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 Advisory 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
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. 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.

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.
• 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 refrigeration 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-reusable 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.
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 ginsenosid.

**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 its 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.

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
**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.

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**POLOMYELITIS 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.
PNEUMOCOCCAL 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 pneumonias cause 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 whom 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. Empirc 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 pneumonias 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 on HIV status of routine infant immunization clients.

High risk clients: Appropriate pneumococcal conjugate vaccines should be administered to 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
**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 the 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 vaccine:**

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.
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 analyzed 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 a key in 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. Default 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
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 establishing a National Independent Technical Advisory Group (KENITAG) which will be responsible for providing independent scientific opinion or guidance on the introduction of new vaccines. The team will be composed of experts from the Universities, senior members of the relevant medical specialties 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 existing 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 AEFI’s 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 currently 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.

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