	1,023,144	21%	988,591	20%
Angola	38,848,267	46,012,775	84%	6,746,998	17,896,626	46%	12,059,919	37%	6,327,907	19%
Guinea	8,390,040	18,385,909	46%	9,845,693	6,111,743	73%	4,477,033	34%	2,510,700	19%
Togo	6,268,140	11,590,232	54%	5,322,092	3,290,821	53%	2,037,429	25%	1,557,538	19%
Ghana	30,378,478	43,502,123	70%	13,026,126	13,047,826	43%	9,491,108	31%	5,807,263	19%
Ethiopia	46,251,810	160,949,016	29%	114,697,206	29,373,478	64%	24,769,870	22%	21,291,403	19%
Guinea-Bissau	1,618,870	2,755,197	59%	1,112,144	562,620	35%	519,455	26%	341,495	17%
Kenya	27,087,630	75,279,820	36%	48,192,190	17,871,145	66%	12,507,476	23%	9,079,472	17%
Libya	6,505,320	9,619,802	68%	3,114,482	3,451,352	53%	2,214,303	32%	1,140,236	17%
Sierra Leone	3,920,960	11,167,779	35%	7,183,761	2,868,978	73%	1,987,563	25%	1,315,830	16%
Namibia	3,047,220	3,557,282	86%	307,151	834,756	27%	453,540	18%	395,625	16%
Equatorial Guinea	820,000	1,964,179	42%	1,144,179	471,006	57%	264,393	19%	212,359	15%
Algeria	33,876,400	61,391,460	55%	27,276,085	15,205,854	45%	7,840,131	18%	6,481,186	15%
Gambia	671,600	3,383,330	20%	2,692,645	649,588	97%	331,266	14%	318,328	13%
Chad	4,537,890	22,996,203	20%	18,458,313	2,347,168	52%	2,212,530	13%	2,087,559	13%
Zambia	8,940,740	25,737,538	35%	16,796,798	3,750,417	42%	3,345,769	18%	2,333,446	13%
Republic of Congo	3,236,630	7,725,329	42%	4,484,441	831,318	26%	693,902	13%	652,422	12%
Djibouti	1,771,230	1,383,203	128%	0	272,655	15%	156,352	16%	116,303	12%
Gabon	1,630,600	3,116,019	52%	1,485,419	556,657	34%	300,871	14%	255,200	11%
Somalia	6,347,040	22,250,507	29%	15,903,467	3,559,066	56%	2,173,928	14%	1,385,138	9%
Sudan	9,652,430	61,388,977	16%	51,736,547	9,567,948	99%	5,919,717	14%	3,610,352	8%
Burkina Faso	7,586,910	29,264,589	26%	21,677,679	2,928,989	39%	2,434,140	12%	1,539,151	7%
Nigeria	64,113,760	288,595,422	22%	223,415,448	38,399,067	60%	25,654,988	12%	14,905,142	7%
Niger	6,077,570	33,889,290	18%	27,699,799	2,692,524	44%	2,190,790	9%	1,549,279	6%
Senegal	6,381,752	23,441,502	27%	16,474,150	2,496,373	39%	1,465,788	9%	1,045,680	6%
United Republic of Tanzania	12,820,424	83,627,898	15%	70,807,474	7,280,582	57%	6,483,895	11%	3,467,885	6%
South Sudan	2,121,370	15,671,221	14%	13,477,631	692,015	33%	643,273	6%	599,766	5%
Mali	6,490,400	28,351,168	23%	21,860,768	1,993,965	31%	1,427,227	7%	1,063,605	5%
Malawi	4,469,720	26,781,937	17%	22,292,607	2,054,585	46%	1,596,607	8%	908,688	5%
Cameroon	3,344,550	37,164,210	9%	33,720,692	1,828,882	55%	1,552,320	6%	1,209,108	5%
Madagascar	4,646,660	38,767,427	12%	33,059,014	2,264,611	49%	1,185,420	4%	1,051,811	4%
Democratic Republic of the Congo	14,394,340	125,385,966	11%	109,986,069	1,143,186	8%	1,771,324	2%	1,064,851	1%
Burundi	953,600	16,647,093	6%	15,693,493	12,464	1%	12,154	0%	11,582	0%
Eritrea		4,964,998		4,964,998						
Total	**772,005,230**	**1,874,357,227**	**41%**	**1,095,921,765**	**493,962,925**	**64%**	**305,382,198**	**23%**	**230,704,828**	**17%**

Data as of: 5/3/2022

Findings based on the support being given to nations by a number of partners indicate that governments may swiftly vaccinate large populations by utilising a variety of vaccination delivery mechanisms, such as mass vaccination campaigns and strong community participation. Positive outcomes depend on political commitment and effective and strong leadership. The COVID-19 vaccination programme's success depends on efficient coordination and enough funds to cover operating expenses (WHO Africa, 2022). These are crucial since data indicate that Africa has only been able to deploy only 64% of the total doses it has received (WHO Regional Office for Africa, n.d.)., despite the vast disparities between the vaccine doses required and those already available.

COVID-19 Vaccine Distribution and Performance Scores in Africa. (See (Nyantayi, 2022)

Global rollout of COVID-19 vaccines revealed that Africa scored an average of **33%** in the preparedness score for the COVID-19 vaccination campaign.

Africa scores an average of 2.5 (The World Bank (IBRD, IDA), 2018) on the World Bank's Logistics Performance Index (The World Banl (IBRD, IDA), n.d.), a reliable indicator of transportation and distribution logistics. The score is on a scale of 1 to 5, with a higher score indicating better performance. In six crucial areas of logistics performance, such as punctuality and tracking, Africa performs the worst out of all the world's major regions. Its detrimental effects on trade in the area have been well-documented for more than a decade. In some circumstances, the cost of imported items is expected to increase by 10% (Nathan Insights, 2014) as a result of customs delays, which is larger than the average effect of tariffs. But it's also now becoming evident how much shoddy transportation arrangements could hold down already sluggish efforts to immunise the local populace (Munemo, 2022).

A WHO evaluation (World Health Organization, 2020) conducted prior to the global rollout of COVID-19 vaccines revealed that Africa scored an average 33% in the preparedness score for the COVID-19 vaccination campaign. This falls well short of the intended standard of 80% in crucial categories like logistical performance and quality.

The quality of logistical performance appears to be connected with the COVID-19 vaccination rate across Africa, according to newly available data (see graph below). It is fascinating to examine vaccination rates between nations with different Logistics Performance Indices, such as the DRC, and nations with different Indices (such as South Africa).

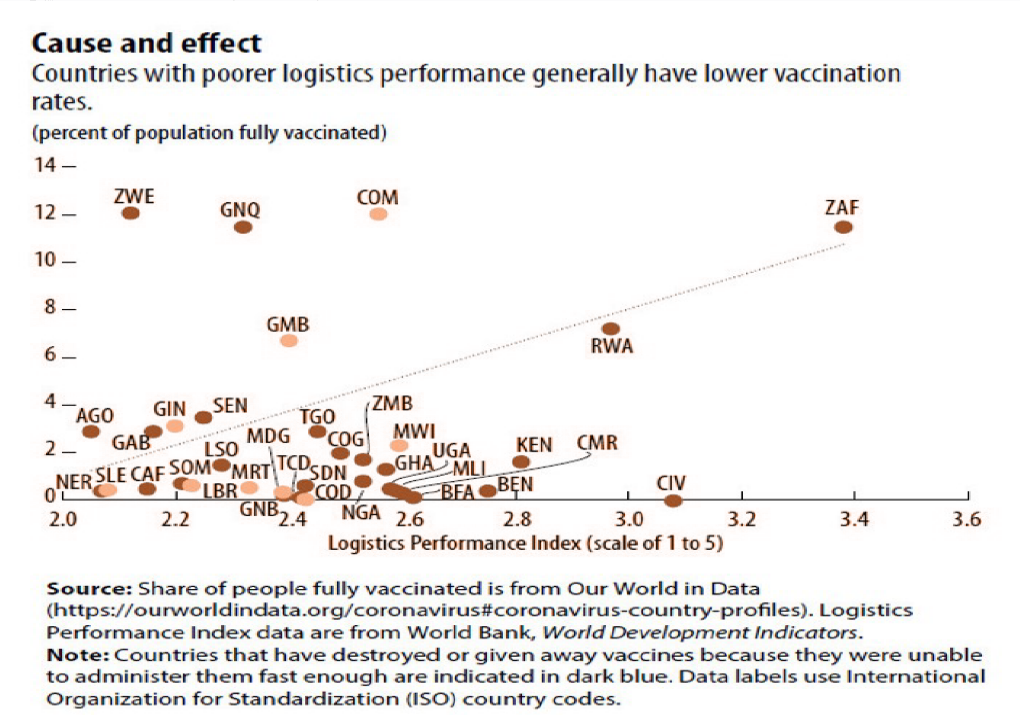


Fig 8: Logistics performance quality and the COVID-19 vaccination rate across
Source: World Bank (EUGENE BEMPONG NYANTAKYI, 2021)

The DRC's low ranking of 2.43 is a result of its problematic transportation system. This has made it challenging to provide vaccines to rural locations, which partially explains why only about 0% of the population has received all recommended vaccinations.

The DRC and other landlocked African nations have additional difficulties in integrating to global supply chains due to location and economics of scale. This has caused transportation and distribution delays, making it impossible for Malawi, South Sudan, and the DRC to deploy and deliver vaccines on short notice. South Africa, on the other hand, comes out as the highest performer with a score of 3.38.

However, despite having lower scores on the Logistics Performance Index, Zimbabwe, Equatorial Guinea, and the Comoros have considerably higher vaccination rates. This shows that vaccine uptake in Africa may be influenced by additional factors. For instance, the vaccination rate considerably increased in major cities when authorities in Zimbabwe warned that those who refuse COVID-19 vaccinations risk losing their access to public sector jobs and services. Despite its subpar logistics performance, it elevated Zimbabwe to one of the continent's nations with the highest vaccination rates.

There are many insightful lessons from various vaccination campaigns in Africa. For instance, when Côte d'Ivoire began its vaccination campaign (TRT World, 2021), clinics designed to immunise 300 people per day had trouble immunising 20 per day. Then, although at a hefty expense, the government sent out mobile clinics and medical buses that traveled to the busiest locations to immunise individuals.

Currently, there are 113 districts with fixed or mobile vaccination centres, and virtually all of them are functioning at or near capacity. Ghana also followed suit deploying its vaccines using mobile drone technologies to hard-to-reach places. With assistance from development organisations, this could be quickly copied and upscaled throughout the region. By learning from South Africa and Nigeria, Africa may make use of digital platforms for registration and information regarding the availability of vaccines. A new e-appointment system allows citizens to schedule their own COVID-19 vaccination appointments at a convenient time and at a centre close by. This however, may lso need to be upscaled particularly for rural areas who may not have access to digital and technology platforms.

It is critical to develop the infrastructure inputs to the supply chain that affect logistics performance, particularly in cold-chain capacity. The COVID-19 vaccines require special treatment, handling in transit and when administered. ***The AstraZeneca vaccine can be stored safely in refrigerated conditions for up to six months. Both the Pfizer and Moderna vaccines require temperatures of –20 degrees Celsius or less. It is therefore quite concerning that a WHO survey of 34 countries found widespread gaps in cold-chain refrigeration capacity in Africa.*** About 30 per cent of countries surveyed have gaps in cold-chain refrigeration capacity in more than half of their districts. Only 28 per cent of health facilities in sub-Saharan Africa are estimated to have access to a reliable power supply. Addressing these structural issues should be a development priority in the medium term.[15]

Africa may make use of digital platforms for registration and information regarding the availability of vaccines. A new e-appointment system allows citizens to schedule their own COVID-19 vaccination appointments at a convenient time and at a centre close by.

16. https://www.downtoearth.org.in/blog/world/covid-vaccines-african-countries-need-to-fix-their-distribution-chains-81469

Part 5

Inequitable Access to COVID-19 Vaccines In Africa

Vaccine Inequality and Inequity

Vaccine inequality is the term used to describe the unequal distribution of vaccines around the globe, which may be caused by socioeconomic issues and/or other factors. Vaccine inequity on the other hand occurs when the inequality becomes unjust. According to the principle of equity, everyone should have equal access to vaccines and vaccination that can prevent illnesses, regardless of where they are in the globe. Hence, the present worldwide disparity in access to COVID-19 vaccinations is undoing earlier achievements in the rapid vaccine development and unnecessarily extending the epidemic.

The global roll-out of COVID-19 vaccines to date is neither inclusive nor adequately planned. Many countries are already administering boosters while the rest of the world remains far behind. Despite the urgent need to increase vaccination, Africa has received too few vaccines from the global supply. According to the Foresight Africa 2022 Report (Sidibé, 2022), as at January 2022, out of more than 9 billion vaccines doses produced, Africa, despite having 17 per cent of the world's population, has only received approximately 540 million—about 6 per cent of all COVID vaccines—and administered 309 million doses. Less than 10 per cent of Africans are fully vaccinated. In other words, approximately 1.2 billion Africans have not received a single dose of vaccine and, at the current rate, many Africans may not be vaccinated until 2023. Given the possibility of harmful mutations that could impair the effectiveness of vaccines, such vaccine inequality is not simply unjust but also epidemiologically wrong. Africa may so end up being the COVID epicentre. Be it inequality or inequity, as long as any nation of the world does not have access to the COVID-19 vaccine they need, the whole world will continue to be at risk.

Inadequate access to the COVID-19 vaccine particularly in Africa and other LMICs threatens all countries of the world, and risks reversing hard-won progress on UHC and the SDGs. A WHO news release of its Global Dashboard on COVID-19 vaccine equity, finds low-income countries would have added $38 billion to their 2021 GDP forecast if they had the same vaccination rate as high-income countries (World Health Organization, 2021). Global economic recovery continues to be at risk as vaccines are not equitably manufactured, scaled up and distribute (World Health Organization, 2021).

More than six months after the COVID-19 vaccines were first distributed, in July 2021, nearly 85% of all doses were distributed in high- and upper-middle-income nations, and 75% of those doses were distributed in just 10 nations, including the United States, the United Kingdom, Germany, and France (Mathieu E., 2021). These dramatic differences in COVID-19 vaccine availability between high-income and low-income nations so far seem to have occurred throughout previous pandemics in a similar pattern. For instance, developed nations first bought and stocked up as much vaccination as was produced during the 2009 H1N1 pandemic. Donations to LMICs were frequently insufficient, even when WHO and UN stepped in to try to procure vaccines for developing countries (Archana Asundi, Commentary - Global COVID-19 vaccine inequity: The scope, the impact, and the challenges, 2021).

Vaccine Nationalism

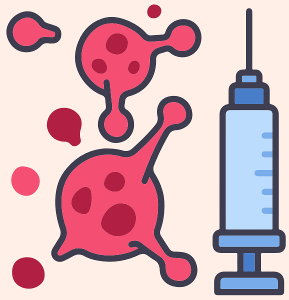
Like vaccine inequality and inequity, vaccine nationalism is not a recent phenomenon and has been practiced by a number of high-income countries during prior health crises. The 'me-first' strategy used by wealthy nations to secure access to vaccinations for their populations while reducing the stock accessible for other 'less fortunate' nations is known as vaccine nationalism, a significant cause of vaccine inequity. It is a broad political notion that can be used in a variety of situations and mainly refers to prioritising the interests of one nation over those of other nations for security or economic considerations (Mehr Muhammad Adeel Riaz, 2021).

As 2020 ended, wealthy nations jumped at the first COVID-19 vaccines that were made available, prior to less wealthy nations having a chance. In fact, the wealthiest nations made advanced contracts with manufacturers, dominating the market and hoarding doses. According to The Guardian, by late January 2021, Canada had secured enough doses to vaccinate its population more than five times over (Ashley Kirk, 2021), while poor countries were pushed to the back of a lengthy queue (Browne, 2021). In January 2022, while the wealthy countries were administering booster jabs, many of the poor countries were battling access to vaccines to fully vaccinate their population.

Prioritising one's population is comprehensible, but the means by which this was done in the context of the COVID-19 vaccine access is thought to be morally and ethically wrong. Many international declarations and treaties emphasise the human right to health, notably ***Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination. Article 12 of the International Covenant of Economic, Social, and Cultural Rights (ICESCR) is the focus of discussion when it comes to the right to health. Although it is highlighted that the ICESCR's text lacks any jurisdictional limitations, it appears to affirm human rights on behalf of every member of the human family.*** Unlike other corresponding international agreements, ICESCR has made it easier for countries to exercise unethical conduct to secure vaccines in enormous quantities while developing countries struggle to attain them at all (Mehr Muhammad Adeel Riaz, 2021).

Drivers of Vaccine Inequity in Africa

External Drivers



The average cost of a COVID-19 vaccine, according to data from UNICEF , ranges from

$2-$37

In addition to vaccine nationalism, another external factor contributing to vaccine inequality in Africa is the price of vaccination—that is, the logistics and procurement costs or, more generally, their affordability. The average cost of a COVID-19 vaccine, according to data from UNICEF,[17] ranges from $2 to $37 (UN News Global Perspective Human Stories, 2021). For low-income countries, where the average annual per capita health expenditure is $41, this poses a considerable financial burden. The vaccine equity dashboard also shows that low-income nations would need to boost their healthcare spending by between 30% and 60% to reach the goal of vaccinating 70% of their population (UN News Global Perspective Human Stories, 2021). Without rapid global financial support, this would be a herculean task.

The growing disparities between Africa's vaccine needs and the amount of vaccines supplied, difficult production forecasts, and the emergence of vaccine apartheid – the gap in vaccine distribution between wealthy countries and LMICs (Univ. of Washington Department of Global Health, 2022) – are additional external factors contributing to vaccine inequity on the continent. Also, vaccine inequity in Africa has been exacerbated by unfulfilled pledges by wealthier nations to provide vaccines, which has resulted in mistrust and low vaccination rates even after the vaccines were finally supplied. Rich nations have been pressured into pledging to contribute a significant amount of doses to underdeveloped and middle-income nations. However, not many of these promises have yet resulted in vaccines at hand. More than 1.3 billion vaccine doses had been pledged as of October 2021, but just about 10% was delivered over the same period. In the meantime, the majority of these developed nations have fully immunised the majority of their populations and are sitting on hundreds of millions of extra doses of COVID-19 vaccine. When these dosages are eventually donated, some of them will already be

17. COVID vaccines: Widening inequality and millions vulnerable | | UN News

nearing the end of their shelf life; again resulting into mistrust and low levels of vaccine uptake in less wealthy countries (Gleeson, Wealthy nations starved the developing world of vaccines. Omicron shows the cost of this greed, 2021)

Internal Drivers

A lack of manufacturing is one reason that just a little of the continent has been fully vaccinated against COVID-19 (Nature, 2022). The COVID-19 pandemic has highlighted Africa's weaknesses in securing access to essential medicines, vaccinations, and medical innovations. More particularly, it has brought attention to the significant gaps in vaccine production as a whole on the continent. Before COVID-19, although consuming more than 25% of all vaccines manufactured globally, Africa has been manufacturing less than 1% of the vaccines it needed, importing over 98% of them. The 10 vaccine production facilities on the continent are located in Egypt, Morocco, Senegal, South Africa, and Tunisia (WHO Africa, 2021); however, the current vaccine production capacity has mainly been focused on supplying internally to each country, with very few exports taking place.

Even now, much of the vaccines produced at these facilities is packaging-formulated and imported from abroad (Mlaba, 2022), even though it has taken these facilities decades to achieve their current manufacturing capacities. For instance, while COVID-19 vaccines are made in South Africa, they are not locally created. The nation's manufacturing facilities only assemble the vaccines into vials and package them. The actual vaccine material is produced abroad.
Africa’s low capacity to manufacture vaccines has contributed largely to inadequate access to COVID-19 vaccines which has become a threat to the global response to the COVID-19 pandemic (Mlaba, 2022).

This should be a global concern since equity principle behoves that all people, wherever they are in the world, should have equal access to the vaccines they need, to protect themselves against disease infection and spread. Since vaccine equity also means that vaccines should be allocated equally across all countries, regardless of regional, developmental or economic status, the low vaccine development and production capacity in Africa should be a cause for concern. Vaccine inequity in the face of a viral-induced crisis is nothing new, and the COVID-19 pandemic has been no different, hence the need to urgently address vaccine production capacities in Africa in preparation of future pandemics.

Africa’s inadequate capacity to develop and manufacture vaccines may be premised on some of the factors identified by Archana et. al., 2021, published on the National Library of Medicine Journal (Archana Asundi 2021). See Box 5 for excerpts.

Medical technology patenting:

Next-generation COVID-19 vaccines incorporate a large number of patent-protected technologies, ranging from the modified adenoviral vectors to the lipid nanoparticles used to deliver mRNA and the design of a stabilised SARS-CoV-2 spike protein that serves as the critical antigen for multiple vaccines. Liberalising intellectual property rules around these innovations via a Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver would make these underlying technologies available for use at a global scale. Proponents point to the Treatment Action Campaign and the TRIPS waiver granted for antiretroviral therapies as evidence that this approach can greatly improve access to COVID-19 vaccines. However, as many vaccine developers actively worked to set up licensing agreements or pledged not to enforce patent protections for COVID-19 vaccines, legal barriers may not be the primary barrier to global vaccine equity. In this event, liberalising patent laws is a first step toward improving equity but will not be the whole solution.

Production and supply chain barriers:
Production and supply chain barriers remain a larger constraint on global vaccine equity. The ability to produce complex biologic products, including vaccines, remains highly unequal and concentrated in certain countries, including the United States, European Union, India, and China. Entire continents, such as Africa, broadly lack vaccine manufacturing capacity, despite having “finish and fill” capabilities. COVID-19 vaccines made in Africa currently utilize active ingredient produced abroad and shipped to these “finish and fill” facilities—at this time there are no complete COVID-19 manufacturing chains in Africa.

This is, in part, a side effect of a constricted supply chain that uses highly specialized materials. For example, the mRNA caps utilized in mRNA vaccine manufacture are primarily produced by a single company that holds the IP rights. Ionizable cationic lipids, which are critical for mRNA vaccine delivery, are subject to a considerable supply bottleneck—limiting the number of doses of mRNA vaccine that can be produced. Currently, the technical capabilities of the vaccine manufacturers that do exist in Africa to produce next-generation vaccines is likely limited.

Technology transfer and regulatory capacity:

Legal and production barriers to expanding vaccine production are further compounded by technical barriers related to technology transfer and regulatory capacity, such as the concentration of vaccine production knowledge in companies in HICs and the current dearth of trained personnel in LMICs. National Regulatory Agencies (NRAs) also play critical role in vaccine development and production process. NRAs are saddled with the responsibility of ensuring the safety of pharmaceutical products including vaccines. So far, most of the NRAs in Africa do not have the capacities to regulate vaccine production.

Research and development as obtained between HICs, LMICs and LICs:
The lack of research and development infrastructure and personnel in LMICs is a significant challenge to vaccine technology transfer and reflects overall urgency for international investment in research capacity strengthening for this and future threats. Likewise, the weaker regulatory and surveillance capacity in many LMICs represents a technical barrier to both producing high-quality vaccines that are safe and efficacious and monitoring the safety of vaccines as they are administered using domestic surveillance capabilities, as opposed to relying on WHO adverse event monitoring. This is a critical barrier to where the manufacturing and deployment of in-country manufactured vaccines can be expanded: the WHO estimates that only 30% of national regulators have the current capability to effectively oversee vaccine manufacturing and administration of those vaccines. Together, these challenges represent immediate barriers to expansion manufacturing capacity but also highlight areas where global investment needs to focus moving forward.

Box 5: Factors contributing to the low vaccine manufacturing capacity of Africa (Archana Asundi 2021)

Apart from vaccine manufacturing and R&D capacity, internal drivers within the continent have also contributed largely to inequity. These drivers are also directly or indirectly related to vaccine hesitancy and low uptake within the continent. These include:

Weak Health Systems

Many African nations struggle structurally to coordinate their national health systems to ensure that COVID-19 vaccinations are strategically prioritised, purchased, and distributed. For instance, notably, only a few member states in Africa currently meet the core public health system requirements necessary to fulfil the obligations to ensure basic health security and essential public health functions after more than a decade under the WHO's revised International Health Regulations (IHR) from 2005. Since no African country has a readiness score of 80, none of them is totally prepared for public health emergencies or disease outbreaks (Resolve to Save Lives, n.d.). The failure to strengthen fragile and underfunded health systems is among the major reasons that vaccination coverage for several infectious diseases, including COVID-19, remains far from optimal on the continent.

Most African countries currently do not have qualified National Regulation Agencies (NRAs) saddled with the responsibility of ensuring vaccine licensure and safety from the point of production. Every country has a regulatory agency that ensures that vaccines used within the country are safe and effective. These bodies are commonly known as the NRAs. Standard NRAs are needed to start local vaccine manufacturing. Many African regulators are unfit to adequately regulate local vaccine production due to a lack of functioning NRAs. Only two NRAs, Tanzania and Ghana, in Africa have attained the World Health Organisation's (WHO) level, required for WHO pre-qualification of local vaccines (ADERINTO, 2021).

These and many other weak points including inadequate funding and ineffective policy implementation, contribute significantly to the continent's weak health systems and limit its ability to meet its vaccine needs.

Suboptimal Governance Structures

Vaccine inequity is also symptomatic of poor governance structures for health security on the continent. Most African countries during the COVID-19 pandemic resulted to ad-hoc or emergency governance structures like COVID-19 tax force and presidential steering committees which oversaw governments' pandemic response programmes. These governance systems were unsustainable and only coordinated responses effectively at the national level as the case may be, leaving sub-national levels to grapple for support and attention. This problem is also evident in almost every government setting making coordination extremely difficult and rendering programme implementation ineffective at grassroots levels.

For instance, in Nigeria, the Nigeria Centre for Disease Control (NCDC) is the coordinating agency for health security, epidemic preparedness and response. However, NCDC is yet to be domesticated within state and local government structures, making health security interventions by the agency extremely difficult across the country. Also in the same country, coordinating with other Ministries, Departments and Agencies having implications on health security also seems difficult, because of competition for resources, duplication of responsibilities and activity prioritisation. To change this narrative, governance needs to be decentralised vertically and horizontally and with relevant government structures strengthened to localise policy and programme implementation in an integrated manner.

Acceptability and Trust

The trust and acceptability of vaccines may be influenced by a number of factors. These may include conflicting cultural and religious views, mistrust of modern science, past negative experiences with vaccines in one's own life and in their community, as well as unpleasant reactions. Stories about negative side effects and a lack of information about them can make whole populations resistant to vaccination.

Public opinion about vaccines is known to be shaped by prior personal and communal experiences with vaccination. For instance, the present COVID-19 immunisation boycott in several areas in Kano state, Nigeria, is related to the tale of a 1996 Pfizer medication experiment and its results. The firm claimed that the debilitating impairments suffered by scores of study participants, including blindness, paralysis, deafness, and neurological deficiencies including the 11 children who died during the research, were caused by meningitis and not the administered drug (ABIDAKUN, 2021).

There are also reports of African countries becoming dumping grounds for expired COVID-19 vaccines. These doses were donated by wealthier countries but were only released for shipments close to the end of their shelf lives. For instance, in December, 2021, Nigeria destroyed more than a million doses of AstraZeneca's COVID-19 vaccine which had been sent to the country despite them being set to expire (euronews, 2022). These instances create mistrust with questions arising as to what the aim of donation of expired vaccine doses to Africa could be.

Communication/Information Gaps and Vaccine Skepticism

Critical elements that also contribute to vaccine inequality in Africa are ignorance, misinformation, and deception. The majority of false information and misinformation that has been spread concerning COVID-19 vaccinations has centred on COVID-19 denial as well as vaccine development, safety, and efficacy. Some of these disinformation strategies emphasised narratives around vaccines containing microchips used by governments for intelligence, spying, and tracking. Or stating that vaccines had metals that interact with magnets and speculations that they were developed to create super-humans by altering the human DNA. Some people even believed COVID vaccines are measures to reduce population as they alter fertility. Most of these narratives contribute to vaccine skepticism.

Stakeholders including the government, must therefore address communication gaps as it relates to COVID-19 and its vaccine. Although there are efforts to disarm miscommunication through media campaigns on media platforms like TVs, radio and social media, however much needs to be done to reach local communities without access to these kind of media services. This will ensure that people are well educated about the pandemic, the importance of the vaccine and vaccination and dispel negative information being spread around. As exemplified in one of Tanzania's districts, beyond media campaign, community engagements helped debunk spreading miscommunications about the COVID-19 vaccine and accelerated uptake in the target communities (All Africa, n.d.).

The Impact of Global Vaccine Inequity

In the concerned nations and around the world, inequities in vaccination coverage have both direct and indirect effects. In addition to the immediate diseases and deaths, continuous susceptibility to case spikes limits the ability of healthcare systems already struggling to address other health issues. The human resources needed to continue responding to COVID-19 and non-COVID-19 health burdens are impacted by illnesses and fatalities among healthcare personnel. Due to delayed vaccination efforts, childhood vaccination rates have fallen dramatically over the past year, delaying immunisation for 13.5 million individuals in some of the world's most vulnerable nations (US GLobal Leadership Coalition, n.d.). Continued COVID-19 transmission fosters an environment for viral evolution to continue. Some of these changes may offer a selective advantage in terms of transmission or immune evasion, as has already happened over the past year. Those who are unvaccinated or who are unable to build a strong enough immune response to vaccination could be particularly at risk from these viral variations in HICs. Additionally, overburdened healthcare and monitoring systems are much less likely to notice any potential hazards from newly developing and endemic infectious diseases (Archana Asundi 2021).

Additionally, the impact and prioritisation of the COVID-19 response have resulted in a significant increase in disease burdens, particularly in LMICs. For instance, according to Archana et. al., 1 million people were undiagnosed and untreated for tuberculosis, undercutting over a decade of investment in curbing this disease globally (Archana Asundi 2021).

Continual resource allocation to COVID-19 response at the expense of other development objectives can prevent countries from returning to normal socially and economically, in addition to the immediate health effects. Millions have been forced into extreme poverty as communities around the world struggle to rebuild their economy; it is anticipated that between now and 2030, 200 million people will be at risk of falling into extreme poverty (Archana Asundi 2021). Additionally, the epidemic has exacerbated food insecurity and had a negative impact on women's empowerment and worldwide early childhood education. The longer the COVID-19 pandemic persists as an acute crisis in LMICs, the greater the anticipated destruction to all the aforementioned indicators.

However, the cost to the economy of unequal vaccination distribution will also have an effect on the global economy. According to a RAND

Europe research, the world's GDP would still decline by $153 billion annually (including a loss of $40 billion in the EU and $16 billion in the US) if the poorest nations do not acquire the vaccine (Hafner M., 2020). Gven these financial expenses, HICs would recover around $4.8 for every $1 spent on vaccine supply.

More transmissible variants appear to be surfacing and increasing in cases in countries that were once believed to have dodged the worst effects of the pandemic due in part to a younger population, making the need for universal vaccine coverage even more urgent. Due to variants that seem to impact younger patients more than the original virus and, in some cases, leading to reinfections in those with prior immunity from natural infection, rises in Brazil and India appear to be driving case increases in countries nearby. The case of India brought to light the likelihood that massive gatherings and repeated introductions of these variants could foster a situation where more LMICs might see significant spikes, making the expediency of vaccination essential. New outbreaks across sections of Africa, Asia, Latin America, and Russia in July 2021 appear to confirm these fears (Archana Asundi 2021).

The Impact of Vaccine Inequity on Africa

Various studies and reports have highlighted and warned of socioeconomic impacts and increased risk of regional and global insecurity as a result of Africa's inadequate access to COVID-19 vaccines. In an opinion post by Tony Blair Institute published on CNBC Africa (Tony Blair Institute, 2021), some of the impacts of vaccine inequity on Africa are presented in Box 6.

Undoing Health Progress: In 2022 and beyond, we are likely to see a resurgence of diseases the world has worked hard to eradicate. Just 12 months of Covid-19 response has already eliminated 12 years of progress in the global fight against tuberculosis, according to a study by the StopTB Partnership, with critical outreach and services set aside, resulting in a 20% drop in diagnosis and treatment worldwide. But the biggest long-running risk posed by Covid-19 is on routine immunisation drives. According to the WHO, more than one-third of countries are still reporting disruptions to immunisation services.

Escalating Poverty and Food Insecurity: The World Bank estimates the pandemic-related economic crisis may push as many as 11m Nigerians into poverty by 2022, signalling a poverty rate of more than 50% for its 200m people. Food insecurity is a growing concern across the continent as prices rise as a result of global shortages, oil price rises due to growing demand from the reopening of advanced economies and currency depreciations which import costs. Global food prices in August were up 33% year-on-year, with emerging markets worst affected. African governments and the global community should prepare for a surge in humanitarian crises across the continent due to a depressed economic recovery.

Weak Growth: Modelling by the Economist Intelligence Unit predicts that developing economies will bear the brunt of output shortfalls because of global vaccine inequity. Countries that are unable to achieve at least 60 per cent vaccination coverage by mid-2022 will suffer $2.3 trillion in GDP losses by 2025. With around $230 billion in cumulative projected shortfalls, Sub-Saharan Africa will experience the highest losses in terms of GDP share, totalling 3% of the region's 2022 to 2025 output forecast.

Increasing Debt, Declining Investment: Weak growth rates will compound negative shocks to fiscal balances and debt positions. Before the pandemic, debt taken on by many African countries was already reaching unsustainable levels. Policy measures required to respond to the pandemic have pushed even more nations into debt distress, with governments having difficulties servicing debt. Many countries in Africa will have to cut back on development-critical spending in order to continue responding to the pandemic while avoiding a loan defaults, making them even more reliant on foreign assistance.

Restricted Travel and Tourism: The fiscal outlook will be depressed by the continuing reduction in tourism revenues. The services sector, which had been growing rapidly and accounted for approximately 55% of Africa's GDP in 2016, will see a slower recovery than others, largely because of continuing restrictions and hesitancy around cross-border travel.

Learning Deficit: In 2022, as the continent continues to move to control new waves of transmission through lockdowns, instead of mass vaccinations, domestic and global educational disparities will widen between the wealthy and poor. The education of millions of young Africans is at stake, as well as the future of the region.
Risk of New Variants: With Covid-19 continuing to spread among unvaccinated populations, there will be a constant risk of potentially more potent variants developing. As we have seen with the global impact of the Delta variant, new variants are a risk to vaccination efforts everywhere, threatening to undo the scientific and public-health progress of the past 18 months. It is in the interest of high-income countries to ensure the world is vaccinated as soon as possible to prevent the development of dangerous mutations.

Risk of instability in Africa and increased Migration: Sustained health and economic insecurity in Africa could heighten domestic unrest and increase opportunities for extremism. As some states lag behind in addressing economic challenges and social frustrations arise from the pandemic, governance-related challenges from terrorist groups may increase. Several terrorist groups are already exploiting the pandemic. Instability could even drive new waves of migration.

Risk of Greater Inequality and Reduced Global Resilience to Existential Threats: A Great Divide is likely to deepen gaps between wealthy and poor countries, increasing global instability, generating economic uncertainty and sowing geopolitical tensions. With this outcome, the world will be even more ill-equipped to address other pressing existential issues, such as the climate crisis or another pandemic.

Risk to the global economy: All these factors – from variants to growing extremism – could drive up instability in Africa, with negative consequences for the global economy, as uncertainty diminishes consumer confidence and holds back investment. The economic impact of the Great Divide will be most acutely felt in Africa, but its sluggish recovery and growing instability will dampen the long-term global economic outlook.

Box 6: Impact of Vaccine Inequity in Africa. Culled from an opinion post by Tony Blair Institute as published on CNBC Africa (Tony Blair Institute, 2021),

Effects of Vaccine Inequity on Population Groups

Women and Girls

During the lockdown resulting from COVID-19 response across many countries and regions, many school children missed learning chances and may never be able to catch up. Only a select few wealthy people could afford to take online courses. Many of these school children who could not go to school during this period will bear these consequences for the rest of their lives. This because – beyond just protecting the rights of children to education, in schools and colleges, girls and young women feel safe. Their education gives them the confidence to defend their rights. They gain respect for doing so in their families and communities.

Many of these girls and young women who could have been in schools become victims of predators who saw an opportunity to molest them since they are either being stranded at home or on the streets due to school closures. According to the United Nations International Children's Emergency Fund (UNICEF), there has been a shadow pandemic of sexual assault, with adolescent females becoming pregnant at an increased rate of over 20 per cent (Amoding, 2021).

During the lockdown, there were numerous instances of violence against women, some of which resulted in fatalities. For instance, according to a report released by the United Nations, Nigeria in May 2020, the State Domestic and Sexual Violence Response Team in Lagos, Nigeria, recorded a threefold rise in phone calls made to their hotlines in a single month. Domestic violence and intimate partner abuse cases sharply increased, according to service providers. The report also showed a sharp increase Gender-Based Violence in a month between March and April 2020. All the country's geopolitical regions and states showed the same pattern in the data (United Nations Nigeria, 2020). (See Table 5 and Fig 6).

Geopolitical Zone	State	Number of Cases per State		Number of Cases per Geopolitical Zone	
		March 2020	*April 2020*	*March*	*April*
North-East	Adamawa	16	20	50	115
	Bauchi	9	30		
	Borno	6	26		
	Gombe	19	39		
North-West	Kaduna	6	23	52	87
	Katsina	23	33		
	Sokoto	23	31		
North Central	Benue	30	52	57	156
	FCT	5	31		
	Nasarawa	5	20		
	Niger	2	8		
	Plateau	25	45		
South-East	Abia	25	46	36	92
	Anambra	3	22		
	Ebonyi	5	2		
	Enugu	3	22		
South-West	Ekiti	25	51	91	296
	Lagos	37	185		
	Ogun	18	22		
	Osun	3	18		
	Oyo	8	20		
South-South	Cross River	8	12	18	35
	Rivers	10	23		

Table 5: Number of reported cases of Gender-Based Violence in Nigeria during March and April 2020 by State and Geopolitical Zone. Adapted from GENDER-BASED VIOLENCE IN NIGERIA DURING THE COVID-19 CRISIS:THE SHADOW PANDEMIC (United Nations Nigeria, 2020).

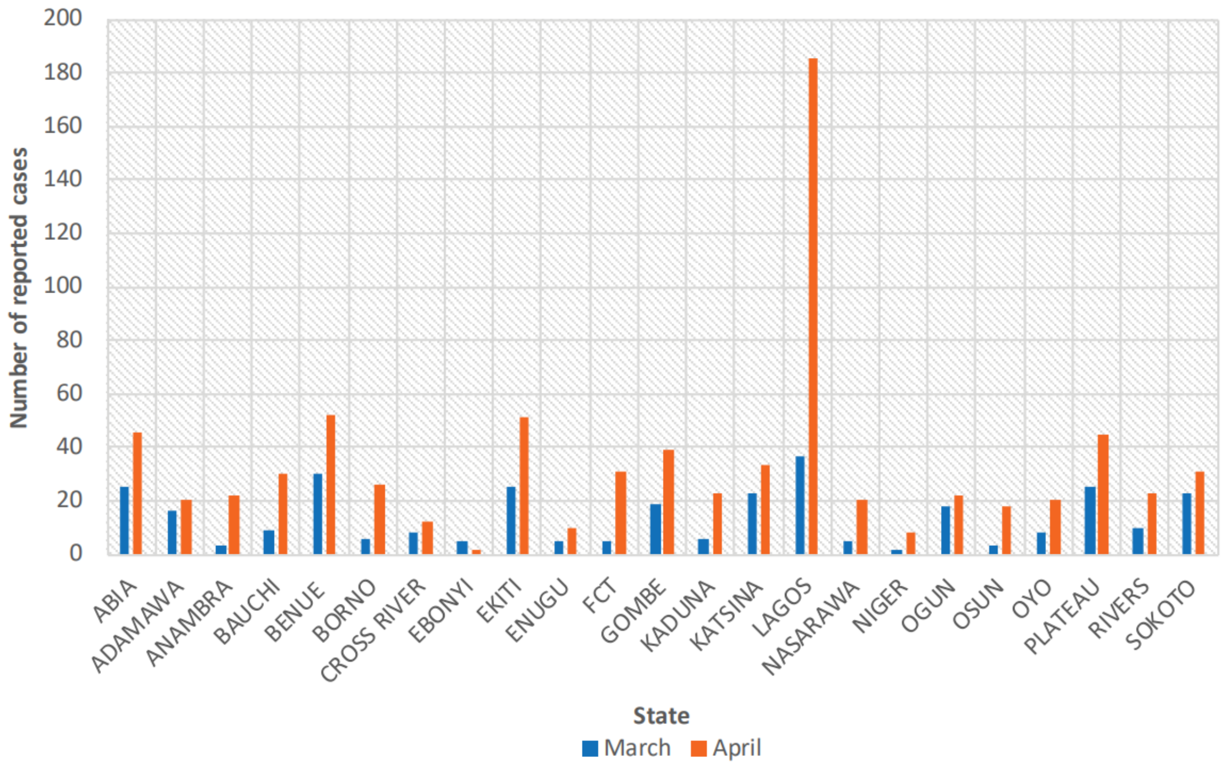


Fig 6: Analysis by UN Nigeria, showing marked increase in gender violence based on reports from across every state in Nigeria (United Nations Nigeria, 2020).

The COVID-19 epidemic is thought to have caused an estimated 114.4 million people to fall into extreme poverty, with women making up roughly 58 million of that number, this is according to the World Economic Situation and Prospects (WESP) mid-year assessment (UN News Global Perspective Human Stories, 2021). In spite of the fact that women make up the majority of health professionals, and other key service providers as suggested by the report, the survey revealed that women have also been the most severely affected. Globally, the labour force participation rate decreased by 2% during the pandemic, compared to only 0.2% during the 2007–2008 financial crisis, however more women than men were compelled to quit their employment to take care of their families. The survey states that women-owned enterprises have performed disproportionately worse.

Children/Students and Teachers

If vaccination inequity is not addressed, children are also greatly affected by the pandemic. The WHO predicted that 42-66 million children could experience extreme poverty as a result of the crisis, adding to the estimated 386 million children who were already living in extreme poverty as of 2019. This estimate was included in the WHO's policy brief on the impact of COVID-19 on children (United Nations, 2020).

Additionally, the pandemic has made learning problems and challenges worse. There were nationwide school closings in 188 countries, affecting 1.5 billion children and teenagers (United Nations, 2020). ***It is difficult to imagine the possible learning losses that could result for the children of today and the growth of their human capital.*** Although many countries set up or reverted to online platforms, however, the use of online learning platforms by children for distant learning raised the danger of their exposure to improper content and online predators (United Nations, 2020).

Children also face threats to their health and survival. This is due to the possibility that the financial difficulties faced by families as a result of the global economic slump could cause more child deaths, undoing the previous years' worth of gains in lowering infant mortality in just a sweep of a single pandemic. Also the pandemic may have also resulted in service interruptions. As 368.5 million children in 143 countries who often rely on school meals as a stable source of daily nutrition must now resort to other sources, it is therefore projected that malnutrition would increase (United Nations, 2020). Additionally significant hazards exist for children's mental health and wellbeing. Children who are refugees or internally displaced, as well as those who are in prison or in locations of active conflicts are especially vulnerable.

People Living with Disabilities and Populations in Conflict Zones

Vulnerable groups with particular requirements, including those who are disabled or have been forced from their homes due to war or other conflicts, are affected specially by the pandemic. These populations typically need specialised care and assistance with both daily requirements and basic and daily necessities. They are given priority by governments around the world, who allocate funding for relief and specialised initiatives. Since aid, support, and programmes intended for them are diverted for the COVID-19 response, increasing their hardship and resulting in insufficient access to basic needs like food and sanitation, the impact of the pandemic and the prolonged response to the pandemic are not less the same on these population. In addition, not providing these vulnerable groups with the adequate refuge in place facilities during lockdowns increases the likelihood that these groups will see or experience violence and abuse. Children in crisis situations are at a high risk of molestation and other security threats, as are children living in unhygienic and congested conditions. Some of them may result to street begging further exposing them to danger from social vices and other security threats.

Healthcare Workers

Due to vaccine inequality, frontline healthcare providers as well as healthcare professionals in general continue to be at risk in Africa. During any disease outbreak, an equitable vaccination strategy should adequately provide for frontline workers among those to be vaccinated first due to their vulnerability and exposure as they treat infected individuals. Though there may be available vaccine mandates and non-mandatory strategies prioritising health workers, these are however the subject of ongoing controversies.

In African nations where vaccination rates are still as low as two people per every 100 inhabitants, this raises severe concerns as far as frontline response and health workers are concerned. Therefore, it is important to give serious thought to the best ways to inclusively expand coverage of vaccination programmes in Africa ensuring that health workers are prioritised as soon as vaccines are available.

Informal Sector

Most countries have no specific vaccination programmes for populations in the informal sector, despite their huge population. This population group lacks access to basic amenities like water, electricity, internet, and the information they need to be properly informed about COVID-19 vaccines. Some live in hard-to-reach places and may have to travel long distances to reach vaccination centres. ***For instance, it is observed that response policies, including both the non-pharmaceutical and pharmaceutical measures developed and enforced by the COVID-19 task forces or committees set up by national governments were all developed with the formal sector in mind. For instance, hand washing policy that stipulates setting up of hand washing points in public places; this directive can only work where water and sanitation facilities are already in place. This is not so in areas populated by this population group. They also lack access to medical supplies like hand sanitisers.***

For pharmaceutical responses, some of the processes involved include online registration to secure dates and location of vaccination. Information concerning vaccinations were disseminated on social media platforms, websites and may be on television and radio as well as print media, this population group may find it difficult to access such information as result of lack of access to electricity, internet, mobile network, among others.

Prioritising response to disease outbreaks by countries may also indirectly affect people in this population group. People in this sector bear the brunt of job losses, losing their sources of livelihood due to economy shrink as a result of the pandemic. According to The Conversation (Racky Balde, 2021), workers in the informal sector experienced the highest job losses. According to the report, in Burkina Faso, Mali and Senegal alone, job losses in the informal sector were as high as 48%, 34% and 42% respectively. To prevent the resultant economic hardships particularly faced by people in the informal sector because of disease outbreak, vaccine inequity must be prevented when the next pandemic arrives, the interests of the whole world—not just the countries with the money

Overcoming Barriers to Vaccine Equity

Archana Asundi, Colin O'leary and Nahid Bhadelia in an article published on the National Library of Medicine in July 2021 (Archana Asundi 2021) provided insights and useful steps to ensuring vaccine equity globally. Excerpt from the article on overcoming barriers to vaccine equity is presented in Box 7.

The first step toward meeting the current global needs must be redistribution of surplus that is starting to develop in some high-income countries. Alternatives, such as increasing production capacity where it is currently possible and then facilitating the export of vaccine components, including active ingredient, to finish and fill facilities globally would ensure that vaccines reach markets with critical need. Continuing research and development, including support through expensive clinical trials, of additional COVID-19 vaccine candidates would further serve to increase supply. Were these candidates (such as protein subunit vaccines) to use different components than mRNA or viral vector-based vaccines, they may not be subject to the same supply chain bottlenecks currently constraining vaccine production. Moreover, initiatives such as COVAX continue to require full funding in order to ensure that COVID-19 vaccine production continues even as demand for vaccines in upper-income countries wanes. Over the next year these actions could dramatically improve equitable access to vaccines.

The possible approval of TRIPS waiver for COVID-19 vaccine intellectual property signals a desire to strive for global vaccine equity but true global vaccine equity will require a long-term, global effort to expand vaccine production capability, facilitate technology transfer, and develop regulatory systems that support vaccine innovation. Efforts are underway, financed by development banks and international development agencies, to expand the physical infrastructure necessary for vaccine production where it is currently nonexistent. Facilitating technology transfer and improving regulatory capability receive less priority—a critical oversight given the importance of a supportive scientific ecosystem to facilitating vaccine development.

Facilitating technology transfer could be paired with efforts to support the transfer of intellectual property rights for vaccines and their underlying components. A system in which established vaccine developers provide production know how to new vaccine manufacturers while licensing their products to these manufacturers would allow them to generate revenue from the use of their technology, while boosting vaccine manufacturing capacity globally. These efforts could be paired with commitments from vaccination programs to purchase vaccines locally, where possible, to support local manufacturers. The African vaccine market, in 2020, was estimated to be worth $1.2 billion annually, with 99% of vaccines imported from outside the continent. There is a market for vaccines that could be transitioned to local production. Moreover, as vaccine candidates for malaria and other endemic diseases that use next-generation vaccine technologies are developed, the size of the market for locally produced, next-generation vaccines will continue to grow.

Improving biopharmaceutical regulatory capacity, on a global scale, could be achieved by increasing collaborative programs between regulatory agencies. As part of their global health initiatives, the Centers for Disease Control and Prevention (CDC) regularly engages peer institutions to boost surveillance and infectious disease management capabilities. This model could be utilised by the Food and Drug Administration (or other medical regulatory agencies) to boost the regulatory capabilities of peer institutions beyond their current efforts.

Such activities should include improving the regulatory capabilities identified as critical in the Global Health Security Index (GHSI) (which was developed to measure readiness of countries to combat infectious disease threats across different sectors), as well as improving capabilities related to vaccine production and post-market adverse event monitoring where appropriate. Regulation is critical to ensuring the safe manufacture, utilizing good manufacturing practices, and use of vaccines, both traditional and next generation. For vaccine production to move forward in new markets and meet WHO standards, it is critical for a robust regulatory apparatus to be in place. The ability to regulate the manufacture of medical countermeasures, such as vaccines, and monitor their use during deployment (to detect adverse events and reduce the burden on WHO personnel) should be made a component of GHSI scoring.

Box 7: Steps to Overcoming Barriers of Vaccine Equity. Culled from National Library of Medicine (Archana Asundi 2021).

Alternatives to Nationalism

The first step towards eradicating vaccine nationalism should be to make efforts to increase global manufacturing and supply without compromising their efficacy and safety. Additionally, epidemiologists, virologists, and social scientists ought to collaborate with governments from all nations to develop an action plan for the quick vaccination of high-risk persons, including as medical professionals and patients with co-morbid conditions. As a result, herd immunity can be achieved quicker rather than the epidemic being prolonged by rising vaccine nationalism. To establish vaccination equity, a more open-minded strategy is needed. If this is not done, vaccine nationalism will have far-reaching effects that could cause irreparable harm to the struggling societies. The moral compass needs to be adjusted, and fairness needs to be supported, in order to address vaccine nationalism.

Part 6

Closing the Gap

Closing inequalities is crucial to influencing the pandemic's trajectory in Africa and around the world after addressing vaccine supply shortages. Because until every country is safe, neither a country nor a region can be considered safe. Access to vaccines shouldn't depend on one's socioeconomic situation. The introduction of COVID-19 virus variants has shown how linked the world is and that novel variants arising anywhere are a hazard everywhere, emphasising the significance of a fair vaccine supply. Setting everyone's safety as a top priority is the best strategy to protect people.

Closing the current gaps to vaccine access will take a complex approach, with actions varying across different timelines and actors. There are some sets of actions that need to be taken immediately to address prevailing issues and challenges. For sustainability, there are also actions for the medium and long terms, that will better prepare the world for future public health emergencies when they occur.

In the Short Term

It is imperative to take steps to significantly boost vaccine delivery and uptake. Countries on the continent must start implementing strategies to deal with unique uptake issues, and international leadership or platforms must find ways to immediately address the existing vaccine crisis and speed up the deployment of vaccines to individuals who have so far only gotten erratic supplies (Ghebreyesus, 2021). Five crucial actions need to be performed immediately on a worldwide level to address the present vaccination disparity crisis, according to a research article published on Plos Global Public Health (Ghebreyesus, 2021). See Box 9

First, those countries that have contracted high volumes of vaccines should swap near-term delivery schedules with COVAX and the African Vaccine Acquisition Trust (AVAT). These mechanisms work but have been underused. At a time of global vaccine scarcity, stockpiled vaccines will ironically make populations less safe by allowing the virus to rip through unvaccinated communities, giving it free rein to potentially mutate into a variant that can evade vaccines.
Second, vaccine manufacturers should immediately prioritise and fulfil their contracts to COVAX and AVAT, and provide regular, clear supply forecasts. The lack of transparency or accountability around vaccine contracts has led to poorer countries sometimes paying more for vaccines than richer countries.

Third, G7 and all dose-sharing countries must fulfil their pledges urgently, with enhanced pipeline visibility, sufficient product shelf life and support for supplementary supplies. High-income countries have promised to donate more than 1 billion doses, but less than 15% of those have materialised so far.

Fourth, all countries must eliminate export restrictions and any other trade barriers on COVID-19 vaccines and the inputs involved in their production. The pandemic has exploited cracks in global solidarity and structural inequalities, with hoarding of personal protective equipment, tests, treatments, and vaccines. If we don't change course, that pattern won't change. It's not only a moral failure, it's epidemiologically and economically self-defeating and is having knock-on effects on everything from food prices to gender equality and even fostering national and regional insecurity.

Finally, getting this right takes leadership, economic capital, and a realisation that for a fast-moving respiratory pathogen, the only way out is to do so together. It is promising that some countries have recently increased their sharing of vaccine doses globally but there needs to be more and it needs to happen faster.
Furthermore, on the manufacturing side, since the beginning of the outbreak WHO has called for the sharing of licenses, technology and know-how.

Box 9: crucial things the world must do to end vaccine inequity (Ghebreyesus, 2021).

Key Recommendations

01 Nations must immediately abide by their pledges to provide COVID-19 doses to less developed nations. Additionally, surplus doses must be given to COVAX to speed up vaccination campaigns in Africa.

02 The supply line by the wealthy nations of the world needs to be cleared, and the COVAX facility and AVAT must be given first priority.

03 Export restrictions and other trade barriers must be lifted for Covid-19 vaccines and the materials used in their manufacture.

Medium-to-long term

The medium- to long-term solution is obvious. Because they cannot rely on the wealthy nations' extra production capacity for vaccine supply during this or future pandemics, less developed and smaller countries require access to local or regional manufacturing facilities. To lessen reliance on the business plans of a select group of commercial entities, a persistent effort to build and expand regional vaccine production capacity is required. This should incorporate agreements for licensing and technology transfer, like those created by the WHO and the Medicines Patent Pool, which have successfully made antiretroviral medications broadly and affordably available to treat AIDS, even in the world's poorest nations (David J. Hunter, 2022).

The WHO has taken things a step further by setting up vaccine hubs, like the mRNA vaccine centres in South Africa and five other African nations, providing the prospect for locally produced and manufactured vaccines for COVID-19 and upcoming pandemics. The establishment of national regulatory organisations is essential as Africa's potential to innovate and manufacture vaccines is enhanced. ***Most African nations lack regulatory bodies that would oversee vaccine production, provide quality control, and issue manufacturing licenses. For regulatory agencies to be developed across the continent, nations with well-established and competent regulatory agencies must offer mentorship and a peer-learning environment for the less developed NRAs of African countries.***

It is clear that, in the event of an emergency, the world will require an agreed worldwide framework for accelerating the creation of global public goods like vaccines, as well as their fair manufacturing and distribution. When WHO and UN member states meet for special sessions, the ideas of treaties or other international agreements for pandemic preparedness and response should be brought up to strengthen the new global health security architecture. Inequitable access to vaccines is a sign that the effort to control the epidemic globally failed. A global vaccine strategy that involves a framework of intellectual property management, manufacturing, and distribution that guarantees that vaccines are made available equitably around the world must address the haphazard methods currently being used for vaccine dissemination.

Key Recommendations

01 African governments need to find new ways to increase funding for the continent's R&D and vaccine production. HICs must be willing to assist and mentor African nations, particularly in building up their regulatory frameworks for the creation and production of vaccines.

02 International treaties that will encourage their members to agree on technology transfer and license sharing in a voluntary and regulated manner must be urgently considered by the UN, WHO, WTO, and other global multilateral bodies.

03 Nations must have flexible systems, institutions, and capabilities in order to roll out vaccines and respond to crises.

Appendix 1

Pandemics & Epidemics: A Short History

Disease outbreaks are not new. Throughout history, humanity has experienced the worst epidemics and pandemics, threatening its existence. These disease outbreaks have infected and killed millions. Some of the worst disease outbreaks in history have doomed whole civilisations and brought once-powerful nations to their knees. Though the study of epidemiology and advancement in science has created opportunities to prevent and respond to these outbreaks, however, they continue to cause socio-economic disruptions, contributing to global morbidity and mortality, as well as severe public health problems among other impacts. In the table below, key past disease outbreaks and their impact are highlighted.

Outbreak	Period	Location	Epidemiology (cause, origin etc)	Devastation/Death toll
Plague of Athens	430 BC, lasted for about 5 years	Athens, Greece	This disease outbreak was most likely to be typhoid fever or Ebola and caused by overcrowding due to the Peloponnesian war of 430BC. People infected experienced violent heats in the head, redness and inflammation in the eyes, tongue and throat becoming bloody and an unnatural fetid breath.	100K
Antonine Plague	AD 165-180, lasted for 15 years	Roman Empire	This is likely to be smallpox, brought back into the Roman Empire by soldiers returning from war.	5M
Plague of Cyprian	AD 250-271	Global	Victims experienced bouts of diarrhoea, continuous vomiting, fever, deafness, blindness, paralysis of their legs and feet, swollen throats, and bloody eyes (conjunctival bleeding), probably caused by Marburg and Ebola viruses	Not known (but as high as 5,000 deaths per day at its peak).
Plague of Justinian	AD 541-542	Global	Victims suffered from delusions, nightmares, fevers and swellings in the groin, armpits, and behind their ears. Originated from North Africa and spread by black rats and fleas on cargo ships.	30–50M (10% of the world's population at the time).
Japanese smallpox epidemic	AD 735-737	Japan	Smallpox caused by *Yersinia pestis* bacteria / Rats, fleas	1M
Black Death (Bubonic plague)	AD 1346-1353	Asia and Europe	It was caused by a strain of the bacterium *Yersinia pestis* that is likely extinct today and was spread by fleas on infected rodents.	200M
New world smallpox outbreak	1520	Indigenous Americas	Eurasian diseases including smallpox caused by *Variola major* virus.	56M. 90% of the indigenous population of the western hemisphere.
Cocoliztli Epidemic	1545-1548	Mexico and Central America	Skeletons of victims have lately shown that victims were infected with a subspecies of Salmonella known as *S. paratyphi C*, which causes enteric fever, a category of fever that includes typhoid. Enteric fever can cause high fever, dehydration and gastrointestinal problems and is still a major health threat today.	15M
Italian plague	1629-1631	Italy	*Yersinia pestis* bacteria / rats, fleas	1M
Great plague of London	1665-1666	London	*Yersinia pestis* bacteria / rats, fleas	100,000/15% of London's population.
Plague of Marseille	1720-1723	France		100,000/30% of the population of Marseille
Russian Plague	1770-1772	Russia		100,000

Philadelphia Yellow Fever Epidemic	1793	USA	High fever caused by mosquito	5,000
Third Plague	1885	China and India	*Yersinia pestis* bacteria / Rats, fleas	12M
Russian Flu Pandemic	1889-1890	Global	Influenza viruses, believed to be H2N2 (avian origin)	1M
Yellow fever	Late 19th Century	US	Virus/mosquito	150K
American polio epidemic	1916	Global		
Spanish flus	1918-1920	Global	H1N1 Virus traced to pigs	100M, with over 500,000,000 infections recorded
Asian flu	1957-1958	Asia	Avian flu viruses	1,1M
Hong Kong Flu	1968-1970	Hong Kong	H3N2 virus	1M
AIDS pandemic and epidemic	1981–Present Day	Global	HIV, the virus that causes AIDS, likely developed from a chimpanzee virus that transferred to humans in West Africa in the 1920s. The virus made its way around the world, and AIDS was a pandemic by the late 20th century.	35M
H1N1 Swine Flu Pandemic	2009-2010	Global	The Swine flu pandemic was caused by a new strain of H1N1 that originated in Mexico in the spring of 2009 before spreading to the rest of the world. In one year, the virus infected as many as 1.4 billion people across the globe.	500k
West African Ebola Epidemic	2014-2016	West Africa	Ebola virus from wild animals	11,325
Zika Virus Epidemic	2015 till date	South and Central America	The Zika virus is usually spread through mosquitoes of the Aedes genus, although it can also be sexually transmitted in humans.	
COVID-19	2019 till date	Global	Coronavirus–SARS-CoV-2	6M with over 458M cases reported.

Timeline of Major Disease Outbreaks in History (Jarus, 2021) (LePan, 2020)

NB: Analysis with infographics-Timeline, showing date, location as well as epidemiology and devastation. See the next page

Fig 1: Timeline, showing date, location, epidemiology and devastation of past disease outbreaks

History of Pandemics

PAN-DEM-IC *(of a disease) prevalent over a whole countryor the world*

Throughout History, as humans spread across the world, infectious diseases have been a constant companion. Even in this modern era, outbreaks are nearly constant. Here are some of history's most deadly pandemics, from the Antonine Plague to Novel Coronavirus(COVID-19)

	Death Toll	Death Toll	
165-180 **Antonine Plague**	5M	30-50M	541-542 **Plague of Justinian**
735-737 **Japanese Smallpox Epidemic**	1M	200M	1347-1351 **Black Death (Bubonic Plague)**
1520 **Smallpox**	56M	3M	1600 **17th Century Great Plagues**
1700 **18th Century Great Plagues**	600k	1M	1817-1923 **Cholera 6 outbreak**
1855 **The Third Plague**	12M	100-150k	Late 1800s **Yellow Fever**
1889-1890 **Russian Flu**	1M	40-50M	1918-1919 **Spanish Flu**
1957-1958 **Asian Flu**	1.1M	1M	1968-1970 **Hong Kong Flu**
1981-Present **HIV/AIDS**	25-35M	770	2002-2003 **SARS**
2009-2010 **Swine Flu**	200k	11.3k	2014-2016 **Ebola**
2015-Present **MERS**	850	4K	2019-Present **Novel Coronavirus* (COVID-19)**

*As at March 11, Officially a pandemic according to WHO

Russian and Spanish Flu (Despite their names, both of these outbreaks are believed to have originated in China)

Appendix 2

Vaccine Development: A Roadmap

The most active ingredients in vaccines to prevent diseases are small pieces of the disease-causing organisms or the blueprints for making the small pieces. Other ingredients in vaccines make them safe and effective. Each of the components has a specific purpose and are all tested for effectiveness and safety during the manufacturing process. According to WHO (World Health Organization, 2020), some important and active ingredients in vaccines are the antigens, preservatives, stabilisers, surfactants, residuals, and adjuvants. Before a vaccine can be introduced into global or local vaccination programme, they are subjected to thorough testing to ascertain that they are safe for use. A typical vaccine roadmap, as highlighted by Pfizer (Pfizer, n.d.) a global vaccine manufacturing giant is presented in Box 2. See also, Figure 3.

STEP 1 – Research and Development (R&D): This is usually exploratory, involving series of laboratory researches conducted for up to five years to identify antigens to be included in the vaccine.

STEP 2 – Preclinical: This is done to ensure safety and efficacy. Researchers conduct testing to assess vaccine candidates' immunogenicity, their ability to elicit the desired immune response. Other areas of focus include short-term toxicology, formulation, and development of a scalable, efficient, and reproducible manufacturing process. This data collection and analysis can take around 2 years.

STEP 3 – Clinical: This process is done to ensure safety and efficacy of the vaccine in humans. In the US for instance, an application for an Investigational New Drug (IND) is submitted to the US Food and Drug Administration (FDA). Only with an IND approval by the FDA does the potential vaccine proceed through three phases of human testing. A first phase which lasts for about two years; 100 volunteers are administered the candidate vaccine in a non-blinded study to determine whether it is safe to proceed to the second phase, and to determine whether a sufficient immune response is provoked. A second phase which lasts for about three years involving a larger group of subjects; the safety, immunogenicity, doses, immunisation schedules, and delivery methods are studied are studied. Lastly, a third phase lasting for about ten years involving a randomised, placebo-controlled, blinded pivotal study which generally involves thousands of people on whom vaccine safety and efficacy are tested. This trial generally includes monitoring potential side effects in subjects, determining whether the vaccine candidate can help to prevent disease, and testing whether it leads to the production of antibodies against the specific pathogen.

STEP 4 – Licensure: This stage involves regulatory review and approval of the vaccine. If the candidate vaccine is determined to be safe and effective, a Biologics License Application (BLA) is submitted to the FDA, which may conduct its own testing. The FDA also inspects the production of the vaccine candidate and monitors its potency, safety, and purity. This entire process could take up to two years.

STEP 5 – Production: This involves manufacturing and scale up production of large quantities of the vaccine, ensuring all product meets the necessary regulatory requirements, including current Good Manufacturing Processes (cGMP).

STEP 6 – Quality Control: This involves performance review and post-marketing. The vaccine is continuously tracked and monitored for its performance, safety, and effectiveness through pharmacovigilance conducted after the product is released into the market.

*Box 2: A Roadmap for Vaccine Development (Pfizer, n.d.) **

For Covid-19, most vaccine manufacturers adopted a somewhat similar path to their various vaccine development process. For instance, for Janssen Vaccines', Johnson & Johnson COVID-19 vaccine, the typical pathway adopted is presented in Box 3.

• **Preclinical Stage:** The overall goal of this research-intensive stage was to determine how the vaccine would work. It is designed to find natural or synthetic antigens—foreign substances that induce an immune reaction in the body—that trigger the same reaction an actual virus or bacteria would. Identifying the right antigen or antigens can often take up to four years. Different vaccine candidates are considered, but the one with the most immune response and evidence of protection is chosen.
Although this stage normally should have taken years, Jansen Vaccines sped up the process using its already tested vaccine platform, called AdVac®, being used in its Ebola vaccine, as well as investigational vaccines for HIV and RSV. The AdVac "viral vector"—a version of adenovirus 26 (Ad26), which normally causes common colds, but that's been disabled so it can't make people sick—transports part of a pathogen's genetic code into the body. This stimulates the immune system to fight the disease caused by the virus so that disease immunity is developed without developing the disease itself.

• **Phases 1/2a and 2b:** This stage for Jansen helped to determine if the vaccine was safe and in what dose should it be administered. Phase 1 testing marks the first time the vaccine is tested in a small group of adults, usually 20 to 80 people, to evaluate its safety and measure the immune response it generates. Phase 2a studies aim to determine the most effective dose and expand the safety experience with the vaccine. Researchers look for expected reactions to the vaccine—headache, muscle pain, redness and swelling at the injection site or low-grade fevers—as well as serious adverse events, which are expected to be rare, over the entire duration of the study.

Phase 1 and 2a clinical trials normally last several months to even a year before proceeding to Phase 2b or Phase 3 trials, in which the pool of people receiving the vaccine increases. Janssen combined Phase 1 and Phase 2 trials for its investigational SARS-CoV-2 vaccine into one phase, known as Phase 1/2a—a step it often takes with its vaccine platform in order to answer many questions in one study, at one time. In July 2020, the company began testing its investigational vaccine in over 1,000 healthy adults between the ages of 18 and 55 in the United States and Belgium, home to a large Janssen site, as part of that 1/2a phase. People aged 65 and over were then recruited as well.

• **Phase 3:** In this stage of the clinical trial, even more volunteers received the vaccine to study its effectiveness. In September 2020, Janssen scientists administered the investigational SARS-CoV-2 vaccine to tens of thousands of healthy people, as well as those particularly vulnerable to COVID-19 in areas with the highest rates of viral transmission. In preparation for this phase, Janssen worked with leading epidemiologists and modellers around the world to predict these hotspots. Before volunteers are vaccinated, they were tested to make sure they currently do not have the SARS-CoV-2 virus. Half of the group was assigned to receive the vaccine; the other half received a placebo. Then they will be watched closely for up to two years to see if they do develop COVID-19-related symptoms, such as fever, headache, shortness of breath, dry cough or gastrointestinal distress. Phase 3 trials can sometimes take years. But Janssen was able to get results much sooner by creating as large a trial as possible, with up to 60,000 people.

• **Regulatory approval and licensure:** After a successful Phase 3 trial, vaccine manufacturers apply to regulatory bodies such as the European Commission or the US Food and Drug Administration (FDA). At this stage, clinical trial data is reviewed to make sure the vaccine is safe and effective. Jansen, among other things, must show manufacturing process is consistent and its ability to produce consecutive batches of the vaccine to induce the same immunity in people. Once the vaccine is approved, enough of the product needs to be manufactured to immunise those who need it. And in this case, Janssen will need to demonstrate that it can provide a supply of doses worldwide to the public, including underserved populations, on a not-for-profit basis for emergency pandemic use. The company achieved this goal by ramping up commercial scale manufacturing while clinical trials were ongoing, with help from partners around the globe.

• **Phase 4:** The goal in this stage is to ensure that the vaccine product is safe down the road. Hence, even after the vaccine is approved and licensed, regulatory agencies stay involved, continuing to monitor production; inspecting manufacturing facilities; and testing vaccines for potency, safety and purity. The FDA also monitors adverse events that may occur related to receiving the vaccine, including through its Vaccine Adverse Event Reporting System and Phase 4 clinical trials—optional studies pharmaceutical companies may be required to perform after a vaccine is licensed to continue to monitor safety and effectiveness.

Box 3 The stages of COVID-19 Vaccine Development by Janssen's Johnson & Johnson Vaccine. Curled from Janssens website (Levine, 2020).

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