GOVERNMENT OF KENYA

MINISTRY OF HEALTH

NATIONAL POLICY GUIDELINES ON IMMUNIZATION 2013

DIVISION OF VACCINES & IMMUNIZATION
MINISTRY OF HEALTH
Prevention made simple

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These National Policy guidelines are the result of a long process of intensive consultations, teamwork, detailed studies and information gathering.

Special thanks go to the members of the Technical Working Group that were tasked to steer the process of developing these policy guidelines. The interest and commitment of this team was invaluable.

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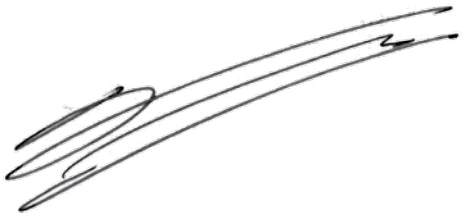

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13 Jan 2014

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FOREWORD

The Kenya Government through the Ministry of Health embarked on the process of formalizing immunization services after the Alma Ata declaration of 1978 by the World Health Assembly. The Kenya Expanded Programme on Immunization – K.E.P.I. was established in 1980 to coordinate these services, which targeted the six childhood killer diseases at the time with the six available antigens then. The Ministry of Health through KEPI addressed itself to the improvement, expansion and intensification of immunization services in the country. This was done by equipping more health facilities with cold chain (refrigeration) equipment in a phased approach, re-training of health workers and continuous monitoring and evaluation of immunization services.

Over time KEPI incorporated new vaccines for childhood and a vaccination program for ante-natal women. A draft immunization policy was developed in 2000 to guide the implementation of immunization services but this was overtaken by events as several new antigens were introduced into the program and new technologies on vaccine administration evolved.

The Ministry of Health also provides vaccination services for other diseases outside the EPI schedule for preventive and emergency disease outbreaks for which no policy exists.

Vaccination has been one of the most successful and cost-effective public health interventions in history as exemplified by the eradication of smallpox, significant lowering the prevalence of poliomyelitis and the dramatic reduction in morbidity and mortality from several other illnesses. Recognising these achievements, the Ministry of Health has consolidated all vaccination services within and outside KEPI under a single unit called the Unit of Vaccines and Immunization services and decided to develop these policy guidelines so as to integrate all current vaccination practices. The aim is to standardize practices and opportunities for vaccination services.

These National policy guidelines for immunization seek to comprehensively guide health workers on vaccination priorities and acceptable practices for the overall good of all Kenyans. They have been developed in consultation with many partners including the World Health Organization, UNICEF, USAID-MCHIP, University of Nairobi, Kenya Medical Association, Kenya Paediatric Association, Moi University among others, and we sincerely thank them all.

All vaccines used in Kenya are subject to the Pharmacy & Poisons Act Cap.244 Laws of Kenya.

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

Dr. Francis M. Kimani
DIRECTOR OF MEDICAL SERVICES
MINISTRY OF HEALTH

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ABBREVIATIONS:

ACSM	Advocacy Communication and Social Mobilisation
AD	Auto Disable syringe
AIDS	Aquired Immuno Deficiency Syndrome
CHADs	Child Health Action Days
DSRU	Disease Surveillance and Response Unit
DfID	Department for International Development
DMOH	District Medical Officer of Health
GIVS	Global Immunization Vision and Strategy
G.o.K	Government of Kenya
HAV	Hepatitis A virus
HepB	Hepatitis B virus
HepC	Hepatitis C virus
HIV	Human Immunodeficiency Virus
IMR	Infant Mortality Rate
KDHS	Kenya Demographic and Health Survey
KEMSA	Kenya Medical Supplies Agency
KEPH	Kenya Essential Package for Health
KEPI	Kenya Expanded Programme on Immunization
MCHIP	Maternal Child Health Integrated Program
MDG	Millennium Development Goals
MMR	Measles Mumps and Rubella vaccine
MNTE	Maternal and Neonatal Tetanus Elimination
MOMS	Ministry of Medical Services
MOH	Ministry of Public Health & Sanitation
NIDs	National Immunization Days
SIAs	Supplemental Immunization Activities
T.T.	Tetanus toxoid vaccine
UNICEF	United Nation's Children's Fund
USAID	United States Agency for International Development
UVIS	Unit of Vaccines and Immunisation Services
VVM	Vaccine Vial Monitor
W.H.O	World Health Organization

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.

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

Non-clinicians: Health workers employed in the health sector but are not involved in the diagnosis or treatment of patients including Pharmacists, Pharmaceutical Technologists, Laboratory Technologists/ Technicians and Public Health Officers & Technicians.

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.

Unit of Vaccines and Immunization services: This is the unit within the Ministry of Health responsible for the provision and coordination of vaccination services in Kenya.

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).

Health worker: This is a broad term referring to health professionals (in an organization or individually) who deliver formal health care to persons in need of health care services.

Health worker/s broadly refers to health professionals – clinicians and non-clinicians 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.

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 for specific vaccines of international public health importance.

This is done by port officials at the port of entry/exit which maybe an airport, sea port, lake port or a land border crossing. Those immigrants/emigrants found not to have the necessary certification of vaccination will be compelled to receive the vaccine at the port or quarantined.

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 use in a client.

01 INTRODUCTION

These National policy guidelines on immunization have been developed in line with the second National Health Sector Strategic Plan 2005–2012 (NHSSP II) which intends to reverse the decline in the health status of Kenyans and; The vision of the Ministry of Health to be an efficient, high quality health care system that is accessible, equitable and affordable for every Kenyan household.

The mission to promote and participate in the provision of integrated and high quality curative, preventive, promotive and rehabilitative health care services for all Kenyans. The NHSSP III is expected to contribute to the achievement of the health related Millennium Development Goals.

In line with the NHSSP III the National policy guidelines on immunization aim at reversing the trends of sub-optimal immunization coverage through the provision of clear directions toward the road to rationalized vaccination practices and vaccine use.

This document has been developed after consulting several references including the 2002 World Health Organization Immunization Policy Guidelines and the Global Vision for Vaccines and Immunization (GIVS) of 2005 among other reference documents.

It summarizes immunological and epidemiological information on target 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. In addition, it provides technical reference and guidelines for health workers who are involved in managing and monitoring immunization service delivery at all levels of the health care system.

This policy document aims to ensure uniform implementation of immunization schedules.

It also attempts to remove any confusion that health workers may have with regard to their roles and relevance of the various vaccines.

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

- Common 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.

As a member of a highly networked global community, it is in the interest of the Government of Kenya that its citizens are adequately protected against as many life- threatening communicable diseases as possible. Vaccination has been shown time and again to be very cost effective in the prevention or amelioration of disease.

It is envisioned that where the opportunity arises to provide this protection at the earliest possible age, it should be through the availability of safe, efficacious and relevant vaccines.

The Government of Kenya has appreciated the impact of its infant immunization programme launched in 1980 that brought about the elimination of diphtheria, the near elimination of pertussis, and marked control of measles.

For twenty two years the country had no cases of poliomyelitis (1984 - 2006). Unfortunately the re-emergence of the disease occurred in the face of less-than-optimal immunization coverage and poor environmental sanitation in the affected areas.

The re-emergence of polio shows how important it is to attain and maintain high vaccination coverages so as to achieve significant herd immunity. It also outlines the continuing need for addressing other public health measures that directly or indirectly contribute to the spread of certain vaccine preventable diseases. In the case of polio this refers to improvement in environmental sanitation and health education activities.

BACKGROUND INFORMATION ON VACCINATION SERVICES IN KENYA

Vaccination against meningitis which is required by travelers proceeding for ***Umrah and Haj*** in Medina and Mecca in Saudi Arabia is obtained from private sector practitioners and through the Port Health Services.

The Ministry of Health established The Kenya Expanded Programme on Immunization (KEPI) in 1980 with the main aim of providing immunization against six killer diseases of childhood, namely tuberculosis, polio, diphtheria, whooping cough, tetanus and measles to all children in the country before their first birthday, and tetanus toxoid vaccination to all pregnant women. KEPI was part of the global Expanded Programmes on Immunization (EPIs), whose main goal was to control killer vaccine- preventable diseases of childhood. Prior to 1980 vaccination services had been provided on an ad-hoc basis mainly through primary schools and the larger health institutions and facilities.

During the late 1970s the National Public Health Laboratories of the Ministry of Health used to manufacture smallpox and cholera vaccines and investigated all outbreaks of public health importance in Kenya. Because of its role in the surveillance for and response to diseases of public health importance the N.P.H.Ls became the repository of all emergency vaccines such as Cholera, Hepatitis B, Typhoid, Rabies and Anti-snake venom. However with the global eradication of smallpox, the N.P.H.Ls ceased manufacturing the small pox vaccine but continued to coordinate the use of the other emergency vaccines except for cholera which was phased out in the 1980s due to poor efficacy.

From the early 1970s when international travel regulations mandated that travelers moving across countries must be appropriately vaccinated to prevent global transmission of regional endemic diseases, the Nairobi City Council coordinated the vaccination of prospective overseas travelers with cholera and yellow fever vaccines.

Subsequently this role was taken up by the Department of Environmental Health within the Ministry of Health and was administered through the Port Health Services in collaboration with the Department of Immigration.

The KEPI programme concentrated initially on establishing and strengthening the health service delivery. However, in the 1990s, having achieved the Universal Child Immunization goals of immunizing at least 80% of the target population, KEPI's focus changed to disease control, elimination and eradication.

The challenges encountered with this new focus included:

- Achieving and maintaining high routine immunization coverage in all districts;
- Elimination of neonatal tetanus;
- Eradication of poliomyelitis by the end of the year 2000;
- Strengthening EPI disease surveillance.

The co-ordination of procurement and distribution of special vaccines to respond to specific outbreak situations was under the Disease Outbreak Management Unit (D.O.M.U). This unit was under the Ministry of Health's Division of Communicable Disease Control (D.C.D.C). DOMU's role was to detect and respond to outbreaks of public health importance and institute an appropriate response. Where the outbreak is due to a vaccine preventable disease, DOMU sourced for the required specific vaccine and coordinated the response activities. DOMU did not maintain stocks of emergency vaccines, but advised on the specifications and quantities of vaccines required when necessary.

The Division of Communicable Disease Control has since July 2007 been restructured and re-named the ***Disease Surveillance and Response Unit or DSRU***

OBLIGATIONS OF THE MINISTRY OF HEALTH ON VACCINATION SERVICES

- The Ministry of Health shall provide all routine vaccination services free of charge except those required for foreign travel, which shall be offered at a cost.
- Vitamin A supplementation when provided as part of the Child Health Services shall also be provided free of charge.
- The main strategy for delivery of immunization services shall be through health facilities (fixed outlets), during working days of the week (i.e. Monday to Friday). However District Health Offices are expected to augment fixed point service delivery with outreach services to address the vaccination needs of specially disadvantaged populations. This is in line with the Kenya Essential Package for Health that aims to address issues of equitable access to health services.
    - *Outreach immunization services can be held on any day of the week including weekend, to cater for parents, especially mothers,whose only free time may be on weekends.*
    - *All outreach immunization activities should normally be part of an integrated service to the targeted community and all outputs must be documented.*
- Facilities that operate maternity (delivery) units must provide BCG and Birth OPV vaccination to newborns seven days a week.
- The Ministry of Health through the Unit of Vaccines and Immunization services must ensure adequate and reliable supply of vaccination related logistics required for the implementation of the National Immunization Services.
- The Ministry of Health through the Unit of Vaccines and Immunization services and the Pharmacy and Poisons Board shall periodically assess all vaccines in use in the country for conformity to desired quality standards and potency.
- The Ministry of Health in partnership with the rest of the health sector shall endeavor to raise and maintain optimal immunization coverage levels for all approved schedules of administration through advocacy mechanisms and collaborative approaches to service delivery.
- The Ministry of Health shall promote the uptake of vaccination services through the community strategy.
- The Ministry of Health through an Immunization Technical Advissory Committee shall continuously review immunization service delivery in line with current information on vaccines, immunological products and new technologies related to immunization service delivery.
- All vaccines 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 (for parenterals).
- All districts and 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".*
- All immunizing facilities should ensure complete vaccination for all individuals receiving non-EPI antigens.

GLOBAL IMMUNIZATION VISION AND STRATEGY (GIVS)

The Global Immunization Vision and Strategy was launched on 25th May 2005 at the World Health Assembly held in Geneva, Switzerland. Governments – *(including the Government of Kenya)*, committed themselves to this strategy designed by WHO and UNICEF to fight vaccine-preventable diseases which kill more than two million people every year, two-thirds of whom are young children.

This immunization strategy that is a framework for planning and implementing national programmes during 2006-2015 period aims to immunize more people, from infants to seniors, with a greater range of vaccines. The main goal is, by 2015 or earlier to reduce illness and death due to vaccine-preventable diseases by at least two thirds compared to levels experienced in 2000.

GIVS has four main aims:

- To immunize more people against more diseases

- To introduce a range of newly available vaccines and technologies
- To integrate other critical health interventions with immunization
- To ensure vaccination programmes and activities are managed within the context of global interdependence.

It provides 24 strategies from which countries can choose for implementation according to their specific needs.

Goals

Between 2006 and 2015, all those working on immunization and related product development should strive to prevent morbidity and mortality by achieving the following goals and targets.

By 2010 or earlier:

- **Increased coverage** - where countries will reach at least 90% national vaccination coverage and at least 80% vaccination coverage in every district or equivalent administrative unit.
- **Reduced measles mortality** - Globally, mortality due to measles will have been reduced by 90% compared to the 2000 level.

By 2015 or earlier (as the case may be) there should be:

- Sustained high coverages.
- Reduced morbidity and mortality due to VPDs.
- Ensured access to quality vaccines.
- Introduction of new vaccines.
- Sustainable capacity for surveillance and monitoring.
- Strengthened systems for vaccination service delivery.
- Assured sustainability of vaccination programmes.

The Ministry of Health through the Unit of Vaccines and Immunisation Services is well positioned to deliver these goals.

ESTABLISHMENT OF INFANT IMMUNIZATION SCHEDULE *(0-11 months)*

The Government of Kenya is a signatory to the Alma Ata World Health Assembly declaration in 1978 that formed the basis for the launching of Expanded Programmes on Immunization in many parts of the world. The Ministry of Health is still committed to the goals outlined in the Alma Ata declaration and continues to sponsor vaccination against the initial six diseases of childhood prescribed at that time. These are:

- Tuberculosis - BCG vaccine,
- Polio – Oral Polio Vaccine,
- Diphtheria – Diphtheria toxoid vaccine,
- Whooping cough - whole cell Pertusis vaccine,
- Tetanus - Tetanus toxoid vaccine,
- Measles - Measles vaccine.

Since 2001, the Ministry of Health has endorsed the introduction of four new vaccines namely;

In 2001:

- Yellow fever in 2 counties of the country
- Hepatitis B vaccine
- Haemophilus Influenza type B vaccine

In 2011:

- Pneumococcal conjugate vaccine

Planned in 2013

- Rotavirus vaccine and measles second dose

02 THE UNIT OF VACCINES AND IMMUNIZATION SERVICES - (UVIS)

The Unit of Vaccines and Immunisation Services (UVIS) became effective from 1st July 2007, and represents the Ministry of Health's new direction in the coordination of immunization services for the general public.

TheUnit of Vaccines and Immunisation Services (UVIS) has grown from the original Kenya Expanded Programme on Immunization (KEPI) but has extended scope to consolidate all vaccination services previously coordinated by other divisions within the Ministry of Health.

Vision: Efficient and high quality immunization services that are accessible, equitable, and affordable to every Kenyan.

Mission: To promote and guide in the provision of high quality immunization services to all Kenyans

Mandate

- To coordinate vaccination services for all vaccine preventable diseases through the provision of guidelines and selected priority vaccines and related biological(sera, immunoglobulins)
- Advice on immunization schedules for all age cohorts in line with the Kenya Essential Package for Health (Ref. NHSSP-II 2005-2010).

The portfolio of ***UVIS*** includes:

1. EPI infant vaccines
2. Tetanus for pregnant women
3. Tetanus toxoid for trauma
4. Vaccinations for special groups
    - TT for special occupational risk groups
    - Hepatitis B vaccine for health workers and other persons at risk e.g prisoners
    - Typhoid vaccine for food handlers and special categories of health workers
    - Vaccination for foreign travelers (e.g yellow fever, meningitis).
5. Routine emergency vaccinations
    a. For animal (dog) bites
    b. For snake bites
6. Special emergency (outbreak response) vaccinations including the following
    a. Poliomyelitis
    b. Measles
    c. Meningitis
    d. Emerging infections – influenzas
7. Specialized products
    a. Immune sera – e.g. rabies immunoglobulins
    b. Anti-D sera for rhesus O-negative pregnant women

OBLIGATIONS OF THE UNIT OF VACCINES AND IMMUNISATION SERVICES

- To ensure equitable access to appropriate vaccination services for all persons in Kenya
- To ensure universal immunization of children in Kenya with appropriate doses of Ministry of Health prescribed childhood vaccines

- To ensure universal immunization of special risk groups with Ministry of Health approved priority vaccines
- To ensure optimum vaccination service delivery in response to specific situations of outbreak of life threatening vaccine-preventable diseases

ROLE OF THE UNIT OF VACCINES AND IMMUNISATION SERVICES:

1. Policy regulation and oversight
2. Commodity security & quality assurance
3. Monitoring and evaluation
4. Advocacy and Resource Mobilization
5. Capacity strengthening
6. Conduct of appropriate operational research

1. Policy Regulation and Oversight

i. Coordinating periodic reviews of the National Immunization Policy

ii. Developing and updating training guidelines and materials for immunization service delivery

iii. Facilitating the training of national and regional trainers

2. Commodity Security and Quality Assurance

i. To ensure continuous availability of adequate stocks of all Ministry of Health procured vaccines, related immunologicals and support logistics at all levels of service delivery.

ii. To monitor consumption of government supplied vaccines, antisera and vaccination devices used for human health within

iii. To monitor national immunization coverage trends and provide periodic reports.

iv. To monitor respective disease burden trends and correlate with immunization coverages (excluding comprehensive disease surveillance activities).

3. Monitoring and evaluation

i. Develop multi-year and annual operational plans

ii. To set multi-year and annual performance targets

4. Advocacy and Resource Mobilization

i. Annually review country wide vaccination social mobilization/advocacy needs.

ii. Develop and periodically revise social mobilization guidelines and strategies in line with vaccination performance trends in the country

iii. Determine multiyear and annual funding needs for universal immunization activities and develop comprehensive resource mobilization plans.

iv. Develop and periodically review resource mobilization guidelines and strategies in line with immunization funding needs.

5. Capacity strengthening

i. Develop and periodically review guidelines and training materials/ teaching aids on vaccine preventable diseases

ii. Spearhead the revision of curricula of medical institutions in relation to

- Current information on vaccine preventable diseases
- Updates required by different cadres of health workers

6. Operational research

i. To identify key operational research problems

ii. To identify resources and researchers to conduct the operational research

OTHER STAKEHOLDERS IN IMMUNISATION SERVICE PROVISION

- DSRU - Disease Surveillance and Response Unit
- KEMRI – Kenya Medical Research Institute
- NPHLs – National Public Health Laboratories
- Private sector players in health
- Training institutions e.g. Universities, mid level training institutions
- PPB – Pharmacy and Poisons Board
- NITAG – National Immunization Technical Advisory Group
- Philanthropic individuals and associations
- Civil society organisations

National Immunization Technical Advisory Group

The Kenya National Immunization Technical Advisory Group (KENITAG) will serve as a 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 the KENITAG.

Terms of Reference:

1. Conduct analyses of vaccine characteristics, vaccine-preventable disease epidemiology, and programmatic capacity to determine the optimal national policies on vaccines and immunization in accordance with the National Health Sector Strategic Plan (NHSSP), specifically:

    a. *Provide recommendations on the continuation or modification of existing policies.*

    b. *Advise on the introduction of vaccines currently not in use in Kenya and of potential relevance to public health.*

2. Identify the need for further data for policy-making and Advise the government in the collection of these data.
3. Advise the national authorities in the monitoring and evaluation of the national immunization program and provide recommendations on the continuation or modification of existing programmatic activities.
4. Keep the national authorities and the immunization program updated on the latest scientific developments in the area of vaccines and vaccine-preventable diseases.

Membership

The KENITAG will be composed of full-rights and liaison members, with Secretariat support from the Unit of Vaccines and Immunization services.

- Appointments by the Director of Medical/ Health Services Services and subsequent gazettement.
- A full member has voting rights.
- Serve a term of three years, renewable.
- Liaison member is incorporated on grounds of technical expertise to offer advise on ad hoc basis.

03 GUIDING PRINCIPLES ON IMMUNISATION SERVICES

- The Ministry of Health will ensure that there is sustained demand for all available vaccines to all eligible Kenyans.
- 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 cannot be guaranteed but the risk of the disease is serious, then the vaccine/immunological should be administered after obtaining 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.
- All vaccines for human use ***must*** be stored in specialized medical refrigerators as prescribed by the World Health Organization. The specifications for these refrigerators can be obtained from the Unit of Vaccines and Immunization services or from the WHO official website.
- NB: Some new generation vaccines and immunologicals may not require refrigiration but this must be clearly specified on the vial labels and secondary packaging.
- All injectable vaccines must only be administered by duly registered clinicians.
- All injectable vaccines are to be administered using ***non re-useable 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 *(normally 6 hours after reconstitution or opening)*.
- All unused doses of a liquid multi-dose vial vaccine without a preservative must be discarded 6 hours after opening of the vial - *e.g. multi-dose vials of liquid Pneumococcal Conjugate Vaccines.*
- Screening for immune status of individuals (including infants) prior to vaccination is not advocated. However where special circumstances dictate this should be overseen by a qualified clinician.
- Routine screening for HIV status prior to vaccination is also not advocated except in special circumstances as determined by a consultant clinician.

- A fully immunized child 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.
- A fully immunized person (other than an infant) refers to an individual who has
  - *received all the prescribed doses for a particular antigen or,*
  - *is beyond the 'window period of efficacy' of an antigen - where only one dose is required (e.g. yellow fever vaccine)*
- 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 Disease Surveillance and Response Unit (DSRU) of the Ministry of Health.
- The notifiable VPDs are Tuberculosis, suspected Poliomyelitis *(using Acute Flaccid Paralysis as an indicator)*, Diphtheria, Pertussis, maternal Tetanus, neo-natal Tetanus, Measles, Meningitis, Yellow fever *(using haemorrhagic fever as an indicator)* Rabies and Snake-bites.
- All notifiable VPDs must be investigated as per the prescribed guidelines from DSRU
- 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 District 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 drop-outs from all immunization schedules through careful counseling 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 presenting at health facilities and outreach sites for their vaccination status*
  - *Screening all women of child bearing age at health facilities and outreach sites for their vaccination status (esp. for tetanus toxoid)*

VACCINATING SPECIAL GROUPS

Pregnant Women

Live vaccines administered to a pregnant woman pose a theoretical risk to the fetus; therefore, live, attenuated virus and live bacterial vaccines generally are contraindicated during pregnancy. No evidence exists of risk to the fetus from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoid. Nevertheless, for lack of safety data, with the exception of the tetanus vaccination, all other inactivated vaccines or toxoids shall be administered to a pregnant woman only if proved that the benefits of vaccination outweigh the potential risks, when the likelihood of disease exposure is high and when infection would pose a risk to the mother or fetus.

Pregnancy recommendations

Recommended: It is generally considered safe to vaccinate pregnant women with the following vaccinations; Inactivated influenza vaccine, tetanus vaccine (TT), Tetanus- diphtheria (Td), Hepatitis B, Meningococcal polysaccharide

2. Cautionary: Pregnancy is a precaution and under normal circumstances vaccination should be deferred (vaccine should only be given when benefits outweigh risks) e.g Rabies, Hepatitis A , IPV, or yellow fever (in case of travel to an area where exposure is likely); rabies (eg, after a possible exposure)

3. Contraindicated: The following vaccines should not be administered to pregnant women. (Pregnancy is a contraindication to vaccination) MMR, varicella, live-attenuated influenza vaccine

HIV Positive Infant/Children

Live vaccines administered to HIV infected children, pose a serious risk of causing disease; therefore live, attenuated virus and live bacterial vaccines are contraindicated in known HIV positive infants/children. In circumstances that the child's HIV status cannot be established, WHO recommend that live vaccines should not be administered to children who are symptomatic for HIV infection.

Immunocompromised Individuals, Non HIV Infected Persons

Live vaccines are generally contraindicated in severely immunocompromised individuals because they could potentially overburden the immune system and result in disease. 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. (see the following tables)

A) Occupational

Other special groups

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

Table 1: RECOMMENDED VACCINES FOR SPECIAL RISK GROUPS

	CATEGORY	EXAMPLES	ANTIGENS
1.	Health Care Workers	• Clinicians • Laboratory staff • Medical Engineering staff • Patient attendants • Clinical students	• Hepatitis B • Typhoid vaccine • Seasonal influenza
2.	Emergency and Essential Service Workers	• Police officers • Armed forces personnel • Staffs of correctional facilities	• Hepatitis B • Seasonal influenza
3.	Carers	• Carers of people with intellectual disability • Staffs of nursing homes and long term care facilities	• Hepatitis B • Typhoid vaccine • Seasonal influenza
4.	Working with Animals	• Veterinarians, veterinary students • Veterinary Laboratory staff • Wild life rangers • Police dog unit staff, dog handlers in security companies	• Tetanus toxoid • Rabies vaccine
		• Herds men • Poultry handlers • Abattoirs workers	• Tetanus toxoid
5.	Others exposed to human tissue, blood, body fluids or sewage	• Tattooist, body–piercers, traditional circumcisers • Embalmers & other funeral workers	• Hepatitis B
		• Plumbers, sewage treatment plant workers, sewage exhauster staff	• Hepatitis B • Typhoid vaccine
		• Intravenous drug users	• Hepatitis B
		• Alcoholics & smokers	• Tetanus toxoid • PCV13
		• Sex Industry Workers	• Hepatitis B
6.	Industrial workers at risk of injuries	• Mechanics & machine operators • Jua kali artisan • Carpenters and masons	• Tetanus toxoid
7.	Food handlers	• Chefs, cooks, kitchen staff, waiters/food servers, prisoners,	• Typhoid vaccine

B) Immuno-Compromised Groups

Table 2: RECOMMENDED VACCINES FOR THE IMMUNOCOMPROMISED

	GROUPS	ANTIGEN
1.	Cancer patients	• Hepatitis B • PCV13 • 23 valent pneumococcal vaccine
2.	HIV/AIDS patients	• Hepatitis B • PCV13 vaccine
3.	Sicklers, Diabetics, asthmatics, & other chronic diseases	• Hepatitis B • PCV13 vaccine • 23 valent pneumococcal vaccine • Polyvalent Meningococcal vaccine • Seasonal influenza
4.	Elderly persons >50 years	• PCV13 • 23 valent pneumococcal vaccine • Seasonal influenza
5.	Travelers	• Yellow Fever • Meningococcal vaccine ACYW135 (for Haj & Ummra)
6.	Persons infested with jiggers	• Tetanus toxoid

GENERAL PROPERTIES OF VACCINES AND DILUENTS

Drugs and vaccines are both classified as pharmaceutical products as they share similar characteristics. A vaccine is however a pharmaceutical product that is a biological medicine, 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 and popular preventive interventions globally. From the beginning of the 20th century the extensive use of vaccines has resulted in significant reductions in the prevalence of many diseases and the eradication of smallpox.

Vaccine components

A vaccine consists of many parts, only one of which is the antigen by which it is known and it is also known 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).

Apart from their ability to stimulate immune responses, vaccine formulations need to be microbiologically stable, that is they should not support microbial growth while sealed.

An ***antigen or immunogen*** is the principle part of any vaccine and has evolved over several years from killed or denatured whole bacterium or viruses, to parts of the disease causing agent such as the capsule or genetically engineered components that mimic the disease causing agent

Diluents include water, aqueous buffer (such as buffered saline), alcohols and polyols (e.g. glycerol). Vaccines marketed as suspensions or solutions already have the diluent constituted into the vaccine. Some diluents are 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 diluents for a given vaccine may compromise the efficacy of the vaccine.

Stabilizers are chemical substances added to vaccines in micro-quantities to maintain vaccine integrity under varying external conditions of temperature and light, and also to sustain physical properties such as solubility.

Adjuvants are substances that are added to some vaccines to increase the body's immune response to the immunogen. Examples are aluminium hydroxide gel, emulsigen, aluminium phosphate, calcium phosphate, quillaja saponin and ginsenoids.

Preservatives are chemical additives to vaccines to ensure that it remains microbiologically stable. That is, preservatives prevent the growth of microorganism and fungi during the long time of storage as well as during it use (especially with multi-dose vials). Common preservatives include formaldehyde, phenol, organic mercury (thiomersal), betapropiolactone and 2-phenoxyethanol.

Not all vaccines contain preservatives. Freeze dried measles and BCG vaccines do not need preservatives because, if handled correctly, they are not in a liquid state long enough to become contaminated and overgrown with organisms such as staphylococcus. Equally important, a preservative in a live-attenuated vaccine would kill or damage the immunogen and make the vaccine useless.

However preservatives are critical to reduce contamination of multi-dose vials of liquid preparations whose rubber stoppers are pricked with needles severally during their use.

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). This however does not apply to the PCV10, pneumococcal vaccine, which should be discarded after 6 hours from the time a vial is opened.*

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.

No existing vaccine works on all people 100% of the time; and even after people are vaccinated they will still need to take other prevention precautions (e.g. good environmental sanitation for polio).

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 will 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, measles vaccine protects vaccinated people and also cuts down on spread of the disease to people who are not infected. However, if too many people are un-vaccinated, 'herd immunity' cannot occur.

Safety – most 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 idiosyncratic reaction to a vaccine so health workers have to be alert for 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 is 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 at 0°Centigrade. 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 destroyed 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 back to the supplier. Here the supplier may be the District 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. color 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 should 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 (outbreak) vaccination services.
- Must have Vaccine Vial Monitors *(commonly known as **VVMs**)*

ADVERSE EVENTS FOLLOWING IMMUNIZATIONS (AEFIs)

Definition: This is a reaction that occurs in a client/patient following vaccination that is considered to be related to the vaccine until proved otherwise.

AEFI occur even in the most careful circumstances but only rarely is there a direct causal relationship between the vaccine and the adverse event.

AEFIs may be localized to the injection site or generalized to the whole body.

AEFIs may be classified as mild, moderate or severe.

AEFIs may manifest immediately after vaccination or any time within 48 hours after vaccination.

Some AEFIs are recognized inherent side-effects of vaccines e.g OPV and vaccine induced paralytic polio.

Management of an Adverse Event Following Immunization

Guidelines for responding to AEFIs must be suitably available/displayed for the health worker to use and cover the following aspects;

- What to notify
- who to notify
- how to conduct the notification
- how to preserve the evidence (vial/syringe etc),

STEPS TO TAKE WHEN AN AEFI OCCURS

The following AEFI should be detected and reported by health workers:

- Injection site abscesses
- BCG lymphadenitis
- Deaths that are thought by health worker or the public to be related to immunization
- Cases requiring admission that are thought by health worker or public to be related to immunization
- Other unusual or severe medical incidents that are thought by health workers or the

  public to be related to vaccination

Immediate steps

1. Take the affected child to the resuscitation room or a safe place away from the 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 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.

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

Long-term steps

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 the operational problem such as knowledge and skills gap

3. Conduct regular supportive supervision and give feedback

4. Improve availability of supplies and the working condition of the equipments to minimize program errors e.g. high temperatures could lead to growth of bacterial in opened unused multi-dose vaccines leading to adverse events. Freezing of freeze sensitive vaccines could lead to aseptic abscesses.

Notification of an Adverse Event Following Immunization

Steps:

- Complete the official AEFI notification form within 48hrs as provided by UVIS – see appendix 4

- Send 2 copies of the completed notification form to the DMOH's office.

- The DMOH sends one copy of the completed notification form to UVIS

- Note: because of the urgency of the investigations of an AEFI, the facility or the DMOH should call and alert UVIS immediately an AEFI is detected.

- Do not address the media without facts. Refer the media to the head, UVIS

VACCINE STORAGE AND MANAGEMENT

Essential Immunization Supplies

UVIS will continue to supply government prescribed childhood and adult vaccines, non-reusable injection devices, safety boxes, monitoring tools, gas and gas cylinders, IEC materials, cold chain equipment and spare parts to all public and government supported immunizing health facilities and those run by other organizations.

Facilities, Districts and Counties are encouraged to supplement the supply of liquid petroleum gas, gas cylinders and refrigeration equipment through other sources of funding but in line with specifications provided by UVIS.

All other vaccines outside the government prescribed schedules such as MMR, hepatitis A, Meningocccocal, varicella, seasonal influenza vaccines must be licensed for use by the Pharmacy and Poisons Board and conform to the Kenya National drug policy.

Until such time as the National Regulatory Authority (NRA) is operationalised for assessment of quality of vaccines, 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.

Distribution of Vaccination Logistics

The Unit of Vaccines and Immunisation Services in collaboration with the Kenya Medical Supplies Agency (KEMSA) shall be responsible for the receipt, storage and distribution of the government vaccination supplies/equipment to the districts and counties.

Maintenance of the Cold Chain

The cold-chain must be maintained at all times along the supply/chain to ensure vaccine potency at the time of administration to a client. Cold-chain efficacy will be gauged 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
- Provision and availability of alternative energy sources for the vaccine refrigerator (i.e. extra full gas cylinder or stand-by generator)

Cold Chain Equipment

The Unit of Vaccines and Immunisation Services will endeavour to supply public health facilities with appropriate, approved vaccine refrigerators based on the known work loads of the facilities. All requests for vaccine refrigerators and other cold-chain equipment from individual facilities must be made to their respective District/ County Medical Officers of Health. The DMOH will in turn compile a summary request ***with justification*** to the Head of the Unit of Vaccines and Immunisation Services.

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 boarded for sale as per the Public Procurement and Disposal Act of 2005.

As part of the Government's effort to adhere to the Montreal and Kyoto Protocols, all cold chain equipment must be 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 $^{+}2^{o}C$ to $^{+}8^{o}C$ with a holdover period of not less than 4 hours for refrigerators, and 17 hours for freezers.

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 maintained between $+2^{o}C$ and $+8^{o}C$ at all times using conditioned ice packs.

Diluents need not be transported at $+2^{o}C$-$+8^{o}C$ unless they are being transported for outreach activities.

At regional or district stores, diluents do not need to be stored in refrigerator or freezer, and should NEVER be frozen. They must however be cooled to between $+2C^{o}$ & $+8^{o}C$ before 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.

However there is special authorization for storage of key pharmaceuticals such as insulin and syntocinon in disadvantaged level 2 & 3 health facilities –but these items must be clearly separated from the vaccines and be clearly labelled. ***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.

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.

OPEN VIAL POLICY

The use of opened multi-dose vials of liquid vaccines *with preservatives*

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
- TT
- Hepatitis B
- Pentavalent vaccine (liquid preparation)

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 expiry date has not passed.
2. The vaccines are stored under appropriate cold chain conditions.
3. The vaccine vial septum has not been submerged in water.
4. Aseptic techniques have been used to withdraw all doses.
5. 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 labeled with the date when they were opened ***before*** they are returned to the vaccine refrigerator.

The revised 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.

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 general 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.

So as to ensure for 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 disposable syringes in immunizations is no longer acceptable in Kenya

The auto-disable (AD) syringe is just one of a growing variety of non-reuseable 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 Public Health & Sanitation therefore recommends the exclusive use of non re-useable injection devices for the administration of all parenteral vaccines.

Disposal of vaccination wastes

Further to the use of the prescribed injection devices, they must be immediately disposed off 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.
- 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 is incineration, preferably in an appropriate high temperature incinerator (>800^{0}C).
- If such an incinerator is unavailable, a low-temperature incinerator (300^0 - 400^{0}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 and damaged/contaminated/ suspect vaccines should be disposed of as per Pharmacy & Poisons Board regulations.

04 POLICIES FOR DIFFERENT VACCINE ANTIGENS

TUBERCULOSIS VACCINE (BCG)

Tuberculosis (TB) is a contagious disease caused by mycobacterium tuberculi 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.

Nearly all TB infections are latent, with carriers showing no symptoms and they are not infectious. However, one in 10 will become sick with active TB in his or her lifetime due primarily to a weakened immune system.

Global situation: Tuberculosis is a worldwide public health problem and more so in low resource countries and in countries with high prevalence of HIV/AIDS. More than two billion people, or a third of the world's total population, are infected with Mycobacterium tuberculosis, the bacteria that causes tuberculosis.

Tuberculosis is the world's seventh-leading cause of death. It is one of three primary diseases that are closely linked to poverty, the other two being AIDS and malaria.

Local situation: Tuberculosis is a common illness in Kenya affecting all age groups and has been on the increase since the onset of the HIV/AIDS pandemic. Kenya ranks 13th on the list of 22 high-burden tuberculosis countries in the world and has the fifth highest burden in Africa.

Treatment: TB is treatable using various regimens of anti-TB drugs as per current guidelines from the National Tuberculosis and Leprosy Programme. However the greatest challenge to the control of tuberculosis is the emergence of multi-drug resistance types.

Prevention: The only available vaccine against tuberculosis has been available for over 40 years. The BCG vaccine has variable efficacy or protection against tuberculosis (TB) ranging from 60-80% for a period ranging from 10-15 years . It is known to be effective in reducing the likelihood and severity of military TB and TB meningitis especially in infants and young children. This is especially important in Kenya where TB is highly prevalent, and the chances of an infant or young child being exposed to an infectious case are high.

Available vaccine preparations: Bacille Calmette Guerin (BCG) is a live attenuated bacterial vaccine named after the original two researchers. The current preparation is prepared from an attenuated strain of 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°C to +8°C degrees centigrade. Once reconstituted, it can be used within six hours and must be discarded after six hours or at the end of the session, which ever comes first.

Schedules: At birth and up to 59 months of age

Dose: 0.05ml 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: Infants who do not develop a scar more than 6 weeks after vaccination should be re-vaccinated once with a similar dose of BCG vaccine unless advised otherwise by a specialist.

If the infant does not develop a scar after the second dose – do not repeat again.

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 BCG vaccination of special risk groups:

- HIV exposed or infected infants are to be vaccinated, unless advised against by a paediatrician
- For BCG vaccination of infants born to TB infected mothers, please refer to the TB treatment guidelines.

Special uses of BCG vaccine: BCG has been found to be effective in the treatment of superficial bladder cancers through intra-vesicular administration. This use of the vaccine is restricted to specialist urologists or oncologists.

POLIOMYELITIS VACCINE (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.

Global situation: Polio cases have decreased by over 99% since 1988, from an estimated 350,000 cases then, to 1,352 reported cases in 2010. The reduction is the result of the global effort to eradicate the disease. In 2012, only three countries (Afghanistan, Nigeria and Pakistan) remain polio-endemic, down from more than 125 in 1988. Persistent pockets of polio transmission in northern Nigeria and the border between Afghanistan and Pakistan are the current focus of the polio eradication initiative. As long as a single child remains infected, children in all countries are at risk of contracting polio. In 2009-2010, 23 previously polio-free countries were re-infected due to imports of the virus.

Local situation: There have been no polio cases in Kenya except for imported cases from Somalia, Sudan and Uganda with the latest case reported in November 2011.

People most at risk: Polio mainly affects children under five years of age.

Transmission: Transmission is primarily person-to-person via the faecal-oral route, i.e. the poliovirus multiplies in the intestines and is spread through the faeces. The time between infection and onset of paralysis is 10-21 days. The virus spreads rapidly to non-immune persons and transmission is usually widespread by the time of paralysis onset. The virus is intermittently excreted for one month or more after infection. The heaviest faecal excretion of the virus occurs

just prior to the onset of paralysis and during the first two weeks after paralysis occurs.

Management: Mainly supportive and rehabilitative

Preventive: Vaccination is the only proven method

Available vaccine preparation: Live attenuated and killed polio virus vaccines

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

    a. Trivalent Oral Polio Vaccine - tOPV containing sero-types 1, 2 & 3 Currently used for routine immunization

    b. Monovalent Oral Polio Vaccine - mOPV
    i. mOPV Type 1 –
    ii. mOPV Type 3

    Currently used only during mass vaccination campaigns for children aged 0 - 59 months in reponse to outbreaks of specific type as they are more immunogenic alone than when combined with the other two serotypes.

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

2. Inactivated polio virus vaccine (IPV) – Serotypes 1, 2 & 3

    c. Currently only one formulation is available in the country in a combination preparation with DPT-HepB & Hib. It is administered parenterally by intramuscular injection at 6, 10 & 14 weeks

Inactivated polio virus vaccines are suited only for countries which have eradicated the wild poliomyelitis disease and only require a vaccine preparation to sustain their immune status. In light of the increased incidence of vaccine derived poliomyelitis, the use of inactivated polio virus 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 trivalent OPV as per the EPI schedule.

Live attenuated polio vaccines are the recommended preparations for use in countries or regions with known transmission or risk of transmission of wild poliomyelitis as they are more immunogenic than the killed virus vaccines.

Schedule for trivalent OPV: In Kenya infants receive 4 doses of trivalent OPV before one year of age

- 1st dose is given immediately at birth or within two weeks of birth. This is known as the ***"birth dose"*** or ***"Zero dose"***
- The other 3 doses should be given at 6, 10 & 14 weeks of age

Route of administration and Dosage: 2 drops administered orally constitute one dose.

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 or bivalent 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

Contra-indication – none

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 diphtheriae the disease is actually results from the toxin produced by this organism.

Global situation: In developing countries children aged 2-15 years are most affected.

Local situation: Diphtheria has not been reported in Kenya for over 20 years, although there is no documentary evidence of the last known case.

Prevention: Primary prevention of disease is by ensuring high population immunity through immunization.

Routine vaccinations: Since the formal launch of the routine infant vaccination schedule in 1980 children < 1 year of age have been vaccinated against diphtheria using a combination vaccine containing diphtheria toxoid. Initially the combination vaccine used was DPT but this was changed at the end of 2001 to DPT-HepB-Hib (*Penta valent vaccine*).

Other variants of DPT containing vaccines have been licensed for use in the Kenya.

Vaccination Schedule: Diphtheria toxoid containing vaccine is administered in three doses at intervals of 4 weeks in a combination preparation with pertussis, tetanus toxoid, hepatitis B and Haemophyllus influenza type b.

The infant schedule for diphtheria toxoid containing vaccine is at 6, 10 & 14 weeks of age.

DPT vaccine is no longer used in routine vaccination in Kenya. However, DPT has a role in the management of outbreaks of pertusis and diphtheria.

Diphtheria surveillance requirements: Diphtheria is a notifiable disease and all suspected cases must be reported to the Disease Surveillance and Response Unit (DSRU) and investigated as per DSRU guidelines.

PERTUSSIS VACCINE

Etiology, signs and symptoms: Pertusis 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.

Global situation: Pertussis is a major cause of childhood morbidity and mortality. In developing countries the case fatality rate is 4% in infants. The mode of transmission is droplets from the nose and throat that are expelled when an infected person coughs or sneezes. Pertussis has an incubation period of 7–10 days.

Although Pertussis may occur at any age, most cases of serious disease and the majority of fatalities are observed in early infancy. Vaccines are the most rational approach to Pertussis control.

Local situation: Exact data of the incidence of pertussis in Kenya is not available. No major outbreaks of pertussis have occurred in over 20 years but isolated scattered incidences do continue to be reported. Pertussis is a notifiable disease.

Because pertussis is a bacterial infection and vaccine derived immunity is not life long, all efforts must be made to ensure sustained complete immunization of all infants.

Prevention: Prevention of pertusis 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***. Acellular pertusis combination vaccine preparations do not generate the desired high titres of antibody protection required in an environment of continuing risk of this disease.

The vaccine is administered in three doses at intervals of 4 weeks in a combination preparation with diphtheria, tetanus toxoid, hepatitis B and Haemophyllus influenza type b.

The infant schedule for pertussis containing vaccine is at 6, 10 & 14 weeks of age.

Acellular pertusis derived vaccine has reduced risk of side effects known to occur with the whole cell vaccine, but has the disadvantage of an unconfirmed duration of protection while being significantly more expensive than the whole cell vaccine.

Acellular pertusis vaccine is indicated where there is low risk of pertusis infection and where there is sibling history of a serious adverse reaction to DwPT-HepB-Hib.

TETANUS VACCINE

Tetanus, also known as lockjaw, is caused by a bacillus Clostridium tetani that is present in the soil, in animal and human feces. After entering the body through a wound, the bacterium produces a neuro-toxin 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 newborn babies and results from contamination with tetanus spores that occurs when babies are delivered in unclean conditions. The incubation period is 3-28 days.

Tetanus is the only vaccine-preventable disease that is not spread from person to person.

Global situation: Tetanus contributes to neonatal and maternal mortality globally wherever maternal protection with tetanus toxoid is low and clean deliveries and clean umbilical cord care practices are not followed.

Local situation: Tetanus has been on the decline in Kenya over the last decade due to the 5 Tetanus Toxoid (5-T.T.) vaccination schedule introduced in 2002 and due to an increase in clean deliveries.

Prevention: 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-T.T. schedule.

Survivors of tetanus disease do not develop reliable immunity to subsequent attacks and must still be vaccinated against the disease before discharge from hospital.

Newborns can be protected from neonatal tetanus during the first 6 weeks of life through vaccination of pregnant women using the 5-T.T. schedule. However additional preventive measures such as clean delivery and clean cord care practices have to be observed.

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.

Table 3: 5-T.T. SCHEDULE FOR PREGNANCY

GRAVIDA	Tetanus toxoid vaccination schedule	Expected maternal outcome	Expected outcome for neonate
First pregnancy	**1st TT dose** *(given from the fourth to sixth month i.e. 2nd trimester)* **2nd TT 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 TT dose** *(given anytime between the forth & eighth months)*	Immunity boosted for 5 years	PAB ≈100% from neonatal tetanus
Third Pregnancy	**4th TT dose** *(given anytime between the fourth & eighth month)*	Immunity boosted for 10 years	PAB for neonate
Fourth pregnancy	**5th TT & last dose** *(given anytime between the fourth & eighth month)*	Immunity boosted for 20 years	PAB for neonate
Subsequent pregnancies	No more TT doses	Immunity adequate for rest of parous life	Adequate. PAB for neonate

Prevention of maternal tetanus is by way of vaccination with tetanus toxoid using the 5-T.T. schedule and clean deliveries.

Prevention of tetanus following trauma is through the use of the 5-T.T. schedule, wound toileting and prophylactic antibiotics

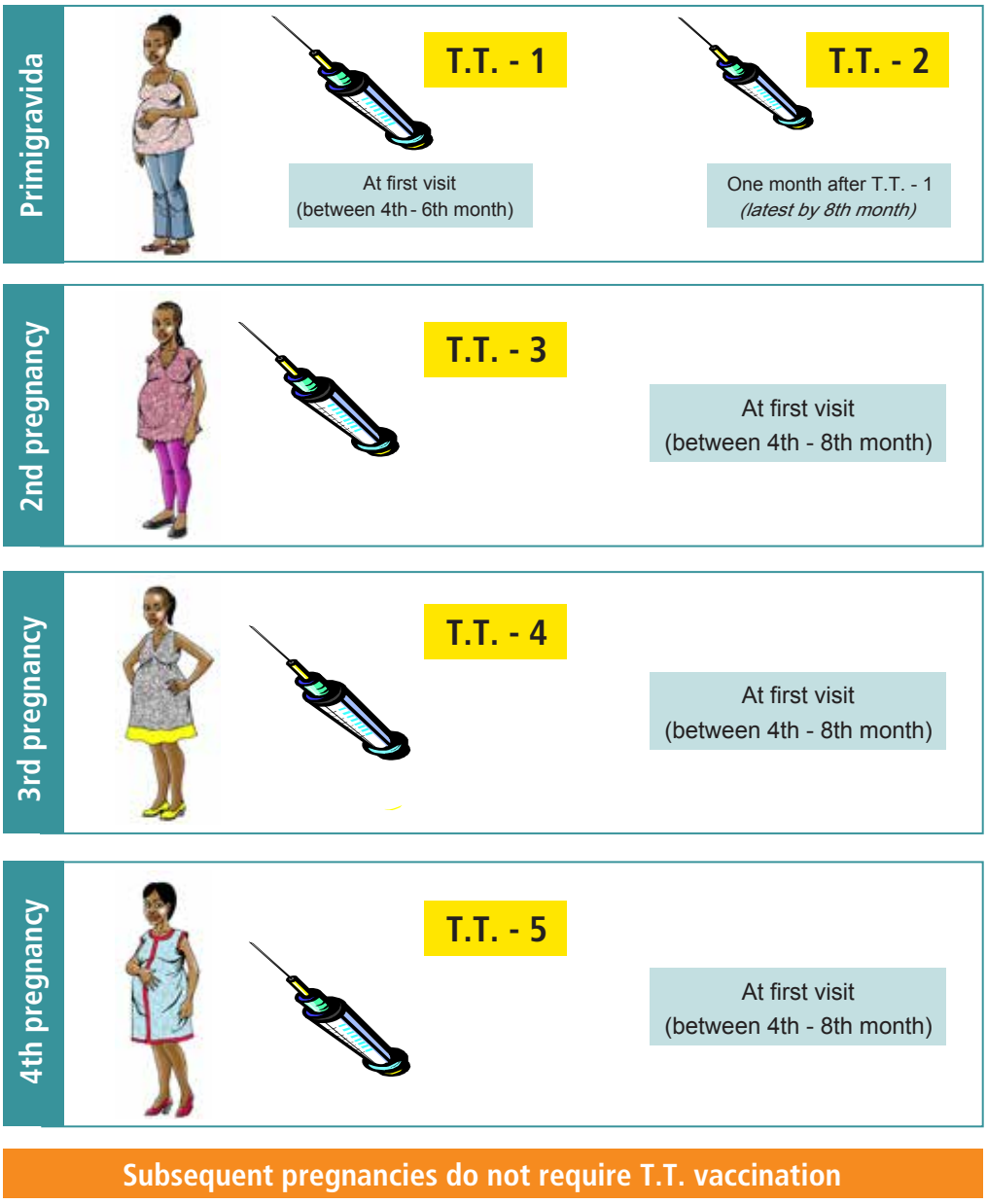

Table 4: 5-T.T. SCHEDULE FOR TRAUMA & OCCUPATIONAL PROPHYLAXIS

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

HEPATITIS B VACCINE

About 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.

Global situation: About 2 billion people worldwide have been infected with the virus and about 350 million live with chronic infection. An estimated 600 000 persons die each year due to the acute or chronic consequences of hepatitis B.

- About 25% of adults who become chronically infected during childhood later die from liver cancer or cirrhosis (scarring of the liver) caused by the chronic infection.
- The hepatitis B virus is 50 - 100 times more infectious than HIV.

Local situation: Hepatitis B is prevalent in Kenya with about one in three persons infected. It is the main cause of liver cancer.

Transmission: In developing countries, the hepatitis B virus is most commonly transmitted to children by:

- Child-to-child transmission through open wounds or shared implements that contain blood or body fluids. This accounts for the majority of hepatitis B infections worldwide.
- Exposure of babies to maternal blood or other fluids during delivery, if the mother is a chronic carrier.

Where infection occurs later in life, the disease is transmitted through sexual activity, contaminated needles and syringes, and contaminated blood products.

In Kenya horizontal transmission rather than vertical transmission plays a significant role in the epidemiology of Hepatitis B viral infection.

Special risk groups for Hepatitis B infection in adulthood include:

- health care workers
- heterosexuals with multiple partners,
- prisoners,
- inmates of drug rehabilitation centres and drop-in centres
- homosexuals
- rape victims
- chronic kidney disease patients
- members of the armed forces & rescue groups

Prevention: Universal infant immunization is now recognized as the ideal strategy for the early long term control of chronic HBV infection and its sequelae (cirrhosis and liver cancer).

Since the major route of transmission of Hepatitis B in Kenya is child to child (horizontal transmission) rather than peri-natal transmission, Hepatitis B vaccination at birth has no significant advantage over Hepatitis B vaccination started at 6 weeks of age, in the reduction of HBV infections of young children.

Infants are vaccinated with 3 doses of Hepatitis B vaccine in combination vaccines containing diphtheria & tetanus toxoids, and haemophyllus influenza type b.

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 0,4 and 6 months.

HAEMOPHILUS INFLUENZA TYPE B VACCINE

Disease burden: The bacterium Haemophillus influenza type b (Hib) causes pneumonia predominantly but may go on to cause invasive disease resulting in bacteremia 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.

Contrary to what the name Haemophilus influenzae suggests, the bacterium does not cause influenza.

Transmission: Hib bacteria are passed from child to child through droplets when an infected child coughs or sneezes. Hib also spreads when children share toys and other things that they put in their mouths. The risk of transmission increases when children spend long periods of time in crowded/ poorly ventilated households and day care settings.

Global situation: *Haemophilus influenzae* type b, or Hib, is a bacterium estimated to be responsible for some three million serious illnesses and an estimated 386 000 deaths per year, chiefly through meningitis and pneumonia. Almost all victims are children under the age of five, with those between four and 18 months of age especially vulnerable.

Local situation: In developing countries, where the vast majority of Hib deaths occur, pneumonia accounts for a larger number of deaths than meningitis. However, Hib meningitis is also a serious problem in such countries with mortality rates several times higher than seen in developed countries; it leaves 15 to 35% of survivors with permanent disabilities such as mental retardation or deafness.

Treatment: Treatment of Hib infection is through an intensive, sustained course of antibiotics, but this is not always accessible to poor populations in developing countries.

Resistance of Hib to several of the more inexpensive but effective antibiotics is a growing cause of concern and provides additional impetus for expanding vaccine coverage.

Prevention: A safe and effective vaccine against Hib infection exists giving high-level protection to 90-95% of vaccinated children. The vaccine is administered in three doses at intervals of 4 weeks either as a monovalent formulation or in combination with diphtheria & tetanus toxoids and hepatitis b. The infant schedule is at 6, 10 & 14 weeks of age.

Vaccination regimen: Hib conjugate vaccines, given by intramuscular injection, are highly effective and have almost no side effects. Three doses are usually administered in infancy, starting at six weeks of age. Hib is administered as part of combination vaccines which can also include protection against diphtheria, tetanus, pertussis, and hepatitis B.

WHO estimates that approximately 20% of meningitis survivors have long-term neurological problems.

COMMON ISSUES ON THE PENTA VALENT VACCINE (DIPHTHERIA, PERTUSSIS, TETANUS, HEPATITIS B, HAEMOPHYLLUS INFLUENZA 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

The recommended combination vaccines are those containing adsorbed toxoids of Corynebacterium diphtheriae and Clostridium tetani, inactivated whole cell Bordetella pertussis, recombinant Hepatitis b vaccine and haemophylus influenza type b conjugated capsular polysaccharide

Dosage: The standard pediatric 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.

Where the five component vaccine preparation contains multiple doses per vial and has had to be reconstituted, any remaining doses in the vial should be discarded at the end of vaccination session or within 6 hours of reconstitution – whichever comes first.

Prevention of hepatitis b infection in adults:

should be through monovalent formulations of recombinant Hepatitis B surface antigen.

Storage Temperature: all combination vaccines should be stored at between $^{+}2^{\circ}C$ to $^{+}8^{\circ}C$ 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.

Hepatitis B vaccination for adults: A monovalent liquid vaccine preparation is available and should be given as a three dose series, with each dose at least four weeks apart. Monovalent Hepatitis B vaccines are available in single-dose and multi-dose glass vials. Multi-dose vials contain two, six, 10, or 20 doses and the open vial policy applies

A 0.5 ml dose of Hepatitis B vaccine is injected intramuscularly, usually into the upper arm – deltoid muscle.

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

MEASLES VACCINE

Definition: 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.

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

- Provision of first dose of the measles vaccines to all infants at 9 months.
- Ensuring that all children get a second opportunity for measles vaccination through periodic mass campaigns.
- Introduction of a second dose of measles into the routine immunization schedule for children aged 18 months.
- 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 has no specific treatment is available, management is purely supportive especially to prevent complications.

Vitamin A supplementation during measles outbreaks: Measles infection and outbreaks are used as an opportunity to administer supplementary doses of vitamin A. (*Ref. Measles guidelines-2006)*

Prevention: Vaccination with measles vaccine is the only preventive method.

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 mumps and rubella vaccine formulation (MMR).

The ***monovalent preparation*** 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

Recommendation: In view of local measles epidemiology and the high susceptibility of infants to measles infection, the Ministry of Health recommends the routine use of monovalent measles vaccine at 9 months of age followed by a s***econd-opportunity dose*** starting from 15 months of age. This ***second-opportunity dose*** may be the monovalent measles vaccine or the combination MMR vaccine.

Second-opportunity doses of monovalent measles vaccine will be given ***for the public good*** through mass vaccination campaigns for management of measles outbreaks. The target age groups for mass vaccination exercises will be determined by the Ministry of Health.

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

of age and this is the earliest age at which an acceptable sero-conversion rate of 85% is achieved.

Measles in combination with Mumps and Rubella

Mumps and rubella rarely ever occur in infants less than 1 year of life and because seroconversion rates for mumps and rubella vaccine are not well documented in this age group, the ***combined measles, mumps and rubella vaccine (MMR) is best utilized to provide a second-opportunity dose for measles at 15 months of age***. This provides non-converters from the primary dose another opportunity that is usually ³95% effective. The seroconversion rates for the mumps and rubella is also maximized at 15 months of age at >95% for both antigens.

Storage: Both monovalent measles vaccine and the MMR vaccine should be stored between +2^{0}C and +8^{0}C at immunizing facilities.

Reconstituted multi-dose measles vaccine should be discarded at the end of the session or after 6 hours, whichever comes first.

Monovalent measles vaccine (lyophilized and reconstituted forms) must also be protected from light during storage.

Dosage and routes of administration: The monovalent measles vaccine is given as a single dose of 0.5ml, deep subcutaneous injection over the deltoid muscle of the left upper arm of the child.

**MMR vaccine is also given as a single dose of 0.5ml subcutaneously.*

Contraindications:

- There are no major contraindications for monovalent measles vaccine except those that may be determined by a specialist.
- MMR vaccine is contraindicated in children known to be allergic to eggs because the mumps virus strain is cultured on embryonated chicken eggs.

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. Such infants should receive monovalent measles vaccines at 6 months of age followed by the normal dose of monovalent measles vaccine at 9 months.

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***.

YELLOW FEVER VACCINE

Definition: It is a mosquito borne viral haemorrhagic fever transmitted to unvaccinated persons from infected persons by mosquitoes of the Aedes Species.

Aetiology: Yellow fever is caused by an arbovirus of the family Flaviviridae, which currently contains over 70 viruses including dengue viruses. The incubation period of yellow fever is 12 – 21 days.

Global situation: It is estimated that 200,000 persons are affected by yellow fever disease with 30,000 deaths reported worldwide annually. The disease is endemic in 33 countries in Africa. Fifty percent of classic cases die between the 7th and 10th day after onset.

Local Situation: An outbreak of yellow fever disease occurred in 1992 in the Kerio Valley and mass vaccination was conducted in Baringo, Keiyo, Koibatek and Marakwet districts.

However no cases of yellow fever have since been reported from these districts and in Kenya.

Since that time, yellow fever vaccination is routinely administered to children at 9 months of age in these high risk counties (Elgeyo Marakwet & Baringo counties) as part of EPI.

Signs and Symptoms: Mild cases of yellow fever present with headache, fever, nausea and vomiting while classic cases present with sudden onset of fever, chills, intense headache, back pain, generalized muscle pains, nausea, vomiting and conjuctival infection. Progressively, patients present with jaundice, vomiting (black vomitus), bleeding from the gums and nose, albuminuria and oliguria.

Treatment and management: There is no specific anti-viral drug therapy for yellow fever and management of patients is through standard supportive therapy.

Prevention: Yellow fever vaccine Is derived from chick embryo propagation of strain 17D. The vaccine induces adequate antibody response within 6 days of administration and this immunity lasts for at least 10 years. Due to risk of adverse reactions, the vaccine should not be given to children less than six months of age. In Kenya it is safely administered routinely at 9 months in the districts mentioned above, at the same sitting with measles vaccine ***but in the left deltoid muscle.***

A single dose of 0.5 ml is administered intramuscularly into the left upper arm (deltoid). Booster doses may be given every 10 years either through routine or campaign vaccination. Adverse reactions to the vaccine are very rare.

Contra indications - Yellow Fever vaccine should **not** be administered to symptomatic HIV infected children since the vaccine is live attenuated. The vaccine is contraindicated for children less than 6 months and for individuals allergic to eggs.

Once a vial is opened it must be kept cold and used or discarded within 6 hours after reconstitution.

Yellow vaccine for travelers

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 travelers 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 travelers 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 six days prior to the day of departure or is within the 10 years of known protection conferred by the yellow fever vaccine derived from strain 17D.

Subsequent vaccination against yellow fever after every 10 years induces an immediate antibody production, so a booster dose given even a day before travel is valid.

Outbreak Response

If a case of Yellow Fever is suspected, the Disease Surveillance & Response Unit (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.

PNEUMOCCOCAL VACCINE

About pneumococcal disease: 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 commonly 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.

Global situation: Pneumococcal disease caused by the bacterium *Streptococcus pneumoniae* is a major public health problem all over the world. At least 1 million children die of pneumococcal disease every year, most of these being young children in developing countries. In the developed world, elderly persons carry the major disease burden. Transmission is through close contact with infected persons mainly through droplet infection.

Local situation: In Kenya, the predominant serotypes are 1, 6B, 14, 5, 23F and 19F.

Treatment: All types of pneumococcal infections are usually treated with antibiotics. Empiric therapy for suspected pneumococcal infection depends on the syndrome but usually includes a penicillin or cephalosporin. Worldwide, many strains are increasingly resistant to penicillin, cephalosporins, and macrolides, and some are resistant to multiple classes of drugs, complicating treatment choices. Antimicrobial susceptibility of strains isolated from blood and cerebrospinal fluid should be determined, and definitive treatment should be targeted on the basis of susceptibility results.

Prevention: Vaccination is the most cost effective method to prevent pneumococcal disease. 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.

Target age group: because streptococcal pneumoniae is the leading causes of infant mortality and morbidity in Kenya, the Ministry of Health introduced a 10 valent pneumococcal conjugate vaccine – PCV10 into the infant immunization schedule in 2011.

The target group will be all infants less than one year old.

Dosage and route of administration for PCV10: 0.5mls of vaccine injected intramuscularly into the anterior upper, outer aspects of the ***right*** thigh in three doses given at 6, 10 and 14 weeks of age.

No screening is done for HIV status of routine infant immunization clients.

High risk clients: 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). All high risk clients should receive a single intramuscular dose of 0.5mls of the specific vaccine as shown on Table 2 (p.22).

MUMPS VACCINE

Mumps is a virus infection caused by a paramyxovirus of the genus Rubulavirus. Mumps typically causes enlargement of the two parotid glands at the angle of the jaw anterior to the ear on both sides of the face.

Global situation: Mumps is a common infectious disease in all the parts of the world, with an annual incidence ranging from approximately 0.1% to 1%, in certain population even reaching 6 %. It is mostly a childhood disease affecting ages 5-14 years but the proportion of young adults who become infected has been rising slowly over the last two decades. Mumps is extremely rare in infants less than one year of age. Infection usually

confers immunity. Human beings are the only known host.
Local situation: No data on local situation is available although it is a familiar disease of childhood that occasionally affects adults. The epidemiology is believed to be the same as in other parts of the world.

Transmission, Signs and Symptoms: Airborne droplets released when an infected person sneezes, or coughs and through direct contact with an infected persons. Sufferers often have a dry mouth and may have fever, headache and difficulty swallowing. Mumps resolves slowly and does not usually cause lasting effects.

However, if infection occurs in males after puberty, mumps may cause swollen, tender, inflamed testicles which may result in sub-fertility in a minority of those affected.

Mumps may also cause inflammation of the pancreas (pancreatitis) sometimes leading to miscarriage and, very rarely, inflammation of the central nervous system eg meningitis, encephalitis, or myelitis.

Incubation period: 14 to 21 days

Treatment: No specific treatment, only supportive management

Prevention: By vaccination given commonly in combination vaccine with measles & rubella in the MMR combined vaccine.

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

Schedule and dose: a single dose of 0.5 mls is given subcutaneously at 12-15 months of age as part of the MMR vaccine. Injection site may be the outer mid thigh or upper arm.

Currently, the Ministry of Health does not provide this vaccine in public and government supported facilities but it is available in the private sector.

Contra-indications: History of severe reaction to a previous dose and those who have allergy to eggs.

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 intraplacentally.

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.

Global situation: Rubella which is usually transmitted by droplets from the nose or throat has a worldwide distribution. The extent and periodicity of rubella epidemics is highly variable in both developed and developing countries. It is estimated that there are 100,000 cases occurring in developing countries each year.

Local Situation: Laboratory comfirmed rubella is highly prevalent in Kenya but the majority of those infected are pre-adolescent group. No data is available on Congenital Rubella Syndrome (CRS), although some studies are ongoing.

The Ministry of Health is continuing with surveillance for rubella and CRS *(refer to draft CRS guidelines)*

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 child bearing 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 child bearing age (WCBA).

Vaccine Preparations: The vaccine is available in combination 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.

Dose: A single dose of 0.5mls is injected subcutaneously into the thigh or upper arm at 12-15 months of age

INFLUENZA

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 human.

Global situation: During inter-pandemic periods between 1918–1991, the average annual rate of excess deaths during influenza outbreaks in the United States was 7.5–23 per 100 000 population. In industrialized countries, influenza is associated with a considerable economic burden in terms of health care costs, lost days of work or education and general social disruption. This apparently low recognition of influenza as a serious infectious disease is most likely a consequence of the lack of epidemiological data on influenza from many of these regions.

Local situation: In Kenya, from the national sentinel surveillance sites, 1254 specimens were received from all 8 provinces of which 178 were positive for influenza; 42 (3%) were positive for influenza A and 136 (10.8%) were influenza B positive. The surveillance is ongoing for influenza like illnesses.

Incubation period: The incubation time for influenza ranges from one to five days with an average of two days. In most cases, the virus is found in specimens from the respiratory tract from one to two days before onset to four to five days after onset of disease, corresponding to the period of communicability.

Signs and symptoms: Clinical onset is characterized by abrupt fever, headache, malaise and myalgias. Systemic symptoms usually last for three days, although occasionally high fever for up to one week is observed. Sore throat, rhinitis and non-productive cough may continue for several days after the systemic symptoms have ceased.

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 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.

Types of vaccines

There are three types:

- whole virus vaccines consisting of inactivated viruses;
- split virus vaccines consisting of virus particles disrupted by detergent treatment;
- sub-unit vaccines consisting essentially of haemagglutinin and neuraminidase from which other virus components have been removed.

Route of administration: Influenza vaccines are administered either intramuscularly or subcutaneously.

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 immuno 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.

In pandemics, all individuals should have the opportunity for immunization, with prioritization for children < 5 years and elderly >65 years.

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 virues include: avian influenza (H5N1) and H1N1 viruses.

Guidelines on the use of these vaccines will be provided by the Ministry of Health as necessary.

Avian influenza: The newly emergent Avian Influenza H5N1 virus pandemic poses a serious threat to the lives and livelihoods of all persons around the world, but especially to the fragile health services and economies of developing countries.

The H5N1 virus originally caused a mild, non fatal illness in infected birds but at some point this virus mutated into a highly pathogenic form which could kill chicken within 48 hours. Infection in humans was first noted in 1997 in Hong Kong where 18 persons were infected and six died. Resurgence occurred in 1999 and 2003 in Hong Kong again but was restricted there. However the resurgence of 2004 resulted in spread to South East Asia, Europe and Africa.

Current information indicates that close contact with dead or infected birds is the most important cause of human infection with H5N1 virus. The greatest risk of infection is seen during the slaughtering, plucking or consumption of infected birds.

H5N1 influenza has so far only been documented to be contracted from affected birds (mainly poultry). No human-to-human transmission has yet been confirmed.

Keen global and local surveillance systems are the mainstays for prevention and control of the spread of this disease, combined with a detailed outbreak management plan and the resources required to implement such a plan.

H5N1 Vaccine

A new vaccine against avian influenza was developed in the United States of America and approved by the Food and Drugs Administration authority in April 2007. This vaccine has restricted supply.

H1N1 Vaccine

The symptoms of H1N1 flu are similar to those of other influenzas, and may include a fever, cough (typically a "dry cough"), headache, muscle or joint pain, sore throat, chills, fatigue and running nose. People at higher risk of serious complications include those aged over 65 years, children younger than 5 years, children with neurodevelopmental conditions, pregnant women (especially during the third trimester), and those of any age with underlying chronic medical conditions.

Transmission: Spread of the H1N1 virus is thought to occur in the same way that seasonal flu spreads. Flu viruses are spread mainly from person to person through coughing or sneezing by people with influenza. Sometimes people may become infected by touching something – such as a surface or object – with flu viruses on it and then touching their face. "Avoid touching your eyes, nose or mouth. Germs spread this way.

Prevention: The H1N1 vaccine is recommended for priority groups such as pregnant women, people who live with or care for babies under six months old, children six months to four years old and health-care workers. Although it was initially thought that two injections would be required, clinical trials showed that the new vaccine protects adults with only one dose.

HEPATITIS A VACCINE

Hepatitis A is an acute, usually self-limiting disease of the liver caused by

Hepatitis A virus (HAV). 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.

Hepatitis A infection presents variably from a total absence of symptoms to a fuminant disease and occasionally death. Acute infection has three stages, the pre-icteric, icteric and convalescence stages. Generally a person is most infectious from 14–21 days before the onset of symptoms, through to 7 days after the onset of symptoms.

Global situation: Hepatitis A disease is primarily a disease of children and is transmitted from person to person through the faecal-oral route directly or indirectly. The disease is endemic the world over varying only in the level of endemicity from low, medium or high. Hepatitis A occurs sporadically and in epidemics worldwide, with a tendency for cyclic recurrences. Worldwide, HAV infections account for an estimated 1.4 million cases annually. Epidemics related to contaminated food or water can erupt explosively, such as an epidemic in Shanghai in 1988 that affected about 300 000 people. The highest incidences worldwide are found in South America, Africa, the Middle East and Asia. In America, approximately 143,000 are affected annually.

Local situation: Kenya is among the high endemicity countries for hepatitis A although the exact magnitude of HAV disease in Kenya is presently unknown. It is a food and water borne disease and is widespread in Kenya. The virus, found in the intestine comes into the body through and food contaminated by sewage. Hepatitis A is common in Kenya and therefore vaccination should be taken as an important precautionary measure.

***Clinical picture**:* Symptoms typically include fever, malaise, anorexia, nausea and abdominal discomfort, followed by dark urine and jaundice. The severity of disease and mortality increases in older age groups. The convalescence following hepatitis A may be slow, and is characterized by fatigue, nausea and lack of appetite.

Complications of hepatitis A include relapsing hepatitis, cholestatic hepatitis and fulminant hepatitis. Fulminant hepatitis occurs in approximately 0.01% of clinical infections and is characterized by rapid deterioration in liver function and a very high fatality rate. Chronic infection with HAV does not occur.

Treatment: No specific antiviral therapy is currently available and management remains largely supportive with use of vitamins and reduction on 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.

The dose of the vaccine, vaccination schedule, ages for which the vaccine is licensed, and whether there is a paediatric and adult formulation varies from manufacturer to manufacturer. No vaccine is licensed for children younger than one year of age.

A combination vaccine containing inactivated hepatitis A and recombinant hepatitis B vaccines has been licensed since 1996 for use in children aged one year or older in several countries. The combination vaccine is given as a three-dose series, using at 0, 1, & 6 months intervals.

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

***Precautions:* -** vaccination in the circumstances below to be determined by a specialist

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

Target population: because hepatitis A disease is most severe in adults, 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 sewerage treatment works in urban councils should also be administered the hepatic A vaccine.

All these candidates for hepatitis A vaccine administration should receive a two dose schedule with a six month interval between doses to ensure a minimum 10 year protection against this disease

HEPATITIS C INFECTION:

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). HCV infection sometimes results in an acute symtomatic 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.

Global situation: About 130–170 million people are chronically infected with hepatitis C virus, and more than 350 000 people die from hepatitis C-related liver diseases each year.

Local situation: Reported to affect about 0.9% of the population.

Treatment: HCV infection is curable using increasingly effective antivirals.

Hepatitis C vaccine: Despite ongoing research, there is currently no vaccine to prevent hepatitis C virus infection.

VARICELLA VACCINE

Description of varicella disease: 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 re-activation of dormant varicella virus sequestered in the dorsal nerve root ganglia of the spinal cord.

Chicken pox 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.

The incubation period (time between exposure to the illness and the appearance of symptoms) of chicken pox is 10 to 21 days. It is contagious for about six to eight days after the rash appears or until all of the blisters have dried out.

Global situation: Both chicken pox and herpes zoster are endemic world wide although herpes zoster presents mainly in immunocompromised persons especially those with HIV/AIDS, and those on cytotoxic therapy. In the USA before varicella vaccine use became widespread, 4 million cases of chickenpox were reported annually. National seroprevalence data for 1988-1994 indicated that 95.5% of adults aged 20-29 years, 98.9% of adults aged 30-39 years, and more than 99.6% of adults older than 40 years were immune to varicella. The disease was responsible for 11,000 hospitalizations each year and approximately 50-100 deaths.

The adoption of universal vaccination against varicella in 1995 reduced the incidence of varicella, as well as the associated morbidity and mortality rates. By 2000, vaccination coverage among children 19-35 months in 3 communities had reached 74-84%, and reported total varicella cases had declined 71-84%. Most of the decline occurred among children aged 12 months to 4 years; however, incidence declined in all age groups, including infants and adults.

Currently, fewer than 10 deaths occur per year, most of them in unimmunized people. Although vaccination coverage has exceeded 80% over the past few years, outbreaks of breakthrough varicella still occur in schools and daycare centers.

Local situation: Chicken pox is common in Kenya but there are no studies that have been done to define the prevalence, incidence and mortality statisitics.

Symptoms of Varicella (Chicken Pox): There are usually no symptoms before the rash occurs but occasionally there is fatigue and some fever in the 24 hours before the rash is noticed. The typical rash goes through a number of stages:

- Initial macules which become papular
- The papules change into fragile vesicles which break and the resultant sores become pustular and form a crusts - the crust is made of dried serum, and not true pus. Itching is severe in the *'pustular'* stage.
- The crust falls away between days 9 and 13 leaving scars which may persist lifelong

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.

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 virus. Among the immunosuppressed individuals, varicella immunoglobulin is recommended.

Dosage: 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).*

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

Chickenpox disease is a life-threatening disease to a small highly specific population of immunosuppressed individuals. The Ministry of Health does not procure varicella vaccines for the national infant immunization schedule.

ROTAVIRUS VACCINE

Rotaviruses are a genus of viruses belonging to the Reoviridae family. Seven major groups have been identified, three of which (groups A, B, and C) infect humans, with group A being the most common and widespread one.

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

Global situation: Rotavirus is the most common cause of severe diarrhea among children, with deaths of over 600,000 children annually worldwide. Globally, 4 sero-types are responsible for the majority of rotavirus disease but additional sero-types are prevalent in some countries. Four commonest rotavirus strains account for 88.5% of the rotavirus diarrhoea among children worldwide[1]

- G1P[8], (64%)
- G2P[4], (12%)
- G3P[8], (3%)
- G4P[8], (9%)

G9 strains are on the increase.

Local situation: In Kenya rota virus contributes to 41% of childhood diarrheal disease burden.

The four commonest rota virus strains in Kenya are:

- G8P[6]
- G10P(8)
- G1P (6)
- G9P(8)

The incubation period: for rotavirus disease is approximately 2 days. The disease is

characterized by vomiting and watery diarrhea for 3 - 8 days, and fever and abdominal pain occur frequently. Immunity after infection is incomplete, but repeat infections tend to be less severe than the original infection

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

Prevention: Through vaccination that prevents severe forms of diarrhea caused by Rotavirus.

Vaccine type: Two types of live attenuated virus formulations for oral administration are licensed locally.

- A monovalent formulation (Rotarix™) which protects against serotypes G1P8 and *possibly* non G1 serotypes such as G2, G3, G4 and G9
- A pentavalent formulation (RotaTeq™) which protects against serotypes *G serotypes* - human G1, G2, G3 and G4*; bovine G6;* human P1A[8] and bovine P7[5]

Dosage:

- Vaccination course for the monovalent vaccine consists of two doses. The first dose should be given between 6 and 14 weeks and the second between 14-24 weeks of age. The interval between doses should not be less than 4 weeks.

- Vaccination course for the pentavalent vaccine consists of three doses. The first dose should be given at 6-12 weeks of age and the two additional doses administered at 4 to 10 weeks interval. All the three doses should be completed before a child reaches 32 weeks of age

Rotavirus oral vaccines can safely and effectively be administered with oral polio vaccine (OPV).

RABIES VACCINE

Description

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 area where rabies is endemic. Dogs accounts for more than 90% of the cases in animals. (WHO report 1992). In Kenya it is also commonly found in wild animals.

Global situation: It is estimated that each year at least 50,000 people die from rabies and more than 10 million receive post exposure vaccination against the disease. Children aged 5-15 years are at particular risk. More than 99% of human deaths from rabies occur in Africa, Asia and South America (WHO 2002).

Kenyan situation: Little is known about the incidence of human rabies infection in Kenya however hundreds of doses of anti-rabies vaccine are administered to victims of animal bites each year.

Prevention of rabies: 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 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: There are three types of rabies vaccines licensed for use in Kenya

The licensed vaccines against rabies are:

1. Purified chick embryo cells (PCEC vaccines) is LEP strains of rabies virus cultured on chick embryo fibroblast and inactivated by B-propiolactone. It is available as 2.5IU in 1 ml ampoule .

2. Human diploid cells vaccines (HDCV) is purified lyophilized inactivated rabies virus grown in human diploid cell culture. Vials contains a single dose of 2.5 IU suspension in 1 ml diluents.

3. Purified Vero Cell Rabies Vaccine (PVRV) is vaccine produced on continous heteroploid cell line and inactivated using ß-propiolactone

Storage: Store all forms of rabies vaccines between +2°C to +8°C

Administration and Dosages: Must always be with reference to the specific vaccine manufacturers instruction and given in two circumstances:

- 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) followed by a booster dose after 1 year*
- 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 0.5 ml 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.*

Note: if post-exposure treatment must be given to immunocompromised individuals, HIV positive persons, people under malaria chemoprophylaxis or people under anaesthesia, Intramuscular vaccine and rabies immunoglobulin are mandatory and their antibody responses should be monitored serologically.

Multisite intradermal vaccination using the purified vero vaccine is being tried in some countries. A fraction of the intramuscular vaccine is inoculated intrademally in multiple sites on the same day, however, only the cell derived vaccine is recommended for this route. The cell derived vaccine avoids the use of brain tissue in the preparation of the rabies vaccine. WHO recommends the discontinuation of brain tissue derived vaccines and encourages countries to use the cell derived rabies vaccines.

- 8 site intradermal vaccines recommended are for the human diploid cell vaccine and purified chick embryo cell vaccine at a dose of 0.1ml per intradermal site
- 2 site intradermal vaccines recommended are the PVRV at a dose of 0.1ml per site or the PCECV at a dose of 0.1ml per site.
- WHO recommends the use of HDC and PCEVC for intradermal inections.

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.

Persons who are previously immunized get 2 doses on day 1 and day 3; and for new cases not previously vaccinated they should get 5 doses on days 0, 3, 7, 14, 28.

Please note the dose of anti-rabies vaccine given to a child is exactly the same as the adult dose irrespective of age or weight because children receive the same dose of rabies virus in any bite.

ALL reports of animal bites must be forwarded to the nearest office of the Department of Veterinary Services or Kenya Wildlife services.

ANTI SNAKE VENOM

Aetiology: 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
- Venoms classification includes:
    - *Neurolytic - destroys nerve cells causing paralysis of respiration and other organs and tissues.*
    - *Haemolytic - destruction of blood cells causing disseminated haemorrhage.*
    - *Cytotoxic - causes localized destruction of tissues resulting in either blisters or gangrene.*
    - *Cardiotoxic - affect the heart function causing arrhythmia, shock and renal failure.*

Global Epidemiology: Snake bites occur throughout the world although some varieties of snakes have differing global distributions**.**

Local epidemiology: Kenya has about 127 different varieties of snakes spread throughout the country and snake bites occur frequently throughout the year especially in rural areas. However only about 34 species are significantly poisonous, and the rest are non-venomous.

Exact data on the annual incidence of snake bites is not available in the country. Deaths from snake bites often occur due to late presentation at health facilities or unavailability of anti-snake venom.

Signs and symptoms: are dependent on the type of venom that has been injected through the snake bite.

- Haemolytic venoms cause disseminated intravascular coagulopathies, gastro-intestinal disorders and death if anti-snake venom is not administered, or it is administered too late.
- Neurolytic venoms cause diffuse pain or numbness around the bite site followed by neuromuscular disorders within one hour. If anti-snake venom is not administered promptly the patient develops progressive paralysis, asphyxia and death.
- Cytotoxic/myotoxic venoms cause severe radiating pain and oedema around the site of the bite. This progresses into necrosis and gangrene at the site of the bite and sometimes beyond.

Management: 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 (non-sedating) 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
- the spreading local damage (marked local or generalized swelling).

Epinephrine (adrenaline 1:1000 solution) should always be drawn up in readiness ***before*** anti-venom is administered.

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

The recommended Ministry of Health procured 10-valent Anti-snake venom preparation in Kenya should be given intravenously as follows:

- An initial dose of 20ml (2x10ml vials) is infused in 250ml of 0.9% sodium chloride solution or 5% glucose solution at the rate of 1ml per minute.

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.

- If the subjects condition does not improve within two hours after completion of the first infusion, then a second dose should be infused exactly as per the first dose.

Anti-venom should never be injected intramuscularly as absorption is exceptionally slow and unreliable.

Tetanus toxoid vaccine should be administered to all victims of snake bites as a single intramuscular injection of 0.5mls.

Prophylactic broad spectrum antibiotics and metronidazole are advisable in cases of cytotoxic venoms.

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

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.

The Ministry of Health recommends 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.

CHOLERA VACCINE

Aetiology*: Cholera disease is caused by a bacterium known as Vibrio cholerae which* is a Gram-negative, rod-shaped non-invasive mainly waterborne bacterium. Serogrouping 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 of these biotypes can be further classified into 2 serotypes: Ogawa and Inaba.

Epidemiology of cholera disease: Cholera is a rapidly dehydrating diarrhoeal disease caused by ingestion of toxigenic serogroups (O1 and less commonly O139) of *Vibrio cholerae*. Humans are the only known natural host for *V. cholerae*, and the disease is spread mainly by faecal contamination of water and food. Direct transmission from person to person is uncommon. Cholera is closely linked to poor sanitation and a lack of clean drinking water. The disease burden is characterized by both endemic disease and epidemics. Throughout history, devastating outbreaks of cholera have resulted in millions of cases and hundreds of thousands of deaths.

Kenya is prone to periodic outbreaks of cholera but no regions where cholera is endemic.

Signs and symptoms: After penetrating the mucus layer, *V. cholerae* colonize the epithelial lining of the gut. They then produce a toxin which affects the small intestine. The toxin causes massive loss of intravascular and extracellular fluids and electrolytes – especially sodium, potassium and bicarbonate – through the stool and vomitus. Cholera is characterized by acute, profuse watery diarrhoea of 1 or a few days' duration. In its severest form, cholera is one of the most rapidly fatal infectious illnesses known. Within 3–4 hours of onset of symptoms, a previously healthy person may become severely dehydrated and if not treated may die within 24 hours.

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 withRinger's lactate solution) is required. Although rehydration may be life-saving, it has no effect on

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.

Available vaccines: Two types of oral cholera vaccines are available:

Shanchol™ and mORCVAX™. These two are identical vaccines in terms of strains but formulated by different manufacturers using different methods.

Shanchol™and mORCVAX™ are bivalent oral cholera vaccines based on serogroups O1 and O139. Unlike Dukoral™, these vaccines do not contain the bacterial toxin B subunit and will therefore not protect against ETEC. Shanchol™ is provided in single-dose vials, mORCVAX™ in single dose and 5-dose vials.

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

Dosages:

- Shanchol™/mORCVAX™ should be administered orally in 2 liquid doses 14 days apart for individuals aged ≥1 year. Unlike Dukoral, Shanchol does not require a buffer or water for administration. A booster dose is recommended after 2 years in cholera endemic areas.

Ministry of Health recommendation: Pre-emptive vaccination with oral cholera vaccines should be undertaken in epidemic prone regions of the country once the risk of cholera becomes significant due to events such as flooding and emergency displacement of communities. Specific targets for pre-emptive vaccination against cholera are internally displaced persons in camps, medical staff and all other personnel involved in relief operations, such as military, paramilitary and aid agency staff.

In the event of an outbreak, oral cholera vaccine should be administered to all personnel involved in the management of the outbreak. However the affected communities should receive prophylactic antibiotics instead of vaccination. The relevant management of environmental sanitation and disinfection of drinking water must be instituted together with health education to the affected community.

Cholera vaccines may also be administered to individuals proceeding on foreign travel if so advised by the country to be visited. Vaccination for travel purposes should be captured on the International Vaccination Certificate (the 'yellow fever' card) under 'other vaccines'.

TYPHOID VACCINE

Definition: 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. The incubation period is 5 – 21 days.

Signs and symptoms: They include high fever, malaise, headache, constipation or diarrhoea, rose-coloured spots on the chest, and enlarged spleen and liver. A healthy carrier state may follow acute illness. Severe forms of typhoid fever may manifest with cerebral dysfunction, delirium and shock and occasionally intestinal perforations and hemorrhages. Symptoms usually develop 1–3 weeks after exposure, and may be mild or severe. Healthy carriers should be excluded from handling food.

Global situation: There are an estimated 16–33 million cases of typhoid fever occur annually resulting in 216,000 deaths in endemic areas. The World Health Organisation identifies typhoid as a serious public health problem. Its incidence is highest in children and young adults between 5 and 19 years old.

Local situation: Typhoid disease is endemic throughout Kenya with noted higher prevalence in urban areas. An average of 4,000 cases of typhoid are diagnosed each year although the age and sex distribution is not known.

Management: Typhoid fever can be treated with antibiotics based on sensitivity testing. However, resistance to common antimicrobials is widespread.

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 human feces or urine are able to come into contact with food or drinking water. Careful food preparation and washing of hands are crucial to preventing typhoid.

There are two vaccines licensed for use for the prevention of typhoid; the live, oral Ty21 vaccine and the injectable Typhoid polysacaccharide vaccine(*Typhim Vi* and *Typherix*). Both are between 50% to 80% protective and are recommended for travellers to areas where typhoid is endemic. Boosters are recommended every five years for the oral vaccine and every two years for the injectable form. There exists an older killed whole-cell vaccine that is still used in countries where the newer preparations are not available, but this vaccine is no longer recommended for use, because it has a higher rate of side effects (mainly pain and inflammation at the site of the injection).

The Vi - polysaccharide vaccine is the currently approved vaccine for public health use in Kenya.

This vaccine is composed of purified vi polysaccharide from S.typhi. It is administered as a single dose either subcutaneously or intramuscularly to individuals over two years of age. The vaccine confers protection seven days after injection.

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

Route of administration: intramuscular injection of 0.5ml into the deltoid muscle.

There are no contraindications other than prior severe reaction to vaccine component.

Booster doses: a single booster dose should be given to these high risk groups every three years.

In view of the epidemiology of typhoid disease the Ministry of Health recommends prioritization of vaccination to those at highest risk of contracting or transmitting the disease.

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.

MENINGOCOCCAL VACCINE

Meningococcal disease describes infections caused by the bacterium (also termed meningococcus). 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 under developed countries worldwide.

Neisseria meningitidis (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.

Global situation: Meningococcal epidemics occur almost annually along the meningitis belt of sub-saharan Africa, which stretches from the western coast of Africa to the Gulf of Aden. The incidence of endemic meningococcal disease during the last 13 years ranges from 1 to 5 per 100,000 in developed countries, and from 10 to 25 per 100,000 in developing countries. During epidemics the incidence of meningococcal disease approaches 100 per 100,000. There are approximately 2,600 cases of bacterial meningitis per year in the United States, and on average 333,000 cases in developing countries. The case fatality rate ranges between 10 and 20 per cent.

Local situation: Although Kenya does not strictly lie within the meningitis belt of Africa, a major meningococcal epidemic occurred in Nairobi in 1989 where 3,800 people were affected and a smaller outbreak occurred in West Pokot in 2006.

Aetiology: Meningococcal disease is an infectious disease caused by Neisseria meningitidis and the disease 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. Meningococci are aerobic, Gram-negative, encapsulated diplococci. Five sero types exist namely: A, B, C, Y and W135. Sero groups A, B and C are responsible for the vast majority of morbidity and mortality.

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

Signs and symptoms: Meningitis is characterized by onset of intense headache, fever, nausea, vomiting, photophobia and stiff neck.

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

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

Conjugate polysaccharide vaccines are available for all serotypes and are recommended for use in controlling meningococcal epidemic disease. The vaccines are purified, heat-stable, lyophilized capsular polysaccharide. Recommended single dose of reconstituted vaccine contains 50 mg of each of the individual polysaccharides. These vaccines are very safe.

Group A polysaccharide vaccine has poor immunogenicity and shorter duration of protection in children below 2 years of age, while group C polysaccharide is not immunogenic in that age group. Group A and C polysaccharide vaccines are not used in routine immunization services. The vaccines used are either bivalent (groups A and C) or tetravalent (groups A, C, Y and W135).

In adults and children, a single dose of meningococcal A, C, Y, W135 induces a rapid rise in antibodies.

Protection lasts for at least one year and often several years longer.

The most common adverse reactions are erythema and slight pain at the site of the injection,

Administration: the licensed meningococcal vaccine for routine use in the country is the quadrivalent vaccine containing four specific antigens related to sero groups A, C, Y and W135 in freeze dried form.

Administration is by intramuscular injection of 0.5mls in adults and in children above two years of age.

A single dose induces a rapid rise in antibodies and protection within 10 days in over 85% of recipients. Protection lasts from one year to several years.

Indications for use:

In the parts of Kenya that border the meningitis belt of Africa, vaccination with conjugate meningitis vaccine A should be considered during epidemics.

*** MenAfriVac is a new meningitis vaccine that is now used routinley in some West African countries**

- Each dose of 0.5ml vaccine contains: PsA10 µg,TT conjugate 10–33 µg, aluminium phosphate adjuvant 0.3mg Al3+ and thiomersal 0.01%
- Highly immunogenic and safe
- Impact on the rhino pharyngeal carriage of the meningococcus
- Can be used in children under 2 years old
- Boosts anti-tetanus immunity

1. Meningococcal vaccines are recommended for groups in which a particularly high risk of disease has been documented. These include army units, travelers to epidemic areas and persons with immunological predisposition to meningococcal disease.

2. The Ministry of Health will provide sero-type specific meningococcal vaccines for the management of meningitis outbreaks as they occur. No presumptive vaccination against any type of meningitis outbreak will be given without laboratory confirmation of the causative bacterial serotype.

3. The Ministry of Health will provide quadrivalent meningococcal vaccine (ACYW135) for pilgrims proceeding to Saudi Arabia, as advised by the Royal Saudi Government. These vaccines will be provided at cost to pilgrims at port health service outlets and limited M.o.H approved facilities only.

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 traveler's health certificate

HUMAN PAPILLOMA VIRUS (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 and33. Types 6 and 11 lead to genital warts and are responsible for 90% of genital warts.
- The risk of HPV-induced cervical cancer is directly related to:
  - *Early sexual debut*
  - *Multiple sexual partners*
  - *Sexual history of the partners*
- Additional risks for developing cervical cancer are:
  - *Tobacco smoking,*
  - *alcohol intake,*
  - *high parity,*
  - *black race and*
  - *HIV infection.*

Global situation: Over 270,000 women die of cervical cancer world wide. This is the leading gynecological cancer in sub-saharan Africa. 493,000 women affected each year. Cervical cancer is the second largest cause of cancer deaths in women worldwide. 80% are in developing countries (>90% by 2020). Cervical cancer is a global public health problem that disproportionately affects poor women in developing countries

Local situation: Cervical cancer is also the commonest gynecological cancer in Kenya and accounts for 70-80% of all genital tract cancers and 8-20% of all cancer cases. Overall incidence of cervical cancer in Kenya is 36.6 per 100,000

Signs/Symptoms: HPV infections are sexually transmitted and are asymptomatic in most women and are only diagnosed during screening for cervical cancer.

Cervical cancer may be asymptomatic in early stages but in later stages patients may have post coital bleeding, vaginal bleeding, foul smelling vaginal discharge and kidney failure.

Treatment:

- Abnormal pap smear : women with abnormal pap smears results can be treated by colposcopy, LEETZ, cryotherapy and hysterectomy.
- Cervical cancer : women with cervical cancer can be treated by hysterectomy, radiotherapy, chemotherapy and palliative care.

Prevention:

- Responsible sexual behavior, including use of condoms
- Vaccination
- Cervical cancer screening

HPV vaccines: 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.

Types of HPV vaccines: - two new polyvalent vaccines are licensed locally

1. 1. A quadrivalent formulation *(Gardasil™)* that prevents against HPV sero-types 6, 11, 16, 18. HPV serotypes 6 & 11 are responsible for about 90% of genital warts, and serotypes 16 &18 are responsible for about 70% of cervical cancers. It also has cross protection against oncogenic HPV serotypes 31 and 33.
2. A bivalent formulation *(Cervarix™)* that prevents against HPV types 16, and 18 which cause 70% of cervical cancers and also has cross protection against oncogenic types 31 and 33

Neither the above two vaccines protect against all types of cervical cancer so it is important that regular cervical cancer screenings are continued.

Target groups

1. The quadrivalent vaccine is recommended for girls and women aged 9-26 years for the prevention of both cervical cancer and genital warts. ***It can also be used in adolescent boys for the prevention of genital warts.***
2. The bivalent HPV vaccine formulation is for girls and women aged between 10 – 45 years for the prevention of cervical cancer alone.

In view of the high prevalence of genital warts disease and the relatively high incidence of cervical cancers in Kenya, the Ministry of Health advocates for the use of the broadest spectrum HPV vaccine in girls and women of child bearing age, so as to benefit maximally from reduced morbidity and mortality from these two diseases.

Ideally prevention of cervical cancer and genital wart disease should start ***before*** onset of sexual activity and therefore HPV vaccines would be most beneficial when administered from 9-14 years of age. After onset of sexual activity the risk of exposure to human papilloma viruses is very high. Since the main focus of use of the HPV vaccines is prevention of persistent infections by the oncogenic Human Papilloma Viruses that cause cervical cancer vaccination, this age should be targeted.

However due to the current high cost of HPV vaccines the Ministry of Health is unable to procure the vaccine for general public use.

Other health sector players may prioritize broad-spectrum HPV vaccines for optimal administration in adolescent girls and boys (ages 9-18 years) and narrower spectrum HPV vaccines for older women (19 years to menopause).

Vaccination of sexually active women with HPV vaccines should ideally be preceded by a pap smear to rule out cancerous changes to the cervix, and should be followed up with annual pap smears until menopause.

HPV vaccines are contraindicated in pregnancy.

Once cervical cancer or genital warts have set in, the HPV vaccines are ineffective in preventing progression of the disease.

05 NEW AND EMERGING VACCINES

The Ministry of Health has prioritized prevention of life threatening diseases of childhood, however, as these diseases get under control, chronic diseases will become a priority. 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.

All vaccines developed in the last 50 years probably protect by stimulating a potent antibody response. However, for pathogens that live within cells of the body, where antibodies cannot reach, it is likely that cell-mediated immunity is required for protection. Examples of such pathogens include ***malaria, TB and HIV***. Each of these is a huge global health problem claiming millions of lives each year for which there is no effective vaccine.

MALARIA VACCINE

Although malaria vaccine development to date has met with only limited success, there are several lines of evidence that suggest that a malaria vaccine is possible.

1. Current clinical studies have shown that new candidate vaccines can induce complete protection against malaria infection.

2. Complete protection against malaria can be induced by infecting volunteers with irradiated malaria parasites.

3. People living in endemic areas who have had multiple exposures to malaria develop immunity against severe malaria disease.

4. Since antibodies are unable to attack the malaria parasite once it has invaded liver cells, new approaches to the malaria vaccine development have been to design a vaccine that will induce potent T-cell responses against the liver stage of malaria infection.

Preliminary Phase III clinical trial results for RTS,S/AS01 malaria vaccine indicate that it is about 50 % efficacious with a protection of 12 months. It is a Pre-erythrocytic stage vaccine candidate (liver stage).

WHO policy on malaria vaccine is expected by 2016.

HIV VACCINE

Despite the international community's best efforts- the HIV pandemic continues unabated. In 2006, more than 39 million people were living with HIV worldwide. Over four million people became newly infected with HIV and an estimated 2.8 million lost their lives to AIDS. Nearly 14,000 people become infected with HIV each day.

On average, people require life-saving antiretroviral treatment (ARVs) 7-10 years after becoming infected. While there has been recent progress in increasing access to treatment and prevention programs, HIV continues to outpace the global response with at least 80% of those in clinical need of ARVs worldwide not receiving them. Further, while decline in national HIV prevalence has occurred in some sub-Saharan African countries, these trends are not strong or widespread enough to have a major impact on the epidemics.

New technologies to prevent HIV transmission remain imperative and the potential positive impact of AIDS vaccines would be enormous. An effective preventive HIV vaccine could prevent almost 30 million of the 150 million new infections projected in the coming decades. There is scientific progress underway in the search for an HIV vaccine. Presently, there are more than 30 clinical trials with HIV vaccine candidates worldwide.

An AIDS Vaccine would make a difference by:

- protecting vaccinated individuals against HIV infection
- reducing the probability that a vaccinated individual who later becomes infected will transmit the infection to others; or
- slowing the rate of progression to AIDS for those who later become infected with HIV.

Currently, there is no licensed vaccine to protect against HIV/AIDS.

The preventive AIDS vaccines currently in human trials do not contain any live virus that could result in infection and thus cannot cause HIV/AIDS. These vaccine candidates are recombinant vaccines that use genetically engineered components of HIV *(i.e. contain only harmless particles or copies of particles of the virus—enough to trigger the body's immune system, but not cause disease)*.

06 VITAMIN A SUPPLEMENTATION

Vitamin A though not a vaccine was integrated into the infant immunization schedule in the 1980s due to its immune boosting effects and the obviously optimal opportunity for administration.

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.

The Unit of Vaccines and Immunization services endorses the continued integration of Vitamin A supplementation within the infant vaccination schedule. This is in line with the overall aim of the Ministry of Health of "Eliminating avoidable childhood blindness by the year 2020".

Remember: *A child should have gotten at least two doses of Vitamin A before the first birthday.*

A key strategy for increasing Vitamin Asupplementation 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.

Table 5: VITAMIN A SCHEDULE FOR LACTATING MOTHERS

Lactating Mothers	Dose	Frequency	Preparation
At delivery or at first presentation to health facility within the first six weeks post partum	200,000 IU	Once	Containing Vit. A (USP) 200,000IU & Vit.E (USP) 40IU per capsule

Table 6: VITAMIN A SCHEDULE FOR CHILDREN UNDER 5 YEARS

Infants	Dose	Frequency	Preparation
6 months	100,000 IU	Once	Containing Vit. A (USP) 100,000IU & Vit.E (USP) 20IU per capsule
12 months (1yr)	200,000 IU	Once	Containing Vit. A (USP) 200,000IU & Vit.E (USP) 40IU 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	

07 MAXIMISING NATIONAL IMMUNIZATION COVERAGES

The following are key strategies for increasing immunization coverage:

Planning of immunization services at district 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 district 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 equipments and power sources to maintain the cold chain, manpower etc.
- Strategies for demand creation for immunization services through partnerships and linkages with the community
- District 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 immunization services with the community

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.

Increasing access of immunization services

In order to increase geographical access to immunization services, health workers will regularly conduct integrated outreach services to areas known to have high numbers of unreached children and pregnant women.

Reduce drop out

In order 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

To limit missed opportunities, 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. 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 toxoid.
- Give children and women all vaccines due because vaccines are as safe and effective in combination as they are individually

- Eliminate false contraindication for vaccination e.g. diarrhea, 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.

Monitoring for action

Immunization data collected in health facilities shall be analized and used to monitor progress and solve problems at all levels. Multiple forums will be used to review performance e.g.;

- Peer reviews in facilities
- Supportive supervision visits
- Immunization review meetings at district level

SERVICE DELIVERY FOR IMMUNIZATION – ROUTINE AND SIAs

1. Introduction

Provision of immunization services is among the Kenya Essential Packages for Health (KEPH). The Ministry of Health has six levels of service delivery to provide immunization services in line with the KEPH.

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 Medical Practitioners & Dentists Board
- Clinical Officers Council
- Nursing Council of Kenya
- Local authorities under whose jurisdiction they operate

NB: Pharmacies, chemists and laboratories are not licensed to administer vaccines

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

Administration of vaccines for research purposes such as during vaccine trials shall be governed by the ethical committee under which the research falls. However all vaccinators involved in vaccine trials must be clinicians.

2. Access to routine immunization services

a. Government supported facilities shall provide…

i. *All vaccines daily from Monday to Friday.*

ii. *In facilities offering maternity services and 24 hour clinical services, vaccinations shall be provided seven days a week.*

iii. *24 hour access must be availed for* **emergency vaccines** *in all hospitals & health centres, e.g. anti-rabies vaccine, anti snake venom.*

iv. *Dispensaries and private clinics should avail emergency vaccines as and when required during working hours.*

v. *All government supported vaccines shall be offered free of charge with the exception of vaccines for travelers which will be provided at a fee.*

vi. *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.*

b. Defaulter tracing

i. *In order to minimize drop outs 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.*

c. Maintaining vaccine schedules during stock-out situations

i. *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.

d. Outreach immunization activities:

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

Where applicable the following should be observed:

i. *The frequency of outreach services shall be at least monthly in collaboration with the target community*

ii. *As far as possible immunization outreach activities must be integrated with other maternal and child survival activities.*

iii. *If privately sponsored, such services must be coordinated with the respective DMOH of the targeted district.*

iv. *Chiefs or the Assistant Chiefs of the targeted location must be fully involved in all outreach exercises and must endorse the outreach forms.*

e. National or sub-national Supplemental Immunization Activities (SIAs)

i. *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 general public by way of one or more of the following:*

1 Media briefings/Press releases/Legal notices

2 National Health Sector fora

3 Regional Directorates of Health

4 Print and electronic Media

i. *Role of immunizing facilities during SIAs include*

-- *Provision of logistical support and service delivery*

-- *Advocacy and resource mobilization for immunization services*

i. *Role of the general public during SIAs in terms of cooperation include*

Cooperation

Creating awareness and mobilizing other community members

f. Localized Supplemental Immunization Activities

i. *The authority in determining and implementation of localized SIAs will be the County coordinators of health and the DMOHs and communicated to the general public by way of:*

-- *Stakeholders fora e.g. meetings of departmental heads, chief 's barazas, schools, religious gatherings*

-- *Local publications & media stations*

ii. *The role of immunizing facilities during localized SIAs includes*

-- *Micro-planning for the activity*

-- *Social mobilization with the community and the local leaders,*

-- *Service provision*

-- *Compilation and submission of data to the next level*

g. Recommended administrators of vaccines –

-- *All injectable (parenteral) vaccines must only be administered by registered clinicians*

-- *Oral vaccines & Vitamin A preparations may be administered by non-clinicians but must be under the supervision of a clinician*

VACCINATION DATA MANAGEMENT

All vaccinating facilities must keep appropriate up-to-date records of all types of vaccines administered detailing the following:

- vaccine formulation by generic or trade name
- manufacturer
- batch number/s used
- number of doses administered by date
- two or more names of each recipient
- contact addresses of all recipients – including telephone contacts

This applies only during routine services and for limited supplemental immunization activities such as the integrated outreach exercises.

Data capture during mass vaccination campaigns will be limited to the ages of the vaccinees, the vaccines and other interventions administered.

Duly completed summaries of monthly vaccination activities are to be submitted to the respective District Medical Officer of Health by the 5th day of the following month every month.

District Medical Officers of Health must compile a monthly summary report of vaccinations in the district and forward the same to the County Coordinators of Heath by the 15th day of each month.

County Coordinators of Heath will then compile the county monthly immunization summary report and forward it to the national level by the 21st day of the every month.

The Unit of Vaccines and Immunization services at the National level will compile the National Summary by the 7th day of every month and share it with the relevant international partners.

NB: All immunization records at health facility level must be well stored for easy retrieval on short notice during verification exercises.

Using data for action

At all levels of immunization data collection the data must be reviewed critically for any of the following unfavourable recordings

- full immunization coverage less than 80% in any facility, constituency, district/county
- vaccination coverage less than 80% for any antigen in any facility, constituency, district/county
- drop-out rate equal or greater than 10% for any antigen in any facility, constituency, district/county

Whenever ***any*** of the above unfavourable recordings is noted, the District/County Medical Officer must institute remedial activities within one month. All remedial action must be documented and reviewed quarterly.

ADVOCACY FOR VACCINATION SERVICES UPTAKE

The Ministry of Health works towards facilitating change in health seeking behavior for vaccination services through advocacy and communication strategies that include providing information, persuasion, and motivation.

The expected result of all the advocacy initiatives is an increase in demand for immunization services by all communities leading to universal coverage with the primary vaccination schedules.

Advocacy and communication for vaccination services entails enlisting support of credible individuals and key organizations responsible for formulating policies, making decisions and allocating resources for immunization services.

Goal: The goal of the Ministry of Health is to ensure that morbidity and mortality due to vaccine preventable diseases is controlled and in some cases eliminated.

Justification: Even when services are accessible, affordable and available, communication is often necessary to make people aware of them and their usefulness.

Despite improved availability and physical accessibility to free infant immunization services there are still population groups and individuals who do not present themselves for vaccination as they are not convinced of their usefulness or even perceive vaccines as being harmful. These unvaccinated persons or communities remain susceptible to various vaccine preventable diseases and serve as entry points for these diseases in their communities. Large numbers of susceptibles in any locality increase the risk of disease outbreaks that may also overwhelm the vaccinated population.

This policy requires the entire health sector stakeholders to advocate for comprehensive, quality and sustainable vaccination services and for the utilization of the services by target populations.

APPENDIX 1: COLD CHAIN RECOMMENDED TEMPERATURES

<table>
<tr><th>Vaccines</th><th>National
Up to 6 months
(Electricity)</th><th>Regional
3-Months
(Electricity)</th><th>County/ District
Up to 3 months
(Electricity/Solar)</th><th>Peripheral
Up to 1 month</th></tr>
<tr><td>OPV, Yellow Fever</td><td colspan="2">-15°C to -25°C</td><td colspan="2" rowspan="2">+ 2°C to + 8°C</td></tr>
<tr><td>Measles, BCG</td><td colspan="2">-15°C to -25°C OR + 2°C to + 8°C</td></tr>
<tr><td>Penta, Hep B, PCV-10, TT, Typhoid, Antirabies, Antisnake 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 in the same tray as the respective</td></tr>
</table>

APPENDIX 2: GUIDELINES FOR INTRODUCTION OF NEW VACCINES & VACCINES RELATED TECHNOLOGIES

Under the Global Immunization Vision and Strategy (GIVS), the second priority is the introduction of new vaccines and related technologies. Currently, there are several new vaccines at different stages of development such as the malaria, TB and HIV vaccines.

Kenya is in the process of establishin a National Independent Technical Advisory Group (KENITAG) which will be responsible for providing independent scientific opinion or guidanceon the introduction of new vaccines. The team will be composed of experts from the Universities, senior members of the relevant medical specialities and relevant personnel from the Ministry of Health. Technical advice will also be sought from experts from WHO, UNICEF, and sources of technical expertise involved in vaccination activities.

The following should be considered when introducing new vaccines:

- The country's health policy and disease burden.
- The proposed new vaccination schedule vis-a vis other exiting vaccines schedules.
- The targeted population.
- The existing vaccine stock management system.
- Evaluation of the existing cold chain system and its functional capacity.
- The volume required for the new vaccine including purchase of new equipment if necessary.
- Vaccine wastage monitoring and how to mitigate the wastage
- Training of staff on safe administration of the new vaccine and monitoring of adverse events
- Adequacy of monitoring of AEFIs and their response as a process of continued monitoring of the safety of new vaccines.
- Data on the new vaccines must be captured for decision making and for monitoring of impact and evaluation.
- Capacity building to enhance broad acceptance and knowledge on the new vaccine.
- Development of a communication plan
- Ability of the country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity. Ideally a country should be able to set up a financially sustainable programme in the short and long term.
- To assess the impact of the vaccine on the disease burden upon introduction of the vaccine high quality disease surveillance should be in place prior to and during the introduction of the new vaccine.

APPENDIX 3: 10 COMMON POISONOUS SNAKES OF KENYA

	Name of the snake & type of venom produced	Physical appearance of the snake	Distribution within Kenya and special characteristics
1	**Black –necked Cobra** The venom is Cytotoxic		Widespread but rare in areas above 1,200 meters except in Nairobi, Thika, and Athi area. Other areas where it is found are Machakos, Kajiado, Kilifi, Meru, Naivasha, Nyanza and Isiolo
2	**Saw-scaled or Carpet Viper (*Echis carinatus)*** The venom is haematotoxic (i.e. an anticoagulant)		Found in Northern Kenya: Samburu, Garissa, Maralal, Nyambene and Eastern Turkana This is nocturnal snake which hides under stones or logs during the day- a hazard to firewood gatherers, bites on hands or feet. Generally not fatal in Kenya
3	**Forest or Black & White Cobra (*Naja melanoleuca).*** Venom is a potent neurotoxin		It is found in forest and woodlands but can also be found on the ground. In coastal forests it lives in high trees. Found in Mt Elgon, Bungoma, Trans Nzoia, Eldoret, Kakamega, Kericho, Nakuru, Rongai, Mt Kenya, Golana and Arabuko Solare forest coastal regions, Msai Mara *It is generally black with pale stomach blotched or freckled. Has several clear black bands across the throat can stand very tall when threatened. The "hood" is long and narrow*
4	**Jameson's Mamba** (*Dendroaspis jamesoni*) The venom is both neurotoxic and cardiotoxic		Found only in Kakamega forest area. *It is a day snake and lives on trees but may come on the ground. May stand high so bite may be found above the knee.*

	Name of the snake & type of venom produced	Physical appearance of the snake	Distribution within Kenya and special characteristics
5	**Green Mamba (**Dendroaspis *angusticeps)* The venom is neurotoxic		Found in Coastal plain, Diani, Kilifi, Malindi, Mombasa, Mtwapa, Simba hills, Shimoni, Watamu, Tana River, Nyanbene and Kibwezi forest Bright green snake with no markings on the body and has a long head.
6	**Puff adder** The v*enom is a potent cytotoxic*		Widely distributed in almost the whole of Kenya
7	**Egyptian Cobra** *(Naja naja)* The venom is potent neurotoxin and is injected in large volumes.		Sporadically distributed across the country in various districts: Kajiado, Machakos, Nairobi, Naivasha, Thika, Isiolo, Samburu Bungoma and Elgon *Lives in holes or termite mounds and rocky areas. It makes sharp explosive hiss when threatened stands and spreads its hood wide*
8	**Black Mamba** (*Dendroaspis polylepis)* The v*enom is a very potent neurotoxin which is rapidly absorbed*		Widespread in low woodland and scrub along the coast, Malindi, Kilifi, Mombasa, Voi, Tsavo, Amboseli, Kajiado, Kutus, Tharaka Meru, Samburu, Maralal, Baringo, Kerio, Bungoma, Kerio, Bungoma, Kitui, Makindu, Mara, Mwingi and Nandi hills *Generally lives in low bush otherwise may be found in trees in savannah areas or among rocks.*

	Name of the snake & type of venom produced	Physical appearance of the snake	Distribution within Kenya and special characteristics
9	**Gaboon Viper** *(Bitis gabonica)* The venom is a potent cytotoxic, as potent as that from the puff adder but injected in larger volumes than that of the puff adder		Found in Kakamega and Nandi forests *A fat forest snake that lives on the ground well hidden in leaf litter. Has large fangs so wound is easily visible on foot or lower leg. It bites very reluctantly (i.e. only under provocation).*
10	**Boomslang** *(dispholidus typus)* Venom is haematotoxic		Common in Kitui and Machakos. *This snake is day time, tree dwelling snake and ranges in colour from light brown to green. It is difficult to see in their natural environment, approach is swift and without warning when attacking.* *The bite may appear as a scratch rather than neat punctures.* The anti-venom for this snake is not combined with other anti-venoms and is manufactured as a specific monovalent antidote. Bites from boomslangs require their own specific monovalent anti-venom and will not respond to the polyvalent anti-venins.

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