African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

Africa Centres for Disease Control and Prevention (Africa CDC)

COVID-19 Vaccine Development and Access Strategy

August 2020

Background

The World Health Organization (WHO) declared the COVID-19 outbreak a public health emergency of international concern (PHEIC) on 30 January 2020, following the initial rapid expansion in confirmed cases globally. As of early August 2020, has thus far resulted in over 18.2 million confirmed COVID-19 cases, and close to 700,000 related deaths worldwide – this includes 891,943 COVID-19 cases and 18,893 related deaths in African nations. Although initially slow to spread in Africa, the impact of COVID-19 has recently surged across the continent, registering a 120% growth in confirmed cases and 85% growth in deaths from June to July 2020.

In an effort to mitigate the impact of COVID-19, the Africa Centres for Disease Control and Prevention (Africa CDC) has developed a comprehensive region-wide strategy focused on:

1. **Preventing transmission** through the procurement of diagnostics, personal protective equipment (PPE) and vaccines, cascading tailored technical assistance on physical distancing, enhanced surveillance through contact tracing, cascading training on best practices around surveillance, laboratory and infection prevention control and facilitating COVID-19 research;
2. **Preventing deaths** through the procurement of therapies and medical equipment (e.g. ventilators), providing technical assistance to Member States, and delivering ongoing clinical management trainings to health care workers; and
3. **Prevention of social and economic harm** by scaling up social protection programmes, promoting community engagement in the planning and implementation of COVID-19 response and research, facilitating continued access to medical care and social support and ensuring responsible lifting of lockdowns.

Key to the all three strategic pillars is the development and roll-out of a safe and efficacious COVID-19 vaccine in Africa. Indeed, only a widely accessible vaccine will protect vulnerable populations (e.g. elderly, immunocompromized), lead to the full functioning of African economies and societies, and enable a return to the continent's development agenda. If COVID-19 continues to spread, the World Bank estimates that economic growth in sub-Saharan Africa will decline from 2.4% in 2019 to between -2.1 and -5.1% in 2020, causing the first recession in the region in 25 years.[1] A vaccine can interrupt this disruption of national economies in Africa and prevent further reversal on the gains made over the past several decades.

Significant progress has already been made on developing a vaccine: more than 165 vaccine candidates are currently in various stages of development with 31 already in human trials,[2] although few of these candidate products are being investigated through clinical trials in Africa.

Experts forecast the development of a safe and efficacious vaccine in the next 12 months. Large countries and regional blocks (e.g. the United States and European Union) have begun securing supply of doses through up-front supply agreements from high-likelihood manufacturers. At the same time, the COVID-19 Vaccine Global Access (COVAX) Facility has been created to ensure fair and equitable access to COVID-19 vaccines for every country in the world, with the goal of delivering 2 billion doses by the end of 2021 and reaching at least 20% of the world's population.

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[1]Assessing the economic impact of COVID-19 and policy responses in sub-Saharan Africa. Africa's Pulse. 2020; 21 (https://openknowledge.worldbank.org/bitstream/handle/10986/33541/9781464815683.pdf).
[2]Draft landscape of COVID-19 candidate vaccines. Geneva: World Health Organization; 2020 (https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines).

Even when supply is secured for Africa, the challenges associated with wide-scale delivery and uptake of the vaccine are immense, given the structures and systems required to implement vaccination for COVID-19 far exceed the delivery capacity of the Expanded Programme on Immunization (EPI) – a system developed to deliver immunization to young children. For these reasons, it is crucial that African countries urgently collaborate to begin preparations for the development, access and roll-out of a vaccine.

On the 24 and 25 June 2020, the Africa CDC hosted a conference on 'Africa's leadership role in Covid-19 vaccine development and access', which brought together over 3000 political leaders and technical experts to discuss COVID-19 vaccine needs on the continent and regional opportunities for driving development, manufacture, distribution and uptake. The following strategy was developed based on those expert inputs, as well as consultations with leading public health experts from across the continent.

Goal

Successful immunization of a critical mass of the African population with one or several safe and efficacious COVID-19 vaccines.

Key objectives

1. Accelerate African involvement in the clinical development of a vaccine.
2. Ensure African countries can access a sufficient share of the global vaccine supply.
3. Remove barriers to widespread delivery and uptake of effective vaccines across Africa.

Objective 1:

Accelerate African involvement in the clinical development of a vaccine

1.1 Clinical trials

African participation in clinical trials is an important step to ensure that the most promising vaccine candidates show positive safety and efficacy data among African populations. Africa has a long history of clinical trials participation for vaccines. It is critical to establish an overarching consortium for COVID-19 vaccine clinical trials with African representation in order to:

1. Coordinate and facilitate partnerships between vaccine developers and African partners to complete clinical trials of selected COVID-19 vaccine candidates;
2. Support the development and identification of additional clinical trial sites across all sub-regions of the continent by building capacity and removing barriers (e.g. through accurate epidemiological data, access to GCP investigators etc.);
3. Strengthen enabling factors for running high-quality clinical trials for COVID-19 vaccines and other new technologies (e.g. by setting up independent regional review boards to pool regional capacity and experience);
4. Accelerate post-trial product regulatory decisions, roll-out and uptake.

Objective 2:

Ensure Africa countries are able to access a sufficient share of the global vaccine supply

2.1 Access, financing and procurement

Global negotiations for supply rights and access to future vaccines are already underway. The concept of 'vaccine multilateralism' – as championed by the Global Alliance for Vaccines and Immunizations (Gavi), WHO and the African Union – presents a promising opportunity for Africa to secure a proportionate share of global supplies. Member

States shall actively participate in and jointly ensure the success of the COVAX facility, which is planning to secure more than two billion doses of vaccine, and equitably distribute these across countries of all income levels. Furthermore, COVAX is raising an initial USD2 billion from global donors to subsidize the vaccines for low- and middle-income countries (LMICs) through an advanced market commitment (AMC) structure – with plans to raise even more funding as needed to help LMICs procure available vaccines. Hence, the COVAX facility offers multiple benefits for Member States:

1. A diverse portfolio of potential vaccine candidates;
2. Highly subsidized prices for LMICs; and
3. Equitable access for all countries to cover up to 20% of their population. In addition to maximizing the benefits derived from COVAX, the African continent can also consider engaging manufacturers (and countries with manufacturing capacity) to secure additional vaccine supplies. In order to secure sufficient supply from COVAX and directly from manufacturers, substantial capital will need to be mobilized from donors and domestic funding sources. Early estimates for the total costs to procure and deliver the COVID-19 vaccine range from USD16 billion to USD21 billion to cover 60% of the African population. African countries should work together with development finance institutions to support vaccine procurement by pooling their resources and raising up-front capital.

2.2 Improve manufacturing capacity

African manufacturing capacity for vaccines is relatively nascent, with only three countries manufacturing and marketing human vaccines locally. However, the drastic scale up in vaccine manufacturing capacity needed to support the continent's demand for a COVID-19 vaccine should be used as an opportunity to help accelerate African vaccine production, placing the continent onto a trajectory where it can manufacture a meaningful share of its own vaccines in the future. Support will be provided to high potential manufacturers to help facilitate the transfer of technology and intellectual property from outside of Africa, along with the requisite financing needed to help begin production in the long term.

Objective 3:

Remove barriers to widespread distribution and uptake of COVID-19 vaccines across Africa

1.1 Regulatory

African Member States will be supported to develop a harmonized, regulatory process that will fast-track the market authorization of safe and effective COVID-19 vaccines once developed. The regulatory process will align with global processes and protocols (e.g. the WHO emergency use authorization and/or prequalification). In addition, an effective pharmacovigilance system will be instituted on the continent to ensure that adverse effects from vaccines can be promptly detected, and information shared quickly with the relevant regulatory and manufacturing stakeholders, and necessary actions taken to prevent harm.

1.2 Delivery

In order to deliver COVID-19 vaccine(s) at scale in target populations, Member States will need to substantially evolve and expand their existing immunization systems to reach adults and vulnerable populations. In collaboration with technical partners and private sector, Member States will be supported with guidance and technical assistance to undertake this significant transformation across a range of areas including supply chain, health worker training, innovations in delivery channels, etc.

1.3 Uptake

Past lessons from vaccine delivery in Africa point to the need for effective community engagement to ensure community support for and uptake of COVID-19 vaccines. Given the large amount of public health misinformation and anti-vaccine sentiment circulating on the continent, it is important to conduct a set of large-scale information dissemination, education and counselling programmes to facilitate COVID-19 vaccine uptake.

Implementation roadmap to achieve key objectives

Achieving the objectives outlined will require significant collaboration between a range of African and global organizations, including Member States, regulatory agencies, implementing partners, donors and the private sector. The African Union and Africa CDC will play a convening and coordination role for the necessary activities.

1.1 Clinical trials

The Africa CDC Consortium for COVID-19 Vaccine Clinical Trials (CONCVACT) has been established to serve as the coordinating body for the ongoing and future human vaccine clinical trials on the continent.[3] The goal of the consortium is to establish and strengthen partnerships between existing clinical trial implementing organizations in Africa with donors and vaccine developers interested in undertaking clinical trials on the continent. CONVACT's key objectives are as follows.

1. Facilitating the start and successful completion of clinical trials in Africa for *at least six* promising COVID-19 vaccine candidates. This includes reaching out to leading vaccine developers, identifying suitable clinical trial sites, negotiating and developing partnerships with developer and sites and facilitating the commencement of trials in Africa.
2. Strengthening enablers of high-quality vaccine clinical trials on the continent through establishing an independent review board and a data safety monitoring board, raising necessary capital, increasing public awareness of and support for hosting clinical trials in Africa, and ensuring laboratories on the continent are capable of analysing samples.

[3]Further details on the CONCVACT are available as an *Addendum* to the current strategy.

3. Supporting the development of vaccine clinical trial sites across all African sub-regions through facilitating essential partnerships (e.g. national and global research institutions), supporting clinical resource organizations, enabling access to reliable, granular and regularly updated epidemiological data and advocating for national regulatory bodies to improve approval processes for trial sites, export licenses, patient samples, etc. in target countries.
4. Accelerating post-trial vaccine regulatory approval, roll-out and uptake of efficacious vaccines by providing objective, fact-based scientific and clinical guidance on results interpretation, promoting the standardization of protocol review and regulatory approvals, establishing pharmacovigilance systems and providing guidance on effective community engagement.

2.1 Financing access and procurement

Africa CDC will form a technical working group to support AU Member States to address challenges to accessing and financing COVID-19 vaccines, in three primary ways:

1. Maximizing the benefits of the COVAX facility, which is a crucial global tool to ensure equitable access to a COVID-19 vaccine. It is important that all Member States, regardless of income level, support and sign-up to the facility to access substantial vaccine coverage volumes (20% of each country's population) at globally negotiated, tiered prices. Gavi-supported African countries should join forces and engage donors to fund the initial USD2 billion seed funding required for the COVAX AMC aimed at supporting LMICs.
2. In addition to the COVAX facility, Africa could also consider securing supplementary deals with individual manufacturers on a needs basis. The volume secured directly from such deals should be placed through the African Medical Supply Platform to leverage the platform's existing procurement and supply chain infrastructure.

3. To effectively finance the purchasing of vaccines – either through the COVAX facility or directly with manufacturers – new financing instruments will likely be needed to secure required capital. In total, it is estimated that from USD16 billion to USD 21 billion will be needed to achieve vaccine coverage sufficient for 60% of the continent's population. Africa CDC is exploring a partnership with the African Export–Import Bank (Afreximbank) to help Member States raise substantial capital to make up-front purchasing commitments, guaranteed by debt promissory notes.

2.2 Manufacturing

Given domestic human vaccine manufacturing remains a long-term goal for the continent – and a relatively limited capacity today – a strategic initiative should be established to develop a formal roadmap for scaling up vaccine manufacturing capacity, including how COVID-19 vaccine development can be used to accelerate this trajectory. The key African organizations that are focused on vaccine manufacturing should come together to develop a collective roadmap, with the following steps:

1. Developing a clear understanding of the current manufacturing capacity on the continent – organizations such as the African Vaccine Manufacturing Initiative could be at the forefront of this effort;
2. Identifying and engaging with sources of support to assist with technology transfer and project financing; and
3. Developing a long-term roadmap for manufacturing scale up and creation of sustainable mechanisms to secure adequate intellectual property and patent rights protection, as well as financing to fund the scale up of their operations (e.g. vaccine bonds, low interest loans, purchasing commitments etc.).

3.1 Regulatory

Global efforts around vaccine regulations are currently underway. Member States will need to adopt a standardized approach to regulatory decisions on the market authorization of potential COVID-19 vaccines, in alignment with global processes and protocols, and with input from country-level regulators. This might include harmonized and expedited decisions for the whole continent once a vaccine receives global-level authorization (e.g. WHO emergency use authorization and/or prequalification) or guidance (developed by the appropriate bodies) disseminated to national regulatory authorities of Member States to promote standardization of processes. Member States will likely need to put in place additional assurances to prevent delays in rollout such as indemnification for vaccine manufacturers. Simultaneously, a pharmacovigilance system will need to be designed and rolled out to enable national regulatory agencies to gather data on adverse events, and to provide recommendations to countries on how to act in the event of significant safety concerns. As an initial step towards these developments, a convening of relevant stakeholders should begin immediately through the African Medicines Regulatory Harmonisation (AMRH) initiative.[4]

3.2 Delivery

Africa CDC will convene a technical working group to work with Gavi, WHO, the United Nations Children's Fund (UNICEF), among others, to support Member States to adapt and strengthen national immunization systems for the delivery of COVID-19 vaccines. The technical working group will focus on:

[4]See: https://www.nepad.org/programme/african-medicines-regulatory-harmonisation-amrh.

1. Providing guidance on key adaptations and innovations in immunization systems and approaches (e.g. new immunization sites in workplaces, retail locations, schools, etc.) and the optimal strategies to improve supply chain capacity (e.g. scaling-up appropriate cold chain infrastructure);
2. Ensuring sufficient financing for delivery activities by engaging global public health donors and domestic resource mobilization;
3. Providing technical assistance and deploying rapid responders to assist Member States with transformation of immunization systems to reach adults and target vulnerable populations;
4. Developing comprehensive monitoring and evaluation capabilities to enable knowledge sharing among Member States and agile adaptation of immunization systems.

3.3 Uptake

Community support and uptake of vaccination will require strategies at the continental level as well as within each Member State.

A. Drive continent-wide communication strategy and execution

The Africa CDC will play a facilitating role in bringing together critical stakeholders such as Heads of State, Ministers of Health, continent-wide media companies, social media platforms and advertising agencies to:

1. Ensure senior political support for vaccinations across Member States;
2. Engage with continent-wide key opinion leaders (e.g. political leaders, celebrities, journalists and religious leaders) to ensure they share accurate information and encourage safe vaccination;
3. Launch continent-wide public educational campaigns (e.g. through use of social media, TV and radio programmes).

B. Country-level community engagement

A technical working group will work the Member States through the Africa CDC to support country-level strategies that will support context-specific community engagement for COVID-19 vaccine uptake in the following ways.

1. Develop a comprehensive guidance on best practice around community engagement at the local level – this should include key stakeholders (e.g. religious leaders, local politicians) and optimal behavioural messaging to increase efficacy of public education campaigns at community level for Member States.
2. Importantly, the technical working group should engage communication experts to actively dispel any emerging misinformation and/or myths regarding COVID-19 vaccines.

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