

Africa Centres for Disease Control and Prevention

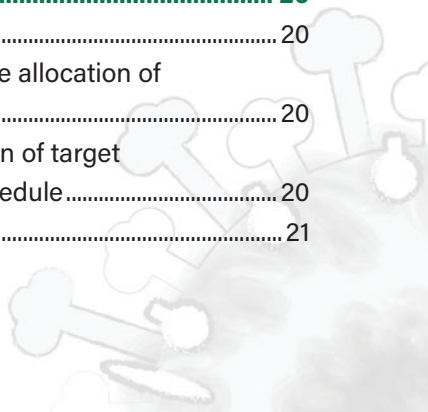
Implementation Guide for COVID-19 Vaccines in Africa

**“Guide to facilitate the implementation of the WHO/
UNICEF “Guidance on developing a national deployment
and vaccination plan for COVID-19 vaccines” for Africa**

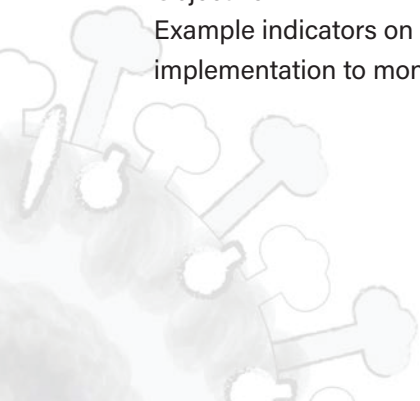


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Acronyms and abbreviations

AEFI	Adverse Event Following Immunisation
AESI	Adverse Event of Special Interest
Africa CDC	Africa Centres for Disease Control and Prevention
AMRH	African Medicines Regulatory Harmonisation
AUDA-NEPAD	African Union Development Agency-New Partnership for Africa's Development
AVAREF	African Vaccine Regulatory Forum
CEL	Community Engagement and Communications Lead
CONCVACT	Consortium for COVID-19 Vaccine Clinical Trials
COVAX	COVID-19 vaccine access facility
FPL	Focal Point for Logistics
IM	Incident Manager
KOL	Key Opinion Leader
MoH	Ministry of Health
NCL	National Control Laboratory
NDVP	National Deployment and Vaccination Plan
NRA	National Regulatory Authorities
PPE	Personal Protective Equipment
WHO	World Health Organization
UNECA	United Nations Economic Commission for Africa
UNICEF	United Nations Children's Fund

About this Implementation Guide

The Implementation Guide for COVID-19 Vaccines in Africa was co-developed by Africa CDC, public health experts from African Union Member States and several technical partners. The guide aims to complement the Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines published by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in providing information on the "How to" of implementing that guidance. It contains action-oriented lists of critical topics to address and checklists tailored to the context of African Union Member States. The contents of this guide aim to guide the development of one comprehensive national deployment and vaccination plan, as proposed and outlined by the guidance – and underlines the need for countries to develop their vaccination plans.

This guide is not meant as a tool to assess deployment readiness. The recommendation to Member States is to use the VIRAT/VRAF 2.0 tool for that, which builds on the COVAX Vaccine Introduction Readiness Assessment Tool (VIRAT) and the World Bank's Vaccine Readiness Assessment Framework (VRAF). The approaches, checklists and principles in this Guide provide practical guidance on how to address the gaps identified through the assessment, highlighting areas not covered by the *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* and providing implementation guidance adapted to the African context.

The target audience of this implementation guide are Ministries of Health and authorities involved in the deployment of COVID-19 vaccines. It aims to provide information on the setup of national governance structures for the deployment (including offices and technical working groups) and to the members of those governance structures, once they have been appointed.

This guide will be complemented with practical information on the vaccine candidates, including logistics information, storage needs, etc. as more information becomes available. We encourage experts from Member States involved in the deployment, implementation and monitoring of COVID-19 vaccines to review the Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines to understand the critical elements of a national deployment and vaccination plan. Member States participating in the COVAX Facility should also refer to the guidance and tools provided by the Facility and the partners involved. This implementation guide should be used as reference to ensure that national plans cover all relevant aspects of COVID-19 vaccination.



Introduction

Objectives

This chapter:

- provides an overview of the impact of COVID-19 in Africa and the continental response, including participation in multinational collaborations such as the COVID-19 vaccine access (COVAX) facility
- outlines critical strategic questions to address in building the national deployment and vaccination plan (NDVP) for COVID-19 vaccines

Impact of COVID-19 in Africa and the continental response

As of 27 November 2020, COVID-19 had claimed 50,628 lives across Africa, with a total of 2,106,931 confirmed cases. The disease has had significant impact economically across the continent and UNECA projects that the pandemic will cause the first recession in 25 years in Africa. Early research indicates a significant impact of the pandemic on other public health priorities, such as the fight against HIV/AIDS, and the impact of countermeasures” with “as well as a significant impact of countermeasures.

Africa’s response to the COVID-19 pandemic is guided by the Africa Joint Continental Strategy for COVID-19 Outbreak, which has a threefold goal of preventing transmission, preventing deaths and preventing socioeconomic harm. One aspect in the implementation of the continental strategy is the development and implementation of the COVID-19 vaccine development and access strategy for Africa. The access strategy was based on recommendations of over 3000 political leaders and technical experts who participated in a virtual international conference that discussed COVID-19 development and access for Africa convened by Africa CDC in June 2020. The access strategy was endorsed by the Bureau of Heads of State and Government of the African Union on 20 August 2020. It aims at the “successful immunisation of a critical mass of the African population with one or several safe and efficacious COVID-19 vaccines” as the only way to prevent continued transmission and deaths from COVID-19 and to safeguard livelihoods in Africa.

The vaccine strategy has three key objectives:

1. **Accelerate African involvement in the clinical development of a vaccine** through facilitation by the Africa CDC Consortium for COVID-19 Vaccine Clinical Trials (CONCRACT) of clinical trials of COVID-19 vaccines in Africa, and strengthen critical enablers and vaccine clinical trial sites across all sub-regions in Africa.
2. **Ensure that African countries can access a sufficient share of the global vaccine supply** by providing guidance and support on financing and procurement. Africa CDC hopes to achieve this through various mechanisms including the COVAX Facility, which is planning to secure and equitably distribute more than two billion doses of COVID-19 vaccine to cover 20% of the population of participating countries. There are other initiatives to help Member States finance and procure the remaining vaccine doses needed to reach the vaccine strategy's aim of immunising at least 60 percent of the population to achieve herd immunity in Africa. This is the goal of the African Vaccine Acquisition Task Team (AVATT), which works with Africa CDC, the World Bank, COVAX and the African Export-Import Bank to develop financing and acquisition strategies.
3. **Remove barriers to widespread delivery and uptake of effective vaccines across Africa** through support for streamlined regulatory approvals, preparations for the delivery of the vaccine, and large-scale community engagement and communication campaigns to facilitate uptake.

As the first vaccines receive commercial authorisation, it is important to prepare for effective and efficient deployment. This guidance, therefore, is part of the third objective of the strategy, aiming to provide practical advice on how to remove barriers to the widespread delivery and uptake in Africa.

Critical strategic questions to address in building the national deployment and vaccination plan

Availability, pricing, as well as technical and financial needs for the deployment, implementation and monitoring of COVID-19 vaccines, are essential issues to consider in the NDVP. The following table shows strategic questions to address:

Strategic question	Guidance and considerations
<p>Target groups – which population groups should receive the COVID-19 vaccine?</p>	<p>The COVID-19 Vaccine Development and Access Strategy for Africa recommends immunisation of 60 percent of the total population in Africa, based on the current estimate of what it takes to generate “herd immunity” against COVID-19.</p> <ul style="list-style-type: none"> ▪ When most of a population is immune to an infectious disease, this provides indirect protection to those who are not immune to the disease, keeping the spread of the disease under control ▪ The level of immunity needed to achieve “herd immunity” differs based on the disease and the living conditions of the populations in question – 60 percent is the estimate for Africa ▪ The doses needed to immunise 20 percent of the population, which the COVAX facility aims to provide, are a critical component of this strategy, allowing the protection of high-risk individuals ▪ To protect lives and livelihoods in Africa, going beyond 20 percent and creating herd immunity is necessary <ul style="list-style-type: none"> ♦ The ability to contain a COVID-19 outbreak with a relatively low percentage of the population immunised depends on a society’s ability to enforce physical distancing, especially for vulnerable groups – this ability is limited especially in urban slums, conflict settings, or where multigenerational households are common ♦ With a high percentage of the population working in the informal economy, and receiving critical supplies such as affordable food from informal markets, the effect of lockdowns and other physical distancing measures is more immediately detrimental to livelihoods

Strategic question	Guidance and considerations
	<ul style="list-style-type: none"> ♦ Herd immunity will help protect those who are at highest risk and may not be able to get vaccinated themselves, or who may not respond to the vaccine due to co-morbidities ♦ Many health systems in Africa have limited capacity to deal with severe COVID-19 manifestations
<p>Sequence – assuming limited availability in the beginning, who should get the vaccine first?</p>	<p>During a continental consultation held on 14 and 15 December 2020, Africa CDC and partners developed a framework for the fair and equitable allocation of COVID-19 vaccines based on African values.</p> <p>The framework is available at: The framework is available on Africa CDC's website.</p>
<p>Regional allocation and equity – how do we ensure fair and equitable allocation of the vaccine</p>	<p>Vaccination programmes should ensure regional equity and fair distribution at every step of the planning process, including:</p> <ul style="list-style-type: none"> • Ensuring regional representation in the governance of the NVDP • Planning for accessible vaccination sites in all areas • Ensuring that logistics and supply chain planning covers all vaccination sites in all areas • Planning community engagement and communication activities to cover all areas, both from an access and a content point of view (targeted messaging and communication channels, networks of organisations and key opinion leaders targeting the whole country)

Strategic question	Guidance and considerations
<p>Vaccine candidates – which ones are the most suitable in the national context?</p>	<p>The following characteristics of candidate vaccines should be prioritised:</p> <ul style="list-style-type: none"> ▪ Safety ▪ Efficacy – at a level that will allow countries to reach herd immunity by immunising 60 percent of the population, considering that not everyone would want to be vaccinated, and that specific factors such as pre-existing antibodies against the adenovirus may limit the efficacy of some vaccines ▪ Price - countries should be able to make vaccines available to recipients at no-cost ▪ Storage needs (e.g. ultra-cold, frozen, refrigerated, warm) ▪ Dosage regimen - single vs. multiple-dose
<p>Other public health priorities – how do we ensure that any trade-offs between the COVID-19 vaccination and other public health priorities, if required, are based on sound evidence?</p>	<ul style="list-style-type: none"> ▪ At every step related to capacity planning, including for budgets, human resources, and materials such as personal protective equipment, ringfence the capacities needed for critical priorities. Where possible, use existing structures is advisable to strengthen existing programmes. ▪ Further guidance including frequently asked questions are published regularly by the World Health Organization, including: <ul style="list-style-type: none"> ♦ WHO guiding principles for immunisation activities during the COVID-19 pandemic (https://www.who.int/publications-detail/guiding-principles-for-immunization-activities-during-the-covid-19-pandemic-interim-guidance) ♦ WHO frequently asked questions: immunisation in the context of COVID-19 pandemic (https://www.who.int/publications-detail/immunization-in-the-context-of-covid-19-pandemic)



Regulatory preparedness

Objectives

This chapter:

- describes key barriers to rapid regulatory approvals
- outlines steps for regulatory and legal preparedness – from the identification of the right documents to collaboration among continental bodies
- provides a checklist of the most important topics to cover for regulatory and legal preparedness

Frequent barriers to rapid regulatory approvals

There are a number of regulatory requirements which have the potential to slow down the process of deployment vaccines in-country without adding significant new information about the safety and efficacy of the product. Among these barriers are, for example, country-specific labelling or certification requirements, requests for similar information (from manufacturers) in different formats, unclear or missing processes for reliance (on SRAs, or processes such as the WHO EUL process), and lengthy customs processes. In some instances, the issue can also be a lack of coordination between the relevant in-country stakeholders. Africa CDC is working with AUDA-NEPAD's African Medicines Regulatory Harmonisation (AMRH) and WHO's and African Vaccine Regulatory Forum (AVAREF) to provide more detailed information on the barriers, as well as guidance and recommendations on how to address them through adherence to multinational frameworks and the implementation of critical processes in-country, leveraging reliance as much as possible.

Steps for regulatory and legal preparedness

The *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* by WHO and UNICEF outlines essential regulatory procedures for emergencies in general, and those considered key to ensure fast and efficient access to COVID-19 vaccines. The recommendation is to:

1. Appoint a focal person for regulatory and legal matters on the introduction of COVID-19 vaccine.
2. Ensure that the focal person is part of the relevant bodies established by AUDA-NEPAD's African Medicines Regulatory Harmonisation (AMRH) and the WHO's, African Vaccine Regulatory Forum (AVAREF).
3. Use the *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* and the checklists provided in this section on critical regulatory and legal frameworks that need to be established to collect information about the status of the relevant regulatory and legal documents.
4. Wherever a critical standard or procedure is not yet available, plan for its implementation, including identifying existing standard processes (e.g. from AVAREF) that could help, or contact the partners at AMRH or AVAREF.
5. For all procedures and standards, check that they have been formally adopted at the highest level required and that approval has been communicated to all relevant stakeholders.
6. For all procedures and standards, check that the relevant stakeholders (such as customs workers, logistics service providers, health workers, and vaccine recipients) have the information (and training) they need to apply the standard or procedure correctly, or that communication and training plans cover the relevant contents. Ensure the funding required for training and surge capacity (if needed) is available.
7. Create a central repository of information on regulatory and legal standards and procedures that all stakeholders involved in the COVID-19 vaccine deployment, implementation and monitoring can access as needed.

Checklist for regulatory and legal preparedness

Regulatory standard or procedure	Recommendations	Stakeholders requiring information, access, and potentially training	Standard or procedures have been		
			Created	Formally adopted at the highest level required	Disseminated/ all relevant stakeholders trained/deposited to central registry
Expedited regulatory approval for COVID-19 vaccines post-Emergency Use Listing Procedure (EUL) listing	<ul style="list-style-type: none"> Process duration of max. 15 working days Leverage AVAREF-led EUL joint review process: enter reliance agreement and commit to country-level emergency use or marketing authorisation decision based on AVAREF-led recommendation (targeting local NRA emergency use or marketing authorisation within 15 working days from EUL listing by WHO) 	<ul style="list-style-type: none"> COVID-19 vaccine manufacturers WHO EUL/ prequalification National regulatory authority (NRA) and Ministry of Health (MoH) officials [If applicable: groups within pooled purchasing facilities facilitating regulatory approval] 		Formally adopted at the highest level required	Disseminated/ all relevant stakeholders trained/deposited to central registry
Expedited import approval for COVID-19 vaccines	<ul style="list-style-type: none"> Process duration of maximum 5 working days Consider reliance on manufacturer's lot testing results submitted to WHO and local ML3/4 lot release mandated under the WHO EUL/PQ process Consider, for approvals under AVAREF-led EUL process, fasttracking (e.g. through reliance) or waiving requirement for importer license for each country of distribution 	<ul style="list-style-type: none"> Vaccine importers Logistics providers MoH NRAS 			

Regulatory standard or procedure	Recommendations	Stakeholders requiring information, access, and potentially training	Standard or procedures have been		
			Created	Formally adopted at the highest level required	Disseminated/ all relevant stakeholders trained/deposited to central registry
Labelling requirements	<ul style="list-style-type: none"> ▪ Waive requirement for tailored labels for each Member State (e.g. by accepting WHO standardised labels) 	<ul style="list-style-type: none"> ▪ WHO ▪ NRAs 			
Customs process	<ul style="list-style-type: none"> ▪ Develop fasttracked customs process to avoid unnecessary delays at the port of entry 	<ul style="list-style-type: none"> ▪ Ministry of Trade and Transport ▪ Customs authorities and workers 			



Legal topic	Example points to cover	Relevant provisions have been		
		Created	Added to central repository of information	Disseminated/ all relevant stakeholders trained
Data privacy	<ul style="list-style-type: none"> Provisions covering databases with patient information Provisions covering information needed for management of patient flows (e.g. sending reminders) 			
Liability & indemnification of vaccine manufacturers	<ul style="list-style-type: none"> COVAX: approach for indemnification laid out by COVAX Non-COVAX: fasttracked assessment and provision of guarantees to manufacturers providing COVID-19 vaccines under emergency approval mechanisms 			
Transport and logistics	<ul style="list-style-type: none"> Requirements for import, warehousing, packaging and shipping of vaccines and other materials Responsibility for integrity of materials in transport Responsibility for maintenance of cold chain 			
Potential compensation mechanism for vaccine recipients suffering adverse events	<ul style="list-style-type: none"> Compensation mechanism for vaccine recipients suffering adverse events 			
Administration	<ul style="list-style-type: none"> Requirements for administration, e.g. patient information, follow-up 			



Planning and coordination

Objectives

This chapter:

- provides a list of principles to consider in setting up the governance for COVID-19 vaccine deployment, implementation and monitoring
- outlines critical activities of the offices and technical working groups as a foundation to assess whether the groups have the right size, capacity and expertise to action them
- guides the potential setup of local implementing committees and networks

Principles to consider in setting up the governance for COVID-19 vaccine deployment, implementation and monitoring

- **Existing structures:** as outlined in the *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines*, relevant bodies should leverage existing structures as much as possible. However, given the scale of the vaccination activities required, and the new elements (such as new types of vaccines and new target groups), the suggestion is to review the critical activities provided in this section and check whether the existing governance bodies have the right size, mandate and expertise to action them.
- **Decision power:** Members of the governance bodies should have the decision power needed to fulfil their roles and responsibilities indicated in this section. In cases where there is a trade-off between expertise and decision power, it is recommended to establish a clear communication channel with the relevant decision-maker in each institution so that any decisions can be obtained within 2-3 working days.
- **Broad representation:** Membership of any of the groups should include equal representation of all regions (or, at the local level, all relevant groups).
- **Expertise:** The key selection criterion should be the expertise of members in the relevant field as evidenced by publications, conference proceedings, or their current position.

- **Avoidance of conflicts of interest:** Members of each group should declare all potential conflicts of interest.
- **Communication:** The governance structure should allow regular communication between the relevant groups and actors, including through the continued collection and update of contact information as well as process documentation with clear decision paths and rights.
- **Collaboration:** Successful implementation will depend on effective collaboration between
 - ♦ different levels – global, continental, national, regional, and local;
 - ♦ sectors, including government, non-government, community organisations, and the private sector
 - ♦ (government) agencies.

Key activities of the offices and technical working groups

The first step in planning is to set up the offices and technical working groups required to manage the significant work involved in the deployment, implementation and monitoring of COVID-19 vaccines. These offices and technical working groups should build on and leverage existing structures, but should also have the right size, capacity and expertise to manage vaccination at the required scale. This suggestion on key office and technical working groups is in line with the *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines*, except for two points:

- The suggestion is to have an additional formal office for the community engagement and communications lead (CEL). Given the importance of community engagement, and the high number of organisations, KOLs, etc. to involve, this role will manage the creation of baseline data, networking with organisations and individuals, and provide guidance at the regional, subregional and local levels on the engagement of organisations and KOLs in creating demand for COVID-19 vaccines.
- As mentioned above, it is recommended to have a specific focal person on regulatory and legal issues for COVID-19 vaccines.

Office/technical working group	Activities and end products (not exhaustive)
Planning and management	<ul style="list-style-type: none"> ▪ Develop and regularly update budgets in collaboration with all technical working groups and other relevant stakeholder ▪ Develop vaccination strategies for each target group ▪ Manage the setup of a vaccination sites network in alignment with the relevant standards, ensure the completeness of records, and manage information flows (providing the facilities with guidance and materials, etc.)
Supply chain management	<ul style="list-style-type: none"> ▪ Manage a network of providers who can support logistics for COVID-19 vaccines with the required standards and equipment ▪ Prepare forecasting based on target groups and phasing ▪ Prepare and regularly update a schedule for vaccine (and other material) shipments, including details on the facilities ▪ Regularly review information on stock levels, warehouse capacities, wastage, etc. and intervene as needed ▪ Create and monitor the use of relevant systems (including for tracking and monitoring), training, guidance and protocols, including on handling of vaccine in transport and cold chain ▪ Monitor safety and security plans for staff and materials
Training and supervision	<ul style="list-style-type: none"> ▪ Create an overview of topics for training, including the management and administration of vaccines, but also legal and regulatory, communication and engagement, etc. ▪ Prepare a training plan accounting for the topics, approximate number of participants, format of training ▪ Ensure that the required training materials are available by collecting existing materials and managing the creation of new ones as needed

Office/technical working group	Activities and end products (not exhaustive)
Demand	<ul style="list-style-type: none"> ▪ Collect data on beliefs and attitudes to provide information for effective communication planning ▪ Design an overarching communication plan ▪ Develop key messages of relevance to target populations ▪ Engage a network of KOLs to support engagement and communication ▪ Build and manage a network of community organisations to provide expertise and support the communication campaigns
Vaccine safety	<ul style="list-style-type: none"> ▪ Collect available information on the potential adverse effects due to the vaccine candidates in use, as well as further information (e.g. specific symptoms, (laboratory) analyses needed for full diagnosis)
Monitoring and evaluation	<ul style="list-style-type: none"> ▪ Develop a framework of indicators for monitoring delivery planning, processes and outcomes – impact of the programme and potentially vaccine effectiveness ▪ Set up a system to regularly collect and collate information, including from the local implementing committees ▪ Design additional tools needed for monitoring and evaluation (e.g. scorecards) ▪ Design and operationalise a regular sequence of meetings to share tracking information and trigger response in case of delays ▪ Define process for the collection, analysis and sharing of data



Setup of local implementing committees and networks

Local implementing committees can play a crucial role in facilitating access to critical information needed by the national offices and technical working groups. The suggestion is to set up such committees that will:

- Support the collection of information on target groups including:
 - ♦ Identifying and contacting local sources of information
 - ♦ Checking to ensure no populations are missed (e.g. prisoners)
 - ♦ Supporting campaigns to collect required contact information
- Support the build-up of the network of vaccination facilities, including:
 - ♦ Identifying potential facilities
 - ♦ Communicating requirements
 - ♦ Supporting facilities in checking requirements
 - ♦ Supporting enrolment of providers with vaccination programme (including collection of data required, access to training, etc.)
- Disseminate relevant guidance and follow-up on its implementation, including.
 - ♦ Guidance and protocols on facilities management
 - ♦ Community engagement and communication guidance
 - ♦ Information and materials for relevant trainings
 - ♦ Information on logistics
- Help track and monitor information, including on logistics
- Set up and manage the local implementing network, including:
 - ♦ Research most relevant organisations to include
 - ♦ Manage outreach
 - ♦ Collect relevant contact information
 - ♦ Disseminate materials



- ♦ Collect feedback from network and provide it to central governance
- Support management of critical protocols, including:
 - ♦ Infection prevention and control
 - ♦ Physical distancing

Membership of the local implement committee should be driven by the activities and organisations that are key to the different areas in the local context. However, a few principles should apply:

- Key areas to represent:
 - ♦ National health system
 - ♦ Immunisation programme
 - ♦ Community healthcare worker
 - ♦ Major healthcare institutions
 - ♦ Clinicians
 - ♦ Existing programmes on other public health priorities, especially if relevant for the target groups for COVID-19 vaccines
- Further expertise required:
 - ♦ Major health institutions (e.g. hospitals)
 - ♦ Emergency preparedness
 - ♦ Legal
 - ♦ Community engagement and communication media/public affairs

Local implementing networks support the successful delivery of COVID-19 vaccines in their areas by:

- helping adapt community engagement formats and materials to local needs
- supporting or executing information campaigns and individual events
- distributing information such as protocols and registration procedures, etc.

Membership of the local implementing networks should include the most relevant community organisations and individuals who are easily reachable and have credibility in the local community, including:

- Local leaders (e.g. of specific communities, including religious communities)
- Community-based organisations including those representing underserved communities, or minorities
- Interest groups for different healthcare priorities
- Representatives of local hospitals, other healthcare facilities, pharmacies
- Representatives of traditional healers
- Representatives of institutions for elderly care
- Representatives of major businesses and employers
- Schools and other education service providers
- Other institutions that may be relevant for target groups (including prisons).





Costing and funding: ensuring funds reach the point of delivery

Objectives

The objectives of this chapter are to:

- summarises critical elements of a budget for COVID-19 vaccine deployment, implementation and monitoring
- outlines key steps for the creation of the budget

Critical elements of a budget for COVID-19 vaccine deployment, implementation and monitoring

- Materials needed, including approximate quantities, should be based on the vaccination schedule and vaccination facilities network and include the most up-to-date information on the candidate vaccines to help understand the materials and quantities needed (e.g. single vs multiple-dose regimens):
 - ♦ Needles (suggestion to account for different target groups and wastage, e.g. planning for 5 percent more than vaccine doses planned)
 - ♦ Syringes (suggestion to account for different sizes and wastage, e.g. planning for 5% more than vaccine doses planned)
 - ♦ Materials needed for preparation (e.g. mixing with diluents)
 - ♦ Skin disinfectants
 - ♦ Bandages
 - ♦ Masks and face shields
 - ♦ Gloves
 - ♦ Other personal protective equipment as required
 - ♦ Materials required for waste management (containers, etc.)
 - ♦ Record cards (unless completely electronic records are used)
 - ♦ Any documentation/guidance required (e.g. on correct administration)
 - preparation and printing
- Systems to create and manage, e.g. system for the management of registration and follow-up with vaccine recipients
- Trainings, based on the anticipated number of participants and costs of teleconferencing or other training venues

- Facilities other than materials,, e.g.
 - ♦ Payments to support facilities in building the necessary capacities and processes – e.g. warehousing
 - ♦ Cost of entirely new facilities, e.g. mobile units to address target populations that cannot easily be covered by other facilities
- Cost of logistics, e.g.
 - ♦ Setup of new warehousing structures
 - ♦ Acquisition of suitable transport vehicles
 - ♦ Transport materials
 - ♦ Waste management
- Cost of personnel surge capacity , including personnel cost for, e.g
 - ♦ Governance
 - ♦ Healthcare practitioners
 - ♦ Legal and regulatory experts to provide surge capacity for approvals, or support training
 - ♦ Laboratory personnel

Key steps for the creation of the budget

1. Collect the latest information needed on the vaccine candidates, and the implications for the materials needed.
2. Estimate the quantity of materials needed based on the draft vaccination schedule and information from ongoing routine immunisation programmes.
3. Break down the quantity according to the vaccination schedule by region, sub-region and local area.
4. Based on the estimates by region, refine view on cost of logistics (warehousing capacity to build).
5. Based on information from the training plan, estimate costs of training.
6. Based on information on available vaccination facilities and their readiness, estimate the cost needed to fill any gaps.
7. Check which of the systems required already exist and where there is potential to repurpose an existing system, and estimate the cost of building a new solution.
8. Regularly review assumptions and update budget, aligning any changes with the Ministry of Finance and other relevant stakeholders.



Identification of target populations

Objectives

The objectives of this chapter is to:

- introduces the African framework for the fair and equitable allocation of vaccines against COVID-19
- provides an overview of essential steps in the identification of target populations and creation of a vaccination schedule
- provides input on a registration and outreach approach

An African framework for the fair and equitable allocation of vaccines against COVID-19

On 14 and 15 December 2020, Africa CDC, in collaboration with the South African Medical Research Council, convened a continental consultation to discuss the meaning, prerequisites, and practical implications of fair, equitable and timely allocation and laid the foundations for a shared African strategy and framework for COVID-19 vaccine equity and allocation. The framework and suggested phasing of target groups for vaccination is available on the Africa CDC website.

Overview of essential steps in the identification of target populations and creation of a vaccination schedule

1. Review available frameworks for the identification and sequencing of target groups and decide on any adaptations for the national level (if needed).
2. Ensure that the definition of the target groups is precise and detailed (including concrete indicators).
3. Research relevant sources – on the national level and in collaboration with local implementing committees, to find the information about target group sizes needed, and the most suitable vaccination strategies for each target group.
4. Prepare tables with information on target group size per geographic unit.
5. Regularly monitor available information (e.g. from Africa CDC) on the timelines for the availability of vaccines, with the number of doses, and

vaccine characteristics. Until the exact number becomes available, use scenario-based planning.

6. Based on the phases, calculate the number of persons to vaccinate per geographic unit per phase, as a preparation for the geographic allocation of resources and planning of resources and logistics capacities.

Input on registration and outreach

Once the target groups are defined, the individual members should be identified and their contact details registered to share appointment information and reminders. Records of contact information are particularly critical for multiple-dose vaccines. Also, the registration of the vaccine is important for the individual to show that they have been vaccinated, e.g. as a prerequisite for international travel. Critical elements for a successful registration and outreach approach include:

- Multi-stakeholder approach to collect the most recent information about target groups, including contact data and how to reach them
- Instruments for tracking of vaccine (card, or, where systems are available, electronic tracking) containing:
 - ♦ Patient contact information
 - ♦ Information on the vaccine provided (manufacturer, type, date)
 - ♦ Timing of the next dose/appointment where possible
- System for (automatic) reminders
 - ♦ Existing systems (e.g. of the healthcare provider administering the vaccine)
 - ♦ Text messages (e.g. in collaboration with telco provider)
 - ♦ Etc



Vaccination delivery strategists

Objective

The objective of this section is to provide guidance on the selection of vaccination sites for the COVID-19 vaccination programmes.

Selection of vaccination sites for the COVID-19 vaccination

The WHO and UNICEF-published *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* contains suggestions on the most appropriate strategies for the vaccination of different target groups, which can be adapted to the local context. To prepare for a large-scale programme, the suggestion is to create a roster of existing facilities that may be used for the vaccination programme based on an assessment of facilities and capabilities, which can then be used depending on the target populations and strategies. These sites could be private or public. Given the scale of the programme, it is advisable to explore all options, including on-site as well as off-site (mobile) vaccination. Mobile vaccination sites can be especially useful in areas with low population density, or where other sites are not available..

Overarching principles for the site network should be:

- Accessibility – the individual vaccination sites should be accessible and the overall network large enough to ensure that the facility can be reached in an acceptable timeframe and cost.
- Acceptability – meeting the expectations of the target groups.
- Safety – the sites should be able to ensure proper implementation of infection prevention, correct storage of supplies at all times, appropriate training of all staff, and all other measures required to avoid harm.
- Cost-effectiveness – if several sites could be used, cost-effectiveness can be the decisive factor in deciding which sites to prioritise.

Checklist for an assessment of individual sites

Topic	Criteria to check for	Guidance
Infection prevention and control	All employees trained	Training should contain at least X, Y, Z [Add concrete requirements, e.g., trainings that employees have to have participates in]
	Rooms are large enough to keep minimum distance between patients	
	Physical distancing of vaccine recipients from infectious patients	
Patient flow management	System for the management of contact data	
	System to provide appointments (to avoid overcrowding)	
	System for the management of reminders for second doses	
	System/tool to record and pass on information about vaccines provided	
Staffing	Oversight and management	
	Medical personnel	
	Support personnel (e.g. to move patients in the facility, manage appointments, etc.)	
Accessibility	Accessibility for individuals with disabilities	
	Significant service disturbances due to weather or environmental conditions unlikely	
Storage capacity	Storage capacity for vaccines	
	Storage capacity for personal protective equipment	
	Storage capacity for syringes and other materials (diluent, needles, other ancillary products)	

Topic	Criteria to check for	Guidance
Confirmations/ agreements to provide	Confirmation of agreement with the terms and conditions for the vaccination specified by the government (e.g. target groups, administration, charging for treatment)	
	Confirmation that COVID-19 vaccine delivery will not interfere with the delivery of routine immunisation programmes	
Processes and SOPs	Waste management and reporting (in particular for vaccine doses)	
	Procurement	
	Storage and handling	
	Reporting of administration errors and adverse events	
	Cleaning	
Safety	Procedures and capacities for staff safety	





Preparation for supply chain and management of healthcare waste

Objective

This chapter:

Suggests and outlines a rapid assessment of logistics capabilities to inform the suitability of different vaccine candidates.

Rapid assessment of logistics capabilities

The WHO and UNICEF-published *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* already provides checklists for the most important topics to cover in preparing supply chain and logistics, as well as links to the most relevant assessment tools. The implications of the supply chain (and especially cold chain equipment) capacities and capabilities on the selection of suitable vaccine candidates, as well as on the planning for different target groups are significant. The recommendation is to either, if possible, perform the full logistics assessment in January 2021, or to do a rapid assessment that can inform the most important choices, by assessing:

- Warehousing capacity overview (highlighting capacity near relevant points of entry)
 - ♦ Location
 - ♦ Ownership
 - ♦ Capacity by temperature level that can be guaranteed:
 - ♦ Refrigerated [2°C to 8°C]
 - ♦ Frozen [-15° to -25°C]
 - ♦ Ultra-cold [-60° to -80°C]
 - ♦ Cost of usage
 - ♦ Accessibility (e.g. by road, rail, air)
 - ♦ Contact information
 - ♦ [if possible: type (brand) of storage unit used]
- Transport capacity overview
 - ♦ Types of transport vehicles (potentially further information – age, brand, etc.)

- ♦ By transport vehicle: capacity by temperature level that can be guaranteed:
 - ♦ Refrigerated [2°C to 8°C]
 - ♦ Frozen [-15° to -25°C]
 - ♦ Ultra-cold [-60° to -80°C]
- ♦ Additional equipment needed (boxes, thermometers, cooling materials, etc.)
- ♦ Ownership of the vehicles, contact information
- ♦ Cost of usage
- ♦ [if possible: type (brand) of storage unit used]
- Equipment available/sources
 - ♦ Temperature management equipment (able to record temperatures suitable for all temperature levels required)
 - ♦ Cold boxes
 - ♦ Cooling materials
- Other inputs to consider
 - ♦ Capacity for the production of dry ice
 - ♦ Location
 - ♦ Capacity
 - ♦ Cost
 - ♦ Availability of mobile vaccination units (e.g. from previous programmes) – need to collect the same information as for other facilities, transport capacity)
 - ♦ Potential ability to collaborate with neighbouring countries on any of the above (especially in the case of Member States with smaller populations)
 - ♦ Staff capacity (e.g. repackaging, warehouse administration, drivers, maintenance)
 - ♦ Administrative capacity (e.g. to provide, fill, check the required documentation, e.g. at ports of entry, distribution hubs, or repackaging sites)



Human resource management and training

Objective

This chapter contains topics for training on COVID-19 vaccine deployment, implementation, and monitoring to consider.

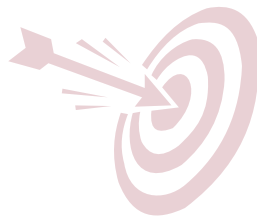
Topics for training

Training, as well as human resource management and planning for surge capacity in general, should look beyond the health workers who will be administering the vaccine. It should consider surge capacity and training needs for other professions involved in vaccine deployment, implementation, and monitoring, including laboratory personnel, legal and regulatory experts involved in creating the necessary standards and procedures, logistics personnel, customs managers and workers, etc.

Potential training should include:

- Administration of the vaccines (per candidate used in the country), including:
 - Preparation
 - Patient counseling (including education about potential reactogenicity and adverse events)
 - Materials to use (appropriate needle sizes)
 - Other specifics about the administration protocol per candidate
 - Injection site preparation and vaccine delivery
- Facilities management, including:
 - Process for ordering and receiving vaccine doses
 - Needs for other materials, sources and process for ordering and receiving them
 - Inventory management (including management of product expiration, reporting)
 - (Medical) waste management

- ♦ Patient flow management (to ensure the safe delivery of the vaccine)
- ♦ Infection prevention and control
- ♦ Safety and security management (facilities and staff)
- ♦ Data privacy
- Logistics, including:
 - ♦ Procurement (including use of procurement tool and process)
 - ♦ COVID-19 vaccine storage and handling in transport
 - ♦ COVID-19 vaccine storage and handling in facilities
 - ♦ Reporting of inventories (including use of procurement tool and process)
 - ♦ Security management
 - ♦ Regulatory requirements
- Legal and regulatory requirements, including:
 - ♦ Specifics of the customs process
 - ♦ Labelling requirements
- Communication, including:
 - ♦ Risk communications for healthcare workers and public health professionals
 - ♦ Communication strategies for community organisations
- Safety and surveillance, including:
 - ♦ Detection and tracking of adverse events (symptoms, etc.)
 - ♦ Training for laboratory staff (if needed)





Vaccine acceptance and uptake (demand)

Objectives

This chapter:

- outline principles for community engagement and communication planning;
- list topics to include in engagement and communication planning;
- guide elements of community engagement and communication planning.

Principles for community engagement and communication planning

Effective community engagement and communication should be:

- Inclusive – the engagement and distribution of information should make sure that all relevant community organisations are included, to maximise equity in the access to information.
- Timely and following the vaccine's lifecycle – community engagement and communication needs to start as soon as possible, communication campaigns should be fully implemented several weeks before the first vaccines become available to ensure access to information, correct registration of recipients, etc. Then, as the implementation of the vaccination programme progresses, so must the communication strategy and messaging. Each phase requires different contents.
- Using existing community organisations and key opinion leaders – they should be involved in the development of the strategy, approaches, and messages as well as in communication and engagement events and campaigns.
- Consistent – Africa CDC will continue to develop a set of messages on the COVID-19 vaccine and its delivery. The more consistent the messaging on the rationale, purpose, target groups, etc. the more convincing. While adjustments to the messaging, tone and communication channels may be needed for different audiences, the main information contents should be aligned. In addition to this, community organisations and key opinion leaders should be involved in the community engagement and

communication campaigns, they should receive training on the basic approaches and messages.

- Targeted – channels and messages should be targeted at populations that need to be reached, using channels they regularly access, or working with relevant community organisations.
- Evidence-based – e.g. providing factual data, addressing widely spreading misinformation campaigns and rumours (making sure to be selective to address only critical ones, not to create the opposite effect of what is intended).
- Practical and accessible – e.g.
 - ♦ Simple Q&As, “one-pagers” for healthcare personnel on the most critical messages and ways to communicate should be available, in addition to more in-depth guidance for the developers of more extensive campaigns.
 - ♦ Simple, effective public health messaging should be available through mass communication channels; in general, a mix of channels should be chosen with all stakeholders in mind.
 - ♦ All relevant languages should be considered for translations.

Topics to include in engagement and communication planning

The WHO and UNICEF-published *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* outlines the critical steps for engagement to drive vaccine acceptance and uptake. For a comprehensive approach, the suggestion is to consider the following topics for engagement and communication across all steps from demand planning to data collection and creating an integrated demand approach:

- Evidence-based information on the rationale for the vaccination (e.g. COVID-19 numbers, economic impact, (long-term) consequences of infections).
- Information about the characteristics of the vaccines in use, regulatory approval process they have undergone, trial results ensuring their efficacy and safety, as well as any risks involved.
- Fact-based responses to any harmful misinformation campaigns.

- Information about the selection and sequencing of the target groups, and the rationale.
- Tactical information for vaccine recipients detailing how to register and access vaccines.
- Information on points of contact for registration, questions and access to support in case of adverse events.
- Testimonies of vaccine recipients, to underline the messaging about the process, address safety concerns and help counter misinformation campaigns.

Elements of community engagement and communication planning

As mentioned above, this guidance suggests creating an additional office of the community engagement lead in the NDVP, to drive the development of a holistic community engagement and communication plan and the setup of networks of community organisations and key opinion leaders.

Stakeholder analysis

Community engagement and communication plans should be based on an analysis of the main stakeholder groups to address. The number of different stakeholder groups to address should be as large as needed, but as small as possible (i.e. addressing different groups with the same messages where possible) because every new stakeholder group adds complexity. A group may have to be considered a separate group in the stakeholder analysis if:

- they have significantly different baseline perceptions (e.g. between urban/rural populations, age groups);
- they have different information needs.

For each stakeholder group, it is crucial to understand the:

- baseline perceptions/beliefs;
- objectives for the engagement (e.g. to provide specific information, address misinformation, or to win them as supporters of the vaccine programme (e.g. key opinion leaders));
- Relevant communication channels.

Communication channels

Communication channels should be chosen to ensure maximum reach. They should be acceptable – it is important to check that there are no existing biases against the channels used. Finally, they should represent the preferences of each group. Usually, this means using a mix of more traditional channels (television and radio announcements, newspapers) and social media. Direct communication through community health workers, trusted organisations and key opinion leaders is typically one of the most effective channels.

Organisations to involve in communication and community engagement

As mentioned above, involving relevant organisations in community engagement and communication is critical. These could be:

- Community or other civil society organisations
- School groups
- Religious groups
- NGOs
- Local/village leaders
- Media outlets

Key opinion leaders

Involving key opinion leaders in the dialogue surrounding vaccination programmes can be helpful to leverage their reach and their ability to tailor the messaging to specific target groups.. These could be:

- Local and village leaders
- Religious leaders
- (Local) celebrities, scientists, athletes
- Government leaders

Phasing of the communications

The successful implementation of vaccination campaigns will require different information to be available to the stakeholders at different times. The suggestion is, therefore, to plan the communication in phases, e.g.:

- **Immediately:** start providing information about the rationale for vaccination, background, and impact of the disease, plans for target groups, etc.
- **As more information becomes available:** provide updates on delivery planning, target groups, as well as practical information about the registration process, identify widely spread rumours and misinformation from social media and traditional media and develop clear messages to counter them.
- **Before the programme starts:** make sure that information about registration and sites is widely available, establish a mechanism to assess the effectiveness of the communication campaigns regularly
- **A few months into the vaccination programme:** provide information on progress and impact.
- **Throughout:** ongoing communication on progress and risks identified (according to guidelines on risk communication).





Vaccine safety monitoring, management of adverse events following immunisation, and injection safety

Objective

This chapter identifies minimum requirements for vaccine safety monitoring, management of adverse events following immunisation (AEFI) for COVID-19 vaccine implementation.

Minimum requirements for vaccine safety monitoring, management of AEFI for COVID-19 vaccine implementation

The WHO and UNICEF-published *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* describes in detail the need for safety monitoring, including passive as well as active monitoring. The following are minimum requirements that need to be implemented before the deployment of the vaccine:

- Process for the detection of AEFIs and adverse events of special interest (AESIs) including definitions of AEFIs (based on Council for International Organizations of Medical Sciences [CIOMS] WHO definitions for AEFI), definitions of AESIs.
- System for the reporting of AEFIs and AESIs that is accessible to a wide range of stakeholders, and central registry to collect data and follow-up information.
- Training materials on the definition, detection, notification, reporting, investigation, and analysis of AEFIs and AESIs:
 - ♦ For all healthcare providers: recognising and reporting AEFIs and AESIs.
 - ♦ For investigators: specific information about the COVID-19 vaccines and potential sources of AEFIs to investigate (based on the preparation and administration details).

- ♦ For laboratory staff (processing of specimens to help diagnosis, treatment, and documentation of AEFIs).
- Training modules tailored to different stakeholders, including at sites participating in vaccination campaigns and involving a variety of healthcare workers.
- Communication strategy:
 - ♦ Risk communication process and guidance, including responsibility for communication of the safety events.
 - ♦ Communication to ensure vaccinated patients know about AEFI and AESI, and processes for reporting these events.
- Laboratory capacity for the analysis of events.





Immunisation monitoring systems

Objective

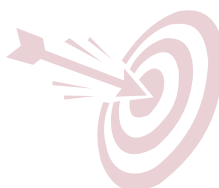
This chapter provides example indicators on COVID-19 vaccine deployment and implementation to monitor.

Example indicators on COVID-19 vaccine deployment and implementation to monitor

The WHO and UNICEF-published *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* summarises the necessary steps of defining objectives and indicators for monitoring, as well as setting up systems and regular reports.

- Community engagement and communication
 - ♦ Number of events
 - ♦ Number of people reached (through different communication channels)
 - ♦ [Changes in specific indicators, such as beliefs, attitudes, behavioural indicators targeted by campaigns]
 - ♦ Number of organisations/key opinion leaders involved
- Delivery readiness
 - ♦ Percentage of local/regional entities for which target group mapping is complete
 - ♦ Percentage of local/regional entities for which vaccine delivery governance is operational
 - ♦ Percentage of planned facilities set up
 - ♦ Percentage of facilities fully operational – including all information, trainings etc. required
 - ♦ Capacity of vaccination facilities (e.g. number of people that can be vaccinated in one day)
 - ♦ Regulatory and legal readiness (e.g. as per checklist)

- Logistics
 - ♦ Materials received (on national level)
 - ♦ Materials distributed to vaccination facilities (vs scheduled amount for facility/local or regional entity)
 - ♦ Average time of materials in storage, facilities before administration
- Administration
 - ♦ Number of doses administered (vs scheduled number for facility/local or regional entity)
 - ♦ Percentage of target group covered (facility/local/regional/national level)
 - ♦ Number, percentage of vaccine doses wasted
- Training (by area)
 - ♦ Number of trainings provided
 - ♦ Number of staff trained
 - ♦ Percentage of anticipated staff needed trained
- Waste management
 - ♦ Percentage of facilities with appropriate waste management capacity
 - ♦ Number of incidents reported
- Safety and surveillance
 - ♦ Number of AEFIs (by vaccine candidate, target group, etc.)
 - ♦ Number of safety issues reported in transport, at facilities, etc.



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