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MINISTRY OF HEALTH

KENYA NATIONAL IMMUNIZATION POLICY GUIDELINES

Vaccinate to Protect.
Ministry of Health

2023

KENYA NATIONAL IMMUNIZATION POLICY GUIDELINES 2023

Vaccinate to Protect

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FOREWORD

Vaccination has been one of the most successful and cost-effective public health intervention in history, as exemplified by, the eradication of smallpox, significantly lowering the prevalence of poliomyelitis, and the dramatic reduction in morbidity and mortality from several other illnesses.

The Ministry of Health is committed to the global goal of controlling, eliminating and eradicating vaccine-preventable diseases in the country. The impact of immunization services in reducing child mortality and morbidity in the country has been significant. It is through the efforts of various stakeholders and County Governments as implementers that this has been possible.

The National Vaccines and Immunization Program was established in 1980, and currently provides 14 vaccines and 5 non-EPI vaccines (Hepatitis B, Anti-snake venom, Anti-rabies, Yellow Fever and Typhoid vaccines). These vaccines are provided to more than 1.5 million infants and a similar number of Pregnant women and 700,000 young girls every year through a network of 9,500 health facilities – Public, Private, Faith based and NGOs, FREE OF CHARGE.

The Ministry of Health, through the National Vaccines and Immunization Program, supported by experts in immunization, and in consultation with various stakeholders, has updated the National Immunization Policy Guidelines, to guide implementation of immunization at all levels, ensure uniformity and standardization with the latest knowledge and advancements, and ensure all stakeholders are aligned on delivery of their mandates.

It is expected that every clinician and all other health care workers in Public, Private and NGO health facilities adhere to this policy to ensure high quality immunization services are offered equitably to all those who are eligible for the various vaccination services as outlined in this document.

The Ministry of Health is committed to ensuring that this strategy is implemented and adopted to the fullest, to protect the lives of our population from vaccine preventable diseases.

Dr. Nakhumicha S. Wafula,
Cabinet Secretary
Ministry of Health

PREFACE

The Government of Kenya appreciates the impact of the immunization Program since its launch, which has led to the elimination of the Maternal Neonatal Tetanus, near eradication of Poliomyelitis and marked control of measles. Currently more than 20 life threatening diseases can now be prevented by immunization.

The global re-emergence of vaccine preventable diseases, such as wild polio, in the face of less-than-optimal immunization coverage shows how important it is to attain and maintain high vaccination coverage so as to achieve significant herd immunity. It also underscores the continuing need to address other emerging vaccine preventable diseases, such as COVID-19.

Immunization is a key component of the primary health care package. The Kenya National Immunization Policy Guidelines aim to improve the quality of immunization and primary healthcare services by enhancing uniform and standardized implementation, and by anchoring quality practices and rational vaccine use. It also spells out the relevance of various vaccines and the roles of healthcare workers in the delivery.

It is envisaged that the policy will guide the health sector on the strategic priorities to focus on in order to protect the people from vaccine preventable diseases and strengthen primary healthcare services. It will be implemented alongside global, regional and national policy documents.

Peter K. Tum, CBS
Principal Secretary
State Department for Medical Services
Ministry of Health

ACKNOWLEDGEMENTS

The Kenya National Immunization Policy Guidelines are a result of a long process of intensive consultations, teamwork, detailed studies, information review and learnings from best practices across the world, aligned with current scientific evidence and National Immunization experiences.

There have been developments in the local, regional and global immunization arena necessitating a review and updating of the 2013 Policy Guidelines to be relevant to the current frameworks. It is essential that the country realigns to tackle the agenda within the realities of the new decade, guided by sound policy guidelines, attuned to regional and global standards.

The Ministry of Health, through the National Vaccines and Immunization Program (NVIP) spearheaded the review of the National Immunization Policy Guidelines to its conclusion. The reviewed Kenya policy guidelines on immunization resulted from concerted efforts of various stakeholders, individuals, and organizations in the Country. The Ministry of Health sincerely appreciates the financial and technical support provided by Gavi, the Vaccine Alliance, World Health Organization (WHO), the United Nations Children's Education Fund (UNICEF) and the African Population Health Research Center (APHRC).

Special thanks go to the members of the Technical Working Group that were tasked to steer the process of developing these policy guidelines. We would also want to appreciate immense contribution of individuals from the following organizations for their contribution towards the development of this policy guideline: Kenya National Immunization Technical Advisory Group (KENITAG), Kenya Paediatric Research Consortium (KEPRECON), Kenya Paediatric Association (KPA), Johns Hopkins Program for International Education in Gynaecology and Obstetrics (JHPIEGO), WHO, UNICEF, PATH, Kenya AIDS NGO Consortium (KANCO), Clinton Health Access Initiative (CHAI), Tony Blair Institute (TBI), John Snow Inc/MOMENTUM - Routine Immunization Transformation and Equity(JSI/M-RITE), Aga Khan University (AKU), KEMRI - Wellcome Trust Research Programme (KWTRP), American Red Cross (ARC), The University of Nairobi (UoN), Kenyatta University, and Alupe University College.

By launching this policy guidelines document, we expect a marked improvement in the quality of vaccination service delivery in the country.

Dr Patrick Amoth, EBS
Ag. Director General
Ministry of Health

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ABBREVIATIONS

AIDS	Acquired Immuno-Deficiency Syndrome
ART	Anti-Retroviral Drugs
AWP	Annual Work Plan
BCG	Bacillus Calmette–Guerin
BOPV	Bivalent Oral Polio Vaccine
CCE	Cold Chain Equipment
CMEs	Continuous Medical Education Sessions
DDSR	Division of Disease Surveillance and Response
EPI	Expanded Program on Immunization
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPV	Human Papilloma Virus
HWs	Health Workers
IGRA	Interferon-gamma release assays
IPT	Isoniazid Preventive Therapy
IPV	Inactivated Polio Vaccine
ISP	Immuno-Suppressed Person
KDHS	Kenya Demographic and Health Survey
KEMRI	Kenya Medical Research Institute
KENITAG	Kenya National Immunization Technical Advisory Group
KEPH	Kenya Essential Package for Health
KEPI	Kenya Expanded Program for Immunization
KHIS	Kenya Health Information System
LMIS	Logistics Management Information System
MCH	Maternal Child Health
MDVP	Multi Dose Vial Policy
MMR	Measles Mumps Rubella
MOH	Ministry of Health
MOPV	Monovalent Oral Polio Vaccine
MR	Measles-Rubella
NICC	National Inter-agency Coordinating Committee
NVIP	National Vaccines and Immunization Program
NVISP	National Vaccines and Immunization Strategic Plan
NVSAC	National Vaccine Safety Advisory Committee
OCV	Oral Cholera Vaccine
OPV	Oral Polio Vaccine

PCV	Pneumococcal Conjugate Vaccine
PPB	Pharmacy and Poisons Board
PrEP	Pre-Exposure Prophylaxis
TB	Tuberculosis
Td	Tetanus-diphtheria vaccine
TPT	TB Preventive Therapy
TST	Tuberculin skin test
TT	Tetanus Toxoid
TWG	Technical Working Group
UHC	Universal Health Coverage
UNICEF	United Nations Children's Fund
VPD	Vaccine Preventable Diseases
VVM	Vaccine Vial Monitor
WHO	World Health Organization
YF	Yellow Fever

GLOSSARY OF TERMS

Animal handlers: refers to those persons whose occupations involve contact with animals and are at risk of contracting diseases such as rabies, e.g. dog handlers, wildlife officers, veterinarians and veterinary laboratory staff.

Catch-up vaccination: Refers to the action of vaccinating an individual who, for whatever reason, is missing or has not received doses of vaccines for which they are eligible, per the national immunization schedule.

Clinicians: These are healthcare professionals involved in clinical practice (direct observation and treatment of patients) and include doctors, nurses, and clinical officers.

Cold chain: The cold chain is defined as a system of ensuring that vaccines are maintained at the required low temperatures from the point of production until it reaches the consumer. It refers to all the equipment, processes and mechanisms used to store and transport vaccines from the producer to the user (including vaccine carriers, cold-boxes, refrigerators, freezers and cold rooms) by air, road and over water bodies.

Delayed dose: Refers to a vaccine dose given "late", or past the window of timeliness set for that vaccine, in the national immunization schedule.

Defaulter: Person who starts but fails to complete the immunisation schedule for which they are eligible.

Food handlers: A food handler is a person employed in a food premise, who at any time may be involved in the manufacturing, preparation, packing/serving of food for sale or direct consumption by the public (through retail outlets or institutional catering units)

Fully immunized child: A fully immunized child by one year is one who has received all the prescribed antigens and at least one Vitamin A dose under the national immunization schedule before the first birthday.

Fully immunized person: A fully immunized person (other than an infant) refers to an individual who has received all the prescribed vaccine antigens and doses for the age group or, is beyond the 'window period of efficacy' of an antigen - where only one dose is required (e.g. 10 days after receiving yellow fever vaccine)

Health worker/s: broadly refers to health professionals – clinicians and non-clinicians engaged in health service provision but excludes health management and support workers who have no specific training in health matters e.g., administrators, accountants & clerical officers working in health institutions.

Minimum interval: is the shortest period permissible between doses of vaccine(s) requiring multiple doses, for it to provide an adequate immune response. If the interval between the doses is shorter than the minimum interval, the vaccine dose may not be effective and is considered invalid.

Missed Communities: Populations which have not accessed immunisation services, like clusters of zero dose and immunised children.

National Vaccine and Immunization Program: This is the Division within the Ministry of Health responsible for the provision and coordination of vaccination services in Kenya.

Periodic Intensification of Routine Immunization (PIRI): An umbrella term to describe a spectrum of time-limited, intermittent activities used to administer routine vaccinations to under-vaccinated populations and/or raise awareness of the benefits of vaccination. Examples include Child Health Days, National Vaccination Weeks, intensified social mobilization efforts, etc. PIRI activities are intended to augment routine immunization services by providing a catch-up opportunity for those who are the usual target for routine services but have been missed or not reached during the year.

Port Health Services: With regard to this policy guidelines on immunization, Port Health Services refer to the screening of Kenyan citizens and foreigners leaving or entering the country, for their vaccination status of specific vaccines of international public health importance. This is done by port officials at the port of entry/exit which maybe an airport, seaport, lake-port or a land border crossing.

Timely dose – refers to a vaccine dose administered within a certain time as recommended in the immunization schedule.

Under Immunised Children: Are children who have not received a vaccine dose for which they are eligible (and may have started the schedule), captured in the program as children who have missed the third dose of diphtheria-tetanus-pertussis containing vaccine (Penta 3).

Vaccine Vial Monitor: The VVM is a heat-sensitive label attached to vaccine vials which gradually and irreversibly changes colour, from light to dark, as the vaccine is exposed to heat. It warns the health worker as to when a vial of a vaccine should be discarded because the vaccine is likely to have been degraded by exposure to heat. VVMs measure cumulative heat exposure from time of production to the time of utilisation.

Zero dose children: Are children who have not received any vaccine in the EPI schedule, captured in the program as children who are eligible but have not received the first dose of diphtheria-tetanus-pertussis containing vaccine (Penta 1).

PART I
BACKGROUND

I. INTRODUCTION

Vaccination has been shown time and again to be very cost effective in the prevention and/or amelioration of disease. It is envisaged that where the opportunity arises to provide this protection, at the earliest possible age, it should be done through availing safe, efficacious and relevant vaccines.

The Government of Kenya ensures that its citizens are adequately protected against vaccine preventable, life-threatening and communicable diseases. The great impact of its infant immunization programme, launched in 1980, has brought about the elimination of diphtheria, the near elimination of pertussis, and marked control of measles.

This document has been developed following extensive consultations and consideration of key references. It summarizes immunological and epidemiological information on targeted vaccine-preventable diseases of public health importance in Kenya (including those in the EPI schedule) and presents recommendations on priority vaccines for Kenya, including vaccination schedules. It provides technical reference and guidelines for frontline health workers who are involved in managing and monitoring Immunization service delivery at all levels of the health care system.

The Kenya National Immunization Policy Guidelines have been developed in line with the Constitution of Kenya 2010, the Kenya Vision 2030 and the Kenya Health Policy 2014–2030. It is also aligned with Immunization Agenda 2030, the WHO Regional Immunization Strategic Plan for Africa, and the Addis Ababa Declaration on Immunization.

Immunization Agenda 2030

The Immunization Agenda 2030 (IA 2030) sets an ambitious, overarching global vision and strategy for vaccines and immunization for the decade 2021–2030. It draws on lessons learnt in the implementation of the immunization programs, acknowledges the continuing and emerging challenges posed by infectious diseases, and capitalizes on new opportunities to meet those challenges.

The vision of the Immunization Agenda 2030 is a world where everyone, everywhere, at every age fully benefits from vaccines for good health and well-being.

The Immunization Agenda 2030 (IA 2030) has three main impact goals:

1. Reduce mortality and morbidity from vaccine-preventable diseases for everyone throughout the life course.
2. Leave no one behind, by increasing equitable access and use of new and existing vaccines.
3. Ensure good health and well-being for everyone by strengthening immunization within primary health care and contributing to universal health coverage and sustainable development.

These National Immunization Policy Guidelines have been developed in line with the National Vaccine and Immunization Strategic Plan (NVISP) 2023-2027. The National Vaccine and Immunization Strategic Plan (NVISP) defines the medium-term immunization priorities and objectives towards attainment of the goal of the NVIP on increasing and sustaining high

coverage and equitable utilization of vaccines.

The National policy guidelines on immunization aims at attaining the aspirations spelt out in the (NVISP) 2023-2027 through the provision of clear directions toward the road to rationalized practices and vaccine use, ensuring uniform and standardized implementation of immunization schedules.

The key factors in the implementation of optimum immunization services include:

- Clear goals and objectives for disease control, elimination and eradication
- Clear guidelines for each intervention
- Qualified staff at all levels
- Appropriate and adequate logistics at all levels
- An effective surveillance system.

2. NATIONAL VACCINES AND IMMUNIZATION PROGRAM

The Kenya Expanded Programme on Immunization (KEPI) was established in 1980 with the main aim of providing immunization against six killer diseases of childhood (tuberculosis, diphtheria, pertussis, tetanus, measles and polio). It is now rebranded as the National Vaccines and Immunization Program (NVIP).

2.1 Portfolio of the National Vaccines and Immunization Program

The vaccine portfolio of NVIP includes:

1. Childhood vaccines including vaccines offered during adolescence
2. Tetanus and diphtheria (Td) for pregnant women and for trauma
3. COVID-19 Vaccines
4. Vaccinations for special groups including:
    - Occupational risk groups like health workers, health allied workers and veterinary workers
    - Food handlers, e.g., typhoid vaccine
    - International travellers, e.g. yellow fever, meningitis
5. Specialized products
    - Rabies vaccine for animal (dog) bites
    - Anti-venom for snake bite
    - Immunoglobulins for hepatitis B, anti-D sera for rhesus O negative pregnant women
6. Outbreak response vaccinations including the following conditions
    - Poliomyelitis
    - Measles
    - Meningitis
    - Emerging/ re-emerging infections, e.g., influenzas, coronaviruses
7. Any other vaccines and other specialized products that may be deemed essential for any sections of the Kenyan population.

The program links with the counties through the departments of health and county health management team where the immunization functions are in the docket of the County EPI focal persons supervised by the County Director for Health. The county health departments have varied organograms where the EPI program is represented at the county and sub county health management teams through the respective EPI focal persons.

PART II
POLICY DIRECTIONS

3. POLICY DIRECTIONS

3.1 NVIP Vision

A Kenya free of Vaccine Preventable Diseases

3.2 NVIP Mission

To save lives and protect people from vaccine preventable diseases by promoting and guiding the provision of efficient, equitable, safe, and effective high-quality immunization services to all Kenyans

3.3 NVIP Mandate

Ensure availability of high-quality Government of Kenya provided vaccines and provide guidance on all immunization schedules for the life course in line with the Kenya Health Policy 2014–2030 objective of eliminating communicable diseases.

The mandate of the program will be achieved by implementing the activities while observing the following core values.

- Professionalism and ethics
- Integrity and accountability
- Partnership and collaboration
- Resilience and efficiency
- Equity, adaptiveness, and innovation

3.4 NVIP Goal

The goal of the NVIP strategic plan is to increase and sustain high coverage and equitable utilization of vaccines, reduce the number of zero-dose children and ensure uninterrupted availability of high quality, safe and effective vaccines in a sustainable manner. While it is premised on the need to accelerate attainment of Universal Health Coverage (UHC) and Universal access to Immunization, it will give special focus to under-immunized population groups in Kenya including in urban informal settlements, remote rural areas, insecurity-affected settings, refugees, and marginalized groups that face social, cultural, economic and gender barriers to vaccination, ensuring that no child is left unprotected against vaccine preventable disease.

3.5 NVIP Guiding Principles

Implementation of the strategic plan will be guided by the following four principles, as outlined in the National Immunization Policy Guidelines.

I. **People centred:** Equitable delivery of immunization services through a strengthened and integrated primary health care system. Delivery of immunization services will be tailored to people's context specific needs, cognizant of special and marginalized groups' specificity and taken into account existing socio-cultural norms including but not limited to gender norms.

II. **National, county and community ownership:** Immunization is key to achieving universal health coverage (UHC) in Kenya. Unvaccinated children is a marker of under-served communities and can direct Primary Health Care services to unreached communities. The strategic plan will foster collaboration between the national and county immunization programs to develop strategies and plans that implement sustainable, high quality immunization services that fit the local context while maximizing on the available resources.

III. **Partnership based:** The strategic plan supports engagement of partners at various levels including the community, non-profit organizations, civil society, other government departments and ministries as well as development partners to work collaboratively to attain the goals of the immunization program.

IV. **Evidence driven:** A robust monitoring and evaluation framework that generates timely data for action is important for tracking and informing improvement areas in program performance. Data from various health sources will provide information on how to optimize immunization delivery approaches across different target population groups and emerging priorities areas, such as, new vaccines e.g. COVID-19, Life Course Immunization, vaccination in emergencies, humanitarian crises, as well as increasing coverage among special and marginalized groups.

3.6 NVIP Policy Objectives

Policy Objective 1: Policy Development, Implementation and Oversight

Oversee high quality, uniform and standardised Immunization delivery.

Priority actions include:

i. Developing, updating and disseminating immunization service delivery guidelines, job aids, manuals and other reference materials.
ii. Facilitating and coordinating periodic reviews of the Immunization Policy.
iii. Advising relevant legislative and regulatory authorities on enactment and implementation of relevant immunization policies and initiatives.
iv. Provide oversight for immunization services.

Policy Objective 2: Commodity Security and Quality Assurance

Ensure uninterrupted availability of potent and safe vaccines.

Priority actions include:

i. Ensure efficient supply chains for vaccines and related commodities vis-a-vis effective vaccines management.
ii. Identify and respond to vaccine safety events in a timely manner.

Policy Objective 3: Monitoring Evaluation Accountability and Learning (MEAL)

Improve data quality, reporting and utilization for strategic decision making.

Priority actions include:

i. Strengthening immunization evidence generation.
ii. Supporting immunization data capture processes, management and use.
iii. Supporting operational research, technology and innovations in data management.
iv. Supporting mechanisms to monitor and validate administrative coverage, including data reviews, sero-surveys and surveillance.

Policy Objective 4: Advocacy, Communication and Demand generation

Drum support for and visibility of immunization services in order to improve access and uptake of immunization services.

Priority actions include:

i. Develop policies on interventions aimed at increased acceptance, reduced vaccine hesitancy and refusals.
ii. Mobilization of partners, stakeholders and communities towards active participation and support for immunization.
iii. Improving the capacity of community health workers communication on immunization.
iv. Designing and Implementing evidence-based communication plans and messaging to address emerging demands on the immunization Program such as life-course immunization and vaccine hesitancy.

Policy Objective 5: Capacity Strengthening

To improve knowledge, skills and competencies of immunization teams and stakeholders for effective, efficient, and people-centred service delivery.

The priority actions include:

i. Determine and guide on the skills set required for the efficient and safe delivery of immunization services.
ii. Support and facilitate transfer of skills and knowledge.
iii. Engagement and fostering linkages with training institutions to update their training curriculum and core competencies on pre and in-service training on immunization.
iv. Guide on approaches to equipping immunization service delivery points to deliver high quality and equitable immunization services.
v. Develop innovative learning methods that includes e-Learning, blended –learning and on-the job training to cover a wide range of HWs.

Policy Objective 6: Partnership and Collaboration

Broadening Immunization services resources (financial, human and technical) through collaboration.

Priority actions include:

i. Broadening and strengthening Immunization partnerships, planning and coordination mechanisms.
ii. Create an enabling environment that fosters public private partnership.
iii. Establish new partnerships to increase knowledge and raise awareness of the value of immunization, building community trust in immunization services.

Policy Objective 7: Resource Mobilization and Immunization Financing

To ensure adequate, specific budget lines & resources are allocated by national and county governments to guarantee quality, uninterrupted immunization services.

Priority actions include:

i. Determine multi-year and annual funding needs for the immunization program and develop comprehensive resource mobilization plans.
ii. Advocacy with state and non-state actors to commit to Universal Access to Immunization.
iii. Enactment of relevant policies and legislation supporting immunization financing,

including outbreak response and catch-up vaccinations.

iv. Evaluate promising innovations and scale up innovations, as appropriate, on the basis of the best available evidence.

3.7 Policy Advisory Groups

The National Vaccines and Immunization Program engages with the following policy advisory groups:

3.7.1 National Immunization Technical Advisory Group (KENITAG)

The Kenya National Immunization Technical Advisory Group serves as an independent scientific and technical advisory body to the Ministry of Health on matters relating to vaccines and immunization policy, within its overall terms of reference. The Ministry of Health will review, prioritize and make the final decisions on all recommendations provided by KENITAG.

3.7.2 Kenya National Vaccine Safety Advisory Committee (NVSAC)

The Kenya National Vaccine Safety Advisory Committee serves a scientific and technical advisory role to the MOH on vaccine safety issues of national concern. This includes providing technical advice on vaccine safety initiatives and guiding the MOH in identifying and responding to adverse events following immunization (AEFI).

3.7.3 National Immunization Interagency Coordinating Committee

The National Immunization Interagency Coordinating Committee brings together domestic agencies and international partners/advisors to advocate for, provide oversight and coordinate efficient and effective use of resources available to the immunization Program.

3.7.4 Vaccine Preventable Disease Specific Advisory Committees

These committees meet regularly and periodically to review activities and status of specific disease eradication (e.g. Polio) Elimination (e.g. Measles, Rubella, Maternal Neonatal Tetanus) and Control initiatives, within their specific terms of reference. The committees develop and update every year a plan of action with timelines aligned to their respective regional and global bodies.

PART III
POLICY IMPLEMENTATION

4. POLICY IMPLEMENTATION

4.1 Policy Implementation Framework

The National Vaccines and Immunization Policy Guidelines shall be implemented in line with existing national policies and legislation through a multi-sectoral approach that includes collaboration and partnerships with state and non-state actors. It is thus aligned to key critical legal and policy documents including the Constitution 2010, Vision 2030, Health Policy Framework 2014-2030 and the Health Act, 2018. The policy also recognizes the functional assignments between the two levels of government with respective accountability, reporting, and management responsibilities.

The Institutional framework will be under the leadership of the Ministry of Health's National Vaccines and Immunization Program and will be managed in accordance with the overall health sector Management and Coordination Structures, and other related Laws of the Republic of Kenya.

The policy will be implemented through five-year National Vaccines and Immunization Strategic Plans, National and County Sectoral Plans, and Annual Work Plans.

4.2 Role of Stakeholders in Immunization

Institution	Roles and Responsibilities
Ministry of Health	▪ The Ministry of Health in partnership with the rest of the health sector shall endeavour to raise and maintain optimal immunization coverage levels for all approved schedules of administration through advocacy mechanisms and collaborative approaches to service delivery. ▪ Provide overall leadership, coordination and regulation of immunization activities in the country ▪ Technical advisory to the Cabinet Secretary on immunization matters. ▪ Development, dissemination, and guide implementation of the Policy at National and County levels ▪ Provide technical and logistical support to ensure that there is adequate capacity for implementation of this policy. ▪ Coordination of partnerships and collaborations for implementation of this policy and immunization strategies and work plans linked to it. ▪ Oversee implementation, monitoring and evaluation of immunization interventions and support counties in the development of work plans in accordance with the policy. ▪ Conduct capacity building on immunization and vaccine

	preventable disease control within the health system. ▪ Promote research and innovation on vaccines and immunization ▪ Manage immunization data and track immunization performance and indicators ▪ Promote institutionalization of immunization and vaccine preventable disease control, ensuring integration in Primary Health Care in the country ▪ ensure adequate and reliable supply of vaccines required for the implementation of the National Immunization Services. ▪ continuously review immunization service delivery in line with current information on vaccines, immunological products and new technologies related to immunization service delivery through the KENITAG ▪ Support investigation and causality assessment of vaccine safety concerns through the NVSAC
County Governments	▪ Provide equitable access to high quality, affordable immunization services as per policy guidance. ▪ All counties should achieve and maintain a minimum coverage of 80% of fully immunized children, based on the principle of "the full protection of any child is based on the collective protection of all children" ▪ Ensure all vaccines are administered should be to the correct target groups, according to the prescribed schedule, through the prescribed route of administration, at the correct dosage and using the recommended injection device and safe practice ▪ Mobilize and allocate resources for immunization service delivery in the county. ▪ provide the refrigeration equipment, non-reusable injection devices, safety boxes, monitoring tools, IEC materials, cold chain equipment and spare parts in line with guidelines ▪ Strengthen capacity for immunization service delivery at the County level. ▪ promote the uptake of vaccination services through community health strategy structures. ▪ Integrate immunization service delivery and vaccine preventable disease control into the broader county health agenda. ▪ Forge appropriate multi-sectoral partnerships at the county level. ▪ Implement national government policies and guidelines for immunization and vaccine preventable disease control.

	▪ Collect and report immunization data in line with this policy guidance. ▪ Conduct investigation of vaccine safety concerns in line with the guidelines
Other Ministries	▪ Mainstream and advocate for immunization and vaccine preventable disease control into their strategies and routine activities.
Parliament	▪ Support resource allocation for ensuring high and sustained immunization coverage and equity, and implementation of the policy. ▪ Enact relevant legislation anchoring immunization policy into law. ▪ Support policy implementation in their areas of jurisdiction.
Pharmacy and Poisons Board	▪ Ensure all vaccines used are registered for use. ▪ Periodically assess all vaccines in use in the country for conformity to desired quality standards and potency.
KEMSA	▪ Facilitate storage and distribution of essential immunization commodities and technologies identified by the Ministry for effective implementation of this policy.
Professional associations, regulatory and statutory bodies	▪ Advocate for, regulate and enforce aspects of the policy related to their respective bodies. ▪ Advocacy for and provision of guidance on immunization to other stakeholders as per policy ▪ Participate in policy formulation, implementation, and monitoring.
KENITAG	▪ Advise the Ministry of Health on immunization policies
NVSAC	▪ Advise the Ministry of Health on vaccine safety issues.
Academic, Research and Health Training Institutions	▪ Enhance Immunization training and capacity building. ▪ Conduct immunization research to inform and guide policy. ▪ Support community mobilization and awareness creation on vaccines and immunization.
Development partners	▪ Mobilize resources for policy implementation. ▪ Provide financial, technical, logistical and capacity building support.

Non state actors, Civil society	▪ Support immunization advocacy, communication, and social mobilization activities at the community level. ▪ Advocacy for resource allocation towards implementation of immunization policy at all levels. ▪ Participate in policy formulation, research, financing, implementation, monitoring and evaluation of immunization.
Media	▪ Advocate for quality reporting on immunization. ▪ Dissemination of accurate information on immunization initiatives to create public awareness.
Individuals and communities	▪ Adopt appropriate healthy lifestyles, healthcare seeking behaviours and participate actively in immunization and disease prevention activities. ▪ Participate in immunization decision making at all levels

Table 1 : Role of Stakeholders in Immunization

5. BASIC GUIDING PRINCIPLES OF IMMUNIZATION SERVICE DELIVERY

The WHO recommends six guiding principles for immunization service provision as per the Global Vaccine Action Plan (GVAP) i.e., country ownership, shared responsibility and partnership, equity, integration, sustainability, and innovation. These anchor the guiding principles of Immunization service delivery, contextualised and elaborated for the setting.

5.1 Guiding Principles of Immunization Service Delivery

- The Ministry of Health will ensure that there is uninterrupted supply and sustained demand for all available vaccines to all eligible Kenyans.
- Vaccines provided by the government shall be provided FREE of charge apart from travellers' vaccinations.
- All immunization services shall be at ALL immunizing health facilities provided on all working days and on demand.
- ALL efforts shall be made to screen children for vaccination status on joining school.
- ALL immunizing health facilities shall report through the Ministry of Health systems as prescribed on ALL vaccines administered whether they are procured by Government or Private entities.
- All vaccines for human use in Kenya must meet quality requirements as determined by the Pharmacy and Poisons Board and must be duly approved for use within the country by the Pharmacy and Poisons Board.
- All vaccines for human use must be certified as safe under normal circumstances of use. All known and unknown adverse effects of specific brands should be well articulated.
- Where the safety profile of a particular vaccine or immunological component cannot be guaranteed but the risk of the disease is serious, then the vaccine/immunological component MUST receive Emergency Use Authorization from the Pharmacy and Poisons Board and should be administered after obtaining informed consent from the client.
- All vaccines intended for simultaneous use with other antigens must have proven immunological efficacy in the presence of the other vaccine and must not significantly interfere with the immune response to the other vaccine.
- Administration of vaccines outside the National Immunization Schedules should be guided by the known disease burden/ risk of the area/region or specific individual/ community risk of exposure to the targeted disease or a specific medical indication of the client, based on an informed, qualified medical opinion or on relevant advisory from the Kenya National Immunization Technical Advisory Group.

- All vaccines for human use must be stored in specialized vaccine refrigerators as prescribed by the World Health Organization Standards. The specifications for these refrigerators can be obtained from the National Vaccines and Immunization Program or from the WHO official website.

  NB: Some new generation vaccines and immunologicals may not require refrigeration but this must be clearly specified on the vial labels and secondary packaging.

- All injectable vaccines must only be administered by duly qualified and registered clinicians/authorised practitioner.
- All injectable vaccines are to be administered using non-re-usable injection devices.
- Reconstitution of all lyophilized (freeze dried) vaccines must only be done with their matching diluents as provided by the specific manufacturer.
- All reconstituted multi-dose vial vaccines must be discarded after the manufacturer's prescribed maximum duration of use.
- All unused doses of a liquid multi-dose vial vaccine without a preservative must be discarded at the end of the vaccination session, or 6 hours after opening, whichever comes first e.g., multi-dose vials of liquid Pneumococcal Conjugate Vaccines.
- ALL vaccines should be distributed bundled with respective matching injection devices.
- Screening for immune status of individuals (including infants) prior to vaccination is not recommended. However, where special circumstances dictate, this should be overseen by a qualified authorised practitioner.
- Routine screening for HIV status prior to vaccination is not recommended except in special circumstances as determined by a consultant practitioner.
- Some Vaccine Preventable Diseases (VPDs) are notifiable and information on all suspected cases of these diseases must be fully documented, and reports forwarded immediately to the Division of Disease Surveillance and Response (DDSR) of the Ministry of Health. The notifiable VPDs are Tuberculosis, suspected Poliomyelitis (using Acute Flaccid Paralysis as an indicator), Diphtheria, Pertussis, Maternal Tetanus, Neonatal Tetanus, Measles, Meningitis, Yellow fever (using hemorrhagic fever as an indicator), Rubella, Influenza and Rabies. All notifiable VPDs must be investigated as per the prescribed guidelines from DDSR [12].
- All health workers must advocate for comprehensive utilization of immunization services to their community leaders and members.
- All immunizing facilities must ensure that vaccinators are updated annually on the principles and practice of immunization service delivery through attendance of

Continuous Medical Education sessions (CMEs) or updates to be conducted by Subcounty or County Health Management Teams, either through seminars or during supervisory visits.

- During ante and post-natal visits, health workers should emphasize to mothers on the importance of breastfeeding as a source of early antibodies and a route of continuous transfer of cell mediated immunity to their babies.

- All efforts must be made by health workers to prevent dropouts from all immunization schedules through careful counselling of clients regarding:
    - The importance of vaccines.
    - Possible side effects and how to manage them.
    - The consequences of not completing the schedule.

- All efforts must be made by health workers to identify and respond to missed opportunities for vaccinations by:
    - Screening all children aged below five years visiting/ presenting at health facilities and outreach sites for their vaccination status.
    - Screening of school-going children in collaboration with the Ministry of Education.
    - Screening all girls aged ten to fourteen years for HPV vaccination status.
    - Screening all women of childbearing age at health facilities and outreach sites for their vaccination status (esp. for tetanus diphtheria).

- All bodies dealing with vulnerable populations like refugees, displaced persons, urban informal dwellers, nomads, and other communities experiencing barriers to immunisation, including missed communities, should make a concerted effort to offer access to immunisation services for these groups.

5.2 Immunization schedule and vaccination of special groups

The National Immunization Schedule shall serve as the standard for all communication related to vaccination in Kenya and the basis on which services are provided and performance monitored. The schedule has been harmonized to minimize the number of visits to the health facility by the caregivers/clients.

5.2.1 Routine Immunization Schedule in Kenya - 2023

Contact	Age of child	Vaccine dose	Dosage	Route
1	At birth or at first contact	BCG	0.05 ml 0.1ml> 1 year	Intradermal
	At birth or at first contact (within the first two weeks of life)	OPV birth dose (bivalent)	2 drops	Oral
2	At six weeks of life or at first contact after 6 weeks.	OPV 1	2 drops	Oral
		DPT-HepB+Hib 1	0.5ml	Intramuscular into the upper outer aspect of left thigh
		PCV10- I	0.5 ml	Intramuscular into the upper outer aspect of right thigh
		Rotavirus-1	0.5ml (5 drops)	Oral
3	At 10 weeks or 4 weeks after OPV 1 DPT-HepB-Hib 1 and PCV10 - 1	OPV II	2 drops	Oral
		DPT-HepB+Hib 2	0.5 ml	Intramuscular into the upper outer aspect of left thigh
		PCV10 – 2	0.5 ml	Intramuscular into the upper outer aspect of right thigh
		Rotavirus-2	0.5ml (5 drops)	Oral
4	At 14 weeks or 4 weeks after OPV II DPT-HepB-Hib 2 and PCV10 - 2	OPV III	2 drops	Oral
		DPT-HepB+Hib 3	0.5 ml	Intramuscular into the upper outer aspect of left thigh
		PCV10 – 3	0.5ml	Intramuscular into the upper outer aspect of right thigh
		IPV	0.5ml	Intramuscular into the upper outer aspect of right thigh, 2.5cm from PCV -3 site
		Rotavirus-3	0.5ml (5 drops)	Oral
5	At 6 months	Vitamin A	100,000IU	Oral
		Measles-Rubella	0.5ml	Subcutaneous right upper arm (deltoid muscle) in the event of measles-rubella outbreak or HIV infected infants who are not severely immunosuppressed

Contact	Age of child	Vaccine dose	Dosage	Route
		RTS,S/AS01 (Malaria Vaccine - 1) (High risk counties)	0.5ml	Intramuscular left deltoid muscle
6	At 7 months	RTS,S / AS01 (Malaria Vaccine - 2) (High risk counties)	0.5ml	Intramuscular left deltoid muscle
7	At 9 months or first contact after 9 months	Measles-Rubella 1st dose	0.5 ml	Subcutaneous into the right upper arm (deltoid muscle)
		Yellow fever (High risk counties)	0.5 ml	Subcutaneous into the left upper arm (deltoid muscle)
		RTS,S / AS01 (Malaria Vaccine - 3) (High-risk counties)	0.5ml	Intramuscular left deltoid muscle
8	At 12 months of age	Vitamin A	200,000IU	Oral
9	At 18 months or first contact after 18 months	Measles-Rubella 2nd dose	0.5mls	Subcutaneous into the right upper arm (deltoid muscle)
	At 18 months	Vitamin A 200,000IU	One capsule	Oral
10	At 24 months	RTS,S / AS01 (Malaria Vaccine - 4) (High risk counties	0.5ml	Intramuscular left deltoid muscle
11	At 10 years girls (Extend to 14 Years for catch up)	HPV vaccine 1	0.5ml	Intramuscular left deltoid muscle
12	10 years, 6 months (Or 6 months after HPV 1)	HPV vaccine 2	0.5ml	Intramuscular left deltoid muscle

Table 2: Routine Immunization Schedule in Kenya - 2023

***NOTE**: The schedule above represents the minimum ages and intervals at which each vaccine dose is administered. Generally, if a vaccine dose was inadvertently given at too young an age or at less than the minimum interval as per the schedule, the vaccine dose is not considered valid and*

must be repeated. E.g., a 1st dose of pentavalent vaccine given before 6 weeks is considered invalid, and the schedule must be restarted, while a second dose given less than four weeks (give an allowance of at least 4 days from the date due) from the first dose is also considered invalid and the valid second dose should be given at least four weeks after this valid dose.

5.2.2 Vaccination of Special Groups

5.2.2.1 Pregnant Women

Pregnancy recommendations

Vaccine-preventable diseases are a major cause of maternal, neonatal, and young infant morbidity and mortality. Immunization of pregnant women can protect them directly against vaccine-preventable diseases, and by extension protect the foetus. The foetus and infant can also receive protection via specific maternal antibodies during the pregnancy.

i. It is generally considered safe to vaccinate pregnant women with the following Inactivated/Toxoid Vaccines: Inactivated influenza vaccine, Tetanus- diphtheria (Td), Tetanus Toxoid (TT). Other inactivated vaccines can only be administered where benefits outweigh the risk. Example, Meningococcal Conjugate vaccines (During outbreak as part of mass vaccination)

ii. Live vaccines administered to a pregnant woman may pose a theoretical risk to the foetus; therefore, should only be given when benefits outweigh risks Examples. Rabies Vaccine, (after a possible exposure) or yellow fever (in case of Outbreak or travel to an area where exposure is likely)

5.2.2.2 HIV Positive Infants/Children/Adolescents

Infection with HIV is not a contraindication to vaccination, including BCG and measles. All asymptomatic HIV infected children should receive BCG at birth and a dose of measles vaccine at 6 months. ***The child should still receive the other doses of measles vaccine at 9 months and at eighteen months as prescribed in the schedule.***

In circumstances where the child's HIV status cannot be established, WHO recommends that live vaccines should not be administered to children who are symptomatic for HIV infection.

5.2.2.3 Immunocompromised Individuals, Non- HIV Infected Persons

i. In mild immunosuppression resulting from conditions such as renal failure, diabetes, alcoholic cirrhosis, asplenia, or sickle cell disease, the risk of contracting some diseases is increased; therefore, routine vaccination should be given.

ii. Live vaccines are generally contraindicated in severely immunocompromised individuals because they could potentially overburden the immune system and result in disease.

5.2.2.4 Preterm and low birth babies

Preterm infants and low birth weight infants (<2500g.) should receive the BCG and OPV vaccine at the time of discharge from hospital irrespective of the current weight. If the

preterm or low-birth weight baby was born at home, BCG vaccination should be given at first contact with the health facility just like all babies born at home. The vaccination schedule should then be followed just like for other children.

5.2.2.5 Hematopoietic Stem Cell Transplant (HSCT) Recipients

Immunity to vaccine preventable diseases declines after a Hematopoietic Stem Cell Transplant. As such, recipients of Hematopoietic Stem Cell Transplant should undergo revaccination under the guidance of a transplant physician.

5.2.3 Recommended Vaccines for Special Risk Groups

When vaccinating these special risk groups always refer to the relevant sections in this policy or consult a paediatrician/physician.

CATEGORY		EXAMPLES	ANTIGENS
1	Health Care Workers	• Clinicians • Laboratory staff • Medical Engineering staff • Patient attendants • Clinical students	• Hepatitis B • Typhoid vaccine • Seasonal influenza • COVID-19 vaccine
2	Emergency and Essential Service Workers	• Police officers • Armed forces personnel • Staffs of correctional facilities	• Hepatitis B • Seasonal influenza • COVID-19 vaccine
3	Carers/Caregivers	• Carers of people with intellectual disability • Staff of nursing homes and long-term care facilities • Home-based caregivers	• Hepatitis B • Typhoid vaccine • Seasonal influenza • COVID-19 vaccine
4	Working with Animals	• Veterinarians, veterinary students • Veterinary Laboratory staff • Wildlife rangers • Police dog unit staff, dog handlers in security companies	• Tetanus-diphtheria vaccine • Rabies vaccine
		• Herds men • Poultry handlers • Abattoirs workers	• Tetanus-diphtheria vaccine
5	Others exposed to human tissue, blood, body fluids	• Tattooist, body–piercers, traditional circumcisers • Embalmers & other funeral	• Hepatitis B

	or sewage	workers	
		• Plumbers, sewage treatment plant workers, sewage exhauster staff	• Hepatitis B • Typhoid vaccine
		• Intravenous drug users	• Hepatitis B
		• Alcoholics & smokers	• Tetanus-diphtheria vaccine • PCV13
		• Sex Industry Workers	• Hepatitis B
6	Industrial workers at risk of injuries	• Mechanics & machine operators • Jua kali artisan • Carpenters and masons	• Tetanus-diphtheria vaccine
7	Food handlers	• Chefs, cooks, kitchen staff, waiters/food servers, prisoners,	• Typhoid vaccine • Cholera vaccine

Table 3: Recommended Vaccines for Special Risk Groups

5.2.4 Recommended vaccines for the immunocompromised and special interest groups:

GROUPS		ANTIGEN
1	Cancer patients	• Hepatitis B • PCV 13 vaccine, then 23 valent Pneumococcal vaccine (PPSV 23 vaccine). • COVID-19 vaccine
2	HIV/AIDS patients	• Hepatitis B • PCV13 vaccine • COVID-19 vaccine
3	Sicklers, Diabetics, Congenital or acquired asplenia, asthmatics, & immune mediated inflammatory diseases and other chronic diseases	• Hepatitis B • PCV 13 vaccine, then 23 valent Pneumococcal vaccine (PPSV 23 vaccine). • Polyvalent Meningococcal vaccine • Seasonal influenza • COVID-19 vaccine
4	Elderly persons >50 years	• PCV13 • 23 valent pneumococcal vaccine • Seasonal influenza

		• COVID-19 vaccine
5	Travellers	• Yellow Fever • Meningococcal vaccine ACYW135 (for Haj & Ummra) • COVID-19 vaccine
6	Persons infested with jiggers	• Tetanus-diphtheria vaccine
7	Trauma cases/Circumcision	• Tetanus-diphtheria vaccine

Table 4: Recommended vaccines for the immunocompromised and special interest groups

6. GENERAL PROPERTIES OF VACCINES AND DILUENTS

A vaccine is a biological product made in, composed of, and/or tested through living systems. Vaccines function by eliciting an immune response and are generally for preventive use, although therapeutic uses are known (e.g., BCG for vesicle cancer).

A lot of research is in progress to develop therapeutic vaccines such as for the treatment of hypertension and smoking addiction. Vaccines are one of the most cost-effective preventive interventions globally. From the beginning of the 20th century the extensive use of vaccines has resulted in significant reductions in the burden of many diseases and the eradication of smallpox.

6.1 Common components of vaccines

A vaccine consists of many parts, one of which is the antigen, by which it is often described, also referred to as the immunogen. A vaccine formulation contains other components such as diluents, stabilizers, adjuvants, preservatives, buffers, surfactants, and proprietary ingredients (such as viscosity controlling agents and osmotic pressure controlling agents).

Antigen: Is the principal part of any vaccine and has evolved over several years from killed or denatured (Attenuated) whole bacterium or virus, to parts of the disease-causing agent such as the capsule or genetically engineered components that mimic the disease-causing agent.

Adjuvants: Substances that are added to some vaccines to enhance the body's immune response to the Antigen. Examples are aluminium hydroxide gel, emulsigen, aluminium phosphate, calcium phosphate, quillaja saponin and ginsenoids.

Antibiotics: Prevent bacterial contamination e.g., neomycin.

Diluents: Include water, aqueous buffer (such as buffered saline), alcohols and polyols (e.g. glycerol). Some vaccines require reconstitution where the diluent is provided separately from the lyophilized (freeze dried) vaccine for reconstitution at the time of use.

Lyophilized vaccines should only be reconstituted with the diluent provided for this purpose by the manufacturer because diluents are specifically constituted to complement the particular vaccine in terms of pH and other buffering effects.

- *There are no 'general diluents' and using a different diluent for a given vaccine may compromise the efficacy of the vaccine*

Preservatives: Chemical additives to vaccines to ensure that they remain microbiologically stable. That is, they prevent the growth of microorganism and fungi during the long time of storage as well as during its use (especially with multi-dose vials) e.g., formaldehyde, phenol, Thimerosal, beta-propiolactone etc. Not all vaccines contain preservatives.

- *Because even the combined effects of a preservative, good cold-chain and the use of sterile needles and syringes are not fool-proof in inhibiting bacterial growth within a liquid vaccine, no liquid vaccine should be used beyond four weeks from the time it is opened. The limit for use of multi-dose liquid vaccine formulations is four weeks (see also 'open-vial' policy).*

Stabilizers: Chemical substances added to vaccines in micro-quantities to maintain vaccine integrity under varying external conditions of temperature and light, and to sustain physical properties such as solubility. e.g., lactose, gelatin.

Trace components: These are left over from the process of manufacture of the vaccine e.g., formaldehyde.

6.2 Properties of Vaccines

Efficacy - A vaccine's efficacy refers to the rate of protection from infection and/or disease under optimal Phase III clinical trial conditions. No vaccine is 100% protective. Some vaccines, like the hepatitis B vaccine, have an efficacy of over 95% if all three doses are received, and this protection can last for up to 10 years. Some vaccines do not protect as many people against disease but may still be able to stop epidemics. People who are vaccinated may be less likely to pass on the infectious organism to others, so protection can be greater for the group.

A vaccine's efficacy may vary according to age of recipient, immune status of an individual and nutritional status (especially malnutrition). Efficacy also has time limitation that varies from vaccine to vaccine (i.e., the duration of protection conferred) due to various factors.

A vaccine's efficacy can be compromised by:

- Exposure to inappropriate temperatures (freezing or high temperatures),
- Wrong reconstitution methods (use of wrong diluent or use of warm diluent)
- Wrong route of administration (e.g subcutaneous injection instead of intra dermal injection)

Effectiveness - Effectiveness describes how well the vaccine reduces disease in the overall population. This depends on the efficacy as defined in clinical trials and characteristics of the general population, including how many people actually get vaccinated, as well as whether they complete the full series of vaccinations.

Herd Immunity - When a large proportion of people in a community are vaccinated against a disease (85%-90%), even those who are not vaccinated in that community get some protection because of a phenomenon called herd immunity. If enough people in the community are vaccinated, there is less chance of the infection spreading from person to person, and unvaccinated individuals may be less likely to get infected because there is a lower risk of exposure. For example, the measles vaccine protects vaccinated people and reduces spread of the disease to people who are not vaccinated. However, if too many people are unvaccinated, 'herd immunity' cannot occur.

Safety – Vaccines are generally safe when used as intended in that they do not cause serious

side effects. Common side effects include transient fevers and pain at the injection site. However, there is always a risk of unusual or unexpected reaction to a vaccine, so health workers have to be alert in case of any adverse event following immunization (AEFI).

Anti-snake venom is inherently risky to administer and therefore must only be administered by a clinician with an anaphylaxis management kit ready.

Some vaccines are not recommended in certain age groups, pregnancy and certain medical conditions (e.g., persons on steroid or cytotoxic treatment, immuno-suppression). In all these cases a medical specialist must be consulted as they will be better placed to determine whether the benefit of the vaccine outweighs the potential risk to the client.

Stability - This refers to the ability of the vaccine to retain its efficacy under various conditions and environments. Stability can be compromised by

- Contamination with bacteria during administration or reconstitution
- Changes in temperature
- Exposure to light (a few vaccines)

Most vaccines are inherently thermo-labile and rapidly lose their potency (i.e., ability to induce an immune response) when exposed to inappropriate extremes of temperature. Some vaccines are very stable when frozen whereas others are denatured after even the briefest storage below freezing point. Some vaccines are stable when exposed to high temperatures for short periods of time whereas others lose their potency within hours. Because of their thermo-labile nature most vaccines do not have shelf lives exceeding 3 years from their date of manufacture.

The stability of lyophilized (freeze-dried) vaccines deteriorates rapidly after reconstitution and therefore no reconstituted vaccine should be used more than six hours after reconstitution. Neither should a reconstituted vaccine be returned to the refrigerator for use later. All reconstituted vaccines should be discarded at the end of every vaccinating session or after six hours – whichever comes first.

Incineration is the best method of destruction for vaccines as they are biological products. Any suspicious vaccine vial/s should be documented in the stock ledger

- Stating the problem noted,
- Number of affected vials/doses,
- The batch number/s

All affected vials should then be referred to the supplier. Here, the supplier may be the Sub County Public Health Nurse or procurement agent.

Because it is impossible to determine the integrity of a vaccine by visual inspection alone, proxy indicators are used. The integrity of a vaccine should be doubted whenever one or both of the following occurs:

- *Any change in the known physical characteristics of the vaccine – i.e., colour or consistency – including presence of foreign bodies,*
- *Stage three or four changes of the Vaccine Vial Monitor (VVM)*

All vaccines for human use in Kenya MUST therefore:

- *Meet the quality requirements as defined in the current WHO policy statement on vaccine quality.*
- *Not interfere significantly with the immune response to other vaccines given simultaneously.*
- *Must have a remaining shelf life of not less than 18 months at the time of arrival in the country – for routine vaccination services.*
- *Must have a remaining shelf life of not less than 6 months at the time of arrival in the country – for emergency response (outbreak) vaccination services.*
- *Must have Vaccine Vial Monitors (commonly known as VVMs), except for vaccines under Emergency Use Listing.*

7. VACCINE STORAGE AND MANAGEMENT

7.1 Essential Immunization Supplies

The MOH through NVIP will continue to supply government prescribed childhood and adult vaccines, to all public and government supported immunizing health facilities and those run by other organizations.

County Governments will provide the refrigeration equipment, non-reusable injection devices, safety boxes, monitoring tools, IEC materials, cold chain equipment and spare parts in line with specifications provided by NVIP and the WHO, and in line with the Government laws on financing, procurement and disposal.

All other vaccines outside the government prescribed schedules such as Measles Mumps Rubella (MMR), Hepatitis A, Meningococcal, Varicella, Seasonal Influenza vaccines must be licensed for use by the Pharmacy and Poisons Board, conform to the Kenya National Drug Policy, be documented in child vaccination records and reported through the MOH NVIP routine immunization reporting system.

Only WHO prequalified manufacturers will be allowed to supply vaccines to the country both for the public and private markets. For vaccines which do not undergo WHO prequalification they must be certified by a recognized regional regulatory authority and licensed by the Pharmacy and Poisons Board.

7.2 Distribution of Vaccination Supplies

Vaccines coming into the country are received, stored and further distributed across the country to the last mile through a four-tier supply chain system.

Vaccines should be bundled with other supplies (injection devices, safety boxes et.c) during distribution especially at the sub county.

7.3 Cold Chain Equipment

The National Vaccines and Immunization Program endeavours to provide to the Counties appropriate guidance and specifications for cold chain equipment and strives to compile a national inventory database of cold chain equipment in the Counties.

7.3.1 Maintenance of the Cold Chain

The cold chain must always be maintained all through the supply chain to ensure vaccine potency at the time of administration to a client.

Cold-chain efficacy will be determined as follows:

- Assessment of the integrity of the Vaccine Vial Monitors (VVMs) on each vaccine vial.
- Through temperature recordings of the vaccine refrigerator at least twice a day
- Verification of thermometer readings of the vaccine refrigerator
- Verification of electronic temperature recording of the vaccine refrigerator

- Temperature mapping reports of cold chain equipment
- Provision and availability of alternative energy sources for the vaccine refrigerator (i.e., extra full gas cylinder or stand-by generator)

7.3.2 Replacement of cold chain equipment

Vaccine refrigerators and other cold chain equipment should ideally be replaced after 10 years to prevent any loss of potency of vaccines stored inside due to inefficient temperature regulation that may be occasioned by wear and tear of rubber seals, hinges and warping of the bodies.

Aged and unserviceable government supplied equipment should be disposed of as per the Public Procurement and Disposal Act of 2005.

Cold chain equipment used to store or transport vaccine should be prequalified by WHO under the WHO Performance, Quality and Safety (PQS) process. The list of prequalified equipment can be found in the WHO PQS catalogue.

As part of the Government's effort to adhere to the Montreal and Kyoto Protocols, all cold chain equipment must be Chlorofluorocarbons (CFC) free including all the freezers, cold rooms, freezer rooms, refrigerators, cold boxes and vaccine carriers.

All donated equipment intended for vaccine use should also be CFC free.

All cold chain equipment supplied, purchased locally, or donated should be able to maintain the strict vaccine temperature range of +2°C to +8°C with a holdover period of not less than 24 hours for refrigerators, and 72 hours for freezers.

7.4 Storage and transportation of vaccines & diluents

At all stages of vaccine transportation, a cold chain monitor must always accompany all vaccines whether in cold boxes, vaccine carriers or portable fridges and the temperature reading must be always maintained between +2°C and +8°C using conditioned ice packs.

Diluents need not be transported at +2°C to +8°C unless they are being transported for outreach activities.

At regional, County / Sub-County stores, diluents do not need to be stored in the refrigerator or freezer and should NEVER be frozen. They must however be cooled to between +2°C & +8°C overnight before the vaccination day and reconstitution. This prevents thermal shock to the vaccine, which can occur if the diluent is warm.

However, at facility level, all diluents must be stored in the vaccine refrigerator and in the same tray as their respective vaccines. This is to ensure that diluents are at the same temperature as their respective vaccines at the time of reconstitution. This also ensures that the vaccine potency is not compromised.

Diluents supplied with vaccines are specific for the vaccine since they contain certain chemicals to stabilize the vaccine or potentiate the immune response or protect the reconstituted vaccine from bacterial contamination. It is essential that diluents are stored, distributed, and used correctly.

Incorrect handling of diluents may cause adverse events following vaccination.

Nothing else should be stored in vaccine cold chain equipment except vaccines and diluents.

NB: Laboratory reagents must never be stored in the vaccine refrigerators.

All vaccine refrigerators and freezers should have an emergency plan pasted/displayed on the doors indicating the actions that should be taken in case of failure/breakdown. This should include the telephone numbers of the supervisors and the local refrigeration technician.

7.5 Dynamic labelling of vaccine Using Beyond-Use Date (BUD) Sticker

Dynamic labelling of a vaccine is done for certain types of vaccines whose shelf life depends on the temperature at which it is stored. Usually the vaccine will be stored in freezing or ultra-freezing conditions for its full shelf life, but once it is thawed (i.e. stored at 2-8°C, the shelf life will be shortened and a new expiry date will need to be recorded. Once the vaccine is thawed, the new expiry date will be calculated based on the manufacturer's instructions. The following are instructions on recording of the expiry dates:

I. If the calculated expiry date is earlier than the manufacturer expiry date, cross out the manufacturer's expiry date and indicate the new expiry date in the BUD sticker together with the date of vaccine thawing and indicate in the stock ledgers.

II. If the expiry date indicated by the manufacturer is earlier than the calculated expiry date, indicate on the BUD sticker and vaccine stock ledger the date the vaccine was thawed only and use the manufacturer expiry date. ***NOTE**: For vaccines with restricted time of travel, once thawed (e.g. Moderna and Pfizer BioNTech (Purple cap) the time of travel, should also be indicated on the BUD sticker.*

BEYOND USE DATE (BUD) STICKER

Dynamic labeling of applicable vaccines when stored at 2°C and 8°C

FOR SUB COUNTY DEPOTS AND HEALTH FACILITIES

ROTAVIRUS VACCINE: can be stored 180 Days at 2°C and 8°C)
COVID -19 VACCINE: Pfizer BioNTech Grey Cap (70 Days), Janssen (J&J) (330 Days) at 2°C and 8°C

Vaccine	
Batch No	
Vaccine Thawing Date	
*New expiry date	

***After this date, do NOT use the Vaccine.**

NOTE: * *If the* **CALCULATED NEW EXPIRY DATE** *is earlier than the printed by manufacturer, Record the* **DATE VACCINE IS THAWED** *and* **Use NEW EXPIRY DATE**

If the* **EXPIRY DATE ***printed by manufacturer*** *is earlier than the calculated new expiry date, Record the* **DATE VACCINE IS THAWED ONLY and Use Manufacturer Expiry Date**

Figure 1: Beyond Use Date Sticker

7.6 Disposal of expired or damaged vaccines

The disposal of expired and damaged vaccines shall be done according to MOH guidelines for disposal of all other drugs and related biologicals. (Refer to Pharmacy and Poisons Board

guidelines and Public Procurement and Disposal act).

7.7 Open vial policy

The Ministry of Health has adopted the WHO policy of using selected vaccines in subsequent immunization sessions. This is what is referred to as the multi-dose vial policy (MDVP) and applies to the following vaccines:

- OPV
- IPV
- Td
- DT
- Hepatitis B
- Pentavalent vaccine (liquid preparation)
- Pneumococcal vaccine (PCV10)

These vaccines contain special preservatives assuring stability to heat and long-lasting potency. The preservatives also prevent or reduce bacterial contamination in the vials. Multi-dose vials of these vaccines from which one or more doses have been removed during an immunization session may be used during subsequent immunization sessions for a maximum of four weeks provided all the following conditions are met:

1. The vaccine is currently prequalified by WHO
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO MDVP.
3. The expiry date has not passed.
4. The vaccines are stored under appropriate cold chain conditions.
5. The vaccine vial septum has not been submerged in water.
6. Aseptic techniques have been used to withdraw all doses.
7. The Vaccine Vial Monitor (VVM) has not reached the discard point.

The policy on the re-use of opened multi-dose vials of vaccines applies to vaccine vials for use both in static as well as outreach vaccination sessions.

All multi-dose liquid vaccines that are not likely to be exhausted in one or more vaccination schedules should be clearly labelled with the date when they were opened before they are returned to the vaccine refrigerator.

> **NB:** *The revised multi dose vial policy does not change the recommended procedures for handling vaccines that must be reconstituted, that is, all freeze dried or lyophilized vaccines. Once these are reconstituted, the vials must be discarded at the end of each immunization session or at the end of 6 hours, whichever comes first.*

7.8 Safe injection practices

Vaccination is considered safe when the correct vaccine is injected with the appropriate equipment into the correct plane for injection, and the used sharps disposed appropriately.

The reuse of standard disposable syringes and needles places the public at high risk of cross infection of blood borne diseases, as it is practically impossible to guarantee their proper use and disposal in all vaccination sites.

To ensure the safety of injections, the Ministry of Health emphasizes on the use of one sterile syringe and one sterile needle for each injection with the specific use of auto disable (AD) syringes for the entire public immunization program. The use of reusable and standard disposable syringes in immunizations is no longer acceptable in Kenya.

The auto-disable (AD) syringe is just one of a growing variety of non-reusable injection devices in the market, which all aim at preventing re-use of the device at source or at any point along the disposal route.

The Ministry of Health therefore recommends the exclusive use of non-re-useable Auto-Disable injection devices for the administration of all parenteral vaccines.

7.9 Disposal of vaccination waste

Further to the use of the prescribed injection devices, they must be immediately disposed of in puncture-resistant receptacles/safety boxes that once full must be burnt & buried or incinerated.

- The needle should not be recapped or removed from the syringe; the whole combination should be inserted into the safety box directly after use.
- Safety boxes should never be emptied and reused, nor should they be kept in areas accessible to the public (i.e., in common areas outside the health facility).
- A system for monitoring the distribution, utilization and destruction of injection equipment should be introduced.
- Used vaccine vials (empty or partially empty) should be disposed of into the yellow bin.
- Additional waste from injections (syringe packaging, cotton wool, etc) should be disposed of appropriately (refer to the MOH injection safety guidelines).
- The method of choice for destruction of full safety boxes and yellow bins is incineration, preferably in an appropriate high temperature incinerator (>800°C-1000°C)
- If such an incinerator is unavailable, a low temperature incinerator (300°C - 400°C) may be used.
- Alternatively, full safety boxes may be incinerated in small numbers by open burning in a dug pit.
- Residue from incineration (oxidized needles, vials etc) should be buried properly.

Under no circumstances should used syringes or needles, or safety boxes, be disposed of in normal garbage or dumped randomly.

All expired or damaged/contaminated/suspect vaccines should be disposed of as per Ministry of Health guidelines by Pharmacy & Poisons Board regulations.

8. ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIs)

An AEFI is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

In order to maintain community confidence in vaccines there is need to maintain a clear guideline of detecting, reporting, investigating and responding to AEFIs.

AEFIs can be classified into 5 types, depending on the cause of the reaction.

1. Vaccine product-related reaction
2. Vaccine quality defect-related reaction
3. Immunization error-related reaction
4. Immunization anxiety-related reaction
5. Coincidental event

AEFIs can also be classified by level of Seriousness/Severity.

An AEFI will be considered **serious** if it:

- Results in death
- Is life-threatening
- Requires hospitalization or prolongation of existing hospitalization
- Results in disability/incapacity
- Medical event which is highly likely to result in the above

Non-serious: an adverse event that is not serious.

Cluster of AEFI: Two or more similar unfavorable medical events following administration of a given vaccine, related in time, place or vaccine.

8.1 AEFI Detection:

i. Clients shall be kept at the site of vaccination by the vaccinating officer for at least 15 minutes after vaccination in order to detect any immediate events such as anaphylaxis

ii. Inquiry about vaccination history as part of evaluation for clients visiting at the Outpatient clinic/Emergency area for treatment shall be done by Health care workers

iii. Reports from the caregiver after vaccination or subsequent visit(s) shall be documented by the attending health care worker

iv. Reports from the community or Community Health Volunteers, including those identified during non-Immunization outreaches shall be captured and recorded

v. Media reports about an AEFI shall be documented and followed up appropriately by the EPI Coordinator in whose jurisdiction the case(s) fall.

8.2 Responding to an AEFI

Once an AEFI has been detected, relevant actions should be taken, including:

a) Management of AEFI as per presentation and according to standard guidelines
b) Reporting of AEFI
c) Investigation of selected AEFI
d) Assessment of the causes
e) Communicating to stakeholders including caregivers and the community

The Immediate steps to take when a serious AEFI occurs are:

1. Triage the affected child and take him/her to the resuscitation room or a safe place away from any crowd and give the correct treatment as per the condition
2. Ask or shout for help from colleagues
3. Re-assure the parent as the child gets treatment
4. Collect the vaccine vial and the diluent which were used using sterile procedures and document the details (date of manufacture, expiry date, batch number and manufacturer)
5. Take a sample specimen as per the condition and take for laboratory analysis
6. Observe until the child's condition improves, and if the condition does not improve within 2 hours refer to the next level
7. Report the AEFI within 24 hours and investigate within 48 hours.

8.3 AEFI Reporting Pathway

The following is the AEFI Reporting pathway:

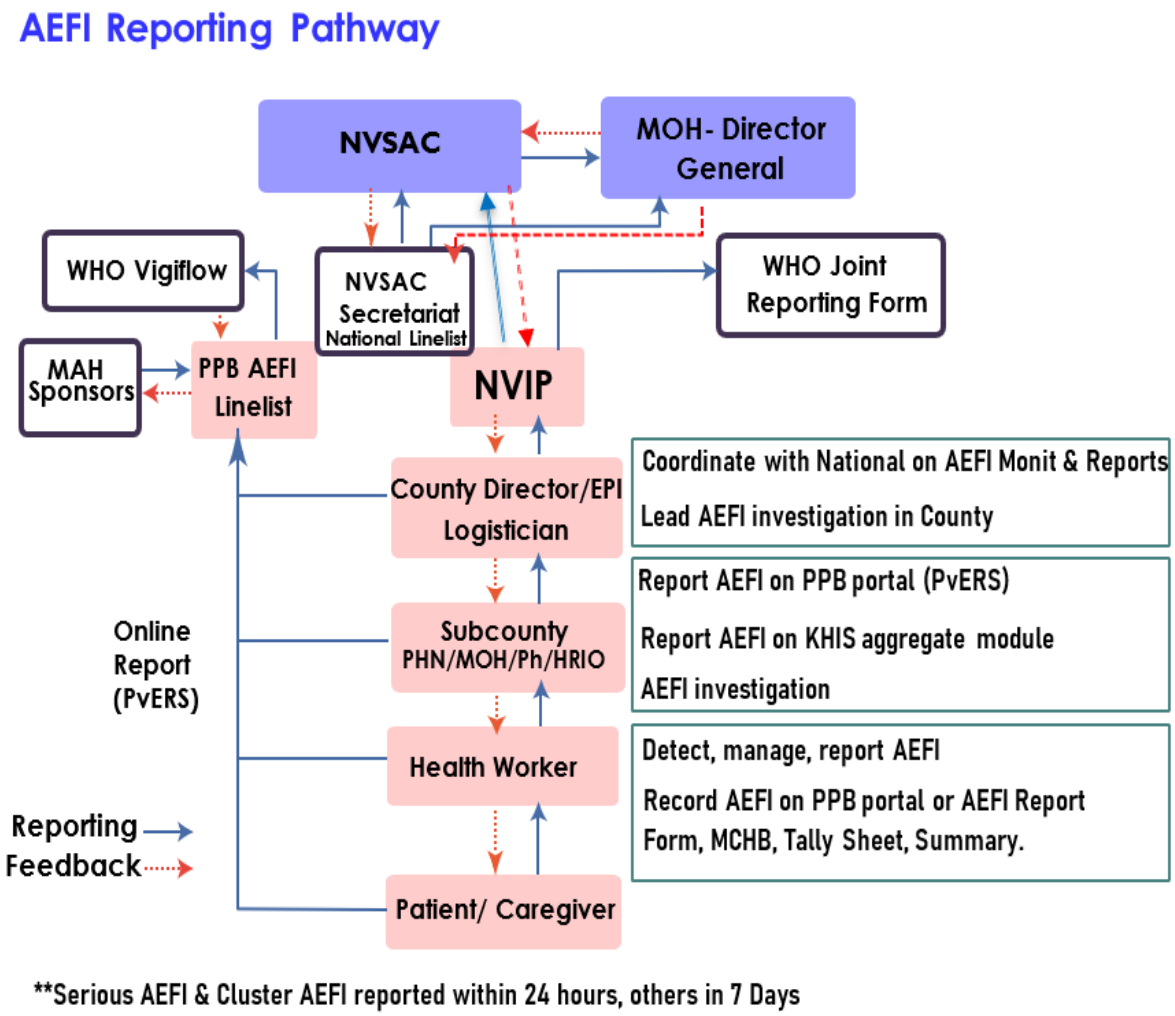

Figure 2: AEFI Reporting Pathway

NB: Because of the urgency of the investigations of an AEFI, the facility or the SCMOH should call and alert NVIP immediately an AEFI is detected. Do not address the media without facts. Refer the media to the head, NVIP.

The following long-term actions need to be undertaken:

1. Communicate to parents, community and 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 availability of supplies and the working condition of the equipment to minimize immunization errors e.g., high temperatures, which could lead to growth of bacteria in opened unused multi-dose vaccines leading to adverse events. Freezing of freeze sensitive vaccines could lead to aseptic abscesses.

Rarely will it be necessary to stop immunization services; such action should not be taken hastily

as it will lead to decreased demand for immunization and increase the risk of disease outbreaks in a community. It can only be considered in consultation with NVIP and PPB.

8.4 Role of the National Vaccine Safety Advisory Committee

The National Vaccine Safety Advisory Committee (NVSAC) consists of experts who provide advice to the Ministry of Health regarding vaccine safety issues. It consists of Pediatricians, Vaccinology experts, Epidemiologists, Pharmacologist, Physicians, Pharmacists, Pharmacovigilance experts, Infectious disease specialists, Pathologist and others. Selected Serious, Cluster AEFI and Unusual AEFI will further be presented to the National Vaccine Safety Advisory Committee for expert causality assessment. The role of National Vaccine Safety Advisory Committee includes:

- Provide recommendations on vaccine safety
- Advise on potential and/or already identified vaccine safety signals
- Advise on the safety profiles and approaches to safety monitoring of new vaccines not in use in Kenya, of pilot vaccine interventions and of vaccine trials
- Keep authorities and the immunization program updated on the relevant latest scientific developments in vaccines and vaccine preventable diseases
- Conduct causality assessment for Adverse Events Following Immunization

The NVSAC operates as per their terms of reference.

Note: For further information on AEFI, including identification, reporting, management, investigation, and overall response, please refer to the Kenyan Guidelines and SOPs on AEFI (14) (15)

9. POLICIES FOR DIFFERENT VACCINE ANTIGENS

9.1 Tuberculosis Vaccine (BCG)

Tuberculosis (TB) is a contagious disease caused by mycobacterium tuberculosis whose spread is airborne or by droplet transmission. It usually attacks the lungs but can also affect other parts of the body including the bones, joints, skin and brain. Tuberculosis is easily spread through the air. When infectious people cough, sneeze, talk or spit, they expel the bacteria. Just a small amount is enough for transmission. Someone in the world is newly infected with TB every second.

Bacillus Calmette-Guérin (BCG) vaccines continue to be the only vaccine in use for prevention of TB. BCG has demonstrated significant effectiveness; however, protection has not been consistent across all forms in all age groups; Research has shown high protection against pulmonary TB from BCG vaccination of neonates, and moderate protection of school-age TST-negative children. Neonatal vaccination provides 82% protection against pulmonary TB: Vaccination in older TST negative school age children provides 64% protection against pulmonary TB. BCG is 85% effective against the most severe forms of TB, such as TB meningitis. BCG has also shown some effectiveness in preventing leprosy, Buruli ulcer (50% in Africa region) and other non-tuberculosis mycobacterial infections.

About 95% of BCG vaccine recipients experience a reaction at the injection site that heals within 2-5 months leaving a superficial scar, this is considered normal. BCG vaccine can be safely co-administered with other routine childhood vaccines including the hepatitis B birth dose. Disseminated BCG disease may occur between 1.56 and 4.29 cases per million doses and can have an incidence of up to 1% of vaccinated infants and HIV-infected children.

Vaccine Formulation: A live attenuated bacterial vaccine derived from Mycobacterium bovis.

BCG is prepared in multi-dose lyophilized (freeze-dried) containing 20 doses per vial, and also as a liquid formulation of single doses.

Storage: At facility level, BCG vaccines and its matching diluent must be stored in the vaccine refrigerator in the same tray at +2 to +8 degrees centigrade. Once reconstituted, it can be used within six hours and must be discarded at the end of six hours or at the end of the vaccination session, whichever comes first. The vaccine should not be exposed to direct sunlight

Schedules: Routinely BCG should be given at birth or earliest opportunity, up to 59 months of age in order to protect the child before exposure to infection occurs. **Note:** In order to avoid missed opportunities for neonatal vaccination, BCG multi-dose vials should be opened and used despite any wastage of unused vaccine. Any reluctance by health workers to open BCG vials and waste vaccine needs to be addressed.

Dosage: Standard dose of BCG vaccine is an intradermal injection of 0.05 mL of the reconstituted vaccine for infants less than one year old, and 0.1ml for children above 1 year.

Injection site: Upper outer aspect of the left forearm, at the junction of the lower two-thirds and

the upper one-third

Route of administration: Intra-dermal

Booster doses: None

Recommended target group:

- Children under five years. In Kenya BCG is given empirically at birth or at any age up to 59 months.
- Pre-term infants and low birth weight infants (<2kgs.) should receive the BCG vaccine at the time of discharge from hospital irrespective of the current weight.
- If the pre-term or low-birth weight baby was born at home, BCG vaccination should be given at first contact with the health facility just like all babies born at home

MOH position on BCG Re-vaccination

- A single dose should be given to all healthy neonates at birth. If the vaccine cannot be administered at birth, it should be given at the earliest opportunity thereafter. Studies have shown minimal or no evidence of any additional benefit of repeat BCG vaccination against TB or leprosy. Therefore, revaccination is not recommended even if the infant does not develop a scar or tuberculin skin testing (TST) reaction, or the result of an IFN-*gamma*-release assay (IGRA) is negative. **Note:** Scar formation is not a marker for protection and is not an indication for revaccination. Approximately 10% of BCG vaccine recipients do not develop a scar
- Tuberculin skin testing will not be routinely performed on neonates or infants prior to administration of BCG vaccine unless requested by a paediatrician.
- A reactive tuberculin test is a contraindication for BCG vaccination.

MOH Position on vaccination of special groups:

- Neonates with unknown HIV status born to HIV-infected women should be vaccinated if they have no clinical evidence suggestive of HIV infection, regardless of whether the mother is receiving ART
- Neonates with clinical evidence of HIV infection should delay BCG vaccination until ART has been started and are immunologically stable.
- HIV-infected children, who are receiving anti-retroviral therapy (ART), are clinically well and immunologically stable should be vaccinated.

Asymptomatic Neonate Exposed to Maternal TB

- If a neonate is born to a mother with TB or is exposed to a close contact with TB, TB Preventive Therapy (TPT) should be given for 6 months once TB disease has been ruled out. BCG can be given 2 weeks after completion of TPT.

In children with suspected TB infection or disease, the BCG vaccination should be deferred till 2 weeks after completion of TB treatment. Defer BCG vaccination until 2 weeks after completion of TPT/TB treatment of the child because the anti-TB medicines will denature the vaccine. It is not necessary to separate the neonate from the mother. However, the mother should be educated on infection prevention control measures. (*Refer to -Integrated guideline for tuberculosis, leprosy and lung disease 2021)*

Vaccination of older age groups

BCG vaccination of unvaccinated, TST-negative or IGRA-negative school children (up to age 16) is recommended for those coming from or moving to high incidence/burden settings.

9.2 Poliomyelitis Vaccines (OPV and IPV)

Polio is a highly infectious disease caused by a virus. It invades the nervous system and can cause total paralysis in a matter of hours. The virus enters the body through the mouth and multiplies in the intestine. Initial symptoms are fever, fatigue, headache, vomiting, stiffness in the neck and pain in the limbs. One in 200 infections leads to irreversible paralysis (usually in the legs). Among those paralysed, 5% to 10% die when their breathing muscles become immobilized.

About poliomyelitis virus:

There are three strains of the poliovirus: types 1, 2 and 3. Poliovirus is highly infectious. An infected individual will probably infect all other non-immune persons in a household, especially where sanitation is poor. Polio (poliomyelitis) mainly affects children under five years of age

Vaccine Formulations: Live attenuated and killed poliovirus vaccines

1) Live attenuated poliovirus vaccines (two types – both oral preparations produced in vero cells)

a. Monovalent Oral Polio Vaccine – mOPV (mOPV Type 1 or mOPV Type 2 or mOPV Type 3); Currently used only during mass vaccination campaigns for children aged 0 - 59 months in response to outbreaks of specific type as they are more immunogenic alone than when combined with the other two serotypes.

b. Bivalent Oral Polio Vaccine - bOPV . This is used in routine immunization or to respond to an outbreak of either type 1 or 3

2) Inactivated poliovirus vaccine (IPV) –Serotypes 1, 2 & 3

Inactivated poliovirus vaccines are suited for countries which have eradicated the wild poliomyelitis disease and only require a vaccine preparation to sustain their immune status. Considering the increased incidence of vaccine derived poliomyelitis, the use of inactivated poliovirus vaccine is recommended due to its inability to potentiate polio disease. However, all infants receiving IPV in combination vaccines must also receive the three doses of the bivalent OPV as per the EPI schedule.

Route of administration and Dosage: for bOPV, 2 drops administered orally constitute one dose; for IPV administered as an intramuscular injection, right upper outer thigh, 2cm away from PCV site; Hexavalent administered intramuscular

Schedules: A bOPV birth dose (a zero dose) followed by a primary series of 3 bOPV doses at 6, 10 and 14 weeks and at least 1 IPV dose, 14 weeks of age (when maternal antibodies have diminished, and immunogenicity is significantly higher). A second dose IPV, IPV2, is under consideration for introduction. For infants starting the schedule late (age >3 months) the IPV1 dose should be administered at the first immunization contact along with bOPV and the other routine vaccines.

Booster doses: No routine booster doses are given above 14 weeks of age, however

supplementary doses are given during mass vaccination campaigns using an appropriate mono, bivalent or Inactivated poliovirus vaccines

Polio vaccine in SIAs: Given as a single dose (two drops) orally during mass vaccination exercises to children aged 0-59 months irrespective of their previous immunization status.

NB:

- All infants receiving IPV in combination vaccines (eg. Hexavalent) MUST also receive the three doses of the bivalent OPV as per the Kenya routine immunization schedule.
- Polio vaccine (IPV or bOPV) may be administered safely to asymptomatic HIV-infected infants. HIV testing is not a prerequisite for vaccination.
- bOPV is contraindicated in severely immunocompromised patients. These children can safely receive IPV.

9.3 Diphtheria Vaccine

Diphtheria is a life-threatening bacterial infection caused by Corynebacterium diphtheriae, transmitted from person to person through close physical and respiratory contact. It is an illness characterized by laryngitis, pharyngitis or tonsillitis and a pathognomonic adherent membrane of the tonsils and pharynx. The only known host is man. Although the causative organism is *Corynebacterium diphtheria*, the disease results from the toxin produced by this organism. Diphtheria has not been reported in Kenya for over 20 years. Primary prevention of disease is by ensuring high population immunity through immunization.

Vaccine: Used in routine infant vaccination schedule as a combination vaccine containing diphtheria toxoid- DPT. DTP may be combined with additional vaccine antigens, such as hepatitis B surface antigen (HBsAg) and Haemophilus influenzae type b (Hib) conjugates as pentavalent vaccines (used in Kenya routine immunization schedule), and with inactivated polio vaccine (IPV) as hexavalent vaccines. DPT formulation is no longer used in routine vaccination in Kenya. However, DPT has a role in the management of outbreaks of pertussis and diphtheria.

Schedule: The infant schedule for diphtheria toxoid containing vaccine is at 6, 10 & 14 weeks of age. Diphtheria toxoid-containing vaccines can be used in immunocompromised persons including HIV-infected individuals. Tetanus-diphtheria (Td, low-dose diphtheria toxoid) formulations or tetanus-diphtheria-acellular pertussis (Tdap) should be administered for unvaccinated children who are above 5 years of age.

9.4 Pertussis Vaccine

Pertussis is a life-threatening disease of childhood caused by the bacterium Bordetella pertussis. Pertussis, also called whooping cough, is a highly contagious, acute bacterial disease affecting the respiratory tract. Pertussis presents as protracted fits of coughing lasting at least two weeks. The mode of transmission is droplets from the nose and throat that are expelled when an infected person coughs or sneezes. Although Pertussis may occur at any age, most cases of serious disease and most fatalities are observed in early infancy.

Vaccines are the most rational approach to Pertussis control. There are two types of pertussis vaccines: whole-cell (wP) vaccines containing killed Bordetella pertussis organisms, and acellular (aP) vaccines containing one or more highly purified individual pertussis antigens. Both vaccine preparations have been found to have an excellent safety profile, with wP having a slightly higher incidence of minor reactogenic adverse events such as local reactions. Compared to wP, due to rapid waning of immunity after the first year of life, aP formulations may have a reduced impact on transmission, risking disease resurgence and necessitating boosters. Pertussis vaccines are usually combined formulations (with other antigens), there is no stand-alone pertussis vaccine.

Prevention of pertussis in Kenya is through routine vaccination of all infants less than 1 year of age with three doses of DPT-HepB-Hib vaccine, which contains preferably inactivated (killed) whole-cell pertussis.

Schedule: The infant schedule for pertussis containing vaccine is at 6, 10 & 14 weeks of age. Pertussis containing vaccines can be used in immunocompromised persons including HIV-infected individuals.

9.5 Tetanus Vaccine

Tetanus, also known as lockjaw, is caused by a bacillus Clostridium tetani that is present in the soil, in animal and human faeces. After entering the body through a wound, the bacterium produces a neurotoxin that causes spasms of all skeletal muscles making breathing and feeding difficult or impossible. Tetanus disease results in death if specialized care is not available. Neonatal tetanus affects new-born babies and results from contamination with tetanus spores that occurs when babies are delivered in unclean conditions. Tetanus is the only vaccine-preventable disease that is not spread from person to person. Vaccination with five appropriately spaced doses of adsorbed tetanus toxoid is known to provide immunity against tetanus for up to 20 years for all recipients. This is also known as the 5-Td. Schedule. At the age of 6 weeks the infant should receive tetanus toxoid vaccination in combination vaccines as per the EPI schedule so as to stimulate its own antibody formation.

Primary Tetanus Vaccination: Offered in Kenya through routine vaccination of all infants less than 1 year of age with three doses of combination vaccine DPT-HepB-Hib vaccine. The infant schedule for Tetanus containing the vaccine is at 6, 10 & 14 weeks of age.

Pregnant women: Pregnant women and their new-borns can be protected from neonatal tetanus during the first 6 weeks of life through vaccination of pregnant women using the 5-Td. Schedule and clean deliveries.

Opportunistic catch-up for adolescents: Could include the delivery of Td with other vaccination campaigns such as HPV vaccination for adolescent girls, during voluntary medical male circumcision services for adolescent and adult males, following trauma or as an occupational requirement.

9.5.1 5-Td. Schedule for Pregnancy

GRAVIDA	Tetanus toxoid vaccination schedule	Expected maternal outcome	Expected outcome for neonate
First pregnancy	**1st Td dose** *(given from the fourth to sixth month i.e. 2nd trimester)* **2nd Td dose** given one month after the 1st dose *(between the fifth & eighth month)*	Works as an immunological primer but does not confer protection against maternal tetanus at delivery. Confers protection from maternal tetanus at delivery & for about 1 – 3 years from tetanus in general *however approx. 10% may respond poorly to 2nd dose*	No protection from tetanus at birth! Confers protection at birth **(PAB) for >90% of neonates due to** adequate titres of maternal antibodies
Second pregnancy	**3rd Td dose** *(given anytime between the forth & eighth months)*	Immunity boosted for 5 years	PAB≈100% from neonatal tetanus
Third Pregnancy	**4th Td dose** *(given anytime between the fourth & eighth month)*	Immunity boosted for 10 years	PAB for neonate
Fourth pregnancy	**5th Td & <u>last</u> dose** *(given anytime between the fourth & eighth month)*	Immunity boosted for 20 years	PAB for neonate
Subsequent pregnancies	No more Td doses	Immunity adequate for rest of parous life	Adequate. PAB for neonate

Table 5: 5-Td. schedule for pregnancy

9.5.2 5-Td. Schedule for Trauma & Occupational Prophylaxis

	Administration schedule	Duration of immunity conferred
1st T.d. dose	At first contact (or at least within seven days of the injury)	<u>Nil</u> - it primes the immune system (anti-tetanus serum may be added)
2nd T.d. dose	One month after 1st T.d.	1 - 3 years protection
3rd T.d. dose	Six months after 2nd T.d.	5 years protection
4th T.d. dose	One year after 3rd T.d.	10 years protection
5th T.d. dose	One year after 4th T.d.	20 years protection

Table 6: 5-Td. schedule for trauma & occupational prophylaxis

9.6 Hepatitis B Vaccine

Hepatitis B infection: Hepatitis B is a viral infection of the liver caused by the Hepatitis B virus. It is an acute illness typically including acute jaundice, dark urine, anorexia, malaise, extreme fatigue, and right upper quadrant tenderness. (None of these symptoms is common in infants and young children). If not fatal, the acute infection either resolves or progresses to chronic infection, which may lead to liver cirrhosis or liver cancer several decades later. When it resolves, patients develop lifelong immunity.

Vaccine Formulation: Hepatitis B vaccines are available as monovalent formulations and in combination with other vaccines (DPT-HepB-Hib vaccine).

Schedule: The infant schedule for Hep. B containing vaccine is at 6, 10 & 14 weeks of age.

A monovalent hepatitis B vaccine can be given as a birth dose, ideally within 24 hours (Not yet introduced in the National Schedule), followed by the above primary series. All infants of HBsAg positive mothers to receive appropriate HBIG + monovalent hepatitis B vaccination at birth (within 24 hours). A birth dose of hepatitis B vaccine can be given to low birth weight and premature infants.

Hepatitis B vaccination for adults

Monovalent Hep B vaccine is recommended for the prevention of hepatitis B in health workers and other risk groups in three scheduled doses administered at 0,1 and 6 months. The risk groups may include patients who frequently require blood or blood products, dialysis patients, diabetes patients, recipients of solid organ transplantation, persons with chronic liver disease including those with hepatitis C, persons with HIV infection, persons interned in prisons, persons who use injecting drugs, household and sexual contacts of persons with chronic HBV infection, men who have sex with men, persons with multiple sexual partners A 0.5 ml dose of Hepatitis B vaccine is injected intramuscularly, usually into the upper arm deltoid muscle.

Note: Hepatitis B vaccine dose for adults above 20 years is 1.0 ml/dose (20 micrograms per dose)

Hepatitis B vaccine should never be frozen as freezing reduces its efficacy.

9.7 Haemophilus Influenza Type B Vaccine

The bacterium Haemophilus influenza type b (Hib) causes pneumonia predominantly but may go on to cause invasive disease resulting in bacteraemia and meningitis which are often fatal in Kenya. Where death does not occur following invasive Hib disease recovery is often accompanied by some neurological disability. Although Hib disease affects all age groups it is most severe in children less than 5 years of age. Bacterial meningitis is characterized by acute onset of fever, headache, and stiff neck. Meningitis is not specific for Hib disease, and Hib disease cannot be diagnosed on clinical grounds. Confirmation is through isolation of Hib from a cerebrospinal fluid (CSF) or blood.

Schedule: The infant schedule for Hib containing vaccine is at 6, 10 & 14 weeks of age

Common Issues On The Penta Valent Vaccine (Diphtheria, Pertussis, Tetanus, Hepatitis B, Haemophilus Influenzae Type B)

For infants the Ministry of Health recommends combination vaccines to address the above diseases because of the following:

- Safe and efficacious combination vaccines are available
- All the current vaccine formulations against these diseases are for parenteral administration and therefore a combination vaccine reduces the number of injections given
- Reduced number of injections encourages compliance to the vaccination schedule

Dosage: The standard paediatric dose of combination five component vaccine is 0.5ml given intramuscularly, into the antero-lateral aspect of the left thigh. The infant vaccination schedule is single 0.5ml doses given at 6, 10 and 14 weeks of age.

Storage Temperature: all combination vaccines should be stored at between +2°C to +8°C at all times and should never be frozen.

Contraindications: Hepatitis B vaccine in a combination preparation with diphtheria, tetanus, pertussis and Hib should never be given at birth. Monovalent Hep B is the only Hep B vaccine that can be used at birth. For unvaccinated children >5years, combinations with low dose diphtheria & acellular pertussis should be used (TdaP & Td)

9.8 Measles Vaccine

Measles is an exanthematous disease caused by a virus of the genus morbilivirus in the paramyxoviridae family. It is an acute and highly infectious illness transmitted through the respiratory droplets or contact with nasal and throat secretions of the infected person.

The first sign of infection is usually high fever which begins approximately 10 to 12 days after exposure and lasts one to seven days. During the initial stage, the patient may develop coryza (runny nose), cough, red and watery eyes and small white spots inside the cheeks known as Koplik spots. After 4-7 days, a rash develops, usually on the face and upper neck. Over a period of about three days, the rash proceeds downward, eventually reaching the hands and feet. The rash lasts for five to six days, and then fades. The rash occurs, on average, on day 14 after exposure to the virus, with a range of seven to 18 days.

Measles is often an unpleasant mild or moderately severe illness. Severe measles is particularly likely in malnourished young children, especially those with vitamin A deficiency, or whose immune systems have been weakened by HIV/AIDS or other diseases.

Children usually do not die directly of measles, but from its complications. Complications are more common in children under the age of five years or adults over the age of 20 years.

Since 2002, the Ministry of Public Health has been committed to the control of measles disease using the following strategies:

- Provision of first dose of the measles containing vaccines to all infants at 9 months.
- Introduction of a second dose of measles containing vaccine into the routine immunization schedule for children aged 18 months.
- Ensuring that all children get a second opportunity for measles vaccination through periodic mass campaigns.
- Enhancing measles surveillance through integration of laboratory confirmation and epidemiological linkage to outbreaks.
- Improving on measles case management for every case, Vitamin A supplementation and appropriate supportive management

Treatment: Measles is a viral infection hence no specific treatment is available; management is purely supportive specially to prevent complications. Measles vaccines are recommended for all susceptible children and adults for whom measles vaccination is not contraindicated.

Vaccine Preparations: The measles vaccine is a live hyper-attenuated preparation derived from the Edmonston strain of the measles virus cultured on human diploid cells. It is then lyophilized. Measles vaccine is available in a monovalent formulation or in combination with rubella vaccine and with or without mumps vaccine formulation (MR and MMR).

Dosage and routes of administration: The combination MR vaccine is given as a dose of 0.5ml, deep subcutaneous injection (or as per the manufacturer instructions) over the deltoid muscle of the right upper arm of the child.

Schedule: The infant schedule for MR vaccine is at 9 and 18 Months of age. The vaccine is administered at 9 months of age in the Kenya routine immunization schedule for infants primarily because measles occurs frequently in infants less than one year of age and this is the earliest age at which an acceptable sero-conversion rate of 85% is achieved.

Note: Measles Rubella vaccine is given at 6 months in the event of a measles outbreak or to HIV Exposed Infants

Contraindications: *Measles Containing Vaccines (*MCVs) should not be given to individuals with a history of anaphylactic reactions or severe allergic reactions to any component of the vaccine (e.g. neomycin or gelatin) or those with any form of severe immunosuppression. Please note that HIV infection is an indication (rather than contraindication) for measles vaccination in Kenya as the risk of severe measles disease is worse than the risk of vaccine derived measles in HIV exposed or infected infants. In situations where displaced people are moving en masse internally or across our national borders, all children aged between 6 months and 12 years should be vaccinated against measles – regardless of previous vaccination status.

9.9 Rubella Vaccine

Commonly known as German measles, it is caused by the rubella virus, genus Rubivirus under the Togaviridae family. It is an infection that primarily affects skin and lymph nodes. Infected pregnant women can pass the virus to the unborn child through the placenta. When a woman is infected with rubella virus early in pregnancy, she has a 90% chance of passing the virus on to the fetus leading to the death of the fetus or may cause congenital rubella syndrome (CRS).

Infants with CRS can transmit the virus for a year or more. CRS is characterized by multiple birth defects particularly of the heart, brain, eyes and ears.

***Signs and symptoms**:* Rubella commonly presents with a rash (pink and fainter than measles), low fever and swollen lymph nodes in the neck. *Incubation period:* 14 – 21 days

***Treatment**:* no specific treatment, mainly supportive.

Prevention: The primary purpose of rubella vaccination is to prevent the occurrence of CRS. Two approaches are usually recommended, one is prevention of CRS only through immunization of adolescent girls and or women of childbearing age. The second, is elimination of rubella as well as CRS through universal vaccination of infants and young children (with or without mass campaigns) together with surveillance and assuring immunity of women of childbearing age (WCBA). The primary purpose of rubella vaccination is to prevent the occurrence of Congenital Rubella Syndrome (CRS).

Introduction of rubella vaccine nationally into childhood immunization program implies a long-term commitment to achieving and maintaining sufficient immunization coverage to ensure sustained population immunity and thereby avoid a paradoxical epidemiological effect.

Vaccine Preparations: The vaccine is available in combination with measles as MR and with measles and mumps as MMR, in a freeze-dried preparation which contains live attenuated Wistar RA 27/3 strain of the rubella virus cultured through human diploid cells.

Schedule: The infant schedule for rubella containing vaccine is at 9 and 18 Months of age.

9.10 Mumps Vaccine

Mumps is a virus infection caused by a paramyxovirus of the genus Rubulavirus. Mumps typically cause enlargement of the two parotid glands at the angle of the jaw anterior to the ear on both sides of the face. Mumps is extremely rare in infants less than one year of age. Infection usually confers immunity. Human beings are the only known host.

Treatment: No specific treatment, only supportive management.

Mumps vaccine is available in a combination formulation with measles and rubella vaccines as MMR.

Vaccine preparation: A live attenuated Urabe AM9 virus strain, cultured in embryonated chicken eggs is licensed in Kenya, in a freeze-dried presentation with diluent.

Schedule: The infant schedule for mumps containing vaccine is at 9 and 18 Months of age.

Storage: Both monovalent measles, MR and the MMR vaccine should be stored between +2°C and +8°C at immunizing facilities and -25°C and -15°C Vaccines Depots/Stores. Reconstituted multi-dose measles vaccine should be discarded at the end of 6 hours or end of the immunization session, whichever comes first. During outbreaks of measles, MR Vaccines may be administered to infants as young as 6 months. Because of the possibility of lower levels of seroconversion, the dose administered at 6 months should not be counted as a valid first dose, and the child should be vaccinated with subsequent dose(s) of MR according to the national immunization schedule. MR should not be given to anyone who has experienced a severe

allergic reaction after a previous MR vaccine dose or vaccine component. It is recommended not to provide the vaccine to those with active TB or severe immunodeficiency (including individuals with symptomatic HIV infection, AIDS, congenital immune disorders, malignancies, or aggressive immunosuppressive therapy).

Note: In the event of a measles outbreak, the age of the primary dose of monovalent measles vaccine may be lowered to 6 months but parents/guardians are reminded to return for the normal vaccine dose at 9 months.

9.11 Yellow Fever Vaccine

Yellow Fever is a mosquito borne viral haemorrhagic fever transmitted to unvaccinated persons from infected persons by mosquitoes of the Aedes Species. Yellow fever is caused by an arbovirus of the family Flaviviridae, which currently contains over 70 viruses including dengue viruses.

Treatment and management: There is no specific anti-viral drug therapy for yellow fever and management of patients is through standard supportive therapy. Yellow fever vaccine Is derived from chick embryo propagation of strain 17D. The vaccine induces adequate antibody response within 6 days of administration. A single dose of YF vaccine is sufficient to confer sustained life-long protective immunity against YF disease. A booster dose is not necessary.

Schedule: Administered routinely at 9 months in high-risk counties (currently-Baringo, Elgeyo Marakwet, West Pokot and Turkana). Yellow Fever Vaccine is given at the same sitting with measles-rubella vaccine but in the left deltoid muscle.

Dosage: A single dose of 0.5 ml is administered intramuscularly into the left upper arm (deltoid).

Booster doses: Not recommended.

Contra indications: Yellow Fever vaccine should not be administered to symptomatic HIV infected children since the vaccine is live attenuated. The vaccine is contraindicated in children less than 6 months, also in individuals with severe allergy to eggs and those who have a thymus disorder.

Yellow fever vaccine for travellers: Due to historical occurrence of yellow fever in Kenya (last outbreak in 1992 in four districts – Baringo, Keiyo, Koibatek and Marakwet) and the existence of both the vector (Aedes aegypti mosquito) and the primary host (monkeys), the country continues to be classified internationally as a high-risk country for yellow fever transmission. This obligates all travellers leaving the country to show proof of vaccination against yellow fever. In conformity with section 32 of the Public Health Act Cap 242 of the Laws of Kenya, all travellers departing the country must have a valid certificate against yellow fever. A valid certificate refers to the evidence that the vaccination against yellow fever was done at least ten days prior to the day of departure. A single dose confers life-long immunity

Outbreak Response

If a case of Yellow Fever is suspected, the Ministry of Health must be notified immediately for the required investigative action. Response to a confirmed outbreak of yellow fever disease will be through a mass vaccination campaign whose scale and duration will be determined by the Ministry of Health.

Vaccination of Pregnant women: A risk-benefit assessment should be undertaken for all pregnant and lactating women noting that:

- In YF endemic areas, or during outbreaks, the benefits of YF vaccination are likely to far outweigh the risk of potential transmission of vaccine virus to the foetus or infant.
- Pregnant women and nursing mothers should be counselled on the potential benefits and risks of vaccination, noting that the benefits of breastfeeding far outweigh alternatives.
- Vaccination is recommended, if indicated, for pregnant or breastfeeding women travelling to endemic areas when such travel cannot be avoided or postponed.

Precautions: *Individuals aged over 60 years:* the overall risk of adverse effects is slightly higher in primary vaccinees ≥60 years of age. A risk benefit assessment should be performed, taking into consideration the following:

- the risk of acquiring YF disease (e.g., location, season, duration of exposure, occupational and recreational activities, and local rate of virus transmission in the potential area of exposure)
- the risk of a potential adverse event following immunization (e.g., age, underlying medical conditions, medications being taken).

Co-administration with other vaccines: YF vaccine may be administered simultaneously with other vaccines (including measles vaccine). Oral polio vaccine may be given at any time in relation to YF vaccination.

Fractional Doses of Yellow Fever Vaccine

A fractional YF vaccine dose can be used as part of an emergency response to an outbreak if there is a shortage of full-dose YF vaccine that exceeds the capacity of the stockpile. This is not intended to serve as a longer-term strategy or to replace established routine immunization practices. As soon as the YF vaccine supply situation can meet the immediate need, the use of Fractional YF vaccination should be replaced by standard full-dose YF vaccination.

Fractional YF vaccination does not meet YF vaccination requirements under the International Health Regulations (IHR), and proof of vaccination for international travel currently requires re-vaccination with a standard full dose. The minimum dose administered should preferentially contain 3000 IU/dose, but no less than 1000 IU/dose; and the minimum volume of the dose should not be less than 0.1 mL because of the practical difficulties of delivering dose volumes smaller than this. Children under 2 years of age should be given a full dose.

9.12 Pneumococcal Vaccine

Pneumococcal disease is caused by the bacterium *Streptococcus pneumoniae* (pneumococcus), which has more than 91 known serotypes. The major clinical syndromes include life-threatening infections such as pneumonia, meningitis and bacteremia.

Pneumococcus is the most identified cause of community-acquired pneumonia. It is also a major cause of milder but more common illnesses, such as sinusitis and otitis media. *S. pneumoniae* is transmitted directly from person to person through close contact via respiratory droplets. The organism frequently colonizes the nasopharynx of healthy people, particularly young children,

without causing illness.

Streptococcal pneumoniae causes primarily a lower respiratory infection – pneumonia, but in a small proportion of those affected it extends (invasive disease) to the blood and other parts of the body causing life threatening septicemia, meningitis and otitis media. Children less than two years of age are the most susceptible to invasive pneumococcal disease which has high mortality and disability in developing countries. The following types of pneumococcal vaccine are currently available and licensed in the Kenya market:

- Conjugate vaccines 10 & 13 valent
- A 23-valent polysaccharide vaccine suitable for children above two years of age and for the elderly.

If a series cannot be completed with the same type of vaccine, either 10 & 13, the available PCV product should be used. Restarting a series is not recommended, even for the primary series.

Dosage and route of administration: 0.5mls of vaccine injected intramuscularly into the anterior upper, outer aspects of the right thigh

Schedule: The Pneumococcal vaccine is administered in three doses given at 6, 10 and 14 weeks of age.

High risk groups: Appropriate pneumococcal conjugate vaccines should be administered to all high-risk clients which includes patients with sickle cell disease, damaged spleen, diabetics and patients on chemotherapy, steroid treatment, HIV infected and the elderly (>60 years).

9.13 Rotavirus Vaccine

Rotaviruses are a genus of viruses belonging to the Reoviridae family.

Signs and Symptoms: Fever, nausea, vomiting, which are often followed by abdominal cramps and frequent, watery diarrhoea.

Treatment: no specific treatment exists so the mainstay of management is supportive by fluid replacement using low osmolarity ORS

Rotavirus vaccinations can be administered simultaneously with other routine infant vaccines.

Vaccine Formulation: is a live, attenuated vaccine. Several formulations are approved by WHO i.e. Rotarix, Rotavac 5D, Rotavac , RotaSil and RotaTeq

Dosage: Vaccination course for the monovalent vaccine consists of three doses,

Schedules: Rota Vaccine is given at 6,10 and 14 weeks; except Rotarix which is given at 6 and 10 weeks. The interval between doses should not be less than 4 weeks.

Storage: At facility level, Rota vaccines must be stored in the vaccine refrigerator at 2 to 8 degrees centigrade, and must be discarded at the end of six hours or at the end of the vaccination session, whichever comes first.

Route of administration: Oral

Booster doses: None

Recommended target group: Children under 1 year.

Precautions: A history of intussusception or intestinal malformations, chronic gastrointestinal disease, and severe acute illness. Vaccination should be postponed when the child has ongoing acute severe gastroenteritis.

In several high- and middle-income countries, a low risk of 1–6 excess cases of intussusception per 100 000 vaccinated infants has been documented for Rotarix® and Rotateq® vaccine. Studies in sub-saharan Africa have not demonstrated this risk, however monitoring is recommended, particularly when new rotavirus vaccines are introduced. The risk of intussusception has not been demonstrated with the Rotavac® vaccine.

Contraindications: The current rotavirus vaccines are safe and well tolerated. Main contraindications for rotavirus vaccination are severe allergic reaction after a previous dose and severe immunodeficiency.

9.14 Human Papillomavirus (HPV) Vaccine

HPV is a double stranded DNA virus that has long been known to be the causative agent for genital warts and has recently been determined to be responsible for cervical cancers. Cervical Cancer: This is cancer of the uterine cervix with 90% of the cancers being squamous cell in origin.

Persistent infection of the cervix with HPV is the primary cause of cervical cancer.

Risk factors of cervical cancer: HPV infection is contracted mainly through sexual behavior which includes multiple sexual partners, new partners, partner sex history and age of onset of sexual intercourse.

There are over 100 types of HPV with types 16 and 18 accounting for 70% of cervical cancers and the remaining being caused by types 31 and 33.

Prevention:

- Responsible sexual behavior, including abstinence and use of condoms
- Vaccination
- Cervical cancer screening as per current screening guidelines

Vaccination against Human Papilloma Virus disease should be done before the onset of sexual activity for optimal protection but can be used in sexually active groups to prevent multiple or persistent infections. Three prophylactic HPV vaccines, directed against high-risk HPV types, are currently available: the quadrivalent vaccine, the bivalent vaccine and the nonavalent vaccine.

The bivalent vaccine contains non-infectious protein antigens for HPV 16 and 18, the quadrivalent against non-infectious protein antigens for HPV 6, 11, 16, and 18 and the nonavalent, non-infectious protein antigens for HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58.

The quadrivalent and nonavalent vaccines offer comparable immunogenicity, efficacy and effectiveness for the prevention of cervical cancer, which is mainly caused by HPV types 16 and 18.

Target population: The recommended primary target population for HPV vaccination is girls aged 9–14 years, prior to becoming sexually active.

Administration and dosage: Administered in Kenya as a 2-dose schedule, 0.5 mls intramuscularly in the left deltoid, 6 months apart (0, 6 Months) to 10-year-old girls. During a period of

acceleration, a catch-up campaign will target girls aged 10-14. HIV infected/immunocompromised should receive a 3-dose schedule (0, 1–2, 6 months). HPV vaccine can be co-administered with other non-live and live vaccines. Efforts should be made to administer the same vaccine for all doses. However, if the vaccine used for prior dose(s) is unknown or unavailable, either of the HPV vaccines can be administered to complete the recommended schedule.

Storage: The vaccine should be stored at a temperature of between +2°C and +8°C.

Vaccination of special groups: HPV vaccine can be administered safely to immunocompromised and/or HIV-infected individuals. HPV vaccination of pregnant women should be avoided due to lack of data, although no adverse effects in mother or offspring have been observed. If a young female becomes pregnant after initiating the vaccination series, the remaining dose(s) should be delayed until after the pregnancy is completed. Breastfeeding is not a contraindication for HPV Vaccination.

9.15 Malaria Vaccine

Malaria is a life-threatening illness caused by a parasite, *Plasmodium*, transmitted through the bite of an infected female anopheles mosquito *Plasmodium falciparum* is the commonest species of the parasite. In our setting Children are at high risk of malaria illness and death. An estimated 1.7 billion cases of malaria and 10.6 million deaths have been averted over the past 20 years as a result of the scaling up of malaria control interventions.

Natural immunity to malaria is acquired gradually with repeated exposure to Plasmodium infection. Immunity is acquired more rapidly against the more severe forms of the disease. Hence, with increasing age, there is progressive protection first against severe malaria and ensuing mortality, then against uncomplicated malaria and, much more slowly, asymptomatic parasitemia. Naturally acquired immunity is believed to wane substantially in people who migrate out of a malaria-endemic region and are no longer regularly exposed to malaria infection for a number of years.

The RTS,S/AS01 vaccine is the first and currently the only malaria vaccine to be recommended for use by WHO. The RTS,S/AS01 malaria vaccine should be used for the prevention of P. falciparum malaria in children living in regions with moderate to high malaria transmission, as defined by WHO.

Vaccine characteristics, content, dosage, administration and storage: RTS,S/AS01 is a pre-erythrocytic recombinant protein vaccine, based on the RTS,S recombinant antigen. The RTS,S antigen is lyophilized and needs to be reconstituted with the liquid AS01 adjuvant system prior to administration. The vaccine is currently produced as a 2-dose RTS,S powder to be reconstituted with a 2-dose AS01 adjuvant system suspension. After reconstitution the total volume is 1 ml (2 doses of 0.5 ml). No preservative is included in either the RTS,S formulation or the AS01 adjuvant system. The vials should therefore be discarded at the end of the vaccination session, or 6 hours after opening, whichever comes first.

The reconstituted vaccine should be administered by injection into the left deltoid muscle in children at 6,7,9 and 24 months of age. The RTS,S/AS01 vaccine may be used seasonally,

with a 5-dose strategy in areas with highly seasonal malaria or areas with perennial malaria transmission with seasonal peaks. This strategy leverages the period of highest vaccine efficacy, just after vaccination, against the period of highest malaria transmission, to maximize impact.

The vaccine should be stored at 2–8 °C. The shelf life of the RTS,S/AS01 vaccine is 3 years. A vaccine vial monitor is on the AS01 vial.

Contraindications: The only contraindication to use of RTS,S/AS01 vaccine is severe hypersensitivity to any of the vaccine components.

Co-administration: The vaccine can be co-administered with other routine vaccines.

Vaccine safety: The RTS,S/AS01 vaccine is safe and well tolerated. There is a small risk of febrile seizures within 7 days (mainly within 2–3 days) of vaccination.

Vaccination of special populations: Malnourished or HIV-positive infants should be vaccinated with the RTS,S/AS01 vaccine using a standard schedule. These children are at particular risk from malaria infection and the vaccine has been shown to be safe in these groups.

9.16 COVID-19 Vaccines

Covid-19 is the disease caused by Severe Acute Respiratory Syndrome coronavirus 2 (SARS COV 2) –the novel coronavirus (nCov) coronavirus (nCov)

The most common symptoms are cough, sore throat or malaise. Other symptoms: fevers, aches and pains, nasal congestion, headache, conjunctivitis, diarrhea, loss of smell or taste, discoloration of fingers and nails.

On exacerbation, there may be shortness of breath and general compromise of the breathing system, and or the other body systems.

Most people who get infected show very mild or no symptoms. But a few deteriorate leading to severe disease.

Disease severity

- 80% of those with symptoms recover without needing hospitalization
- Some of the severe cases become severe which may lead to death if the couse is not averted, especially in high-risk persons (older persons, and those with underlying medical conditions like diabetes, hypertension, lung and heart diseases, and cancers).

COVID19 Infection Prevention measures include: Hand hygiene, Cough etiquette, Social and physical distancing, Use of PPE in different setting including face masks, and Vaccination.
As of January 2022, the following vaccines had been evaluated and met the WHO criteria for safety and efficacy, and approved for emergency use listing:

- AstraZeneca/Oxford vaccine
- Johnson and Johnson
- Moderna
- Pfizer/BioNTech
- Sinopharm
- Sinovac

- COVAXIN
- Covovax
- Nuvaxovid

In Kenya COVID-19 vaccines deployed for use, some under emergency use authorisation, by the Pharmacy and Poisons Board include mRNA vaccines (Pfizer & Moderna), Viral Vectored vaccines (AstraZeneca and Janssen and Janssen) and Inactivated vaccines (Sinopharm).

NB// Kenya is working to integrate COVID-19 Vaccination into Routine Immunization, Primary Health Care and other care points. Please refer to integration plan/guidelines for further details. For additional information on COVID-19 and the related vaccines, please refer to current COVID-19 specific guidelines.

9.17 Influenza Vaccines

Various strains of influenza viruses have been identified in Kenya, some of which match existing vaccines in the market. Influenza virus types A and B are both common causes of acute respiratory illnesses. Although both virus types may cause epidemics of considerable morbidity and mortality, influenza B infections are often limited to localized outbreaks whereas influenza A viruses are the principal cause of larger epidemics including worldwide pandemics. In tropical regions, the virus may cause disease throughout the year, although often displaying a biannual pattern. Influenza C virus is common but rarely causes severe disease in humans.

Population at risk: Rates of infection are highest in children, but severe morbidity and mortality from the disease are more common among the elderly and in specific high-risk groups. Antigenic shift of influenza virus: Minor changes on the viral capsule causes minor strains leading to annual epidemics, while major changes lead to major pandemics every 30 – 40 years.

Prevention: This is through vaccination. In elderly and individuals at risk, the aim of vaccination is to reduce mortality while in children, the aim is to reduce morbidity. In elderly and individuals at risk, the aim of vaccination is to reduce mortality while in children, the aim is to reduce morbidity. Seasonal influenza vaccines include two influenza A-strains and one influenza B strain. The composition of the influenza vaccines is updated annually by WHO from information gathered by the Global Influenza Surveillance and Response System (GISRS)

Types of vaccines: There are two types:

- inactivated influenza vaccines (IIV)
- live attenuated influenza vaccines (LAIV)

Both IIV and LAIV are usually designed to protect against 3 different seasonal influenza viruses

Route of administration:

Influenza vaccines are administered either intramuscularly (IIV) or intranasally (LAIV) .

Target groups: Children <1yr of age; Elderly persons, above 65 years; Elderly non-institutionalized individuals suffering from chronic conditions such as pulmonary or cardiovascular illness, metabolic diseases including diabetes mellitus and renal dysfunction,

and various types of immune-suppression including persons with AIDS and transplant recipients; All adults and children aged over six months suffering from any of the conditions mentioned above; Health care workers in regular, frequent contact with high-risk persons; Household contacts of high-risk persons; Pregnant women Influenza vaccination is recommended every year, particularly for high risk groups. In pandemics, all individuals should have the opportunity for immunization, with prioritization for children < 5 years and elderly >65 years.

IIV can be used in people aged 6 months and older. One dose is recommended but children aged 6 months to 8 years who have not received seasonal influenza vaccine during the previous influenza season should receive 2 doses administered at least 4 weeks apart. LAIV should be used only in persons aged 2–49 years who do not have underlying medical conditions. Do not administer LAIV to pregnant women. LAIV is given as a nasal spray, 1 dose only; but children aged 2–8 years who have not received seasonal influenza vaccine during the previous influenza season should receive 2 doses, at least 4 weeks apart.

Occasionally, animal influenza strains may infect humans and cause serious illness, such as the Avian flu virus. In such situations, international measures of outbreak control should be observed. (Refer to the IDSR guidelines).

Other special influenza vaccines: When need arises, special influenza vaccines are made available in response to emergence of newer viruses of combination of existing viruses. Some of these viruses include avian influenza (H5N1) and H1N1 viruses. Guidelines on the use of these vaccines will be provided by the Ministry of Health as necessary.

9.18 Hepatitis A Vaccine

Hepatitis A is an acute, usually self-limiting disease of the liver caused by Hepatitis A virus (HAV). Severe and with fatal outcomes are more prevalent in older age groups rather than children. HAV belongs to the picornaviridae family in the heptovirus genus. There is only one serotype for HAV which induces protective antibodies against all other viral strains. The virus is highly stable to physical and chemical agents and retains its infectivity for prolonged periods in the environment, water and food. Humans and primates are the natural hosts for HAV although each is affected by different strains.

Treatment: No specific antiviral therapy is currently available, and management remains largely supportive with use of vitamins and reduction of stress to the liver function.

Prevention: Several inactivated or live attenuated vaccines against hepatitis A have been developed, but only four inactivated hepatitis A vaccines are currently available internationally. All four vaccines are similar in terms of efficacy and side-effect profile. The vaccines are given parenterally, in two-dose regimens, 6-18 months apart.

Two types of hepatitis A vaccines are currently used worldwide: (a) inactivated vaccines and (b) live attenuated vaccines.

Contra-indications: severe allergic reactions e.g., anaphylaxis during previous vaccine dose or to a vaccine component.

Precautions: Vaccination in the circumstances below are to be determined by a physician

- Pregnancy

- Patients with liver disease
- Moderate or severe illness with or without fever

a) Inactivated hepatitis A vaccines, alone or in fixed combinations, are widely used internationally. These vaccines are licensed for use in persons ≥12 months of age and the manufacturers recommend a 2-dose schedule with 6–12 months interval, however the interval between doses is flexible and can be extended up to 18-36 months interval between the 2 doses. The vaccine is delivered intramuscularly. Inactivated hepatitis A vaccines are interchangeable and can be administered simultaneously with any other routinely used vaccine. High vaccine efficacy can be achieved also with one single dose of inactivated hepatitis A.

b) Live attenuated hepatitis A vaccines are largely available China and administered as a single subcutaneous dose. However, live attenuated vaccines are not recommended for use in pregnant women and in severely immunocompromised patients.

Target population: Because hepatitis A disease is most severe and with fatal outcomes in older age groups rather than children, vaccination in Kenya against this disease is most appropriate in adults exposed to the highest risk of infection. These are all health workers but especially laboratory workers. Workers at sewage treatment works in urban councils should also be administered the hepatitis A vaccine. To control community-wide outbreaks, a single dose regimen of hepatitis A vaccine is used early in the outbreak, targeting high coverage of multiple age-cohorts.

Route of administration: Administered as an intramuscular injection in a 2-dose schedule, 6 months apart, while live attenuated hepatitis A vaccine is administered as a single dose. As a rule, live vaccines should not be used in pregnancy or in severely immunocompromised patients. ***Contra-indications:*** severe allergic reactions e.g., anaphylaxis during previous vaccine dose or to a vaccine component.

9.19 Hepatitis C Vaccines

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). HCV infection sometimes results in an acute symptomatic illness. It can range in severity from a mild illness lasting a few weeks to a serious, lifelong chronic condition that can lead to cirrhosis of the liver and liver cancer. HCV is transmitted through contact with the blood of an infected person.

There is currently no vaccine to prevent hepatitis C virus infection.

9.20 Varicella Vaccines

The varicella virus commonly causes chicken pox infection, which is a disease primarily of childhood, but it is also responsible for the disease Herpes zoster in adulthood. Herpes zoster disease (also known as shingles) results from reactivation of dormant varicella virus sequestered in the dorsal nerve root ganglia of the spinal cord. Chickenpox is contracted by touching an infected person's blisters, or anything (e.g., clothes, towels) that has been contaminated by them. The virus is also thought to be spread by droplets since it may be caught from an infected person by coughing and sneezing even before the rash develops. Chicken pox can also be contracted by contact with herpes zoster lesions.

Treatment of varicella (Chicken Pox): No specific treatment is available for chickenpox and management is mainly supportive to control the intense pruritis and to reduce the fever. Antiviral treatment is recommended for those at high risk of severe disease. Herpes zoster may be treated with antiviral agents and potent analgesics.

Prevention of varicella (Chicken Pox): Chicken pox can be prevented through vaccination using the live attenuated Oka strain of the varicella zoster virus. Among the immunosuppressed individuals, post exposure prophylaxis using antivirals and varicella immunoglobulin is recommended.

Dosage: Monovalent varicella vaccines are administered as a single dose for children under 13 years; while two doses for adolescents and adults administered 4-8 weeks apart by subcutaneous injection. The varicella vaccine is a live attenuated virus that protects against the viral disease caused by Varicella zoster virus (VZV). Varicella vaccine reduces the risk of shingles (also called Herpes Zoster). Combination vaccines can be administered to children aged from 9 months to 12 years (e.g. MMRV). Varicella vaccines are not indicated for protection against Herpes Zoster (shingles) disease.

Herpes zoster vaccine: A vaccine which contains higher amount of antigen has also been developed specifically to prevent shingles in the those aged ≥50 years, and is administered as a single dose subcutaneously.

Schedule: A single dose for children under 13 years, while two doses for adolescents and adults administered 4-8 weeks apart by subcutaneous injection. Combination vaccines e.g. MMRV are can be administered to children as a two dose schedule with a minimum interval of 4 weeks between the two doses

Contra-indications: Pregnancy, reaction to previous dose, any advanced immune disorders or cellular immune deficiency, symptomatic HIV infection and severe illness.

9.21 Rabies Vaccine

Rabies is a disease caused by infection with the lyssaviruses. Human infection occurs through contact with infected domestic animals or from exposure to wild animals in areas where rabies is endemic. Dogs account for more than 90% of the cases in animals. (WHO report 1992). In Kenya it is also commonly found in wild animals. Human deaths from rabies can effectively be prevented by vaccination, either pre-exposure vaccination or as part of post-exposure treatment.

Pre-exposure vaccination: May be recommended for anyone at increased risk to rabies virus e.g Veterinarians and veterinary laboratory staff, animal handlers, wildlife officers and visitors to high rabies-enzootic areas.

Post-exposure vaccination: The indication for post-exposure vaccination, with or without rabies immunoglobulin, depends on the type of the contact with the rabid animal. There are three types of contact:

- *Category I*: Touching or feeding a suspected animal, licks on the skin
- *Category II*: Nibbling of the uncovered skin, minor scratches or abrasions without bleeding, licks on the broken skin
- *Category III*: Single or multiple trans-dermal bites or scratches; contamination of mucous membrane with saliva from licks.

No treatment is needed for category 1 type of contact. Immediate vaccination is needed for category 2 and vaccination and immunoglobulin administration is recommended for category 3.

Vaccine Preparations: modern, concentrated, purified cell culture and embryonated egg-based

Inactivated rabies vaccines (CCEEVs) have replaced the nerve tissue-based vaccines that were used previously. Vials contain a single dose of 2.5 IU

Storage: Store all forms of rabies vaccines between +2°C to +8°C. Reconstituted vaccines are to be discarded after 6 hours or at the end of the vaccination session, whichever comes first.

Administration and Dosages: Must always be with reference to the specific vaccine manufacturers instruction. Vaccines can be administered by either the Intradermal or Intramuscular route (Whole vial). The recommended site for IM administration is the deltoid area of the arm for adults and children aged ≥2 years, and the anterolateral area of the thigh for children aged <2 years. Rabies vaccine should not be administered IM in the gluteal area.

1. Pre-exposure prophylaxis – Primary Prophylaxis (using vero cell derived vaccine); 0.5mls intramuscularly in the deltoid muscle on days 0, 7 and 28 (3 doses). The vaccine can also be given intradermally – 0.1ml on days 0, 7 and 28 (3 doses). Day 0 is the first day of vaccination.
2. Post-exposure prophylaxis (using vero cell derived vaccine); For persons previously immunized within the last 3 years - Give 2 booster doses on day 0 and 3 intramuscularly in the deltoid muscle; non-immunized persons - Give 5 doses of 1 ml (0.5ml depending on manufacturer) each on days 0 3, 7, 14, 28 by intramuscular injection into the deltoid muscle in adults or the antero-lateral aspect of the thigh in children. For intradermal route, four doses should be administered (2 injections of 0.1 ml at 2 different sites) as per the Updated Thai Red Cross regimen (2-2-2-0-2).
3. In those previously fully immunized (pre-exposure or post-exposure prophylaxis), 2 doses of 1 ml given by intramuscular route or 2 doses of 0.1 ml by intradermal route (at 1 site) on Day 0 and Day 3 are recommended.
4. The dose of anti-rabies vaccine given to a child is the same as the adult dose irrespective of age or weight.

Note:

It has been shown that vaccination of 80% of dogs is sufficient to break the canine transmission chain. Efforts to eliminate rabies must involve vaccination of the animal hosts, mainly dogs. This implies control of the dog population, vaccination of stray dogs using bait and traditional routine vaccination of domesticated dogs.

Changes in rabies vaccine product and/or the route of administration during the same PEP course are acceptable, if unavoidable, to ensure PEP course completion. The intradermal (ID) regimen requires a reduced volume of vaccine to be utilised than any of the intramuscular regimens therefore, reducing vaccine cost by 60-80%. This method is appropriate where vaccine or/and money are in short supply, particularly in rural areas with high-flow clinics and where the staff is skilled to undertake the intradermal injection technique.

Should a vaccine dose be delayed for any reason, the PEP schedule should be resumed (not restarted).

Rabies immunoglobulin administration:

Rabies Immunoglobulin (RIG) provides passive immunization and is administered only once, as soon as possible after the initiation of PEP and not beyond day 7 after the first dose of vaccine. Correctly administered, RIG neutralises the virus at the wound site within a few hours.

- The maximum dose is 20 IU (Human RIG) and 40 IU (Equine RIG) per kg body weight. There is no minimum dose.
- Infiltrate as much as possible into the wound; the remainder of the calculated dose of RIG does not need to be injected IM at a distance from the wound but can be fractionated in smaller, individual syringes to be used for other patients, aseptic retention given.

If RIG is not available, thorough, prompt wound washing, together with immediate administration of the first vaccine dose, followed by a complete course of rabies vaccine, is highly effective in preventing rabies. Vaccines should never be withheld, regardless of the availability of RIG.

Vaccination of special groups

Pregnant and lactating women – Rabies vaccine and RIG should not be withheld from pregnant or lactating women and any of the WHO-recommended PEP regimens can be applied.

HIV-infected and other potentially immunocompromised individuals – HIV-infected individuals receiving ART, who are clinically well and immunologically stable (normal CD4 percent >25% for children aged <5 years or CD4 cell count ≥200 cells/mm³ if aged ≥5 years) can receive rabies vaccination.

For immunocompromised individuals (such as HIV-infected persons who are not receiving ART or who are receiving ART but do not meet minimum CD4 cell count criteria) with WHO category II and III exposure, the following is recommended: Thorough washing of the wound should be emphasized; and administration of a full course of rabies vaccine, plus RIG in all cases, even if previously immunized. Serologic testing should be done 2-4 weeks after the first rabies vaccine administration to assess whether an additional vaccine administration is needed. Consultation with an infectious disease specialist or an immunologist is advised.

9.22 Anti Snake Venom

Snake bites result from the bite of a snake with resultant injection with venom. It should be noted that: 70% of snake bites are not poisonous. Most snakes have more than one venom. Snakebite envenoming can be classified as follows:

- *Neurotoxic* - destroys nerve cells causing paralysis of respiration and other organs and tissues.
- *Haemorrhagic* - destruction of blood cells causing disseminated haemorrhage.
- *Cytotoxic* - causes localized destruction of tissues resulting in either blisters or gangrene.
- *Myotoxic* – increased muscle pain and tenderness, descending paralysis.

Antivenom is the only specific antidote to snake venom. However, determining whether anti-snake venom is indicated or not is very difficult if the patient has presented early and no systemic signs of poisoning are present. Most victims of snake bites cannot identify the species that bit them, and most clinicians cannot differentiate between poisonous and non-poisonous snakes even if the (dead) snake was presented to them.

Immediate treatment of snake bites includes:

- Administration of anti-venom and tetanus toxoid,
- Administration of antibiotics and (nonsedating) pain relief
- Allaying of anxiety,
- Management of shock or haemorrhage,
- wound stabilization

Available anti-snake venom preparations, schedules and route of administration

Normally available are the polyvalent purified enzymes prepared from several snake venoms, refined and concentrated. This should be given as early as possible, following the bite, to patients while also monitoring and managing systemic symptoms and the spreading local damage (marked local or generalized swelling). Antivenom should, however, not be used routinely but only when indicated because

- there is a risk of anaphylactic reactions
- some bites are from non-venomous snakes or may not be envenomed ('dry bites')
- anti venoms are specific to particular venoms and may not be useful for other snake venoms
- antivenom is very expensive and usually in short supply.

Antivenom should be used only if there is a risk to life or limb.

Epinephrine (adrenaline 1:1000 solution) should always be readily available before antivenom is administered alongside antihistamines and corticosteroids.

N.B. Antivenom treatment always carries a risk of severe adverse reactions.

Antivenom that is procured should be suitable for the local snake profile, some venoms that have been manufactured are not suitable for the types of snakes usually found in Kenya. Involved. A polyvalent anti snake venom is recommended.

Manufacturer's recommendations should be followed when using the antisnake venom and multiple doses may be required.

Please note the dose of anti-venom given to a child is exactly the same as the adult dose irrespective of age or weight because children receive the same dose of venom in any bite. However, care should be taken to prevent volume overload.

Antivenom is most effective when given intravenously. I**ntramuscular injection should not be given** as absorption is exceptionally slow and unreliable. It can be given exceptionally, under the guidance of a physician, where intravenous route is totally impossible. Prophylactic broad-spectrum antibiotics and metronidazole are advisable in cases of cytotoxic venoms.

Adverse effects of anti-snake venom: Allergic reactions including shock.

Contraindications to antivenom: There is no absolute contraindication to antivenom when a patient has life-threatening systemic envenoming. However, patients with an atopic history (severe asthma, hay fever etc.) have an increased risk of severe reactions.

Prevention of snake envenomation: There is no vaccine or medication that can be given prior to a snake bite and therefore persons moving into areas known to have poisonous snakes should follow precautionary measures from the Kenya Wildlife Services and the National Museums of Kenya.

It is recommended that all snake bites are to be treated as poisonous and patients administered the highest valency anti-snake venom available under strict supervision of a qualified clinician.

Treatment of snake bites should be started immediately the patient presents to the health facility and arrangements started to move the patient to a suitable higher-level facility (Levels 4 - 6 i.e., facilities with an intensive care unit) for further management.

9.23 Cholera Vaccine

Cholera disease is caused by a bacterium known as Vibrio cholerae which is a Gram-negative, rod-shaped non-invasive mainly waterborne bacterium. Sero-grouping is based on the polysaccharides of the somatic (O) antigen. There are more than 200 serogroups of *V. cholerae* but only 2 serogroups – O1 and O139 – cause epidemic disease. Serogroup O1 has 2 biotypes: El Tor and classical. Both biotypes can be further classified into 2 serotypes: Ogawa and Inaba.

***Treatment*:** The first line management is the administration of low osmolarity oral rehydration solutions containing salts and glucose solutions. In severe cases, aggressive intravenous rehydration treatment (preferably with Ringer's lactate solution) Although rehydration may be lifesaving, it may not alter the course of the disease or dissemination of the infection. Antibiotics are a part of the treatment of severe cholera but are not needed for mild cases and are contraindicated for prophylaxis. Antibiotic sensitivity should be assessed on a representative sample of isolates to guide treatment during an outbreak.

Prevention: The mainstay of prevention of cholera is by improved environmental sanitation through prevention of faecal contamination of the environment, and the provision of safe drinking water to communities. Cholera vaccines are only an adjunct to this. Two types of oral cholera vaccines (OCVs) are currently available at:

(i) WC-rBS, killed whole cell monovalent (O1) vaccines with a recombinant B subunit of cholera toxin (Dukoral®) and

(ii) WC, killed modified whole cell bivalent (O1 and O139) vaccines without the B subunit (Shanchol®, euvichol® and mORCVAXTM®); the 3 WC vaccines are based on the same cholera strains.

Cholera vaccines should be used in areas with endemic cholera, in humanitarian crises with high risk of cholera, and during cholera outbreaks. In all settings, a series of criteria should be considered to guide the decision to vaccinate:

- The risk of cholera among the targeted populations and the risk of geographic spread
- The programmatic capacity to cover as many persons as possible who are eligible to receive the vaccine and living in the targeted area (e.g., those aged ≥1 or 2 years, depending on the vaccine used)
- Implementation of previous OCV campaigns. Cholera vaccination should not be carried out if a campaign has been conducted in the previous 3 years in the same population, unless justified by continuous transmission resulting from inadequate vaccine coverage during the previous campaign and/or substantial population movements.

Storage: The oral cholera vaccines should be refrigerated at $+2^{0}C$- $+8^{0}C$

Schedule: for primary immunization OCVs should be administered orally using the intervals and

age-restrictions for which the specific vaccines are licensed, For WC-rBS vaccine,3 doses should be given to children aged 2–5 years and 2 doses to children aged ≥6 years and adults, with an interval of 1–6 weeks between doses in both groups. For WC vaccines, 2 doses should be given 14 days apart to individuals ≥1 year. Cholera vaccines can be co-administered with other injectable or orally administered vaccines (e.g., OPV). Vaccination should be guided by an assessment of the risk of cholera and targeted to cholera hotspots.

Pregnant and lactating women and HIV-infected individuals should be included in OCV campaigns. OCV should be considered for travellers and emergency and relief workers at high risk, especially those who are likely to be directly exposed to cholera patients or to contaminated food or water

9.24 Typhoid Vaccine

Typhoid fever is a serious systemic infection caused by the enteric pathogen Salmonella typhi. The infection is spread by the faecal oral route and closely associated with poor food hygiene and inadequate sanitation. Only humans are affected, and most often, acquisition of S.typhi occurs through ingestion of food or water contaminated with excreta from carriers of the bacteria.

Prevention: Typhoid disease can be prevented by good personal and environmental hygiene and by vaccination. Sanitation and hygiene are the critical measures that can be taken to prevent typhoid. Typhoid does not affect animals and therefore transmission is only from human to human. Typhoid can only spread in environments where there is contamination of food and water with human faeces or urine. Careful food preparation and washing of hands are crucial in preventing typhoid.

Currently 3 types of typhoid vaccines are recommended by WHO for control of Typhoid Fever:

- Injectable typhoid conjugate vaccine (TCV)
- Injectable unconjugated Vi polysaccharide (ViPS)
- Oral live attenuated Ty21a vaccines.

TCV is preferred at all ages for routine programmatic use as it can be administered to younger children and has a longer duration of protection. It is recommended that the typhoid vaccine be deployed in the context of other efforts to control the disease, including health education, WASH, and training of health professionals in diagnosis and treatment. The Vi - polysaccharide vaccine and typhoid conjugate vaccine (TCV) are the currently approved vaccines for public health use in Kenya. The Vi - polysaccharide vaccine is composed of purified vi polysaccharide from S.typhi while TCV consists of Vi polysaccharide antigen linked to tetanus toxoid protein (also referred to as Vi-TT conjugate vaccine). Each vaccine dose comprises 25 µg of purified Vi-capsular polysaccharide conjugated to tetanus toxoid.

Administration and Dosages: TCV is administered as a single dose either subcutaneously or intramuscularly, of 0.5ml into the anterolateral aspect of the thigh for infants or into the deltoid muscle for older children and adults, in individuals >6 months up to 45 years of age. The vaccine confers protection seven days after injection.

Schedule*:* At the time of introducing TCV, a national TCV catch-up campaign for all children aged 9 months up to 15 years will be carried out followed by introduction of TCV into the national immunization schedule for routine immunization at 9 months co-administered with the first dose of MR vaccine, yellow fever vaccine, and malaria vaccine in selected counties.

Storage: The vaccine should be stored at a temperature of between +2°C and +8°C.

Contraindications: There are no contraindications other than prior severe reaction to vaccine components.

Booster doses: a single booster dose should be given to these high-risk groups every three years. Catch-up vaccination of multiple age cohorts is likely to accelerate impact.

Vaccination of special populations, contraindications and precautions: Food handlers and especially those employed in institutions of learning and prisons should be vaccinated. Laboratory staff should also be vaccinated against typhoid as well as employees of sewerage and treatment works. Immunocompromised persons, including those with HIV infection, should receive TCV or ViPS vaccine.

9.25 Meningococcal Vaccine

Meningococcal disease describes infections caused by the bacterium Neisseria meningitidis (also termed meningococcus). N. meningitidis is a gram-negative aerobic diplococcal bacterium which causes disease only in humans. It is classified into 12 serogroups (A, B, C, 29E, H, I, K, L, W135, X, Y and Z). It carries a high mortality rate if untreated. While best known as a cause of meningitis, widespread blood infection is more damaging and dangerous. Meningitis and Meningococcemia are major causes of illness, death, and disability in both developed and underdeveloped countries worldwide. Most of the invasive meningococcal infections arecaused by organisms expressing one of the serogroup A, B, C, X, W135 or Y capsular polysaccharides. In the African meningitis belt, serogroup A has been the most important cause of disease, followed by serogroups C and W135, and most recently by serogroup X.

Meningococcus is a leading cause of meningitis outbreaks and fulminant septicemia and a significant public health problem in most countries. The disease occurs either as small epidemics or unpredictable devastating epidemics. It is associated with high case-fatality rates (5%-15%) even where adequate medical services are available. N.meningitidis is the only bacterium capable of generating large epidemics of meningitis.

Neisseria meningitidis is transmitted by aerosol or direct contact with respiratory secretions of healthy patients or healthy human carriers. Rapid progression of meningoccccal disease frequently results in death within one or two days of onset.

Management: Cases of meningitis are treated using antibiotics and supportive therapy. Prevention:

Prevention: Meningococcal meningitis is prevented by immunization and immunity is sero group specific.

There are three types of vaccines available

- Polysaccharide vaccines - bivalent (A and C), trivalent (A, C and W-135), and quadrivalent (A, C, W-135 and Y) preparations
- Conjugate vaccines- monovalent (A or C) and quadrivalent (A, C, W-135, and Y)
- Serogroup B protein-based vaccines- Vaccines against serogroup B using OMV preparations

The vaccine preparations have different age eligibility and dosing criteria.

MenAfriVac, containing 10 µg of purified meningococcal A polysaccharide antigen conjugated with tetanus toxoid (PsA-TT), was used during a mass campaign in 2019 for those aged 1–29 years residing counties that fell in the Africa meningitis belt. Meningococcal vaccine is expected to be introduced into the routine childhood immunization programme within 1–5 years following campaign completion, along with a one-time catch-up campaign for birth cohorts born since the initial mass vaccination. The vaccine can also be used for epidemic response.

The quadrivalent meningococcal vaccine (ACYW135) is recommended by the Kingdom of Saudi Arabia for pilgrims proceeding to Saudi Arabia. The quadrivalent meningococcal vaccine will be given to all pilgrims >2years old at least 10 days prior to the date of travel. Doses are to be repeated every 3 years. The vaccination will be endorsed on the traveller's health certificate.

Storage: The vaccine should be stored at a temperature of between +2°C and +8°C.

10. NEW AND EMERGING VACCINES

Introduction of new vaccines and technologies

The introduction and implementation of any new interventions (vaccines and technology) will be guided by available evidence and the country's needs. The immunization program has in place an existing structure that allows for synthesis and interrogation of available evidence and alignment with the operational and implementation structures before the introduction of new interventions. This can be done with the guidance of:

- KENITAG
- National Immunization TWG
- National Immunization Interagency Coordinating Committee(N-ICC) and
- National Immunization Steering committee (as the need arises)

Time-limited working groups may be formed within the KENITAG and the National immunization TWG to guide the process for decision making, planning, and coordinating for the new interventions. Stakeholder engagements through the existing immunization thematic working groups will be undertaken to ensure ownership and a one country participatory approach before any of the new interventions are adopted, introduced, and implemented as part of the immunization activities.

11. VITAMIN A SUPPLEMENTATION

Vitamin A Supplement is a supplement integrated into the infant immunization schedule as recommended by WHO due to its immune boosting effects. It's known for reducing the risk of adverse effects of measles infection, as well as improve outcomes in other illnesses, especially amongst undernourished/vulnerable groups.

Vitamin A deficiency is a cause of preventable blindness in Kenya and therefore all efforts must be made to strengthen the supplementation of Vitamin A for all infants and young children.

The National Vaccines and Immunization Program endorses the continued integration of Vitamin A supplementation within the infant vaccination schedule. *Remember: A child should have gotten at least two doses of Vitamin A before the first birthday*. A key strategy for increasing Vitamin A supplementation coverage to all infants and young children is Regular Vitamin A supplementation of infants and young children up to their 5th year of life. The Ministry of Health recommends the following schedules of Vitamin A supplementation:

Vitamin A schedule for children under 5 years

Age	Dose	Frequency	Preparation
6 months	100,000 IU (30mg Retinol Equivalent) Vitamin A	Once	Containing Vit. A 100,000 IU(30mg Retinol Equivalent) per capsule
12 months (1yr)	200,000 IU	Once	Containing Vit. A 200,000 IU (60mg Retinol Equivalent) per capsule
18 Months (1½ yrs)	200,000 IU	Once	
24 Months (2 yrs)	200,000 IU	Once	
30 months (2½ yrs)	200,000 IU	Once	
36 months (3 yrs)	200,000 IU	Once	
42 months (3½ yrs)	200,000 IU	Once	
48 months (4yrs)	200,000 IU	Once	
54 months (4½ yrs)	200,000 IU	Once	
60 months (5yrs)	200,000 IU	Once	

Table 7: Vitamin A schedule for children under 5 years

12. VACCINES INNOVATIONS AND RESEARCH

The Ministry of Health regulates research in vaccine preventable diseases. The Ministry will continue to invest in vaccine research and development against diseases of public health importance through its research collaborating institutions including KEMRI, Universities and other related research bodies in the country.

Most vaccines developed in the last 50 years offer protection by stimulating a potent antibody response. However, for pathogens that live within cells of the body, where antibodies cannot reach, cell-mediated immunity is likely required for additional protection. Examples of such pathogens include malaria, TB and HIV. There has been progress in developing vaccines and protective measures against some of the diseases, but there're still gaps to close to ensure widespread protection against these high burden conditions.

Several vaccines have completed or have progressed in clinical trials, both locally and globally, and they may be available in Kenya in the next few years. These include new Tuberculosis Vaccines, Shigella Vaccine, Dengue Vaccine, Ebola Virus Vaccine, Human Immuno-deficiency Virus (HIV) Vaccine, Respiratory syncytial virus (RSV) amongst others. As these and other vaccines (and technologies) become available, planning and coordination for their introduction and eventual implementation will be guided by recommendations in this policy document and by the program.

13. MAXIMIZING IMMUNIZATION COVERAGE

The National Vaccines and Immunization Program, as per The Immunization Agenda 2030, and guided by the GAVI 5.0 Strategy on 'leaving no one behind', has made concerted effort to close the gaps on coverage and equity, especially amongst vulnerable populations.

Planning of Immunization Services at Sub-Counties and Health Facility Levels

Health facilities shall prepare evidence based annual micro-plans to guide the implementation of immunization services in their catchment areas. Activities and priorities in the micro-plan should be adjusted quarterly based on performance results. Health facilities micro-plans shall be consolidated into a subcounty micro-plan. The micro-plans should clearly articulate the following areas:

- Immunization performance problem identification and solutions
- Estimation of resources needed to operationalise the micro-plan e.g., Vaccine and supplies forecasting and distribution, inventory of cold chain equipment and power sources to maintain the cold chain, manpower etc.
- Strategies for demand creation for immunization services through partnerships and linkages with the community
- Sub County micro-plan should include a schedule for supportive supervision to coach and mentor operational level health workers.
- A plan to regularly monitor immunization performance with regular performance reviews

Communication for Immunization Services & Linking Community with Immunization Services

Using culturally acceptable, evidence based and appropriate communication channels and individuals (gatekeepers and opinion leaders), information on immunization services should routinely be availed to the community.

In order to foster community ownership and utilization of immunization services, every effort should be made to involve the community through partnerships in the planning, implementation and monitoring of immunization services.

Health facilities should foster community ownership and utilization of immunization services, by involving the community through partnerships in the planning, implementation and monitoring of immunization services.

Increasing Access of Immunization Services

In order to increase geographical access to immunization services, health workers will regularly conduct targeted integrated outreach services to areas known to have high numbers of zero dose and under vaccinated children and pregnant women, including hard to reach areas.

Strengthen the EPI services to focus on Immunization beyond infancy by engaging relevant stakeholders, in a bid to Life Course Immunisation. This includes HPV vaccination, COVID 19

vaccination, among others.

Reducing Drop Out

To ensure continuation of vaccination services, health workers should regularly identify defaulters from the immunization permanent register and institute measures to promptly track and bring all defaulters back to complete the vaccination schedule.

Limiting Missed Opportunities for Vaccination

To reduce missed opportunities for vaccination, the health workers should ensure the following:

- Check children's and women's vaccination status every time they come into contact with health facilities or outreach sites, regardless of the reason for the visit, and offer them appropriate vaccines. Sick children should always be screened for vaccination before they are discharged from the health facilities.
- Women receiving antenatal should be screened and, if eligible, vaccinated with tetanus Diphtheria (Td).
- Give children and women all vaccines due, based on these Immunisation guidelines.
- Eliminate false contraindication for vaccination e.g., mild diarrhoea and or vomiting, low grade fever etc.
- Health workers should open a multi-dose vial of a lyophilised vaccine even for one child.
    - Avoid scheduling of vaccination services.
    - Encourage eligible women and caregivers of eligible children to bring the vaccination card (mother-child health booklet) to every clinic visit for checking by the health worker for vaccination status.

Catch-Up Vaccination Strategy

A catch-up vaccination strategy is an essential part of a well-functioning national immunization programme and should be implemented on a continuous basis.

Catch-up vaccination refers to the action of vaccinating an individual who, for whatever reason, is missing or has not received doses of vaccines for which they are eligible, per the national immunization schedule.

Catch-up vaccination can be conducted through regular routine immunization service delivery (fixed, outreach, mobile, school-based), periodic intensification of routine immunization (PIRI) activities, or through innovative local strategies that ensure individuals have the opportunity to receive routine immunizations for which they are overdue and eligible.

Principles of catch-up vaccination

- Everyone should fully benefit from vaccination by receiving recommended vaccines as soon as they are eligible, and those who arrive "late" should not be denied vaccination.
- Providing catch-up vaccination for those who have missed doses can have a major impact on closing immunization gaps that would otherwise compound as populations increase in age. As these individuals age, it becomes harder to identify effective ways to reach them with the needed vaccines.

- Catch-up vaccination strategy is an essential part of a well-functioning routine immunization programme and should be implemented on a continuous basis to ensure an individual's right to be offered the benefit of vaccination, even if it is late.
- Recommended vaccines should be administered if vaccination history is incomplete or unknown.
- Do not restart or add doses to vaccine series if a long time has elapsed between doses.
- All touchpoints with the health system should be used to reduce missed opportunities for vaccination, by assessing vaccination status and vaccinating or referring individuals for catch-up vaccination if they have missed any doses.

Note: *No one should miss out on the right to the protection that vaccines offer, simply because they are unable to access services in time. Refer to the catch-up schedule (Annex 4).*

14. SERVICE DELIVERY FOR IMMUNIZATION, ROUTINE AND SIAs

Provision of immunization services is among the Kenya Essential Packages for Health (KEPH) integrated within the Primary Health Care package.

Routine Immunization & Supplemental Immunization Activities (Campaigns)

Regulations pertaining to vaccination (immunizing) centres: All immunizing facilities must be duly registered by the relevant authorities who include:

- The Kenya Medical Practitioners & Dentists Council
- The Ministry of Health and County Departments of Health
- Clinical Officers Council
- Nursing Council of Kenya
- Local authorities under whose jurisdiction they operate

Immunizing facilities must:

1. Be duly inspected by the County Health Inspection authorities
2. Be equipped with WHO EPI prequalified cold chain equipment
3. Be issued with MOH Master Facility List code
4. Have qualified and registered health staff by relevant professional bodies
5. Utilize MOH reporting tools and submit reports to Sub County Health Record and Information Officers or KHIS on a monthly basis
6. Adhere to the standard NVIP vaccine management guidelines

All vaccinations should be administered by qualified clinicians/ authorised practitioner

Special temporary vaccination centres & strategies will be operated during management of disease outbreaks and during authorized outreach and medical camps (including vaccination in schools). The authorizing officers will be the Director General of Health and/or the County Director of Health.

Administration of vaccines for research purposes such as during vaccine trials or operational research shall be governed by the relevant ethical committee and approved by the Pharmacy and Poisons Board. However, all vaccinators involved in vaccine trials must be clinicians. Research that interferes with the National Immunization Schedule or with any other policy guidance in this document should, in addition to other necessary approvals, be approved by the Ministry of Health through the National Vaccines and Immunization Program. Policy recommendations from research should be disseminated to the relevant authorities at all levels.

Access to Routine Immunization Services

Government approved immunizing facilities shall provide services as follows:

- Routine vaccinations services should be offered daily from Monday to Friday; 8.00 am to 5.00 pm. In addition, sub counties and health facilities are expected to augment fixed point service delivery with outreach services and extra-ordinary hours to address the vaccination needs of special populations- including weekends and public holidays.

- Outreach immunization services can be held on any day of the week including weekends, to cater for parents, especially mothers, whose only free time may be on weekends.
- All immunizing facilities should ensure complete vaccination for all individuals receiving non-EPI antigens.
- Facilities that operate maternity (delivery) units must provide BCG and Birth OPV vaccination to new-borns seven days a week.
- 24-hour access must be availed for emergency vaccines in all hospitals & health centres, e.g., anti-rabies vaccine, anti-snake venom.
- Dispensaries and private clinics should avail emergency vaccines as and when required during working hours.
- All government supported vaccines shall be offered free of charge with the exception of vaccines for travellers which will be provided at a fee.
- Vaccination services are to be delivered to the clients within 20 minutes of arrival at a facility on a 'first-come-first served' basis in public health facilities.

Defaulter Tracing

In order to minimize dropouts from immunization services, all immunization service providers must have clearly defined methods or strategies for tracing drop-outs from immunization services so as to ensure completion of schedules.

Maintaining Vaccine Schedules During Stockout Situations

When a stock-out of a particular vaccine/s occurs, clients should be immediately referred to the nearest facility known to have the required vaccine so as to reduce unacceptable intervals between doses. The sub county EPI logistician should redistribute available stock to minimize stock outs.

Outreach Immunization Activities

The purpose of outreach immunization services is to increase access to clients in hard-to-reach areas, it is therefore not always applicable, in all places, and at all times.

Where applicable the following should be observed:

- The frequency of outreach services shall be at least monthly in collaboration with the target community
- As far as possible immunization outreach activities must be integrated with other maternal and child survival activities.
- If privately sponsored, such services must be coordinated with the respective SCMOH of the targeted sub county.
- Chiefs or the Assistant Chiefs of the targeted location must be fully involved in all outreach exercises.

National or Subnational Supplemental Immunization Activities (SIAs)

The need and urgency to conduct localized or nationwide supplemental immunization activities for the public good will be determined by the Ministry of Health and communicated to the

public by way of one or more of the following:

- Media briefings/Press releases/Legal notices
- National Health Sector fora
- Regional Directorates of Health
- Print and electronic Media

Role of immunizing facilities during SIAs include:

- Provision of logistical support and service delivery
- Advocacy and resource mobilization for immunization services

Role of the public during SIAs include:

- Cooperation with the Health Authorities
- Creating awareness and mobilizing other community members

Recommended Administrators of Vaccines

- All injectable (parenteral) vaccines MUST only be administered by registered, authorised clinicians/ authorised practitioner.
- Oral vaccines & Vitamin A preparations may be administered by trained non-clinicians but must be under the supervision of a clinician.

15. PROGRAM MONITORING, EVALUATION, ACCOUNTABILITY AND LEARNING (MEAL)

15.1 Monitoring Overview and Strategies

To ensure the success of this Immunization Policy Guidelines, it will be important to assess its implementation in terms of changes in the health situation with regards to vaccine preventable diseases and immunization program performance. The existing health and immunization information systems will contribute to producing the data and information required.

Program monitoring, evaluation, accountability and learning entails tracking the process of enacting and implementation of the immunization policy.

Inclusion of immunization indicators in surveys, operational research and other assessments and review activities will contribute to monitoring the policy implementation. Regular assessment of the immunization system and practices will provide the necessary information for taking corrective action.

This policy shall promote collection, analysis, and utilization of age and sex disaggregated data for all populations. The Ministry of Health shall support capacity building of program managers, planners and service providers on data utilization for decision making.

All vaccinating facilities MUST keep appropriate up-to-date records of all types of vaccines administered and report to the Ministry of Health, through established channel, details of all vaccination, regardless of source.

Strategies for effective monitoring shall include:

i. Evaluate the effectiveness of different policy objective strategies such as advocacy, quality assurance, resource mobilization etc (e.g., advocacy, policy dialogue, policy analysis, strategic planning) to determine contributions to policy outcomes.
ii. Document best practices and learn lesson to improve policy review process.
iii. Communicate findings of policy monitoring through various communication forums .
iv. Evaluating outcomes of immunization program implementation.
v. Build strong relationships among sectors and between national and county level decision making instruments to adequately monitor the full policy implementation process.

15.2 Monitoring Responsibilities

The following responsibilities for Monitoring and evaluation shall apply:

Community Level

Each community should have Community Health Volunteers and their roles should encompass amongst other activities to include:

- Keep record of basic community information (target population distribution, mapping, etc.)
- Share reports with Health workers and Community Health Assistants on the number of pre-registered clients, for compilation.
- Conduct and document on defaulter tracing using existing systems.

Health Facility Level

The health care worker in each health facility should observe the following requirements with regards to immunization:

- Forecast vaccines and other logistics requirements at the facility level, including data collection and reporting tools' requirements.
- Ensure the availability of all latest versions of recording and reporting tools (registers, tally sheets, summary forms, antigen ledger books, AEFI reporting forms and vaccination cards).
- Maintain appointment schedules and re-appointment dates.
- Daily recording of vaccinated population (eligible population) in the immunization register, tally sheet and summary sheet.
- Maintain daily records on vaccine antigens and other logistics in the vaccine ledger book.
- Verify and check completeness and accuracy of all summary reports that are shared with the sub county monthly.
- Send immunization summary reports to the sub county by 5th of the following month.
- Regularly update the sub county with late reports.
- Read and record the temperature of the antigen refrigerator in the morning and evening daily, including weekends, and take action if necessary.
- Fill and submit AEFI reports as they occur.
- Archive used tally sheets and summary sheets by month and year, for at least 3 years.
- Conduct monthly data review meetings and track key performance indicators at facility level.
- Use EPI data for decision making.

County & Sub-County Level

- Consolidate and harmonize population data with facilities.
- Forecast Vaccines and other logistic' requirements.
- Ensure the availability of stock and buffer stocks of all latest version recording and reporting tools (registers, tally sheets, summary forms, antigen ledger books, AEFI forms and vaccination cards, defaulter tracing, support supervision tools, forecasting tools).
- Forecast, procure, print and distribute all the standardized MOH immunization data collection and reporting tools.
- Maintain a database of immunizing facilities.
- Ensure distribution of updated immunization recording and reporting tools to immunizing health facilities based on demand.
- Receive reports (monthly reports) and cold chain equipment temperature monitoring from all health facilities by 5th of every month and upload to the KHIS by 15th of every

month

- Ensure consistency, timeliness, accuracy and completeness of reports in the KHIS.
- Provide monthly feedback to facilities regarding the reports they submit.
- Update in KHIS the accurate number of the target population.
- Enter all late reports into KHIS whenever they are submitted.
- Maintain daily Record on antigens/ diluents and other logistics (using manual means or eLMIS, as it applies to the Sub County).
- File systematically all MOH 710 reports and other related immunization forms.
- Analyse immunization data by designated health facility and Display COVID-19 immunization coverage, dropout rates and unreached population monthly.
- Promote use of data for decision making and program improvement.
- Conduct quarterly EPI data management quality, data reviews, use supportive supervision using a checklist (on job training, Mentorship, group training, Data Quality Assessment, defaulter tracing etc.) and provide feedback.
- Develop and share monthly, quarterly and yearly performance report.
- Convene quarterly Immunization performance review meetings.

National Level

- Consolidate and harmonize population data with Counties.
- Forecast vaccine and other logistics requirements.
- Design and share with counties standardized formats of all immunization data collection, reporting and monitoring tools.
- Ensure immunization data elements in KHIS are harmonized with updated hard copy data tools
- Monitor timeliness and completeness of reporting by county and sub county.
- Ensure consistency, timeliness, accuracy and completeness of reports in the KHIS and liaise with counties in case of any irregularities.
- Provide periodic policy guidance on immunization data management.
- Train and provide technical support to county and sub county teams on data management and use, periodically.
- Analyse routine immunization data and provide feedback to counties quarterly.
- Share data using standard format with WHO, UNICEF and other Immunization stakeholders.
- Convene, biannually, immunization performance review meetings.
- Conduct data quality assessment and give feedback to counties and partners annually.
- Develop and share quarterly immunization bulletins.
- Provide technical Assistance to Counties.

15.3 Monitoring Indicators

Monitoring and Evaluation of this policy shall be guided by the following indicators and targets:

	Baseline (2022)	Midterm (2024)	Target (2026)	Source of Data
-% of Total Health Expenditure (THE) Allocated to immunization	**2.0%**	**2.8%**	**3.5%**	Annual Budgetary Allocation
Proportion of infants vaccinated with DPT-HepB+Hib 1(Pentavalent 1) Vaccine	**89%**	**93%**	**95%**	KHIS
Proportion of infants vaccinated with DPT-HepB+Hib 3 (Pentavalent 3 Vaccine	**86%**	**89%**	**90%**	KHIS
Proportion of infants vaccinated with Measles Rubella 1 Vaccine	**86%**	**88%**	**90%**	KHIS
Proportion of 10-year-old girls Vaccinated with HPV Vaccine	**58%**	**70%**	**80%**	KHIS
No of stock out of vaccine or supply per year by sub county	4	0	0	Chanjo (LMIS), KHIS

Table 8: Monitoring Indicators

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17. ANNEXES

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7.	Athanasius Ochieng	Ministry of Health
8.	Barako Katelo	MOH - NVIP
9.	Benter Otieno	Kenya Paediatric Research Consortium
10.	Catherine Munyao	MOH - NVIP
11.	Catherine Silali	MOH - NVIP
12.	Cherotich Rono	MOH - NVIP
13.	Chris Malala	MOH - NVIP
14.	Christine Chege	Kenyatta University
15.	Christine Miano	MOH - NVIP
16.	Christopher Odero	Program for Appropriate Technology in Health
17.	Christopher Okwako	Kenya Paediatric Association
18.	Collins Tabu	UNICEF- Kenya
19.	David Githanga	Kenya Paediatric Research Consortium
20.	Dorice Opondo	MOH - NVIP
21.	Edwina Anyango	MOH - NVIP
22.	Elizabeth Muchoki	Kenya AIDS NGO Consortium
23.	Ernest Some	MOH - NVIP
24.	Esther Mungai	Tony Blair Institute (TBI)
25.	Eunice Shankil	MOH - NVIP
26.	Everlyne Etemesi	MOH - NVIP
27.	Everlyne Rono	MOH - NVIP
28.	Fabian Esamai	Alupe University College

29.	Fathiya Said Hamumy	MOH - NVIP
30.	Florence Kabuga	Nairobi Metropolitan Services
31.	Florence Yonga	Ministry of Health
32.	Fred Were	Kenya Paediatric Research Consortium
33.	Gaye Agesa	African Population Health Research Centre
34.	George Okello	Tony Blair Institute (TBI)
35.	Grace Rukwaro	Kenya Paediatric Association
36.	Hillary Limo	Ministry of Health Kenya
37.	Irene Amadi	Kenya Paediatric Research Consortium
38.	Isaac Mugoya	M-RITE/John Snow Inc
39.	Jack Ndegwa	Kenya AIDS NGO Consortium
40.	Jalemba Aluvaala	The University of Nairobi
41.	Jamlick Karumbi	Ministry of Health
42.	Jane Mangwana	African Population Health Research Centre
43.	Kevin K'Orimba	Tony Blair Institute (TBI)
44.	Lawrence Owino	Kenya Paediatric Association
45.	Lucy Kanja	UNICEF- Kenya
46.	Lucy Mecca	MOH - NVIP
47.	Makeba Wandabwa	World Health Organisation
48.	Melissa Wanda	PATH
49.	Nakato Juma	Ministry of Health
50.	Nelson Maina	Kenya Paediatric Research Consortium
51.	Peter Kamau	MOH - NVIP
52.	Peter Okoth	UNICEF - Kenya
53.	Rose Jalango	MOH - NVIP
54.	Samson Thuo	MOH - NVIP
55.	Shem Kiptoo	WHO
56.	Stephen Mutwiwa	JHPIEGO
57.	Tabitha Okech	FELTP - Kenya
58.	Teclar Kogo	MOH - NVIP

59.	Wahu Gitakah	Aga Khan University Hospital
60.	Wycliffe Opwoko	MOH - NVIP

Annex 2.: Cold Chain Recommended Temperatures

<table>
<tr><th>Vaccine</th><th>National – Up to 6 months (Electricity)</th><th>Regional – Up to 3 months (Electricity)</th><th>County/Sub-County – Up to 3 months (Electricity/Solar)</th><th>Health Facilities – Up to 1 month (Electricity/Solar)</th></tr>
<tr><td>OPV
Yellow Fever</td><td colspan="3">-15°C to -25°C</td><td>2°C to 8°C</td></tr>
<tr><td>BCG
Measles Rubella</td><td colspan="2">-15°C to -25°C OR 2°C to 8°C</td><td colspan="2">2°C to 8°C</td></tr>
<tr><td>DPT-HepB-Hib (Penta)
Pneumococcal (PCV)
Rotavirus
IPV
HPV
Malaria
Anti-rabies
Anti-snake venom</td><td colspan="4">2°C to 8°C</td></tr>
<tr><td>Diluents</td><td colspan="3">Room Temperature</td><td>Store in the Vaccine Fridge at the same temperature as associated vaccine</td></tr>
</table>

Annex 3: Cold Chain Recommended Temperatures for COVID-19 Vaccine

<table>
<tr><th colspan="4">Vaccine storage conditions</th></tr>
<tr><td>Vaccines</td><td>Central Vaccine/ Regional Vaccine Store</td><td>Sub-County Level</td><td>Health Facilities (SDP)</td></tr>
<tr><td>Pfizer/BioNTech</td><td>– 80^0 C to – 60C^0</td><td colspan="2" rowspan="4">+ 2^0 C to + 8^0 C</td></tr>
<tr><td>Moderna
Johnson & Johnson</td><td rowspan="2">– 15^0 C to – 25^0 C</td></tr>
<tr><td>AstraZeneca
Sinopharm</td><td rowspan="2">+ 2^0 C to + 8^0 C</td></tr>
<tr><td>Diluent</td><td colspan="2">Room Temperature</td><td>+ 2^0 C to + 8^0 C</td></tr>
</table>

Annex 4: Catch Up Vaccination Schedule

Recommendations for Interrupted or Delayed Routine Immunization in healthy individuals						
Antigen	Age of first Dose	Doses in Primary Series	Minimum Interval Between Doses	Doses for those who start Vaccination Late		
				≤ 12 months of Age	>12 Months of Age	Comments
BCG	At Birth or as soon as possible	1 Dose	NA	1 Dose	1 Dose	Children under five years. In Kenya BCG is given empirically at birth or at any age up to 59 months. Older unvaccinated children moving to a high burden TB country should be considered for vaccination
Oral Polio	At Birth or within two weeks and 1st Dose at 6 Weeks	4 Doses	4 Weeks	3 Doses	3 Doses	Up to 59 months unless recommended prior to travel. All children under 5 years should also receive additional OPV doses during mass vaccination campaigns.
Rotavirus	6 Weeks	3 Doses	4 Weeks	3 Doses	NA	NOT recommended to start if > 12 months old, all doses to be completed by 24 months
DPT – HepB- HiB	6 Weeks	3 Doses	4 Weeks	3 Doses	3 doses	NOT required for children above 5 years, give TdaP for those above 5 years
PCV10	6 Weeks	3 Doses	4 Weeks	3 Doses	3 Doses	NOT required for children above 5 years
IPV	14 Weeks	1 Dose	NA	1 Dose	1 Dose	NOT required for children above 5 years
Measles Rubella	9 Months	2 Dose	4 Weeks	2 Doses	2 Doses	If a child is 18 months and over during the First Visit – Give the 1st dose and give Return date of 4 Weeks for 2nd Dose. Vaccinate all children that missed particularly those under 15 years of age.
Yellow Fever	9 Months	1 Dose	4 Weeks	1 Dose	1 Dose	Vaccinate if under 15 years of age.
Malaria	6 months	4 Doses	4 Weeks	4 Doses	4 doses	Up to 5 years of age. The 4th dose is given at 24 months with an exception - Children who receive 3rd Dose after 23 Months of age, should receive 4th dose four weeks after the 3rd dose and not earlier
HPV	As soon as possible from 10 years of age	2 Doses	6 Months	2 Doses	2 doses	10-14-year-old girls 2 doses (0 and 6 months)
Tetanus Diptheria	Pregnant Women	5 Doses	4 Weeks	NA	Refer to Td Schedule	Vaccination with five appropriately spaced doses of adsorbed tetanus toxoid is known to

						provide immunity against tetanus for up to 20 years for all recipients

*If more than one vaccine is due or overdue provide one dose of each vaccine at that visit. Do not unnecessarily defer giving vaccines that are due or overdue. Example: * A child aged 16 months arrives for vaccinations and has never received any vaccination since Birth. Which Antigens will the child get and at what time. Answer - The child is eligible for BCG, 1st OPV, 1st DPT – HepB- HiB, 1st PCV10, IPV, Measles Rubella 1 and Vitamin A, Give A return Date of 4 Weeks for 2nd Doses then return date Four Weeks for 3rd Doses.

Example 2 * if a child arrives at 9 months for MR vaccine, but has not yet received OPV3, Penta3, and IPV – the child is eligible for all four of these vaccines, and one dose of each antigen can be given at the same visit.

***For All the Antigens - Resume without repeating the previous dose*

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