**REPUBLIC OF KENYA**

# MINISTRY OF HEALTH

# National COVID-19 Vaccines Deployment and Vaccination Plan, 2021

**National Vaccine & Immunization Program**

**February 2021**

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# ACRONYMS

| | |
|---|---|
| **ACT** | Access to COVID-19 Tools (ACT) |
| **AEFI** | Adverse Event Following Immunization |
| **AESI** | Adverse Event of Special Interest |
| **CEPI** | Coalition for Epidemic Preparedness Innovations |
| **CHAI** | Clinton Health Access Initiative |
| **CHMTs** | County Health Management Teams |
| **CIHEB-Kenya** | Center for International Health Education and Biosecurity |
| **CMYP** | Comprehensive Multi-Year strategic Plans |
| **COVID-19** | Corona Virus Disease-2019 |
| **CSOs** | Civil Society Organizations |
| **DHIS** | District Health Information System |
| **DSRU** | Disease Surveillance and Response Unit |
| **DVS** | District Vaccine Stores |

| | |
|---|---|
| **EPI** | Expanded Programme on Immunization |
| **EVMA** | Effective Vaccines Management Assessment |
| **GAVI** | The Vaccine Alliance |
| **HFs** | Health Facilities |
| **HIV** | Human Immunodeficiency Virus |
| **HSS** | Health Systems Strengthening |
| **IA2030** | Immunization Agenda 2030 |
| **ICAT** | Infection Control and Assessment Toolkit |
| **IM** | Intramuscular |
| **IPC** | Infection Prevention and Control |
| **IPV** | Inactivated Polio Vaccine |
| **JICA** | Japan International Cooperation Agency |
| **KANCO** | Kenya Aids NGOs Consortium |
| **KEHP** | Kenya Essential Health Package |
| **KENITAG** | Kenya National Immunization Technical Advisory Group |
| **KFW** | German State-owned Development Bank |
| **KSH** | Kenya Shillings |
| **MCHIP** | Maternal and Child Health Integrated Program |
| **MERS** | Middle East Respiratory Syndrome |
| **MoH** | Ministry of Health |
| **NDRA** | National Drug Regulatory Authority |
| **NGOs** | Non-Governmental Organizations |
| **NVIP** | National Vaccine Immunization Program |
| **PHC** | Primary Health Care |
| **PHEIC** | Public Health Emergency of International Concern |
| **PPB** | Pharmacy and Poisons Board |
| **PPE** | Personal Protective Equipment |
| **SARS** | Severe Acute Respiratory Syndrome |
| **SARS-CoV-2** | Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) |
| **SDGs** | Sustainable Development Goals |
| **SOPs** | Standard Operating Procedure |
| **ToTs** | Trainer of Trainees |
| **UHC** | Universal Health Coverage |
| **UNICEF** | United Nations International Children's Emergency Fund |
| **UNICEF SD** | United Nations International Children's Emergency Fund-Supply Division |
| **VE** | Vaccine Effectiveness |
| **VVM** | Vial Vaccine Monitor |
| **WHO** | World Health Organization |

# FIGURES & TABLES

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# EXECUTIVE SUMMARY

**By the end of January 2021, over 100 million cases of the Corona Virus Disease (COVID-19) and 2.2 million deaths had been reported globally since this global pandemic was first reported in December 2019.** Kenya's index case was reported on 12th March 2020 and as at 31st January 2021, 100,773 cases and 1,763 deaths had been reported.

In December 2020, scientists globally had developed vaccines against the disease and had started deploying them for use. Kenya constituted a country-led multi-stakeholder taskforce with the mandate of supporting the MOH to adopt, deploy and ensure the administration of vaccines alongside other measures to reduce the spread and transmission of COVID-19. The vaccines are expected to contribute towards the reduction of morbidity and mortality arising from COVID-19 infection and mitigate the broader socio-economic effects of the pandemic.

**The task force immediately developed this plan to guide the deployment and vaccination program.** The objectives of Kenya's National Vaccine Deployment plan (NVDP) are to:

1. Facilitate the deployment, implementation, and monitoring of the COVID-19 vaccine(s) in Kenya
2. Ensure the plan and related financing is well aligned to the overall national COVID-19 recovery and response plans

**The plan consists of 10 chapters.** Chapter 1 contains background information on COVID-19 and the current landscape of the vaccines. Chapter 2 describes the regulatory preparedness requirements; Chapter 3 describes the proposed coordination mechanisms at the two levels of government (national and county). Chapter 4 contains the costing, financing, and resource mobilization strategies, while chapter 5 deals with the vaccination strategies including population targeting and eligibility criteria. Chapter 6 deals with the procurement and supply chain management strategies while chapter 7 describes human resource management and capacity building of health workers. Chapter 8 describes strategies to create vaccine demand through advocacy, communication, and community mobilization. Chapter 9 describes how the vaccine safety will be monitored and chapter 10 contains plans to monitor and evaluate the impact of the vaccine's deployment.

**Kenya has resolved that any vaccines adopted for deployment in Kenya will have Emergency Use Authorization from a stringent regulatory authority** and be registered for use in Kenya by the Pharmacy and Poisons Board.

**GAVI supports Kenya with vaccines through a co-financing approach to promote country ownership and financial sustainability of the routine immunization program.** The country is set to access safe and effective COVID-19 vaccines to cover approximately 20% of the population through the GAVI COVAX Facility and will self-procure additional doses to cover an additional 10% of the population for a total of 15.8 million people during the introductory rollout. Recognizing the vaccines supplies are currently limited, there are plans to increase coverage to 40% of the population (20 million) once more supplies become available. The GAVI indicative price for ALL vaccines available through the COVAX facility is USD 7 (Ksh 770) per dose when delivered to the port of entry.

**Kenya will adopt a phased approach to the vaccine roll-out aligned to the government fiscal year.** Phase 1 covering the period February 2021-June 2021 will target front line health workers and other cadres in priority sectors to cover 1.25 million people. Phase II covering the period July 2021-June 2022, will target populations at most risk of severe disease and death to cover 9.7 million people. Phase III will cover the period July 2022-June 2023 focusing on populations in congregate settings while ensuring equitable vaccination of other vulnerable groups.

**Kenya has adequate storage capacity for both positive and negative temperature storage vaccines at the central vaccine store in Kitengela and 8 regional stores to support the vaccine's deployment.** The National Vaccine store has a total of 8 cold rooms with a net capacity of 130$M^3$ for positive temperature cold storage (2-8°C) and 2 freezer rooms with net capacity for negative temperature cold storage (-20°C) of 14 $M^3$. For vaccines requiring -70$^oC$ storage temperatures, the country will need to procure additional cold chain storage capacity to comply with the storage needs of these vaccines.

**The training of health workers will be organized around three phases.** Phase 1 for level 4-6 health facilities will be done through blended online/virtual training and face to face/peer demonstration. These will also be recorded for later use in phase 2 and 3 and used to undertake TOT training. For every phase, a training guide for health workers containing information on the COVID-19 disease, the vaccine characteristics, and the immunization procedures will be developed to ensure standardization and smooth implementation of training activities. The training guide will be developed based on WHO generic training modules and contextualized to phase (target population) and county specific situation.

**The MOH will develop a communication plan that includes risk communication to ensure buy-in of key stakeholders in creating demand for the vaccine and address hesitancy issues.** The crisis communication plan will address any potential

adverse events, myths, misconceptions, and hesitancy that may arise associated with either COVID-19 or the vaccine.

**The Monitoring and Evaluation of the COVID-19 vaccine introduction will begin prior to the vaccination launch and will continue through the established reporting systems which will be enhanced to consider COVID-19 vaccine approvals.** Data Management will utilize the existing DHIS 2 system for aggregate reporting from summary sheets. A digital vaccine registry platform with a mobile application and aggregation system has been developed to track longitudinal information on targeted vaccination and vaccine stocks.

**Impact studies will be conducted in select counties, leveraging the consortia of partners involved in local COVID-19 Studies.** Existing longitudinal population-based surveillance systems will be utilized, to evaluate the decline in incidence of COVID-19 disease attributable to the vaccine introduction. National Research Fund will be engaged to fund multi-disciplinary research.

# 1 INTRODUCTION

Corona Virus Disease (COVID-19) was unknown prior to the outbreak in Wuhan, China, in December 2019. The disease spread rapidly across the globe. On 30th January 2020, WHO declared the COVID-19 outbreak a Public Health Emergency of International Concern (PHEIC) and on 11th March characterized it as a pandemic. Globally, as of 2nd December 2020, there have been 102,399,513 confirmed cases of COVID-19, including 2,217,005 deaths, reported to WHO.

Kenya's index case was reported on 12th March 2020. As of 31st January 2021, 100,773 cases and 1,763 deaths had been reported. This ranks Kenya as 7th on the case fatality rate in Africa.

The COVID-19 vaccine program is part of ongoing efforts to reduce the spread and transmission of COVID-19, and therefore reduce associated morbidity and mortality and to mitigate the broader socio-economic effects of the pandemic.

The objectives of Kenya's National Vaccine Deployment plan (NVDP) are:

1. Facilitate the deployment, implementation, and monitoring of the COVID-19 vaccine(s) in Kenya
2. Ensure the plan and related financing is well aligned to the overall national COVID-19 recovery and response plans

This document consists of 10 chapters covering the major areas and key activities necessary to successfully deploy, implement and monitor COVID-19 vaccination. The understanding of COVID-19 epidemiology continues to evolve and is rapidly changing. A description of the COVID-19 disease, what is currently understood of its transmission patterns and the situation in Kenya can be found in Annex 8. Properties of currently available vaccines are described in Annex 7.

*Figure 1: Trends of COVID-19 outbreak cases Kenya*

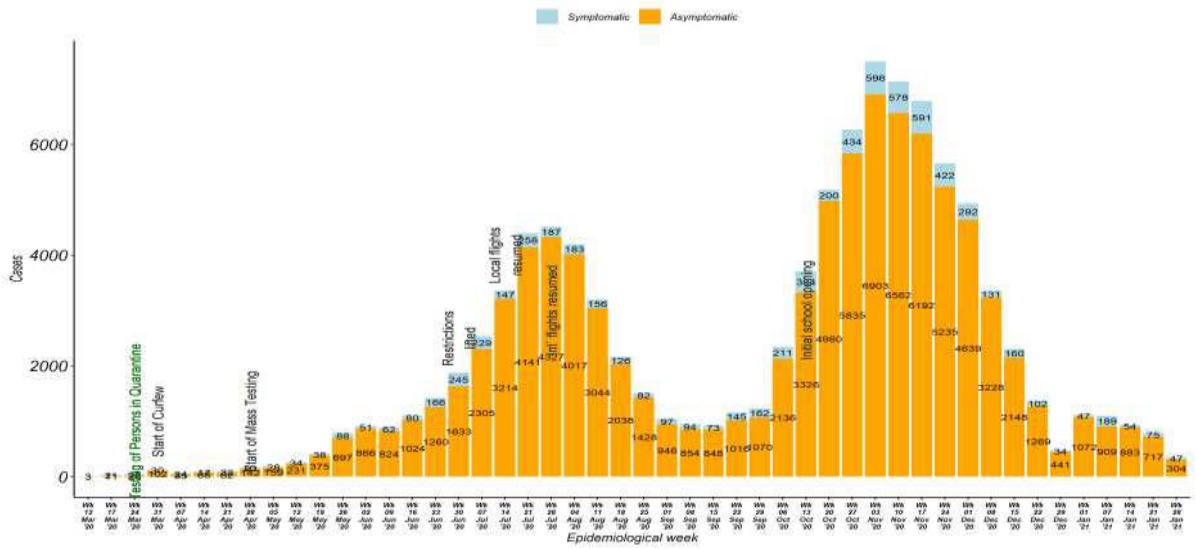
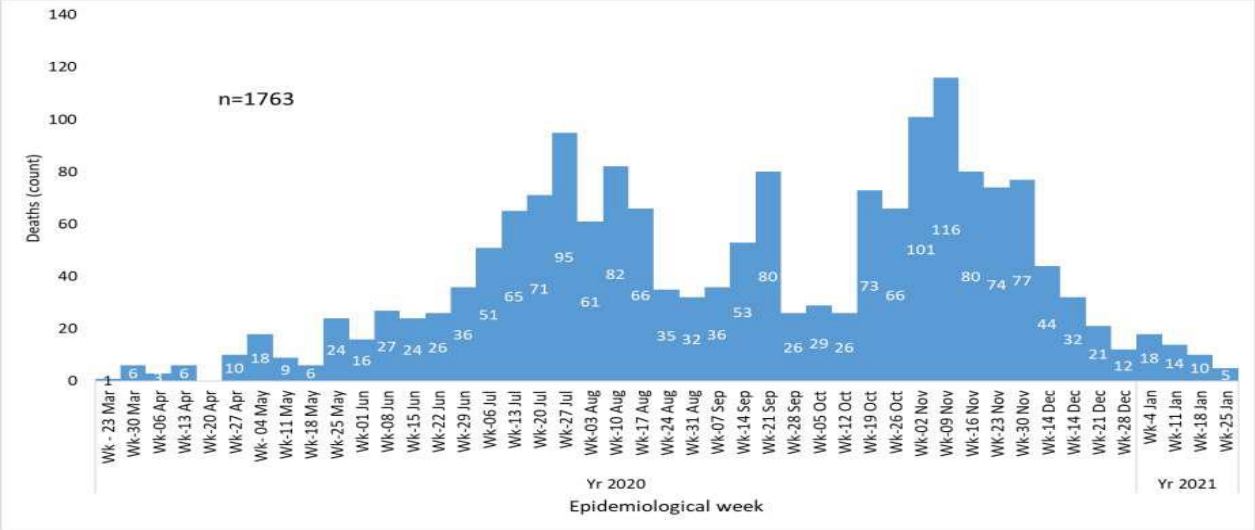
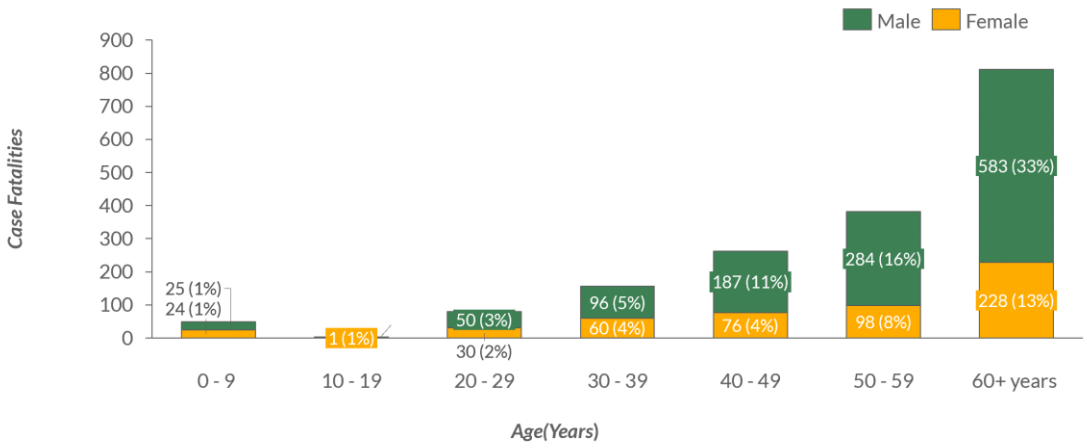



*Figure 2: Trends of fatalities by week, Kenya*




A total of 1,586 deaths have been reported so far, 1,123 (71%) being males and 463 (29%) females (Figure 3).

*Figure 3: Age and sex distribution of COVID-19 case fatalities, Kenya*




Kenya is witnessing a community-level transmission of the COVID-19 disease. Nairobi County has the highest attack rate of 885.5 per 100,000 population followed by Mombasa County at 682.2 per 100,000 population.

## 1.1.1 Background

Kenya is a signatory to the Addis declaration on immunization that required counties to attain Universal Access to Immunization. In 2019, immunization coverage was 82% (target >90%). In the last ten years, eight new vaccines have been successfully introduced into the national immunization program. Currently, it costs the country Ksh 6.0 Billion to procure and distribute vaccines for routine immunization and maintain depots of which GAVI contributes Ksh 3.8 billion, and the Government 1.4 billion, leaving a gap of Ksh 0.8 billion. Having become a LMIC, Kenya is expected to begin self-financing for immunization by 2027.

### 1.1.1.1 COVID -19 Vaccine rollout

The National Emergency Response Committee and the Kenya National Immunization Technical Advisory Group endorsed the introduction of COVID-19 vaccines in Kenya and to leverage the immunization program infrastructure for vaccine distribution.

The coordination of the immunization program is supported by the N-ICC (National Immunization Interagency Coordinating Committee), the KENITAG (Kenya National Immunization Technical Advisory Group), and the NVSAC (National Vaccine Safety Advisory Committee). They provide overall technical and policy advisory on immunization, as per their Terms of Reference. They report to the Cabinet Secretary,

Health, and National Steering Committee, for purposes of the COVID-19 Vaccine introduction.

#### 1.1.1.2 COVID-19 vaccines

The World Health Organization (WHO) has to date approved three vaccines for deployment, namely: Pfizer BionTech, Moderna and AstraZeneca while a few other vaccines are finalizing trials and will be reviewed for registration soon.

The above vaccines require two doses for optimal immunogenicity and efficacy. Various vaccine candidates use different technology platforms and will likely have different characteristics, including immunogenicity, dosing schedules, safety profiles, cold chain requirements and manufacturing time. These factors have implications for how each vaccine can be used. Currently, there are vaccines based on at least six vaccine platforms being deployed against the coronavirus globally.

*Table 1: Vaccines Landscape*

| Name of Vaccine | WHO pre-qualification Or SRA's | Countries Using the Vaccine | Cost | Price under COVAX |
|---|---|---|---|---|
| **Pfizer/ BionTech** | Yes (WHO, USFDA, MHRA, EMA, Swissmedic) | USA<br>UK<br>Belgium<br>Canada<br>Costa Rica<br>Czech Republic<br>Greece<br>Germany<br>Sweden<br>Switzerland | USD 20/dose in the US | USD 7 |
| **Moderna** | Yes (MHRA, EMA and USFDA) | USA<br>Germany<br>Canada<br>Netherlands<br>Spain | USD 32-37 /dose | USD 7 |
| **AstraZeneca / Oxford** | Yes (MHRA) | UK<br>Scotland<br>Northern Ireland | USD 7 | USD 7 |

| | | | | |
|---|---|---|---|---|
| **Sinopharm** | No | Brazil<br>Bahrain<br>China<br>UAE | Less than USD 88 for 2 doses | TBD |
| **Johnson** | No | USA<br>UK<br>Philippines<br>S. Africa<br>Brazil<br>Columbia | TBC | TBC |
| **Novavax** | No | USA<br>South Africa<br>Australia | TBC | TBC |
| **Sinovac** | No | Brazil<br>Turkey<br>Bangladesh<br>Indonesia | USD 3- 10 (Indonesia) | TBC |

#### 1.1.1.3 Lessons learnt from influenza A H1N1 and other vaccine introductions.

Kenya has been implementing an influenza vaccination demonstration project among children aged 6-23 months in two counties (Mombasa and Nakuru) since January 2019. Data from this demonstration project will inform the COVID-19 vaccine deployment and vaccination plans.

*Table 2: Summary of lessons learnt from influenza A H1N1 and other vaccine introductions.*

| Element | Lessons Learned | Actions |
|---|---|---|
| **Coverage** | • A campaign strategy yields high coverage. However, adopting this as the primary strategy is costly and could be difficult to sustain. The estimated financial and economic costs amounting to US$ 20.67 and US$ 44.77 respectively (inclusive of vaccine costs, in the case of HPV). | • Revise the primary strategy/mode of delivery to a more sustainable approach i.e., facility-based approach<br>• Complement the facility-based approach with accelerated immunization activities (Immunization Days) outreach approach varied depending on country context<br>• Ramp up advocacy and social mobilization efforts to ensure that the target population receives the message and seeks the vaccine at the facility. |
| **Microplanning** | • Inaccurate target numbers of individuals to be vaccinated during new vaccine introductions, causing miscalculation of the required number of vaccines, with subsequent stockouts and/or un-realistic coverages. | • Ensure accurate and timely micro-planning and mapping of the target population in liaison with counties and KNBS<br>• Ensure timely and adequate vaccine supply<br>• Use appropriate advocacy and social mobilization using the disease specific platform. |
| **Staff Training** | • Importance of having adequate training materials developed and distributed to all service points on time. | • Ensure technical guidelines and job aides are available at all levels including service points<br>• Technical guidelines and other materials should be bundled and delivered early in advance. |

| | | |
|---|---|---|
| **Cold Chain/ Storage Capacity** | • Following previous vaccine introduction, counties reported increased cost of operation, especially costs related to the transportation of vaccines due to increase in the frequency of vaccine collection. This is due to inadequate storage/ transportation space.<br>• Need to address gaps in temperature monitoring. | • Ensure adequate planning and mapping of sites with adequate CCE<br>• Ensure continuous temperature monitoring devices (FT2) at all levels are available and working correctly<br>• Various investments (e.g., Gavi, KFW) have increased the cold chain capacity. NVIP has developed a 5-year Cold Chain Expansion and Rehabilitation Plan (CCERP) that will guide investment in the cold chain. To finance the plan, the MOH will enhance its advocacy activities with county leadership and immunization partners, as well as mobilize resources for CCE through Gavi HSS and CCEOP. |
| **Vaccine Acceptability and Dropout Rates** | • Due to intensive collaboration with relevant stakeholders and packaging of messages, minimal hesitancy and refusals have been encountered<br>• Use of SMS and other reminders to clientele resulted in great penetration and demand generation for vaccination. | • Increased engagement with stakeholders, especially religious leaders, and immunization champions, to reduce vaccine hesitancy and dropout rates<br>• Packaging the vaccines as a COVID-19 Control strategy<br>• Collaboration with other ministries e.g., Education, Interior will lead to the success of the rollout<br>• Apply strategies that have worked in the past to increase demand for the vaccine e.g., use of SMS. |

| | | |
|---|---|---|
| **Others** | • Concerns regarding virus mutation among health workers<br>• concerns as to why only specific groups were being vaccinated and not all other populations<br>• Concerns about the short expiry nature of the vaccine<br>• Some health care workers linked the Influenza vaccination drives to a COVID-19 trial vaccine<br>• Most health care workers requested for Influenza Vaccine notification cards as proof of immunization and requested for annual vaccination. | • Ensure technical guidelines and job aides are available at all levels including service points, ahead of the introduction<br>• Conduct an audience segmentation and adapt messages to specific audiences targeting the concerns raised<br>• Engage relevant experts to continuously engage and regularly provide updates to health workers on the COVID-19 Vaccines |

# 2 REGULATORY PREPAREDNESS

In Kenya, the Pharmacy and Poisons Board (PPB) is charged with the responsibility of regulating the practice of pharmacy and trade in health products and technologies. The core mandate is to ensure the provision of quality, safe and efficacious medical products, and health technologies. The law requires that all drugs and vaccines must receive prior approval before use in Kenya including the COVID-19 vaccines.

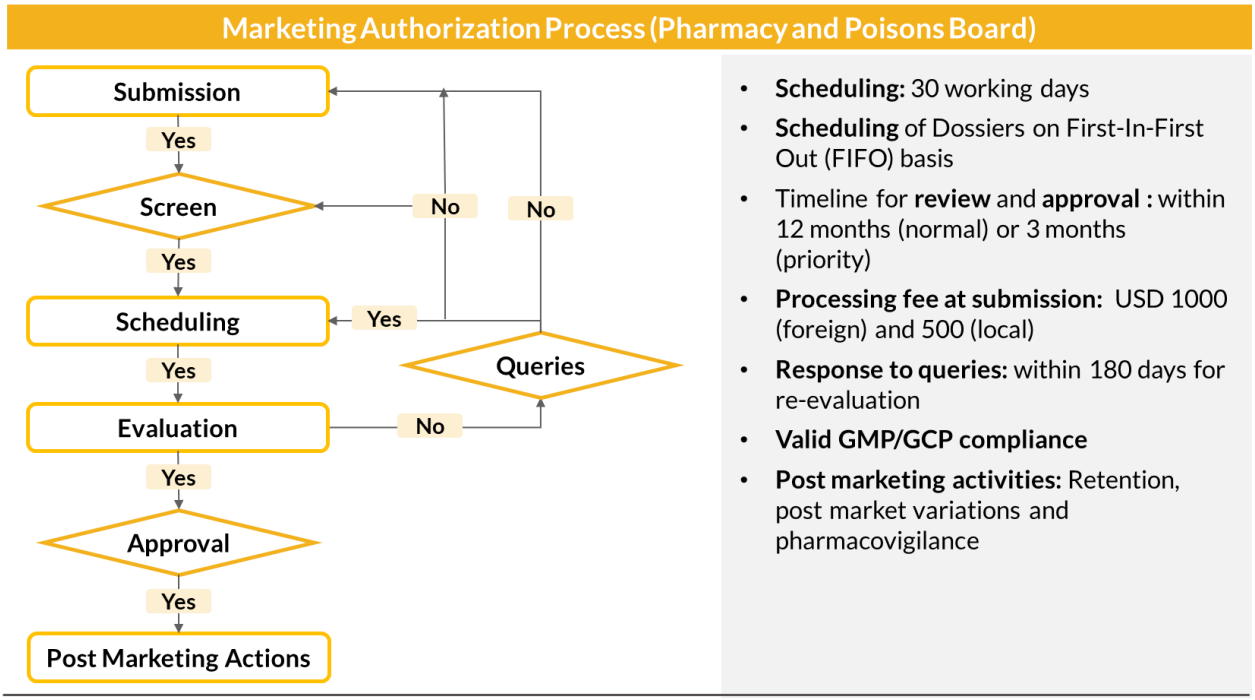
## 2.1.1 COVID-19 Vaccine Regulatory Approval

The review process of COVID-19 vaccines will involve evaluating submitted data on quality, safety, and efficacy.

COVID-19 vaccines that have already received approval from stringent regulatory authorities (SRAs) or WHO will be expedited for approval within seven (7) days, upon application by the manufacturing company or their agent. The PPB recognizes regulatory decisions (marketing authorization or emergency approval) of Stringent Regulatory Authorities (SRAs) e.g. USFDA, MHRA, EMA, Swissmedic and WHO.

The diagram below shows the steps involved:

*Figure 4: Steps involved in licensure of medicines and biological products*




**Source:** www.pharmacyboardkenya.org

*Table 3: The following key parameters must be met for COVID-19 vaccines approval (adopted from EMA)*

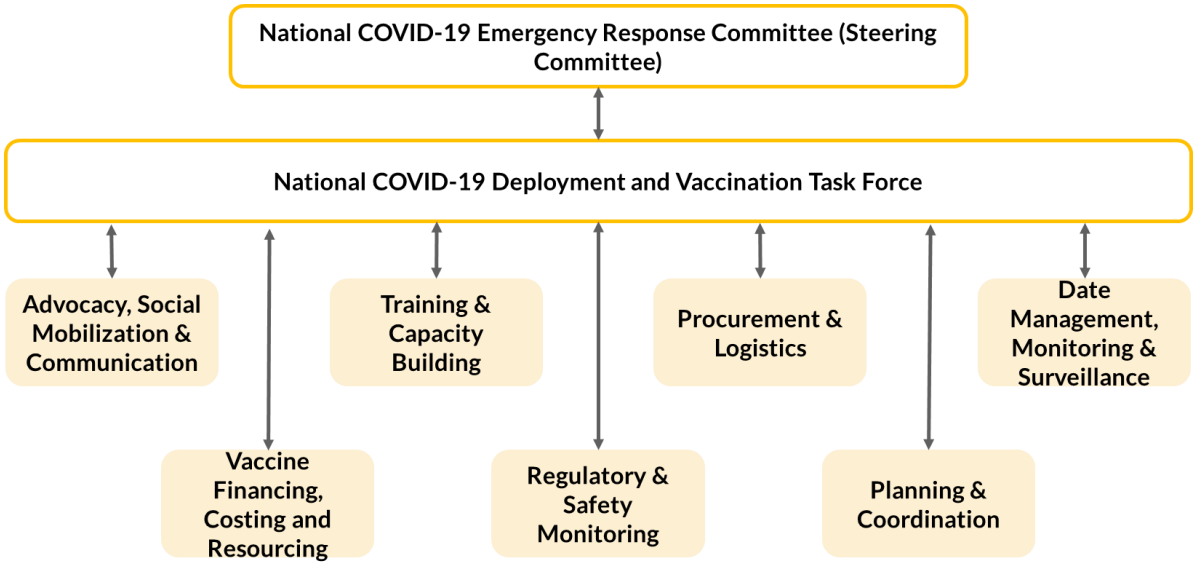
| Parameter | Specification |
|---|---|
| **Primary Endpoint** | Prevention against symptomatic COVID-19 disease of any severity. |
| **Secondary Endpoint** | Prevention of severe disease or infection. |
| **Point Estimate Vaccine Efficacy** | 50-60%, lower bound of 95% CI between 20-30%, preferably above 30%. As per literature, all COVID-19 vaccines have an efficacy of > 70%. |
| **Clinical Safety Database (3000 subjects)** | Followed for at least 6 weeks. |
| **Pre-Clinical data** | Toxicology studies and challenge model tests tailored against a vaccine construct, if available. |
| **Primary assays of immunogenicity e.g., neutralizing antibodies assay** | Should be established. |
| **Correlates of Protection** | Should be explored. |

# 3 PLANNING AND COORDINATION OF THE VACCINE INTRODUCTION

The COVID-19 Vaccine introduction will be done through a strong country-led, multi-stakeholder and evidence-based decision-making process. The introduction is envisaged to be fast tracked under the direction of the Ministry of Health, with the support of other stakeholders.

A coordination structure, coordinated at three levels has been set up as shown below:

*Figure 5: Summary of National Level Coordination Structures*




## 3.1.1 National COVID-19 Vaccine Deployment and Vaccination Steering Committee (NSC)

### 3.1.1.1 Members of the steering committee

The mandate of the steering committee is to oversee development execution of the National COVID-19 Vaccine Deployment and Vaccination Plan at the National Level.

*Table 4: Members of the national COVID-19 Vaccine Deployment and Vaccination Steering Committee*

| Name | Position | Role |
|---|---|---|
| Hon. Sen Mutahi Kagwe | Cabinet Secretary, Health | Chairman |

| | | |
|---|---|---|
| Dr. Fred Matiang'i | Cabinet Secretary, Interior and Coordination of National Government | Designated Representative |
| Hon. Amb Ukur Yatani | Cabinet Secretary, National Treasury | Designated Representative |
| Prof. George Magoha | Cabinet Secretary, Education | Designated Representative |
| H.E. Hon. Martin Wambora | Chairman, Council of Governors | Designated Representative |
| Dr. Patrick Amoth | Director General, Ministry of Health | Member |
| Dr. Ruddi Eggers | WHO Kenya, Country Representative | Member |
| Dr. Maniza Zaman | UNICEF Kenya, Country Representative | Member |
| Dr. Jane Chuma | World Bank Kenya, Country Representative | Member |
| Dr. Gerald Macharia | CHAI Kenya, Country Director | Member |
| Dr. Marc Bulterys | CDC Kenya, Country Director | Member |
| Rt. Rev. Peter Mbatia | Catholic Health Commission | Member |
| Dr Samuel Mwenda | CHAK, General Secretary | Member |
| Mr. Ole Nado | SUPKEM, Representative | Member |
| Prof. Fred Were | KENITAG, Chair | Member |
| Dr. Fred Siyoi | Pharmacy and Poisons Board | Member |

#### 3.1.1.2 Terms of Reference of the Steering Committee

1. Provide oversight for the planning and implementation of the COVID-19 Vaccine introductions, through review of recommendations of the technical working groups and provide appropriate guidance
2. Address any impediments to the implementation of the COVID-19 Vaccine introduction
3. Advocate for, guide and facilitate the implementation of COVID-19 Vaccine introductions, resource mobilization, funds (including disbursement modalities and accountability), technical support, expediting any legal formalities and facilitating high level engagement
4. Review the recommendations of the technical committee and give guidance on implementation of the vaccine introduction
5. Participate in the launch of the COVID-19 vaccine introduction

### 3.1.2 National COVID-19 Vaccine Deployment and Vaccination Taskforce

The mandate of the taskforce will be to provide overall technical leadership for vaccine deployment planning and implementation.

*Table 5: Members of the National Taskforce on COVID-19 Vaccines Deployment*

| Name | Position | Role |
|---|---|---|
| Dr. Willis Akhwale | Disease control specialist/ Senior Advisor MOH | Chair |
| Dr. Pacifica Onyancha | Head, Directorate Preventive and Promotive Health Services | Member |
| Dr. Githinji Gitahi | AMREF | Member |
| Dr. Nazila Ganatra | Head Strategic Public Health Programs | Member |
| Dr. Collins Tabu | Convenor/ Head, Division of National Vaccines, and Immunization Program | Member |
| Mr. Mburugu Gikunda | MoH Advisor, Communications (Task Lead, Advocacy, Communication and Community Mobilization) | Member |
| Mr. Benson Murimi | MoH Kenya, Finance (Task Lead, Vaccine Financing, Costing & Resourcing) | Member |
| Dr. Ayub Manya | Task lead- Data management, monitoring and surveillance | Member |
| Dr. Linda Makayotto | MoH, Surveillance | Member |
| Dr. Peter Mbwiri | Pharmacy and Poisons Board | Member |
| Mr. Onesmus Kamau | Data Management | Member |
| Dr. Peter Okoth | Immunization Specialist, UNICEF | Member |
| Dr. Kibet Sergon | WHO | Member |
| Dr. Richard Ayah | University of Nairobi | Member |
| Prof. Bernhards Ogutu | KEMRI | Member |
| Mr. Anthony Ngatia | CHAI | Member |
| Mr. Kenneth Munge | World Bank | Member |
| Edwine Barasa | Kemri Wellcome Trust | Member |
| Dr. Edward Abwao | USP | Member |
| Health Committee, CoG | Representative, Council of Governors | Member |
| Dr. Cosmas Mugambi | MOH | Member |
| Dr. Victoria Kanana | MoH, Secretariat | Member |
| Dr. Stephen Muleshe | MoH (Task Lead, Planning and Coordination) | Member |
| Mr. John Kabuchi | MoH, (Task Lead, Procurement and Logistics) | Member |

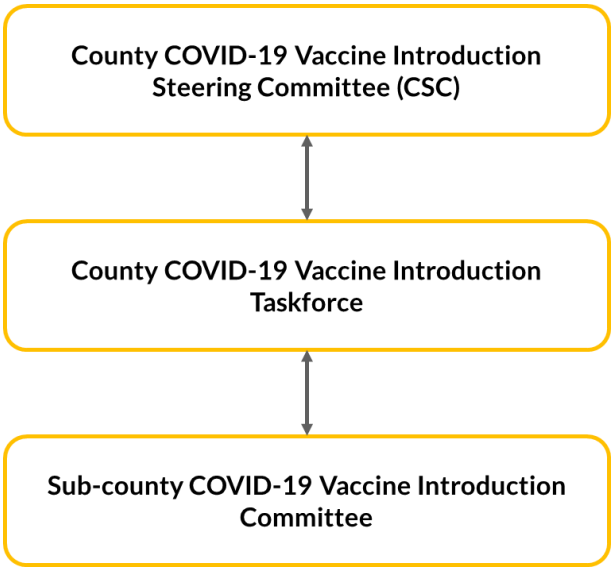
| | | |
|---|---|---|
| Dr. Salim Hussein | MoH, Head, Department of Primary Health | Member |

#### 3.1.2.1 Terms of reference of the Taskforce

1. Identify resource needs and make recommendations for inclusion in the COVID-19 Deployment and Vaccination Plan
2. Guide technical sub-committees in the planning and implementation of the COVID-19 vaccine introduction
3. Review the work plans of the COVID-19 vaccine introduction technical sub-committees, guide as appropriate and monitor their implementation
4. Review and approve the technical COVID-19 vaccine introduction materials including print, electronic, vaccine logistics, training, tools among other vaccine introductions materials
5. Guide the technical communication, training, supervision, and monitoring of the COVID-19 Vaccine introduction
6. Advise and report to the National Steering Committee regularly on the progress of the COVID-19 Vaccine introduction and undertake any other duties as may be assigned by the NSC

Health is a devolved function and hence the need to have strong and well-coordinated structures at both the county and sub-county levels. At the county level, there will be establishment of the **COVID-19 Vaccine Deployment and Vaccination Steering Committee and Taskforce**. The County Emergency COVID-19 Response Committee could be adopted to form the Steering Committee.

*Figure 6: Summary of County Level Coordination Structures*



#### 3.1.2.2 County COVID-19 Vaccine Deployment and Vaccination Steering Committee (CSC)

1. County Governor (Chairperson)/or a designate
2. County Commissioner
3. County Secretary
4. ALL County Executive Committee Members
5. Representatives of National Government Departments within the County
6. Any other member as may be co-opted by the Chair

The roles and responsibilities of the County Steering Committee include:

- Provide oversight for the planning and implementation of the COVID-19 Vaccine introductions in the county
- Moderate on any impediments to the implementation of the COVID-19 Vaccine introduction at county level
- Review the recommendations of the technical committee and give guidance on implementation of the vaccine introduction at county level
- Participate in the launch of the COVID-19 vaccine introduction

#### 3.1.2.3 County COVID-19 Vaccine Deployment and Vaccination Taskforce

1. County Director for Health (Chairperson)
2. County Nursing Officer
3. County EPI Logistician
4. County Disease Surveillance Coordinator
5. County Health Records and Information Officer
6. County Health Promotion Officer
7. County Community Health Services Officer
8. County Health Accountant
9. County Referral Hospital Medical Superintendents

**The specific tasks to be undertaken are:**

*Preparatory phase:*

- Monitor progress of database of beneficiaries on COVID-19 Vaccine
- Ensure training of all concerned HR on COVID-19 Vaccine into a training database
- Monitor progress on key activities such as microplanning, communication planning, cold chain, and vaccine logistics planning. Accountability to be fixed for each activity at all levels

- Planning and mapping of vaccination sessions where HCWs and priority sector workers and other Priority Groups will be vaccinated during the initial phase of COVID-19 Vaccine roll-out
- Involve other relevant departments and partners. Involve the local and religious leaders
- Identify vaccinators across government and private sectors to minimize disruption of Routine Immunization services while introducing the COVID-19 vaccine
- Anyone legally authorized to give an injection may be considered as a potential vaccinator
- Mapping human resources across departments that could be deployed for vaccination sessions for verification of beneficiaries, crowd management and overall coordination at session site

*Implementation phase (upon availability of vaccine):*

- Monitor the roll-out of COVID-19 Vaccine in the county for progress made and resolving bottlenecks
- Requisition of required human resource and infrastructure including vehicles if needed from other departments for implementation and monitoring
- Ensure minimal disruption of other routine health services during the rollout of COVID-19 Vaccine
- Ensure identification and accountability of senior officers in sub-counties. They should visit these sub-counties and provide oversight to activities for the rollout of COVID-19 Vaccine, including participation in training, monitoring etc.
- Ensure safe storage, transportation, and delivery of vaccine doses with sufficient police arrangements so that there are no leakages in the delivery system
- Robust communication planning at all levels to address rumor mongering as well as vaccine eagerness. Ensure an adequate number of printed IEC materials (as per prototypes) are printed and disseminated to blocks/planning units in time. Ensure that these materials are discussed and used in the sensitization workshops
- Track sub-counties and facilities for adherence to timelines for various activities required for introduction of COVID-19 Vaccine
- Share key qualitative and quantitative feedback at county level for review
- Monitor meetings of County AEFI Committee for expedited investigation of AEFI

#### 3.1.2.4 Sub-county COVID-19 Vaccine Introduction Committee

1. Sub-county Medical Officer for Health
2. Sub-county Public Health Nurse
3. Sub-county EPI Logistician
4. Sub-county Disease Surveillance Coordinator
5. Sub-county Health Records and Information Officer

6. Sub-county Health Promotion Officer
7. Sub-county Hospital Medical Superintendent

**The specific tasks to be undertaken are:**

*Preparatory phase:*

- Monitor progress of database of beneficiaries to be shared with county and uploading to database
- Ensure training of all concerned HRH
- Monitor progress on key activities such as microplanning, communication planning, cold chain, and vaccine logistics planning. Accountability to be fixed for each activity
- Planning and mapping of vaccination sessions where HCWs and other Priority Groups will be vaccinated during the initial phase of COVID-19 Vaccine roll-out.
- Involve all relevant departments and partners
- Identify vaccinators across government and private sectors to minimize disruption of Routine Immunization services while introducing COVID-19 Vaccine. Anyone legally authorized to give an injection may be considered as a potential vaccinator
- Mapping human resources across departments that could be deployed for vaccination sessions for verification of beneficiaries, crowd management and overall coordination at session site

*Implementation phase (upon availability of vaccine):*

- Monitor the roll-out of COVID-19 Vaccine in the sub-county for progress made and resolving bottlenecks
- Requisition of required human resource and infrastructure including vehicles if needed from county and/or other departments for implementation and monitoring
- Ensure minimal disruption of other routine health services during rollout of COVID-19 Vaccine
- Ensure supervision of vaccination sessions being conducted for COVID-19 Vaccine
- Implementation of communication plan while addressing the local context and needs to address rumor mongering as well as vaccine eagerness. Maximize use of local influencers (including religious leaders) for countering misinformation
- Ensure an adequate number of IEC material pertaining to COVID-19 vaccination is displayed at prominent places and at the session's site
- Ensure adherence to timelines for various activities required for the introduction of the COVID-19 Vaccine
- Share key qualitative and quantitative feedback at county level for review

#### 3.1.2.5 FBOs, CSOs and Private Sector Engagement

The FBOs, CSOs and Private Sector are represented at the National COVID-19 Vaccine Deployment Steering Committee and will play a pivotal role in the following areas:

- Identification and registration of clients
- Provision of facilities and vaccination services
- Public awareness creation
- Training & Capacity Building of the Health Care Workers
- Safety monitoring and reporting
- Logistical support including provision of vaccine storage facilities and maintenance

# 4 COSTING, FINANCING AND RESOURCING

The resource requirements for the introduction of the COVID-19 Vaccine were estimated based on the following phased approach presented in more details in Section 5 -11 of this plan:

- The vaccine introduction will occur over the period Jan 2021 to December 2023 straddling three Kenya government financial years FY 2020/21, FY 2021/22, and FY 2022/23
- The population coverage by the end of that period is aimed at 30%
- Vaccines will be sourced mainly from the COVAX facility though other options for purchase will be considered
- Vaccine introduction will be phased and based on priority populations, supply availability and health system capacity to deploy the vaccine
- Other activities planned for successful introduction include: capacity building of health workers, information management, surveillance, communication, advocacy, and community engagement

The estimation of resource requirements is also informed by the following assumptions:

- Kenya plans to vaccinate 30% (or 15.8 million) of a total population of 49,070,876 by the end of June 2023 in 3 phases
- Kenya will receive vaccine support from Gavi to vaccinate 20% of the population and self-procure vaccine for 10% of the population
- The vaccination will be rolled out in three phases to progressively cover all target groups based on vaccine availability - phases may overlap
- Early vaccination to focus on administration sites that can reach prioritized populations with as much throughput as possible - Levels IV, V and VI hospitals estimated at 5% of the total facilities
- Positive storage temperature vaccines will be prioritized during Phase I while negative storage temperature vaccines, if available, will be considered during Phases II & III
- Individuals will need to receive at least two (2) doses of the vaccine; during the rollout, the MoH will hold a second dose reserve

### 4.1.1 Vaccine financing

GAVI supports Kenya with vaccines through a co-financing approach to promote country ownership and financial sustainability of the routine immunization program.

The country is set to access safe and effective COVID-19 vaccines to cover approximately 20% of the population through the GAVI COVAX Facility and additional doses to cover an additional 10% of the population. The GAVI indicative prices for ALL vaccines available through the COVAX facility is USD 7 (KSH.770) per dose. It should

be noted that currently there are limited vaccines stocks globally, but these are projected to increase during Phases II&III.

The total budget required to implement the sub-activities in the above indicated thematic areas is KSH.34.02 billion. GAVI through COVID-19 Vaccine Global Access (COVAX) Facility will provide in-kind support equivalent to KSH.19.71 billion by procuring vaccines and injection devices to vaccinate 20% of the population (approx. 11 million people). The GoK is expected to provide budgetary resources totaling KSH.14.31 billion to vaccinate an additional 10% of the population (approx. 4.9 million people) and all related operational costs.

The two tables below provide a summary of the National COVID-19 Vaccine Deployment Budget.

*Table 6: Summary of COVID-19 Vaccine Deployment Budget (KSH)*

| **Main Activity Description** | **Financing (KSH)** | | **Total (KSH)** |
|---|---|---|---|
| | **GoK** | **GAVI** | |
| Procurement of Vaccines and Injection Devices (Covering 30% Population), Warehousing and Distribution | 11,137,133,621 | 19,711,056,609 | 30,848,190,230 |
| Cold Chain Equipment Capacity Expansion | 1,446,529,104 | 0 | 1,446,529,104 |
| Trainings & Capacity Building | 175,834,854 | 0 | 175,834,854 |
| Planning & Coordination | 102,728,334 | 0 | 102,728,334 |
| Data Management, Monitoring & Surveillance | 564,517,418 | 0 | 564,517,418 |
| Advocacy, Communication and Community Mobilization Initiatives | 879,824,000 | 0 | 879,824,000 |
| **Total** | **14,306,567,330** | **19,711,056,609** | **34,017,623,939** |

*Table 7: COVID-19 Vaccine Deployment Budget per Financial Year (KSH)*

| **Main Activity** | **FY 2020/21** | | **FY 2021/22** | | **FY 2022/23** |
|---|---|---|---|---|---|
| | **GoK** | **GAVI** | **GoK** | **GAVI** | **GoK** |
| Procurement of Vaccines and Injection | 857,491,715 | 2,248,423,476 | 1,440,937,455 | 17,462,633,133 | 8,838,704,451 |

| | | | | | |
|---|---|---|---|---|---|
| Devices (Covering 30% Population), Warehousing and Distribution | | | | | |
| Cold Chain Equipment Capacity Expansion | - | - | 1,446,529,104 | - | - |
| Trainings & Capacity Building | 156,405,054 | - | 19,429,800 | - | - |
| Planning & Coordination | 53,492,084 | - | 49,236,250 | - | - |
| Data Management, Monitoring & Surveillance | 292,605,478 | - | 215,149,440 | - | 56,762,500 |
| Advocacy, Communication and Community Mobilization Initiatives | 295,608,000 | - | 584,216,000 | - | - |
| **Total** | **1,655,602,330** | **2,248,423,476** | **3,755,498,049** | **17,462,633,133** | **8,895,466,951** |

GAVI through the COVAX mechanism has committed to supply 4.1 million doses of the AstraZeneca Vaccine, while the Government has availed a budget of KSH 933.2 million for Phase I of the introduction. A summary of the budget is shown in the table below:

*Table 8: Introductory Vaccines GoK Budget (KSH)*

| Main Activity | GoK |
|---|---|
| Procurement of Vaccines and Injection Devices (Covering 280,000 of the targeted Population), Warehousing, Distribution, Taxes & Clearance | 592,617,352 |
| Trainings & Capacity Building | 70,802,082 |
| Planning & Coordination | 17,166,340 |

| Main Activity | GoK |
|---|---|
| Data Management, Monitoring & Surveillance | 20,573,740 |
| Advocacy, Communication and Community Mobilization Initiatives | 232,008,000 |
| **Total** | **933,167,514** |

During Phase I, the Ministry of Health intends to finance the total budget of Ksh 933.2 million from its budgetary resources.

# 5 TARGET POPULATIONS AND VACCINATION STRATEGIES

The rationale for the priority target populations is aligned with the WHO Strategic Advisory Group of Experts (SAGE) recommendations, in the context of limited supply and values framework for the allocation and prioritization of COVID-19 vaccination and adapted to country context through consideration of Local COVID-19 epidemiological data including evidence of on-going community transmission

The objective of the introduction is to reduce morbidity and mortality due to COVID-19, through maintaining the most critical essential services, protecting individuals most vulnerable to severe disease and death from COVID-19, and subsequently achieving equity and reducing transmission of COVID-19.

### 5.1.1 Approach to vaccination of target groups

Kenya plans to vaccinate 30% (or 15.8 million) of a total population of 49,070,876 by the end of June 2023 in 3 phases.

During Phase 1, the initial COVID-19 Vaccine supply will be limited but it is anticipated that more COVID-19 vaccines will become available for distribution during Phases II and III. There are plans to increase coverage to 40% of the population (20 million) once more supplies become available. It should however be noted that these phases are not exclusive and may overlap.

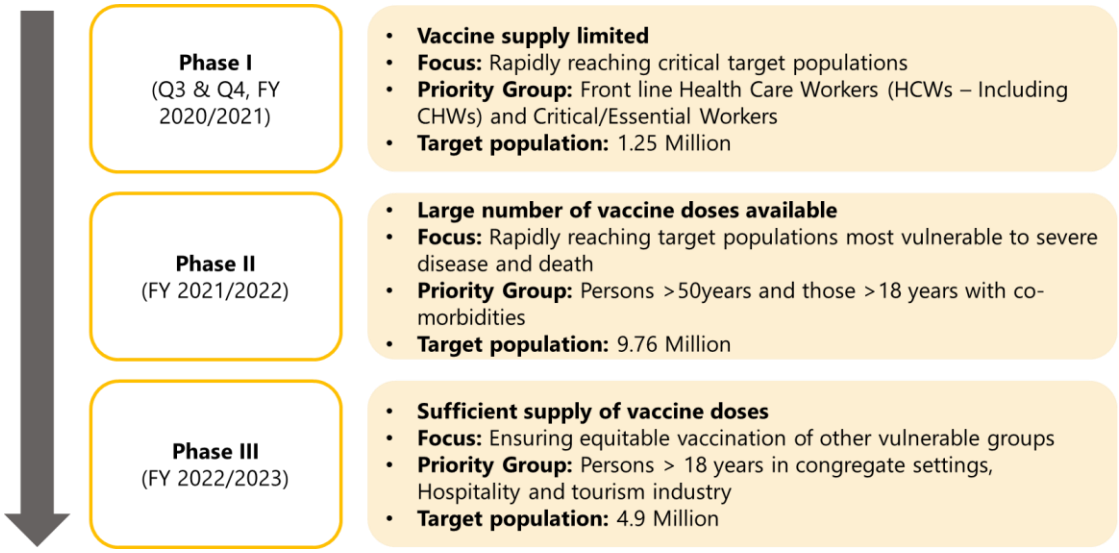
Early vaccination will focus on administration sites that can reach prioritized populations with as much throughput as possible - Levels IV, V and VI hospitals estimated at 5% of the total facilities (Approx. 284 GoK and 195 Private HFs); Phase II will focus on administration sites most effectively able to assess comorbidities - Level III and above (Approx. 1,302 GoK and 2,582 Private HFs); Phase III will focus on all immunizing facilities (Approx. 4,338 GoK and 3,539 Private HFs)to achieve equity.

Administration of negative Storage Temperature Vaccines will be considered during phases II and III.

Individuals will need to receive at least two (2) doses of vaccine; during the rollout, the MoH will hold a second dose reserve to ensure that the individual receives the same vaccine.

The COVID-19 Vaccine rollout is envisaged in phases as below:

*Figure 7: COVID-19 Vaccine rollout phases*

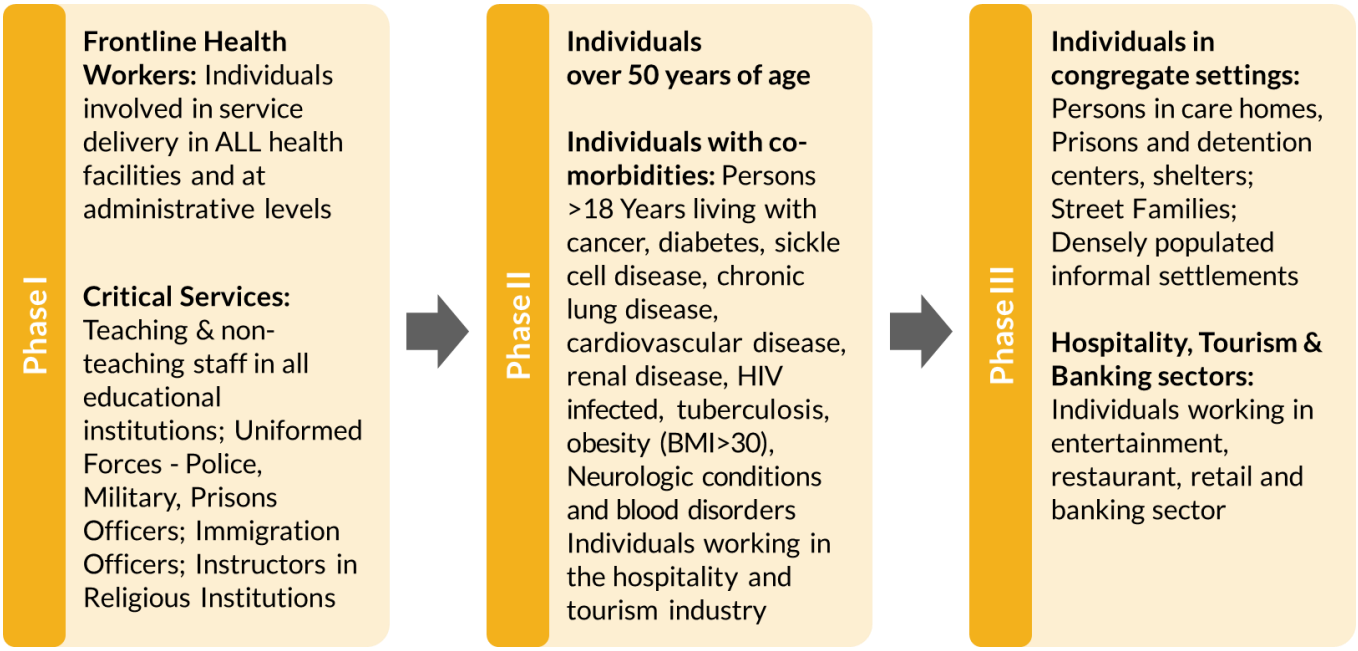



The phases are aligned with the GOK financial years: Phase 1 – February -June 2021; Phase II - July 2021-June 2022; Phase III - July 2022-June 2023.

### 5.1.2 Identification of and prioritization of target populations

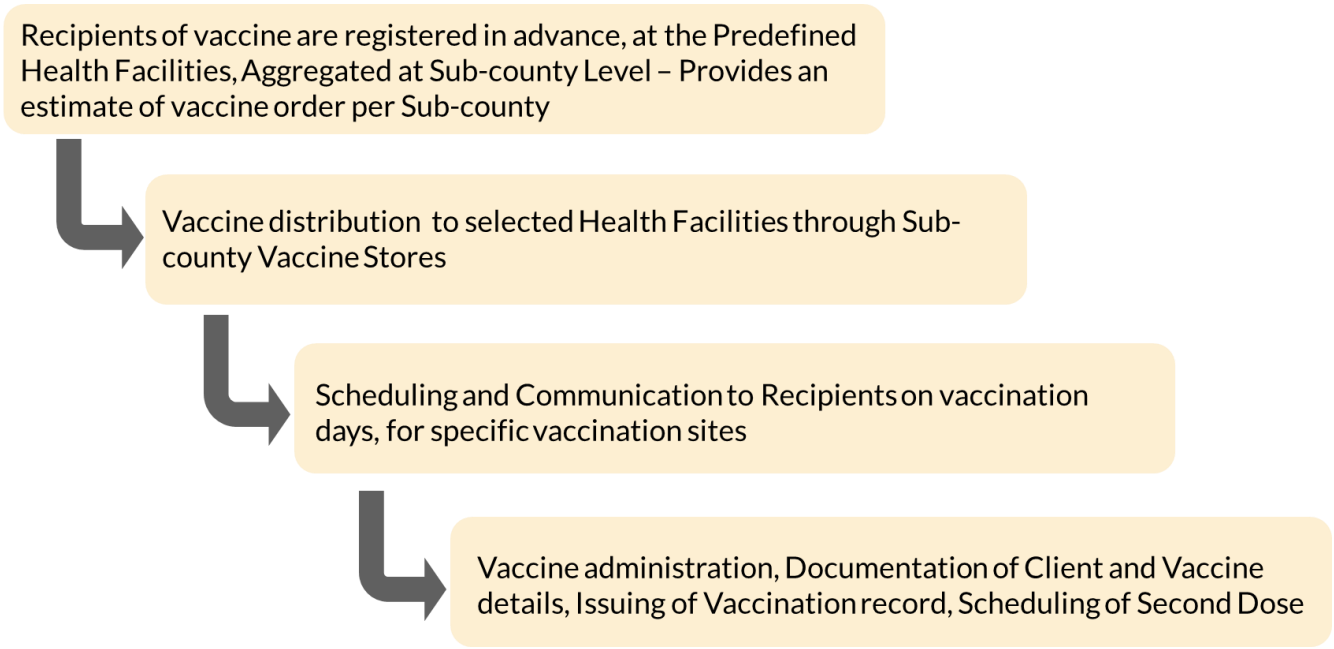
The priority target populations are defined in Figure 8 below:

*Figure 8: Definition of priority target groups*




The country will identify and map vaccine providers to administer vaccines in Public, Private, Faith-based, and NGO-run facilities to target populations following the schema below:

*Figure 9: Schema of Public, Private, Faith-based, and NGO run facilities*




Facilities that can conduct targeted outreach in Phase III will be identified at the county level, depending on the county context and mapping of targeted populations, with the frequency varied based on informed county needs.

COVID-19 Vaccine will provide Kenya with opportunities to strengthen health systems, extend immunization services across the life course and improve integration of immunization with other health services. Furthermore, the contact with the vaccine recipients will be used to identify any missed opportunity of routine infant vaccination and to build public confidence in vaccines.

### 5.1.3 Site of vaccine administration

The National Vaccines and Immunization Program policies on vaccine administration will be adopted and only a qualified clinician will administer the vaccine.

The site of injection for the COVID-19 Vaccine will be the **left deltoid region** as an intramuscular injection. This is standardized to enable individuals and clinicians to monitor the vaccine delivery and any adverse events following immunization. However, if there are new vaccines with different vaccine administration methods, the guidance to vaccinators will be reviewed and updated accordingly.

### 5.1.4 Eligibility for vaccination

Individuals will be eligible for vaccination if they:

1. Present themselves to an immunizing health facility within the selected sub-county, where they have been registered for vaccination, or any other health facility and present evidence of registration for vaccination
2. Are among the target groups identified for vaccination at the time when they present themselves to the immunizing health facility and had not been vaccinated against COVID-19 before
3. Have no fever (temperature currently ≥ 38°C) and no reported allergies for eggs or chicken, (Individuals who present with fever (temperature currently ≥ 38°C) will be asked to return for vaccination once the fever has subsided)
4. Have not suffered COVID-19 infection within the last 6 months preceding the day they present for vaccination
5. They are not pregnant or breastfeeding at the time of vaccination. However, a pregnancy test will not be required before vaccination
6. They provide verbal/written consent for them to be vaccinated

Being a novel vaccine, with recommendations for the initial target population, Kenya will explore non-traditional vaccine delivery approaches to ensure maximum reach for especially the target populations e.g. the utilization of special clinics at health facilities for vaccination of people with comorbidities.

### 5.1.5 Health facility adjustments for COVID-19 Vaccine delivery

The following adjustments will be made to accommodate COVID-19 vaccines:

1. Designate a specific area/tent away from the MCH clinics for COVID-19 vaccination, and preregistration.
2. Follow the existing guidelines on COVID-19 infection prevention measures during immunization sessions
3. Avoid crowding in waiting rooms by advanced scheduling/staggering of immunization visits in the day
4. Allocate ventilated areas and ensure social distancing for clients and dedicate separate specific rooms for sick visits, away from the well-check visits and immunization
5. Assess and triage immunization clients for acute respiratory symptoms and risk factors for COVID-19 first to minimize chances of exposure
6. Observe aseptic techniques during the vaccination sessions and perform hand hygiene with alcohol-based hand rub before and after all client contact with potentially infectious material. Use soap and water if hands are visibly soiled
7. Routine cleaning and disinfection procedures to be carried out as appropriate in immunization clinics

8. Anticipate increased risk of coincidental AEFIs with COVID-19 vaccines, Report and investigate ALL serious AEFIs as per existing protocols

### 5.1.6 Infection prevention measures to be undertaken

To ensure the safety of vaccination teams and caregivers, the following measures will be undertaken:

- Each vaccination site will be supplied with hand sanitizers to be used by clients and team members
- Soap for handwashing for fixed sites
- Surgical face masks (1 face mask for each member of the team per day)
- Crowd control to ensure physical distancing, including vaccination in open spaces
- Clear communication to communities by community volunteers and leaders on vaccination sites, date of visit and guidance to clients on observing safety measures (face masks and physical distancing)
- Clients will be encouraged to visit vaccination sites wearing face masks as per national guidance. No one will be turned away for not having a mask
- Engagement of national and county leadership for oversight, accountability, and ownership
- Microplanning and mapping of health facilities that will offer COVID-19 vaccines (Level 3 upwards) and areas with the highest number of individuals in target priority groups
- Determination of the start dates for vaccination
- Development of a county-specific tailored approach to reach the targeted priority groups.

To create demand, intensified communication and social mobilization activities will be undertaken as follows:

- Engage local community leadership through Health Facility Management Boards to mobilize communities for COVID-19 vaccination
- Engage Community Health Volunteers to pass messages and follow up vaccines
- Use local mass media to mobilize individuals to seek vaccination services

Enhanced immunization at static facilities and outreaches will be promoted as follows:

- Contact all individuals from immunization registers and other sources who will have received the first dose of COVID-19 vaccines to ensure they receive the second dose
- Share messages during COVID-19 vaccination sessions on COVID-19 prevention

- Ensure all health facilities (Level 3 and above), Public, Private, Faith-Based and NGOs offer COVID-19 vaccinations daily
- Identify facilities that will conduct COVID-19 vaccination targeted outreach focusing on areas with the highest number of individuals in target priority groups
- Ensure uninterrupted availability of COVID-19 vaccines and other supplies at the immunizing health facilities

It is expected that teams at both national and county levels will leverage the existing routine immunization systems including internal resource mobilization to bridge resource gaps and in consultation with the National Treasury making applications for credit facilities from the World Bank.

# 6 SUPPLY CHAIN MANAGEMENT

### 6.1.1 Vaccine Preference

For the introduction, the following country preferences have been selected in the vaccine request to Gavi.

- **Vaccine Platform:** Viral Vector
- **Regulatory process:** Vaccines that have been Prequalified by WHO
- **Vaccine Storage/Cold chain requirements:** Vaccines with traditional cold chain requirements 2-8°C and or -20°C
- **Price:** Lowest Price

### 6.1.2 Licensure and Importation

The Kenya Ministry of Health, Pharmacy and Poisons Board, will grant special approval, expedite market authorization, and provide a release waiver to facilitate the importation and use of the COVID-19 vaccines in the country. In addition, approval will also be granted for continued evaluation of the COVID-19 vaccines in the context of community deployment.

### 6.1.3 Logistics and Supply chain Management

The Ministry of Health will leverage on UNICEF Mechanisms under the Vaccine Independence Initiative Agreement. The outsourcing of vaccine clearance at ports of entry and delivery to national and regional stores has eliminated delays at the port of entry. The amount of time taken to clear vaccine consignments held at ports of entry currently does not exceed 48hrs.

From the regional depots, a mixed approach will be employed to deliver vaccines to the counties – some counties will pick vaccines from the nearest regional depots while others will have the vaccines delivered to them by air freight.

The vaccine distribution is expected to follow the existing distribution patterns, from national to sub-county levels.

The 'Chanjo' electronic logistics management information system (eLMIS) will be used to manage vaccine stocks, vaccine cold chain management and to provide an immunization data dashboard that presents the vaccine coverage, stock levels and integrated indicators for immunization performance.

The program will continue to require that the sub-counties update their records by the 15$^{th}$ of every month.

### 6.1.4 Cold Chain Capacities

Storage capacity for both positive and negative temperature storage at all the nine (9) regional stores is adequate for introduction of COVID-19 vaccines as confirmed through the 2013 EVMA and vaccine forecasting using WHO EPI Logistics Forecasting tool (2014).

The National Vaccine store has a total of eight (8) cold rooms with a net capacity of 130M³ for positive temperature cold storage (2-8°C) and 2 freezer rooms with a net capacity of 14 M³ for negative temperature cold storage (-20°C).

The capacity at the national cold rooms is sufficient for deployment of vaccines requiring the +2°C to 8°C / -20°C of cold storage, with a quarterly vaccine delivery schedule to the national and regional vaccine stores. Minimal expansion will be required to provide for less frequent shipment schedules and introduction of other vaccines in future.

For vaccines requiring storage temperatures of -70°C, the country will need to procure additional cold chain storage capacity to comply with the storage needs of these vaccines.

*Figure 10: Schema showing the location of the National and Regional vaccine depots and the counties served*

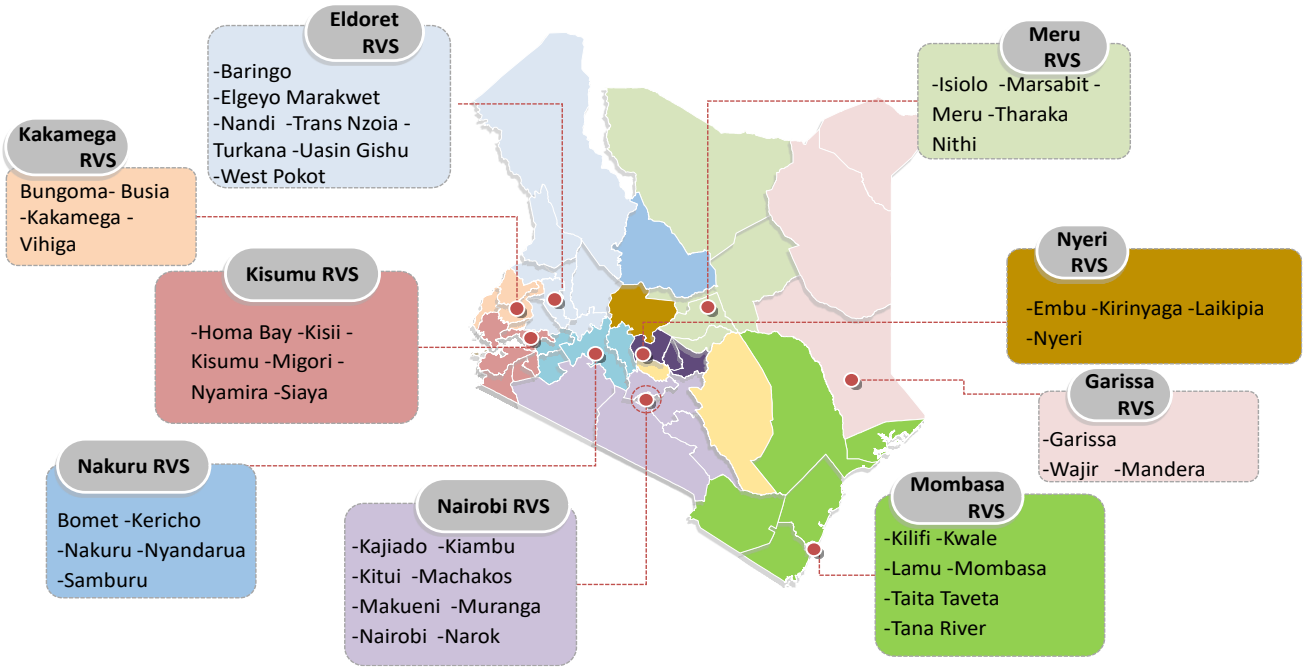


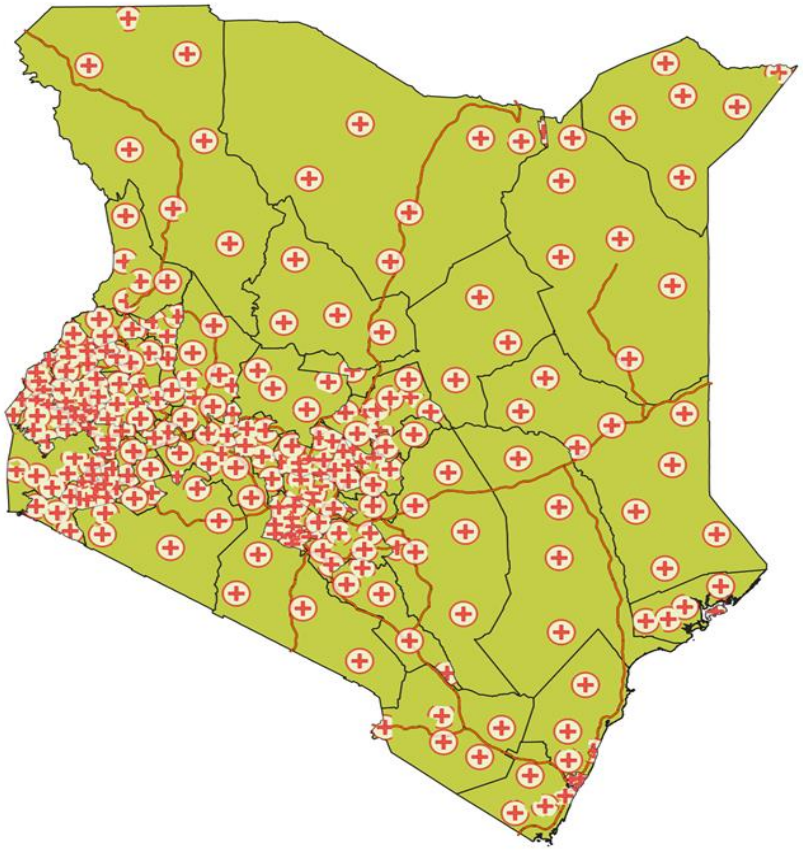
*Table 9: Kenya National and Regional vaccine cold store capacity estimates*

| Store | Net Refrigeration Volume (Litres) | Net Freezing Volume (Litres) | Ownership | Responsibility | Staff | Status |
|---|---|---|---|---|---|---|
| Kitengela Central Vaccine Store | 130,000 | 14,000 | MOH/NVIP | MOH/NVIP | 2 MOH | Functional |
| Nyeri Regional Vaccine Store | 20,000 | 813 | KEMSA | MOH/NVIP | 1 MOH + 1KEMSA | Functional |
| Meru Regional Vaccine Store | 10,150 | 542 | MOH/NVIP | MOH/NVIP | 1 MOH | Functional |
| Mombasa Regional Vaccine Store | 20,150 | 813 | KEMSA | MOH/NVIP | 1 KEMSA | Non-Functional |
| Nairobi Regional Vaccine Store | 23,000 | 7,000 | MOH/NVIP | MOH/NVIP | 2 MOH | Functional |
| Nakuru Regional Vaccine Store | 20,000 | 1,355 | KEMSA | MOH/NVIP | 1 MOH +1 KEMSA | Functional |
| Eldoret Regional Vaccine Store | 20,000 | 1,626 | KEMSA | MOH/NVIP | 1 MOH + 1 KEMSA | Functional |
| Kakamega Regional Vaccine Store | 10,300 | 542 | MOH/NVIP | MOH/NVIP | 2 MOH | Functional |
| Kisumu Regional | 23,000 | 542 | KEMSA | MOH/NVIP | 1 MOH +1 KEMSA | Functional |

| | | | | | | |
|---|---|---|---|---|---|---|
| Vaccine Store | | | | | | |
| Garissa Regional Vaccine Store | 13,330 | 450 | MOH/NVIP | MOH/NVIP | 1 MOH | Functional |
| **Newly Established County Vaccine Cold Storage Points** | | | | | | |
| **Store** | **Net Refrigeration Volume (Litres)** | **Net Freezing Volume (Litres)** | **Ownership** | **Responsibility** | **Staff** | **Status** |
| Turkana County | 13,330 | 542 | MOH/NVIP | MOH/NVIP | 1 MOH | Functional |
| Wajir County | 13,330 | 813 | MOH/NVIP | MOH/NVIP | 1 MOH | Functional |
| Mandera County | 13,330 | 813 | MOH/NVIP | MOH/NVIP | 1 MOH | Functional |

Overall, total cold chain capacity at the national and regional level is sufficient to hold COVID-19 vaccines. However, there exists significant inequity in cold chain capacity distribution among and within counties. With a monthly supply cycle, less than 75% have sufficient capacity to accommodate the COVID-19 vaccines and all the other routine vaccines.

*Figure 11: Schema showing the distribution of sub-county stores*



The Program plans to bridge the cold chain capacity gaps through:

1. Procurement and installation of additional cold chain equipment from Gavi and World Bank support
2. Implementation of year 2 & 3 of the Cold Chain Equipment Optimization Platform Project
3. Review of the delivery cycles
4. Redistribution of cold chain equipment
5. Collaboration with the private sector for cold chain storage

All the old cold rooms and refrigerators in depots and health facilities countrywide are equipped with continuous electronic temperature monitoring devices that record the temperature status continuously.

All regional depots and sub-county stores have Remote Temperature monitoring devices to ensure real-time monitoring of temperature and response to temperature excursions. This is crucial to ensure viability of the stored vaccines.

### 6.1.5 Cold Chain Equipment (CCE) Needs Estimates and Scenarios

From the analysis of CCE Estimates, the estimates presented herein are based on pre-selected equipment models using a template provided for the Cold Chain Equipment Optimization Platform (CCEOP) by Gavi.

Also included is an analysis based on the current capacity gaps existing in storage, prior to the selection of a COVID-19 Vaccine.

The Country elects to receive 6 months' supply interval for other routine vaccines, and 3 months for COVID-19. This would yield the cold chain requirements estimated below:

*Table 10: Needs Estimates of Cold Chain Equipment (CCE)*

| No. | Item Description | Quantity/ Number |
|---|---|---|
| 1 | Installation of 13 Walk-In Cold Rooms 40CBM with a Surge Protector for central vaccine store and RVS | 13 |
| 2 | Installation of 1 Walk-In Freezer Room of 20CBM with a Surge Protector for central vaccines store | 1 |
| 3 | Installation of 44 Walk-In Cold Rooms 40CBM with a Surge Protector for county depots | 44 |
| 4 | 1 KVA Single Phase Extended Range Voltage Regulator | 2,401 |
| 5 | On-grid Cold Chain Equipment, with freezer compartment and capacity for remote temperature monitoring for **Health Facilities**, under a 10-year warranty | 1,502 |
| 6 | Off-grid Solar Direct Drive Cold Chain Equipment, with freezer compartment and capacity for remote temperature monitoring for **Health Facilities**, under a 10-year warranty | 150 |
| 7 | On-grid Cold Chain Equipment, without freezer compartment and capacity for remote temperature monitoring for **Health Facilities**, under a 10-year warranty | 300 |
| 8 | Off-grid Solar Direct Drive Cold Chain Equipment, with freezer compartment and capacity for remote temperature monitoring for Health Facilities, under a 10-year warranty | 100 |
| 9 | On-grid Cold Chain Equipment without freezer compartment for **Sub-counties**, under a 10-year warranty | 145 |
| 10 | On-grid Cold Chain Equipment -freezers for **subcounty and regional depots**, under a 10-year warranty | 154 |
| 11 | Standard 5L Vaccine Carriers for **Health Facilities** | 38,600 |
| 12 | Standard 5-25 L Cold Boxes for **sub-county stores** | 600 |
| 13 | Assorted Spare parts for ILRs, number of kits-TCW 2000 AC | 181 |
| 14 | Assorted Spare parts for SDDs, number of kits-HTCD 90 SDD | 15 |
| 15 | Assorted Spare parts for ILRs, number of kits-TCW 40R AC | 30 |
| 16 | Assorted Spare parts for SDDs, number of kits-TCW 15 SDD | 10 |
| 17 | Assorted Spare parts for ILRs, number of kits-TCW 4OOO AC | 15 |

| | | |
|---|---|---|
| 18 | Assorted Spare parts for Freezers, number of kits-HBD 286 | 16 |
| 19 | Temperature Monitoring Devices (TMD) for Fridges-FT2E | 9,000 |
| 20 | 10 KVA Three Phase Voltage Regulator, for WICRs and WIFRs-Sollatek, AVR3LE20 | 58 |
| 21 | Modification of Designated Existing Rooms at county levels to accommodate Walkin Cold Rooms and other Cold Chain Equipment at county Level | 47 |

### 6.1.6 Waste management and injection safety

The country plans to procure Auto-Disable syringes as a measure for infection prevention and adequate safety boxes for proper storage and disposal of used syringes.

The COVID-19 Vaccine waste materials will be managed through the current injection safety and medical waste management policy, adapted to the COVID-19 pandemic contexts. Extra precautions will be observed in the management of waste related to COVID-19 vaccination. Safety boxes for disposal of sharps, followed by incineration and deep burial, will be used to dispose of used injection equipment in the program.

The waste management plan will be in line with the national healthcare waste management plan and will include:

- Identification of waste disposal site and personnel responsible for waste management
- Estimation of the number of safety boxes needed
- Bundling of waste disposal boxes with vaccines and syringes during delivery
- Plan for the waste disposal sites and procedures for the disposal of all waste generated irrespective of vaccination site
- Special attention will be made to ensure healthcare waste management in schools and other outreach sites are carried out according to best practices
- Plans for transportation and disposal of the waste from outreach posts such as schools
- Include waste management in the training material and documentation
- Monitoring and evaluation of waste management to ensure waste management is carried out to a high standard

Specifically, to ensure the safety of vaccinating health workers and caregivers, the following measures will be undertaken:

- Each vaccinating site will be supplied with hand sanitizers to be used by caregivers and team members
- Soap for handwashing for fixed vaccinating sites

- Surgical face masks (1 face mask for each member of the team per day)
- Crowd control to ensure physical distancing, including vaccination in open spaces, in designated areas away from the MCH Clinic
- Clear communication to communities by health workers, community volunteers and leaders on vaccination site, date of visit and guidance to caregivers on observing safety measures (face masks and physical distancing)
- Caregivers will be encouraged to visit vaccination sites wearing face masks as per national guidance. However, no one will be turned away for not having a mask.

# 7 HUMAN RESOURCES MANAGEMENT AND TRAINING

Kenya still faces an acute shortage of human resources for health in general and disparity in health workforce distribution across counties, which is influenced by demographics, the number of health care facilities and epidemiological profile of individual counties. Available health workers are pressed for time and must meet regulatory and accreditation standards while working continuously to document and improve health outcomes. This calls for training that is rigorous but flexible to allow the shortest possible time to achieve vaccine deployment competency for the individual health worker and the program.

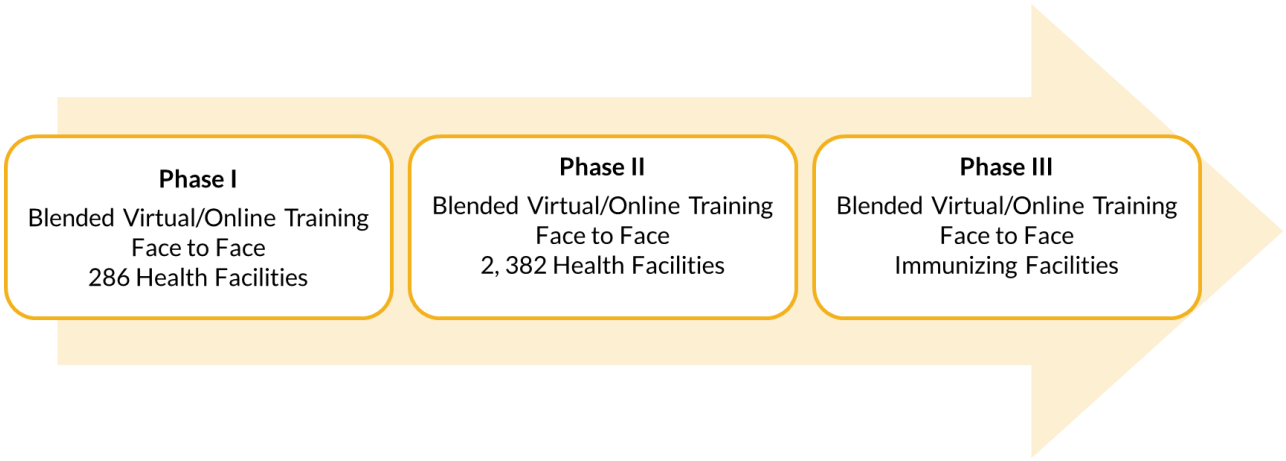
Current health facilities' staff establishments especially at national and sub-national levels will be adequate to rollout the COVID-19 Vaccine especially in Phase 1. The COVID-19 Vaccine deployment will leverage staff in Public, Private, NGOs and Faith-Based health facilities. Where necessary, redistribution of health workers at implementation levels will be done to bridge any gaps that exist. No additional human resources will need to be hired, besides those with specific skills and competencies to be recruited at the national level to provide technical assistance at both levels of government.

Building human resource capacity to deliver COVID-19 Vaccine will need health workers trained and competent on; knowledge on COVID-19 disease; knowledge and skills in COVID-19 Vaccine demand creation, health facility preparation, safe vaccine administration, infection control practices, patient data management, adverse event reporting and management, documentation and monitoring of vaccine utilization and logistics, communication, waste management, mental health, multi-disciplinary team work.

The COVID-19 Vaccine introduction will draw experiences in lessons learnt from past introductions of new vaccines and experiences in online training. The training opportunity will also be used to update health workers on the revised National Immunization Policy Guidelines, address gaps noted in the 2020 Effective Vaccine Management Assessment and the Immunization Data Quality Assessment.

The training will be organized around the 3 phases. Phase 1 for level 4-6 health facilities will be done through blended online/virtual training and face-to-face/peer demonstration. These will also be recorded for later use in phases II and III and used in TOT training.

*Figure 12: Health facilities training phases*




### 7.1.1 Healthcare Worker COVID-19 Vaccine delivery Training

For every phase, a training guide for health workers containing information on COVID-19 disease, the vaccine characteristics, and the immunization procedures will be developed to ensure standardization and smooth implementation of training activities. The training guide will be developed based on WHO generic training modules and contextualized to phase (target population) and county specific situation.

This will involve the following steps:

**Step 1:** Planning, development of online and face-to-face training and IEC materials, to be used across various training platforms including webinars, social media. Conducting a baseline assessment.

**Step 2:** Preparation of a training plan comprising of activity timelines, sources of support, target audience, budget, training platforms, monitoring and evaluation and other training logistics.

**Step 3:** Training will include orientation of stakeholders at national level, training of the national TOTs cascaded to the county level then sub-county and finally the service delivery point (immunizing health facility public and private).

Each of these steps will be reviewed for Phase I, II and III of vaccine administration.

### 7.1.2 Implementation of COVID-19 Vaccine Introduction training

Blended training of health workers (HW) will be organized to cover the whole country in a cascaded manner, following the 3 phases and incorporating both face-to-face and online/virtual training. An initial pilot training will be done, followed by the development of training didactics, demonstration videos, quizzes allowing self-paced

learning and certification. Different training modules will be developed for the different groups from vaccinators, other clinicians, data management to administrators. The training material will be reviewed at the national level which will also be a Training of Trainers (TOT) course.

### 7.1.3 Online Training Registration Platform

An online platform for registration will be used to ensure certification and monitor the progress of training. This is critical because of the evolving knowledge and will allow health workers to update their skills and knowledge over the program period. CPD points will be awarded to motivate participation in the COVID-19 Vaccine program by all health workers, not just those selected as vaccinators.

This approach will allow a rapid and horizontal approach to training ensuring equity, effectiveness and overcoming some of the HRH limitations outlined above.

The specific approach followed will be:

1. Simulation or dry run to validate the content and evaluate the trainers (National level TOT, for staff from NVIP & Partners)
2. Development of online platform including HW registration, social media discussion platforms, quizzes, and certification
3. Recording of online materials and uploading online platform
4. Phase 1: Sensitization of HW, support supervision by county level (CHMT) drawn from 47 counties incorporating the 284 health facilities
5. M&E support supervision, identify training gaps, update training materials
6. Phase II and III further sensitizations of HW from each sub-county and health facilities. Sub-county training of 5 SCHMT members from each sub-county. All immunizing facilities in the counties, 2 health facility staff
7. M&E support supervision
8. Training of the Community Health Volunteers (CHVs) at the community unit

The training content will cover the following:

*Table 11: Summary of health care worker training content*

| Topic | Training content |
|---|---|
| Epidemiology of COVID-19 pandemic | • Overview of COVID-19 pandemic<br>• Etiology and clinical presentation of COVID-19<br>• Clinical management, surveillance and reporting of confirmed cases and suspected cases |

| | |
|---|---|
| Description of the vaccine<br><br>Recommended schedule and target population<br><br>Mode of Administration | • The vaccines will be described & their administration demonstrated –NB: COVID-19 Vaccine to be injected IM on the upper outer quadrant of the left arm and how to counsel about the vaccine<br>• The schedule for administration and how they will be integrated into the routine EPI schedules<br>• Case studies<br>• Managing the patient (side/adverse) events |
| Cold Chain issues | • General cold chain aspects of EPI will be discussed, emphasizing COVID-19 Vaccine cold storage requirements<br>• Introduction of new distinctly coloured vaccines trays, and how to tackle storage challenges of high output facilities |
| Documentation and record-keeping | • Trainees will be introduced to the revised reporting forms, stock monitoring tools and other monitoring tools, including electronic platforms<br>• Health facility staff will be trained on how to document and report any adverse events following immunization (AEFIs)<br>• Basics on monitoring key indicators, SOPs, wastage, |
| Injection Safety | • General review of injection safety measures regarding injectable vaccines and other injection waste. |
| IPC | • PPE use, hand hygiene, hand hygiene resources<br>• Standard precautions for IPC<br>• Social distancing<br>• Waste management (facility and community) |
| Demand generation and communication | • Health workers will be trained on approaches for creating awareness on the COVID-19 vaccines, risk communication and interpersonal communication |
| Team building | • Multi-cadre teamwork, recognizing mental health issues,<br>• Referral system, micro-planning |
| E-learning | • Accessing online training materials, evaluating information sources, social media use |

### 7.1.4 Supportive supervision

Supportive supervision visits will be provided to the national and county teams to provide technical assistance, and mentorship, to complement existing efforts by the

county governments. This will be deployed through virtual platforms from national level but will include field visits at county level.

These will be conducted periodically with a predefined checklist. The checklist will be developed during planning for introduction and supervisory visits to monitor the process of introduction at all levels, observe implementation and assure maintenance of quality and standards in the vaccine rollout.

### 7.1.5 Key in HW Training Rollout

Risks that need to be mitigated include HW industrial discord, lack of staff engagement, ethnic biasness, different organizational cultures, and risks of unintended consequences. A risk mitigation plan specific to counties will have to be developed.

# 8 VACCINE ACCEPTANCE AND UPTAKE (DEMAND GENERATION)

Whereas adherence to the containment measures is critical, the introduction of the vaccine in the market provides another level of protection that introduces greater confidence in daily lives amongst the people. This means that the country will be required to manage the process of community demand creation through awareness and managing vaccine hesitancy as well as creating channels for risk communication – exchange of timely information and advice between the public and the experts to enable Kenyans to make informed decisions to protect their lives and those of other people.

The buy-in of key stakeholders will be crucial in creating the demand for the vaccine and address hesitancy issues. These key stakeholders will include:

1. Political and religious leaders at both national and county government levels
2. Health workers through professional Associations
3. Civil Society Organizations
4. Media practitioners and social media influencers
5. Community leaders

From the experience gained with other new vaccine introductions, and Influenza vaccinations, vaccine acceptance has been high in Kenya. However, the COVID-19 Vaccine surveys indicate a 15% hesitancy level and this may increase due to misinformation, rumours, and conspiracy theories.

To best define local communication needs, a communication needs assessment will be conducted by MoH in select counties prior to the deployment of the vaccines and the findings will inform the communication plan strategies and risk communication.

Sensitization for COVID-19 Vaccine will begin well in advance of introduction. To achieve this, the following will be developed:

1. A communication plan incorporating risk and crisis communication aspects
2. Key messaging and visualization including artwork, audio, and video production with a focus on determined primary and secondary audience groups
3. Message delivery plan to include the use of key opinion leaders, key media channels including TV, radio, posters and banners, SMS, Twitter, Facebook, and Instagram as well as a plan for Frequently Asked Questions through a hotline and a WhatsApp bot

4. Post deployment message and channel evaluation and adaptation of plans based on feedback

In addition, the vaccine will be ceremonially launched at the national and county level involving high profile personalities in order to drum up support for the vaccine and the vaccination exercise while adhering to the principles of equity.

At the community level, opinion leaders such as chiefs, ward administrators, ward education officers, head teachers, village elders and community health volunteers will be sensitized on COVID-19 vaccination.

### 8.1.1 Development of a communication strategy, risk communication and a crisis communication plan

The MOH will develop a communication plan that includes risk communication.

A crisis communication plan will be integrated within the communication strategy to address any potential adverse events, myths, misconceptions, and hesitancy that may arise associated with either COVID-19 disease or the vaccine. The crisis communication plan will outline activities for all levels addressing:

- Risk communication on vaccine safety
- Communicating with individuals and addressing concerns in real-time
- Vaccine hesitancy and response to misconceptions and rumours in the media including social media.

The Ministry of Health will seek to effectively communicate on COVID-19 disease prevention, with an emphasis on vaccination alongside other primary prevention strategies.

The communication plan will also outline other possible strategies that COVID-19 Vaccine advocacy can be integrated with for example screening for NCDs. Further, because the deployment plan is intended to be rolled out in a phased manner, the communication plan will also need to be supportive of this phased approach.

The communication plan will include:

1. Key stakeholders to be engaged at each level and time e.g. policy makers and key opinion leaders, health workers, local and national leaders, religious leaders, civil society organizations, private sector etc.
2. Key messaging for each stakeholder

3. Key channels to be used for each stakeholder e.g. one-on-one meetings, public meetings, traditional media, social media, bulk messaging, promotional materials etc.

The specific activities for the communication strategy will include:

1. Development of a Communication Plan
2. Development of Key Messages
3. Communication assets development including training tools:
    a. Development of radio & TV shows including content influenced by existing entertainment and current affairs programs.
    b. Production of short training video(s) to support capacity building for training of trainers.
    c. Creation of media assets including graphics, texts, and short videos for engagement on digital platforms.
    d. Development of Public Service Announcements and advertisements.
    e. Print media pullouts and native content production.
    f. IEC materials; Seed material for sites and billboards at county border points.
4. Media events
    a. Media training
    b. Media launch, national and county
    c. Regular media field visits
5. Identification and facilitation of county-based champions
6. Community engagement.
    a. Listenership/viewership groups
    b. Opinion leaders
7. Distribution of communication assets
    a. Broadcasting (TV & radio)
    b. Print media publication including opinion pieces, pullouts, advertisements.
8. Bulk messaging to target facilitators and internal stakeholders' mobilization.
9. 24-Hour Hotline manned by health workers to answer vaccination related questions from access, to administration and adverse events.

The communication plans will be informed by local data and outline tailored strategies, segmented per audience and per area of activity.

MOH will identify capacity building gaps and challenges for vaccine acceptance and uptake early in the process and ensure that they are fully addressed during the training of frontline health workers, social workers and community influencers and mobilizers.

There shall be a monitoring framework put in place as an essential part of the communication plan, including media monitoring and a rumour log system.

#### 8.1.1.1 Key considerations that will be made to support risk communication and community engagement activities to address vaccine hesitancy

- Listening to communities and gathering social data to understand their concerns and beliefs and addressing them through timely and targeted communication and other strategies.
- Use of channels, including media and social media, to proactively share information about vaccination in general, the COVID-19 Vaccine development process, determination of best vaccine for Kenya, key risks and challenges, to build public awareness on and trust in the development and rollout process.
- Sharing of information from trusted sources in local languages about eligibility and rollout plans, with details on populations that are initially prioritized for vaccination.
- Partnering with national and community civil society organizations, faith-based organizations, NGOs, etc., and include training of journalists and content producers as key advocates in the response.
- Working with community, religious and influential leaders to dialogue and deliver messaging; community leaders will also be empowered with access to more detailed information on the vaccines and rollout plans.
- Engaging local medical providers to ensure that they support vaccination activities, and transparent and routine reporting on the progress and effectiveness of rollout plans.

### 8.1.2 Empowering frontline health workers

MOH will develop a vaccine deployment strategy that ensures health workers have positive experiences as early beneficiaries of the COVID-19 Vaccine. This will be essential given their influential role as vaccinators, advocates, and change agents in the community, including communication skills training to support them in dealing with rumours, misinformation, and vaccine hesitancy.

Capacity building for health workers will be done in advance of the vaccine roll-out. They will be equipped with decision-making and job aids to support them in prioritizing eligible vaccine recipients, and tailored messaging to reach diverse community contexts. There shall be training sessions to build their skills in listening, interpersonal communications and community dialogue that will help to equip them to hold difficult conversations both in the face of demand from those not eligible to receive the vaccine in the first phases, and those who are hesitant about receiving the

vaccine. Listening and collating early experiences, concerns, successes, etc. from health workers will help inform ongoing vaccine delivery.

Key objectives will be to educate health workers on the COVID-19 Vaccine; increase health worker uptake and early satisfaction with the vaccine, inoculate priority recipients, improve health workers' ability to communicate and engage with priority groups and caregivers, and endorse COVID-19 vaccination.

Since health workers (in addition to community members) are susceptible to misinformation and vaccine hesitancy; guiding principles and high-level actions will be taken at national and county levels to support health worker capacity to increase the COVID-19 Vaccine demand and uptake. Demand activities shall initially focus on health workers and other high-risk groups (e.g. older adults) that have been prioritized by the country.

### 8.1.3 Crisis communications

Because of the scope of vaccination, adverse events are likely, whether related to the vaccine or not, and may be misattributed to the vaccine, suppressing vaccination uptake if not addressed swiftly and competently, with clear messages and actions. To prepare for this, we shall develop crisis communications plans that include actions to take before, during and after the crisis.

Crisis communication will ensure that the country is prepared to respond first, fast and in a coordinated manner to any rumours and adverse events following COVID-19 immunization. Crisis communication management plans will be informed by social listening, community feedback and other relevant data and will be in place prior to deployment of the vaccine. Existing coordination mechanisms for planning and response to events will also be harnessed so that in the case of an event, communication shall take place rapidly, with transparency and empathy, and rule out multiple conflicting voices.

A core team will be responsible for coordinating and managing crisis communication and for the following key functions:

- SOPs for managing crisis communication
- Development of content and guidance to detect and respond to rumours, misinformation, and disinformation with real-time rapid response, especially online
- Development and dissemination of key messages; ensuring that immunization programs and stakeholders speak with one voice
- Training of media and spokespersons
- Social mobilization and communication activities; and

- Communicating with affected populations and other target audiences in case of adverse events following COVID-19 immunization.

# 9 VACCINE SAFETY MONITORING AND MANAGEMENT OF AEFI AND INJECTION SAFETY

The country will deploy a robust monitoring system to identify, report and investigate all adverse events following immunization (AEFIs) leveraging heavily on the current immunization AEFI reporting structure.

AEFI reporting, investigation and monitoring will be implemented using:

1. The routine pharmacovigilance and AEFI reporting through the NVIP AND PPB, as per the National AEFI Guidelines
2. Sentinel hospital monitoring and tracking of safety data
3. Global AEFI monitoring and review of clinical trial data for safety profile data

The National Immunization Program and the Pharmacy and Poisons Board have a harmonized system for AEFI reporting. Health workers will report any AEFI through the sub-county and county focal persons to the Head NVIP, who shares the reports with the Pharmacy and Poisons Board (PPB), in addition to online self-reporting systems deployed by the PPB.

The NVIP and PPB will collaborate to implement a vaccine safety strategy in strengthening the country's COVID-19 AEFI surveillance. The Ministry of Health aims to reach a reporting rate of 10 or more AEFI per 100,000 population. To further strengthen AEFI surveillance, the following activities are planned:

1. Sensitization of health workers on vaccine safety reporting (including vaccine pharmacovigilance) prior to the COVID-19 Vaccine rollout to provide baseline information on AEFI
2. Training and sensitization of the Kenya National Vaccines Safety and Advisory Committee (KNVSAC) expert committee
3. Printing and dissemination of copies of the AEFI guidelines
4. Printing and distribution of AEFI forms
5. Field AEFI investigation simulation exercises for County Health Management Team and Sub-county Health Management Teams, as part of the COVID-19 Vaccine training

The country will develop a list of Adverse Events of Special Interest (AESI) for which active surveillance methods will be employed in sentinel hospitals.

Market authorization holders (MAHs) shall also submit AEFI reports as per the existing guidelines on the vigilance of vaccines including having pharmacovigilance and risk management plans.

### 9.1.1 Causality Assessment and the National Vaccines Safety Advisory Committee

Kenya has a National Vaccine Safety Advisory Committee (NVSAC) in place composed of experts from different professional backgrounds to provide advice to the ministry on matters regarding vaccine safety. It consists of Pediatricians, Vaccinology experts, Epidemiologists, Pharmacologist, Physicians, Pharmacists, Pharmacovigilance experts, Infectious Disease specialists and Pathologists amongst others with clear terms of reference.

AEFI reports once received will be analyzed at the county level and by PPB and NVIP. The line lists from PPB and NVIP will be examined and merged into a National AEFI database by the National Vaccine Safety Advisory Committee (NVSAC) secretariat. The NVSAC secretariat consisting of PPB and NVIP will meet periodically to share and analyze AEFI reports and guide on appropriate action to be taken, and present to the NVSAC for further analysis.

Selected Serious COVID-19 Vaccine AEFI will further be presented to the National Vaccine Safety Advisory Committee for expert causality assessment.

The following steps undertaken to ensure vaccine safety include:

1. Communicate to patients, the community and the public at large about AEFI's and reassure them about immunization safety
2. Train all concerned persons as a corrective measure for any operational challenges such as knowledge and skills gap
3. Conduct regular supportive supervision, to institutionalize vaccine management practices and give feedback
4. Improve the availability of supplies and the working condition of the equipment to minimize immunization errors

*Table 12: Roles and responsibilities of the various stakeholders in assuring the COVID-19 Vaccine safety*

| Stakeholder | Responsibility |
|---|---|
| **Ministry of Health** | • Policy formulation<br>• System and database maintenance (DHIS)<br>• Resource mobilization |

| | |
|---|---|
| **National Vaccines and Immunization Program** | • Provision of vaccines<br>• Training of health workers<br>• Feedback and information sharing<br>• Share Information with PPB immediately for Serious AEFI<br>• NVSAC secretariat<br>• Participating in investigation<br>• Provision of reporting tools<br>• Participate in post-market surveillance<br>• Reporting through Joint Reporting Form<br>• Signal detection<br>• Causality assessment<br>• Training of health workers<br>• Maintenance of database and AEFI line list |
| **Pharmacy and Poisons Board** | • Licensing of vaccines<br>• Regulatory action<br>• Issue import permit for vaccines<br>• Feedback and information sharing<br>• Share Information with NVIP immediately for Serious AEFI<br>• NVSAC secretariat<br>• Participating in AEFI investigation<br>• Post-market surveillance<br>• Reporting through Vigiflow®<br>• Signal detection<br>• Causality assessment<br>• Provision of reporting tools<br>• Training of health workers<br>• Maintenance of database and AEFI line-list |
| **County Government** | • Provision of vaccination services<br>• Training of health workers<br>• Feedback and information sharing to the lower level<br>• Lead AEFI investigation, request technical assistance<br>• Participate in post-market surveillance and pharmacovigilance activities<br>• Reporting of AEFI<br>• Maintenance of AEFI line-list<br>• Resource mobilization |

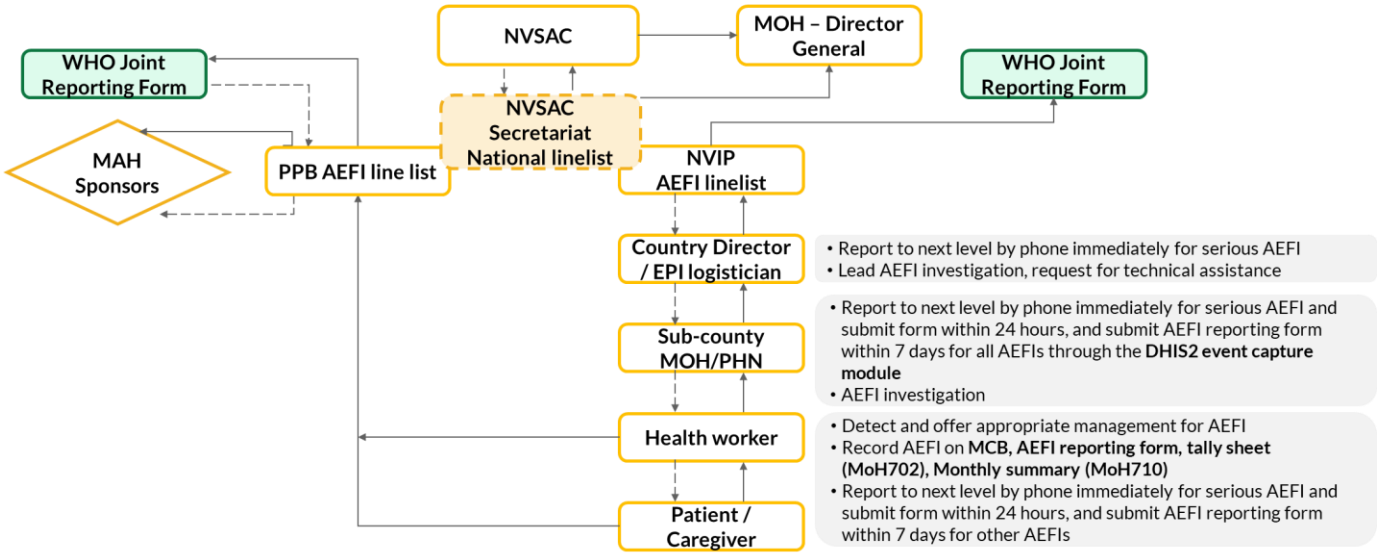
| | |
|---|---|
| **Sub-county health management team** | • Provision of vaccination services<br>• Training of health workers<br>• Feedback and information sharing to the lower level<br>• Initiate AEFI investigation<br>• Participate in Post-market surveillance and pharmacovigilance activities<br>• Reporting of AEFI<br>• Maintenance of AEFI line list<br>• Resource mobilization<br>• Entering of AEFI reports into DHIS 2 by HRIO |
| **Health care worker** | • Detection, management, and timely reporting of AEFI<br>• Provision of vaccination services<br>• Providing information on vaccines to clients<br>• Feedback to caregivers |
| **Development partners** | • Resource mobilization<br>• Technical assistance |
| **World Health Organization** | • Technical assistance<br>• Providing information/guidance documents |
| **Media** | • Responsible reporting<br>• Support awareness creation |
| **Caregiver/client** | • Report AEFI<br>• Adhere to guidance of health worker |
| **Laboratories: NQCL, Government Chemist, NPHLS** | • Timely testing of specimen<br>• Provide advice |
| **NVSAC** | • Advisory role - Refer to NVSAC Terms of Reference |
| **NVSAC secretariat** | • Merge and update the joint NVIP & PPB national line list<br>• Select cases for NVSAC to review, summarize findings from NVSAC deliberations<br>• Share recommendations of NVSAC to NVIP and PPB<br>• Coordinate investigations |

### 9.1.2 AEFI management and reporting

1. AEFI reporting forms will be provided to all health facilities which are the first port of call for all AEFI and AESI.

2. Each facility will provide a contact person to be informed following an AEFI and this will be clearly outlined in each facility.
3. Each county will have an overall safety point person to coordinate all AEFI and AESI within the county and this point person will interface and coordinate with the National Vaccine Safety Committee. The point person will also manage information flow within the county stakeholder ecosystem.
4. Reporting of ALL AEFI and AESI will be through the PPB self-reporting portal and through DHIS for AEFI reporting forms completed in facilities
5. The NVCS will develop monthly summaries to be shared with the MoH Director General, national COVID-19 Vaccine deployment taskforce and other stakeholders to guide the vaccine deployment strategy.

*Figure 13: Kenya AEFI Reporting Pathway*



# 10 IMMUNIZATION MONITORING SYSTEM & EVALUATION

The Monitoring and Evaluation of the COVID-19 Vaccine introduction will begin prior to the launch and will continue through the established reporting systems which will be enhanced to consider COVID-19 Vaccine approvals.

The COVID-19 Vaccine data management, deployment monitoring and evaluation will ensure that there is:

1. Stock tracking of the COVID-19 vaccines
2. Supply and demand forecasting and matching
3. Individual patient registration and management of records
4. Management of priority groups and special groups
5. Data capture and reporting
6. Data for decision making and decision-making matrix
7. Data for impact assessment and evaluation
8. Data for analytics and visualization
9. Data for communication and demand generation

### 10.1.1 Details of Data Management Procedures and Activities

#### 10.1.1.1 Stock tracking of the COVID-19 vaccines

COVID-19 Vaccine stock monitoring will be done via the Chanjo ELMIS for the stores and through DHIS for facility-level stock data.

The primary data capture tools will be:

1. Vaccine ledger book - Vaccine ledger book captures vaccines received and issued at the immunization facility and vaccine stores
2. Temperature monitoring sheet - Vaccine temperature will be monitored twice a day through the temperature monitoring sheet. A copy of the temperature monitoring sheet will be shared with the supervising manager
3. Bin cards, Issue vouchers such as S11 will be utilized as required

Data from the vaccine ledger will be summarized in the Chanjo ELMIS system for aggregation and national reporting. The Chanjo ELMIS system will capture batches, daily, weekly, and monthly vaccine stock balances, and VVM statuses of all vaccines.

Temperature monitoring sheets will also be supported with remote temperature monitoring systems where available to provide real time temperature data for example the national vaccine store real time temperature monitoring system.

#### 10.1.1.2 Supply and demand forecasting and matching

To achieve the ambitious task of immunizing 40% of the population, the Government will ensure that demand forecasting and the supply are matched. To determine the expected demand, the program will develop and monitor detailed plans on target population by county/sub-county and ward. The targets will be informed by the phase of the vaccination program.

Demand monitoring will also be guided by social media tracking of public sentiment to ensure demand is being tracked adequately and appropriate responses and actions being implemented.

#### 10.1.1.3 Individual patient registration and management of records

COVID-19 vaccination status will be a critical data point to track due to future needs to be able to establish immunization status for employment, travel and to provide reliable proof of vaccination where it would be required.

To ensure that reliable status individual tracking of people vaccinated is required as well as personal proof of documentation will also be required by the population. To achieve this objective, the Government will develop electronic and paper-based forms to ensure that tracking is possible. This will include a patient card, a patient immunization certificate, linkage of patient ID number or other identification number in a national immunization registry managed by the Government.

#### 10.1.1.4 Management of priority groups and special groups

The COVID-19 Vaccine will be introduced in phases with different phases targeting different priority sectors and groups. The deployment plan will identify national priority groups and with support from the county, the different counties will identify and develop their pre-registration records of the different groups before vaccination.

The priority groups vaccination prioritization will also be managed considering available vaccine supplies, state of the COVID-19 epidemic in Kenya and other country priorities.

#### 10.1.1.5 Data capture and reporting

Monitoring of COVID-19 Vaccine performance will be monthly through the routine immunization system and the following immunization reporting tools will be utilized.

1. Permanent Register Book- Captures comprehensive patient level data
2. COVID-19 Vaccine Tally Sheet - Tally sheet used by vaccinators to track immunization and doses
3. COVID-19 Immunization summary Sheet - This summary sheet captures the daily immunization summary as captured by the tally sheet and summarizes data into a monthly format
4. COVID-19 Patient Vaccination Card - Card utilized by patient to show the vaccine received, batch numbers and provides information on next due date
5. AEFI Reporting Sheets - Used to capture AEFI and AESI at facility level

Data Management will utilize the existing DHIS 2 system for aggregate reporting from the summary sheet. A digital vaccine registry platform with a mobile application and aggregation system that tracks longitudinal information on targeted vaccination will also be utilized.

The digital platform will be accessible from a browser, mobile phone, tablet /iPad thus every vaccination center will be able to vaccinate and report to the centralized server which will be set up at a centralized location either at county or at national Level

Specifically, the platform aims to support the electronic registration of population to be vaccinated at each vaccination point to capture vaccination data, provide clinical decision support, track vaccinations at multiple facilities in a single location and produce reports that support public health decisions at the facility, sub-county, county and national level.

The system will also have the capability to generate digital health certificates linked with the vaccine registry platform and where possible integrate them with digital vaccination cards that we intend to embed within the system for the purposes of identifying those who have received the vaccine and to eliminate fraudulent certificates.

All mobile devices will automatically synchronize the information to this central repository when an internet connection is available. This central repository will be used as the primary data repository for client identification, aggregate reporting, and management.

The Feedback mechanisms for COVID-19 Vaccine delivery performance will be done through monthly and quarterly bulletins as well as through an integrated visualization dashboard. The program will also leverage on quarterly data review meetings to monitor performance and give feedback.

The coverage of both the first and second dose of COVID-19 Vaccine will be monitored through regular data analysis and evaluation of performances across the country as well as dashboards for monitoring vaccination delivery which includes drop-out rates and AEFIs. This will ensure that individuals are monitored for the full course of vaccine dose regime.

We will also evaluate the possibility of adopting the full DHIS 2 COVID-19 Vaccine delivery system which easily integrates into the DHIS 2 system that provides us with a data-driven deployment approach of vaccine delivery.

Data security, privacy and security of individual data will be provided by ensuring that the digital system to be adopted is role-based and therefore only accessible through system login based on the user's role in the facility thus ensuring that only authorized personnel access the client's data. The system will be hosted in a secure centralized environment that ensures even the data at rest is always secure and stable to avoid loss of data integrity.

#### 10.1.1.6 Data for decision-making and decision-making matrix

The Government will be the primary owner of all data on COVID-19 vaccination. The Government will provide the tools, systems, and infrastructure to capture all relevant data related to the COVID-19 vaccination.

This data will be availed to relevant health managers, health institutions, other Government institutions and other bodies as deemed fit by the Government.

*Table 13: COVID-19 Vaccination Data Decision-making matrix*

| Component | Description | Users/decision |
|---|---|---|
| **Primary data capture forms** | This is data captured at immunization centers and will include data on vaccines, provide batch numbers, expiry date, patient identifiable data, expected date of return etc. | Full access: Health facility/facility and sub-county health managers<br><br>Limited access: Other than primary facility staff express permission is required from the County Health Director for access to primary data forms |
| **Secondary** | Summary facility data will be | Online access to aggregated |

| | | |
|---|---|---|
| **aggregate data/online systems** | captured through several online systems such as KHIS, Chanjo and the national electronic database system | data will be managed by the KHIS program through password access.<br><br>Access to online data repositories will be managed by the Ministry of Health in line with Kenya data laws. |
| **National aggregate data from other Government sources** | Data will be required from other Government departments and ministries, for example, data on employment status, cadres, location for prioritization of vaccine provision | Data from other Government departments required for COVID-19 vaccinations will be accessed and managed by the national Ministry of Health in collaboration with the other Government departments providing the data. |
| **Non-Government data** | Other data sources not from Government sources but are still required for COVID-19 vaccination will also be captured and managed by the national MOH.<br>These data sets can include survey data on public opinion, social media tracking of public sentiment etc. | These data will be aggregated by the national MoH where applicable and linkages with other data sources will be through the national MoH |

#### 10.1.1.7 Data for impact assessment and evaluation

Monitoring of vaccine introductory activities will be done through the Checklist & Timeline of activities. In addition, each subcommittee will prepare a Gantt chart that will be aggregated at the National Taskforce level. This will provide accountability and visibility to co-dependent processes being performed by different working groups.

To track and monitor the overall vaccination program as well as support the reporting of the impact of the vaccine to meet international reporting standards, the program will carry out the following:

1. Annual reporting to the WHO/UNICEF through the joint reporting forms
2. Implement post-introduction evaluation of the different vaccination phases
3. EPI program review
4. Vaccination coverage survey
5. Impact surveys

### 10.1.2 Annual reporting to the WHO/UNICEF joint reporting form

The country annually reports on the WHO/UNICEF joint reporting form on the performance of antigens. The need for reporting may be heightened with the introduction of the COVID-19 Vaccine. The country will regularly report on COVID-19 after introduction.

### 10.1.3 Post introduction evaluation (PIE) of Phase1-3

A post-introduction evaluation will be conducted six months after launch to identify challenges and lessons learnt during the implementation period. This will evaluate the process of introduction, implementation, coverage, and strategy. It is expected that the results will translate to more focused and targeted technical support to the subnational levels.

WHO PIE tools will be adapted to the country context, followed by visits to implementation sites and analysis of data and report writing.

### 10.1.4 EPI program reviews

The COVID-19 Vaccine introduction will leverage other planned NVIP program reviews to assess the impact of the vaccine introduction into the routine system. The EPI review will highlight sector-wide challenges the program is facing and areas for further interventions.

### 10.1.5 Vaccination coverage surveys

The program will also work closely with the Kenya National Bureau of Statistics (KNBS) to include COVID-19 vaccination status in the demographic health survey. This will also provide a measure of the effectiveness of the program in reaching its goal.

### 10.1.6 Impact Studies

Impact studies will be conducted in select counties, leveraging consortia of partners involved in local COVID-19 studies - Universities, KEMRI, CDC/Welcome Trust in central, western, and coastal parts of Kenya. National Research Fund will be engaged to fund multi-disciplinary research.

Existing longitudinal population-based surveillance systems will be utilized, to evaluate the decline in the incidence of COVID-19 disease attributable to vaccine introduction.

#### 10.1.6.1 Data analytics and Dissemination

There will be huge volumes of data being generated during the COVID-19 vaccination. The data will be managed through:

1. **Data analytics**

The Ministry of Health will implement appropriate data analytics process to pool and aggregate data and apply advanced data analytics procedures such as forecasting and regression, machine learning and artificial intelligence analytics to provide critical insight to support the COVID-19 vaccination process.

The data analytics will be critical for the procurement and logistics of COVID-19 vaccines and other related supplies, prioritization, and management of the overall epidemic.

2. **Analytic dashboards**

Analytical dashboards will be developed to inform decision makers at sub-county, county, and national levels both within the Ministry of Health and outside.

Data dashboards will be critical and simple visualization to support decision-making,

3. **Data stories and infographics**

Data stories and infographics will also be developed to provide the public with summarized information on the progress of the overall COVID-19 vaccination.

#### 10.1.6.2 Data for communication and demand generation

Data for communication and demand generation will be developed and collected by the Ministry of Health through public data and Ministry of Health sources.

*Table 14: Risk Matrix for the COVID-19 Vaccines Deployment and Vaccination*

| Group | Assumptions | Risk | High/Medium/ Low | Mitigation |
|---|---|---|---|---|
| **Pre-deployment phase** | Vaccine approved | Delays in deployment | Medium | Process of vaccine approval timelines clear/key DM engaged |
| | Budget approved | Delays in Deployment | High | Budget process timelines clear/key DM engaged |
| | Key stakeholders (COG, counties, private sector, priority sectors) | Delayed/ Skewed Vaccine Deployment | High | Stakeholder communication plan implemented |
| **The disease/virus** | COVID-19 is not present | Low Vaccine Uptake | Medium | Promote Vaccine as a preventive measure |
| | COVID-19 wave | Vaccine Appears to Be Ineffective | Medium | Communication of the role of vaccine vs other COVID-19 measures |
| | New COVID19 strain | High or Low Vaccine Uptake | High | Continuous monitoring of vaccine efficacy and communication |
| **The vaccine** | Vaccine not available or insufficient doses | Slow Vaccine Deployment | Medium | Planned rollout well communicated (eligibility) and pre-registration |
| | Vaccine found to be defective | Low Vaccine Uptake | Medium | Research, timely release of results (by trusted authority) |
| | Deaths associated with vaccine | Low Vaccine Uptake | Low | Timely investigation and communication, financial payout |
| **Vaccine deployment** | Adequate funding | Slow, Inept Vaccine Deployment | Medium | Planned rollout well communicated. |

| Group | Assumptions | Risk | High/Medium/ Low | Mitigation |
|---|---|---|---|---|
| | | | | Robust monitoring |
| | Adequate health system capacity for program | Slow, inept vaccine deployment | High | Additional resource budgeting (2021-2023) |
| | HW industrial action | Slow vaccine deployment | High | |
| | Legal challenges | Slow vaccine deployment, expiry of stock | Medium | Clear mandates for deployment |
| **Unintended Consequences** | Vaccine deployment does not drain other Health system functions | Low Health indicators | Medium | Regular review of other health system activities, synergies |
| | Corruption | Low trust | High | Well planned communication, robust procurement |
| | Another crisis emerges | Reduced funding/focus | Low | Uncertainty |
| | Other countries stop vaccine deployment | Questions on effectiveness of vaccine deployment | Low | Monitor key country comparators, engage WHO |
| | Political change (2022 elections) | Loss of focus on vaccine deployment | Medium | uncertainty |
| | Kenya LMIC status expires 2022/23 | Reduced grants to health | Low | Additional resource budgeting (2022-2023) |
| | No categorization of target population | High vaccine deployment/ vaccine stock out | Medium | |
| | Vaccine donations (Non-GAVI) | | Low | |

### 10.1.7 COVID-19 Disease Surveillance

As COVID-19 vaccination is new, the MOH will set up additional surveillance leveraging existing systems e.g., Influenza sentinel sites, Acute Febrile Illness (AFI) sentinel sites etc. to aid in measuring and understanding the effects and impact of vaccination. Additionally, considering that the vaccine will be deployed in phases targeting specific subpopulations, specific surveillance systems will be established to collect critical data from selected subpopulations. To accomplish the objectives, rigorous planning, methodical designing, standardization of procedures and collection of quality data will be crucial in generating credible scientifically sound information. This information will be disseminated in a timely manner to policy makers for decision making, and shared with WHO to allow for a global perspective on vaccine effectiveness and impact.

The burden of COVID-19 disease will continue being monitored through the existing COVID-19 surveillance systems, managed by the Division of Disease Surveillance and Response (DDSR). The existing data collection and management tools will be modified to include vaccination related data elements. Data will be analyzed and disseminated regularly.

# ANNEXES AND BIBLIOGRAPHY

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