NATIONAL IMMUNIZATION PROGRAM
MANUAL OF OPERATIONS

BOOKLET 3

CHAPTER 4

The Vaccines

Cover Photo from the National Vaccine Storage,
Research Institute for Tropical Medicine

Chapter 4

THE VACCINES

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A. Rationale

Chapter 4 details the essential information on the immunization or vaccination process, the various types of vaccines, their availability and which the DOH is recommending for the VPDs described in the previous chapter. This section further describes how immunization works and the basic principles relative to the timing and spacing, storage, handling and administering vaccines. The information will also help you in giving appropriate advice and counsel to parents and clients as well as in educating other stakeholders in your community or catchment area.

B. Objectives

After reading Chapter 4, it is expected that we will be able to:

1. describe the immunization or vaccination process and classify the various types of vaccines generating immunity;
2. enumerate the key principles in handling and administering vaccines; and
3. specify the key features of each vaccine product recommended by the NIP.

C. Scope and Coverage

The chapter defines immunization and immunity; lists the types or categories of vaccines; and describes the basic principles related to:

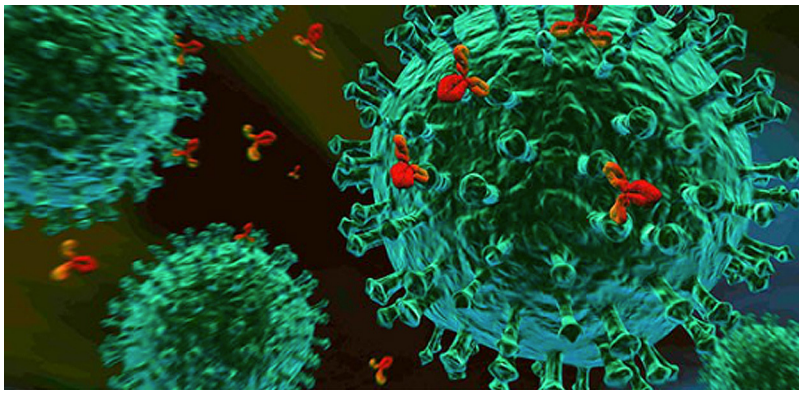
- Efficacy and safety and adverse effects
- Proper storage and transportation
- The age of administration
- The number and size of doses
- Administration site and route of giving vaccine

The Chapter also provides a summary table of the vaccines used in the NIP for easy reference.

D. What is Immunization?

D.1 Disease Control, Elimination and Eradication

1. **Immunization** is the process where a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease.



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Antibodies attacking viruses

2. **Immunity** refers to protection from disease through the formation of antibodies. There are two basic mechanisms for acquiring immunity:
   - 2.1. **Passive Immunity:** Acquired through the administration of products derived from human or animals providing short-term protection, usually a few weeks or months. The three ways of gaining passive immunity are either from blood products, through administration of immune globulins or vertical transmission from mother to newborn.
   - 2.2. **Active Immunity:** Formed by stimulating the immune system to produce cellular and antibody immunity. Ways of producing active immunity include:
     - Exposure to an infection or disease, although infection does not lead to immunity in all cases.
     - Vaccination to produce immune responses similarly evoked by natural infection without the development of the disease and its complications. The immune response to vaccination is influenced by the:
       - › nature and dosage of administered antigen
       - › route of administration
       - › adjuvants
       - › maternal antibodies
       - › age
       - › nutritional status, co-existing diseases
       - › other host factors

3. Types of Vaccines

3.1. **Live Attenuated Vaccines** are derived from wild viruses or bacteria which are modified or weakened in laboratories. Immunity is elicited by replication of the attenuated organism in the vaccinated person. The immune response to a live attenuated vaccine is identical to that induced by natural infection.

- However, immuno-deficient or immuno-compromised individuals may only receive such vaccine with caution as this may cause serious adverse reactions as a result of uncontrolled replications
- Currently available live attenuated vaccines are those for TB (BCG), Oral Polio, measles, mumps, rubella, and JE.

3.2. Inactivated Vaccines are produced by growing the bacteria or virus in culture media which are then subjected to heat or chemical agents. In fractional or sub-unit form of these vaccines, organisms are treated to be able to derive those components needed to produce the vaccines. Both the inactivated or sub-unit preparations must contain sufficient antigenic mass to stimulate the desired response since it is incapable of replicating inside the host.

Forms of inactivated vaccines include:

- Whole viruses (e.g. influenza, IPV, rabies)
- Whole bacteria (e.g. pertussis, typhoid, cholera)
- Subunit or fractional vaccines (e.g. influenza, hepB, etc.)
- Pure polysaccharides and conjugates (e.g. Hib, PPV, PCV, etc.)
- Toxoids: diphtheria, tetanus.

- Inactivated vaccines may not elicit the range of immunologic response provided by the live-attenuated agents.
- Maintenance of long-lasting immunity with inactivated viral or bacterial vaccines often requires periodic booster doses.
- Unlike live attenuated vaccines, inactivated vaccines cannot replicate in or be excreted by the recipient as infectious agent and thus cannot adversely affect immunosuppressed hosts or their contacts.

E. Basic Principles in Immunization

E.1 Timing and Spacing of Vaccines

Timing and spacing in administering vaccines are the two most important considerations in ensuring optimal results:

1. Multiple vaccines can be administered at the recommended schedule and time using different injection sites. Consider the following: (i) the chance of clients coming back for additional dose to prevent drop-outs; and, (ii) the capacity of the client to receive multiple doses.

2. Two to three inactivated injectable vaccines can be given in the same visit. Example: PENTA, PCV and IPV can be given at the same immunization schedule at different injection sites.

    2.1. Simultaneous administration of 2 live vaccines can be given in same visit. Example: Oral Polio and MMR

    2.2. Two live parenteral vaccines can be given together, with the 2nd dose of the same vaccines usually administered after 4 weeks. Example: MMR and JE can be given together.

    2.3. Longer interval between doses does not reduce the effectiveness of the vaccine. It is not necessary to restart the series of any vaccine due to extended interval between doses. Example: When the child does not come back for the 2nd dose of PENTA at 10 weeks but rather after the child is already 5 months, we can still continue with the 2nd dose and advise parents to come after a month for the 3rd dose.

    2.4. Vaccine doses should not be administered at less than the recommended minimum intervals or earlier than the indicated minimum age.

E.2 Administration of Vaccines

Appropriate method of vaccination is a critical component of the NIP. As a vaccine provider, you must observe utmost professional care to ensure the optimal immune response of the recipient.

1. Client Preparation and Care

- IMPORTANT: Always screen clients for possible contra-indications every time you administer a vaccine.
- Explain to the client how the vaccines work, including safety and risk. Establish an atmosphere in which clients and their parents can freely evaluate information, discuss vaccine concerns and make informed decisions regarding the vaccination.
- Make the vaccination least stressful to the client and their parents or guardians. This can be done through:
  - › A positive attitude through your facial expression, body language and comments.
  - › A soft and calm tone of voice.
  - › Eye contact even with small children.
  - › Explaining why vaccines are needed.
  - › An honest explanation of what to expect. Never say that injection won't hurt.

2. Infection Control

- Wash your hands thoroughly before and after each new client contact.
- It is not necessary to wear gloves when administering vaccines unless you have open lesions or are likely to come in contact with potentially infected body fluids.
- Properly dispose of used needles and syringes to prevent needle stick injury and reuse.

E.3 Site and Route Administration

The route recommended for administration of a particular vaccine is primarily based on clinical trials, practical experience and theoretical considerations. This is usually indicated in the packaging and in the manufacturer's product information of each vaccine. There are five acceptable routes used in the administration of vaccines. Intranasal administration of vaccine is not common and thus not explained in this manual.

Non-compliance to recommended route of administration may reduce vaccine efficacy or may result in exaggerated local adverse reaction.

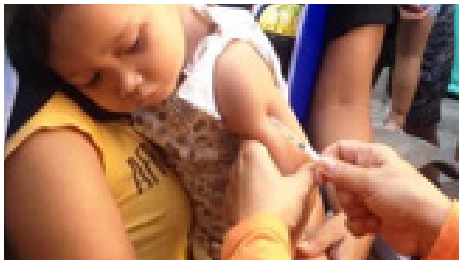
1. Oral Route (Per Oral - PO)

1.1. Commonly oral polio, rota and oral cholera vaccines are the licensed-vaccines administered by the oral route.

1.2. Oral vaccines should be administered first before giving injectable vaccines or performing other procedures that might cause discomfort especially in children.

- Administer the liquid agent slowly down one side of the inside of the cheek toward the back of the infant's mouth.
- Take extra care not to trigger the gag-reflex while administering the oral vaccine.
- Do NOT administer or spray the vaccine directly into the throat.

2. Subcutaneous Route (SC)



2.1. Injections are administered into the fatty tissue underneath the dermis and above the muscle tissue.

2.2. Recommended sites are the upper outer triceps of the arm.

3. Intramuscular Route (IM)

3.1. Vaccines are administered into the muscle tissue below the dermis and the subcutaneous tissue.

3.2. Mostly inactivated vaccines are administered by intramuscular route.

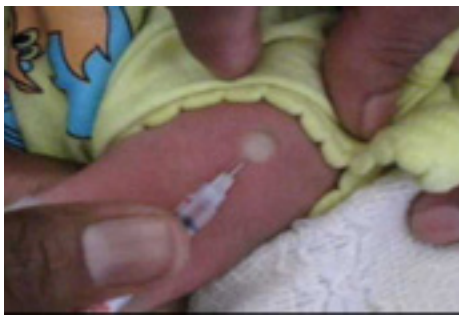
3.3. Many inactivated vaccines contain adjuvants that enhance immune response to the antigen administered.

3.4. The anterolateral thigh (vastus lateralis muscle, lower left photo) and upper arm (deltoid muscle, lower right photo) are the two routinely recommended sites for intramuscular route of administration.

3.5. There is less chance of hitting nerves or blood vessels through this route.

3.6. Administration through this site depends on the individual's age and degree of muscle development.

4. Intradermal Route (ID)



4.1. The vaccine is administered in between the layers of the skin until a wheal appears.

4.2. This is the route of choice for only a very limited number of vaccines such as Bacille Calmette Guerin (BCG) against tuberculosis and post exposure rabies vaccination.

4.3. For intradermal injection, insert a small thin needle (25 or 27 gauge) and 3/8 to 3/4 inch (1-2 cm) underneath the skin to introduce the vaccine. The bevel should be facing upward.

E.4 Administering multiple vaccines at the same time

If you are giving more than one vaccine:

1. Do NOT use the same syringe for more than one vaccine.
2. As much as possible, do NOT inject the same arm or leg more than once. However, if it is necessary to administer at least 2 vaccines on the same site, ensure that the injection sites are at least 2 finger breadths apart (e.g. PCV, IPV).
3. Do NOT give more than one dose of the same vaccine in one session.
4. Give doses of the same vaccine at the correct intervals.
5. Wait at least 4 weeks between subsequent doses of OPV, DPT-HepB-Hib (PENTA), and PCV.

E.5 Contraindications to Immunization

1. Contraindications and Precautions

   While vaccines benefit most individuals, there are rare situations where vaccination is not recommended. Contraindications and precautions identify situations when vaccines should not be given.

   Contraindications are conditions in the recipient that greatly increase the chance of a serious adverse reaction.

   Precautions are conditions in the recipient that may increase the chance of an adverse reaction or may impair the ability of the vaccine to produce immunity. Study and remember the appropriate restrictions for each vaccine.

   Most contraindications and precautions are temporary, so the vaccine may still be given once the condition passes. Since contraindications and precautions vary by vaccine, health workers should screen recipients carefully.

Use every opportunity to immunize eligible infants and adults, unless the person has a health condition that does not permit vaccination. Sometimes there are reasons why a specific vaccine should NEVER be administered (also called an absolute contraindication) and there are times when you should delay giving the vaccine for a short period of time (also called a temporary contraindication). Review and remember the correct reasons for withholding immunization.

2. The following are reasons why specific vaccines should NEVER be administered and reasons why vaccines may be DELAYED for a short time.
   - Reason for **NEVER** administering a specific vaccine (Absolute contraindications): An infant or person who has a history of anaphylaxis or a severe hypersensitivity reaction during previous immunization is an absolute contraindication to subsequent doses of a vaccine. Persons with a known allergy to a vaccine component should NOT be vaccinated.
   - Reasons for **DELAYING** administering a specific vaccine (Temporary contraindications).
     - › If a mother/parent strongly objects to immunization of a sick infant. Ask the mother to come back when the infant is well.
     - › If a child is suffering from some chronic condition and is under medication. , Consultation with the primary physician could result in postponed immunization until after the medication or treatment is completed.

3. Report to supervisors IMMEDIATELY if a reaction does occur upon vaccination. There are precautionary measures for particular vaccines which are explained on the following pages.

F. Vaccines Available in the Philippines and Recommended by DOH for Use Against VPDs

The following table summarizes the vaccines available in the Philippines recommended by the DOH for VPDs:

Some of the vaccines are currently in process of nationwide expansion and some are about to be introduced.

TABLE 3.
Vaccines Used in the NIP

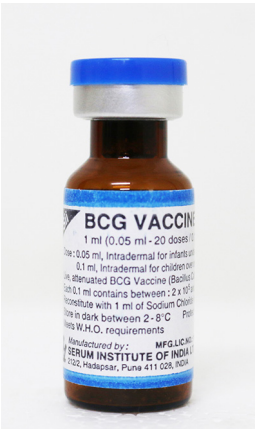
Vaccine	Disease	Type of Vaccine	Formulation (1st column)	Usual No. of doses in primary series and route of administration	Common vial sizes*	Damaged by freezing?
BCG	Tuberculosis	Bacillus Calmette - Guérin (BCG): live attenuated mycobacterium bovis	Freeze-dried	1 dose - intradermal	20 dose	No, but diluent should not be frozen
Hepa B Vaccine	Hepatitis B	Liquid	Monovalent	1 dose - intramuscular	1 dose 10 dose	Yes
OPV	Polio (Oral Polio Vaccine)	Live attenuated OPV contains 2 types of polio virus	Liquid	2 drops per dose 3 doses - oral	10 dose 20 dose	No
IPV	(Inactivated Polio Vaccine)	Inactivated, whole-cell IPV contains 3 types of polio virus.	Liquid	1 dose - intramuscular	1 dose 10 dose	Yes
PENTA DPT-HepB, Hib	Diphtheria, Tetanus, Pertussis, Hepatitis B, Haemophilus influenzae type b (Hib) diseases	Inactivated: conjugate polysaccharide vaccine	Liquid lyophilized	3 doses - intramuscular	1 dose 2 dose 10 dose	Yes
PCV	Pneumonia	Inactivated conjugated	Liquid	3 doses - intramuscular	1 dose 10 dose	Yes
PPV	Pneumonia	Inactivated polysaccharide	Liquid	1 dose - intramuscular	1 dose	Yes
MMR	Measles – Mumps-Rubella	Live attenuated	Freeze-dried Monovalent, measles-rubella (MR), and measles-mumps-rubella (MMR)	1 dose - subcutaneous	1 dose 10 dose	No but diluent should not be frozen

Vaccine	Disease	Type of Vaccine	Formulation (1st column)	Usual No. of doses in primary series and route of administration	Common vial sizes*	Damaged by freezing?
MR	Measles - Rubella	Live attenuated	Freeze-dried Monovalent, measles-rubella (MR), and measles-mumps-rubella (MMR)	1 dose - subcutaneous	1 dose 10 dose	No but diluent should not be frozen
Rotavirus Vaccine	Rotavirus	Live attenuated	Liquid oral suspension	2 doses – oral	1 dose	No
JE Vaccine	Japanese Encephalitis	Live attenuated	Lyophilized powder	1 dose - subcutaneous	1 dose	No but diluent should not be frozen
Td Vaccine	Tetanus Diphtheria	Inactivated: toxoid	Liquid Multivalent form: Td vaccine	SBI [2 doses] – Intramuscular WCBA [2 dose in 1st pregnancy and 1 dose in each subsequent pregnancy for 5 total doses] – Intramuscular	10 dose	Yes
HPV vaccine	Human Papilloma Virus	Recombinant	Liquid	2 doses - intramuscular	1 dose	Yes
Influenza Vaccine	Influenza	Inactivated	Liquid	1 dose - intramuscular	1 dose 10 dose	Yes

F.1 Tuberculosis Vaccine - BCG

What is BCG vaccine?

BCG vaccine protects infants against tuberculosis. The letters B, C, G stand for Bacillus Calmette-Guérin. Bacillus describes the shape of a bacterium while Calmette and Guérin are the names of the people who developed the vaccine.



What are the forms and presentations of BCG?

BCG vaccine comes in powder form. BCG vaccine is freeze-dried, so it must be reconstituted with a diluent before use. It is essential that only the diluent made by the same manufacturer as the vaccine be used. BCG vaccine should be kept at +2°C to +8°C after reconstitution. Like other reconstituted vaccines, BCG has a short life span and, once reconstituted, must be discarded after six hours or at the end of the immunization session, whichever comes first.

How safe is BCG vaccine and what are its potential adverse effects?

BCG is a safe vaccine with rare adverse events. Most children do have a reaction at the site of injection. Normally, when BCG vaccine is injected, a small raised lump appears at the injection site. This usually disappears within 30 minutes. After about two weeks, a

red sore forms about the size of the end of an unsharpened pencil. The sore remains for another two weeks and then heals. A small scar, about 5 mm across remains. Health workers look for this to determine whether a child has been vaccinated. However, the absence of a scar does not mean that the BCG vaccination did not work.

- When given properly, BCG vaccine has no side effects other than that described above.
- Sometimes the glands in a child's armpit or near the elbow swell after injection with BCG vaccine, or he/she may develop an abscess. Swollen glands or abscesses occur because an unsterile needle or syringe was used, too much vaccine was injected, or most commonly, the vaccine was injected incorrectly under the skin instead of on its top layer.
- Generalized infection due to BCG vaccination occurs at a rate of 5 per million doses of vaccine given.

How effective is BCG?

Vaccination of uninfected children can provide protection for more than 90%, but the protective effect varies.

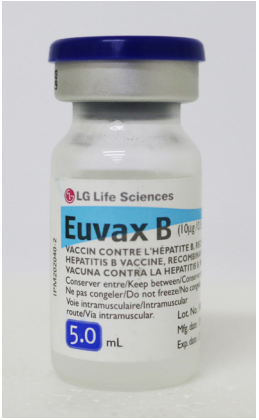
Administration Summary

Type of Vaccine	Live bacterial
Number of Doses	1 dose
Schedule	Given preferrably 90 minutes after birth. Areas with high TB infection incidence should routinely immunize infants with a single dose of BCG at birth. If not given at birth, BCG may be given at the infant's first contact with the health system before turning one year old. BCG immunization of infants born of mothers positive for TB should be delayed and should be given after one month after negative PPD Test.
Booster	None
Contraindications	Known HIV infection and other immune deficiency. **<u>PRECAUTION FOR HIV:</u>** If the Mother is HIV positive, the new born must be tested for HIV. However if the HIV test is not available, BCG vaccine is NOT given. • If the Baby is positive with HIV infection, BCG vaccine is NOT given. • If the Baby is negative for HIV infection, BCG vaccine is given. **<u>PRECAUTION FOR TB:</u>** If the new born baby is exposed to smear positive tuberculosis clients (mother or other first degree relative), it is recommended that the infant be treated with Isoniazid for 6 months before administering BCG vaccine.

Adverse Reactions	Local abscess, regional lymphadenitis; rarely, distant spread to osteomyelitis, disseminated disease
Special Precautions	Correct intradermal administration is essential. A special syringe and needle is used to administer BCG vaccine. Health workers must keep in mind that BCG is the most difficult vaccine to administer because of the tiny arms of the newborn and the vaccine must be injected intradermally (at the topmost layer of the skin). They need extensive and continuing practice to master this skill. A short narrow needle (15 mm, 26 gauge) is needed for this injection.
Dosage	0.05ml
Injection Site	Outer upper arm or shoulder just below the deltoid. Health workers MUST administer BCG in the same place on every child so that their colleagues know where to look for the BCG scar.
Injection Type	It is injected intradermally
Storage	Store between +2°C to +8°C (vaccine maybe frozen for long-term storage but not the diluent)

F.2 Hepatitis B (HepB) Vaccine

What is HepB vaccine?



Hepatitis B vaccine protects against Hepatitis B infection. The vaccine contains only one antigen (monovalent). Only monovalent HepB vaccine should be used as a birth dose (within 24 hours). It is available in combination and should not be used at birth, but may be used in subsequent doses. If HepB vaccine is left standing for a long time, the vaccine may separate from the liquid. In this state, the vaccine looks like fine sand at the bottom of the vial. Shake the vial to mix the vaccine and liquid before using the vaccine. HepB vaccine should NEVER be frozen. The "shake test" will determine if the vaccine has been damaged by freezing. If the vaccine fails the shake test you must discard it.

What are the forms and presentation of Hep B vaccine?

HepB vaccine is a cloudy liquid provided in single or multi-dose vials or in prefilled auto-disable (AD) injection devices. Hepatitis B vaccines are available in single-dose and multi-dose glass vials. Multi-dose vials contain 2, 6, 10, or 20 doses.

How effective is Hep B vaccine?

Hep B is one of the safest and most effective of vaccines. Studies show that it is 95% effective in preventing chronic infection. For infants exposed through the mother at birth, monovalent Hep B vaccine is 90% effective in preventing transmission if the first dose is administered within 24 hours and the series completed at the recommended intervals using the combination vaccines.

How safe is HepB vaccine and what are its potential adverse effects?

Mild, temporary local reactions are common after an injection of Hep B vaccine. It is highly unusual to see an anaphylactic reaction. Reactions and complications due to the vaccine are rare. Allergic reactions, such as rash, difficulty in breathing, and choking, occur about once every 600,000 doses. No fatal allergic reaction has been reported. Mild reactions include:

- Soreness. About 15% of adults and 5% of children experience tenderness, redness, or mild swelling at the injection site.
- Fever. About 1% to 6% of those who receive the vaccine develop a mild fever that lasts one or two days after injection of the vaccine.

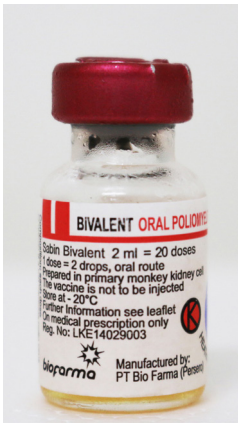
Administration Summary

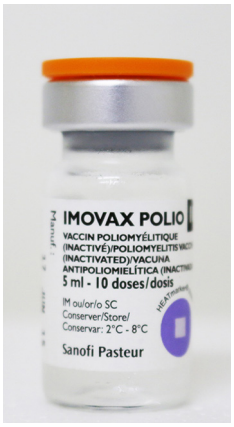
Type of Vaccine	Recombinant DNA
Number of Doses	1 dose
Schedule	Give within 24 hours, ideally 90 minutes after birth. If Hep B vaccine is not given within 24 hours after birth, it can still be given within seven days.
Booster	Booster doses are not recommended. Hep B vaccinations is also not usually recommended for health workers because it is likely that they have been exposed to the virus during childhood, and are less likely to be carriers if they become infected as adults.
Contraindications	There are no contraindications, except if a very rare anaphylactic reaction to a previous dose has occurred. In this case, Hep B should not be given again.
Adverse Reactions	Local soreness and redness, rarely anaphylactic reaction
Special Precautions	Birth dose must be given if there is a risk of perinatal transmission
Dosage	0.5ml
Injection Site	For infants, Hep B vaccine is injected usually into the outer part of the mid-thigh. For children and adults, it is injected in the outer upper arm. If more than one vaccine is injected at the same time, different sites should be used for each injection.
Injection Type	Intramuscular
Storage	Store between +2°C to +8°C.

F.3 Polio Vaccine

What is polio vaccine?

Polio vaccine protects against the poliovirus. Two types of polio vaccines are used throughout the world to provide immunity to poliovirus. One uses inactivated (dead) poliovirus and the other uses attenuated (weakened) poliovirus. The vaccines became available in 1955 and 1962, respectively. Interruption of person-to-person transmission of the virus by vaccination led to global polio eradication. The two vaccines have eliminated polio from most countries in the world, and reduced worldwide incidence from an estimated 350,000 cases in 1988 to just 37 cases in 2016.





What are the forms and presentations of polio vaccine?

1. **Oral Polio Vaccine (OPV)**
    - Contains live, attenuated (weakened) virus
    - Administered by drops
    - Inexpensive
    - Easy to administer
    - Provides mucosal/gut immunity
    - Protects close contacts who are unvaccinated

2. **Inactivated Polio Vaccine (IPV)**
    - Contains killed virus
    - Administered by injection
    - Highly effective
    - Used commonly in developed countries
    - More expensive than OPV
    - Requires trained health workers
    - Provides immunity through blood
    - Carries no risk of vaccine-associated polio paralysis (VAPP) or vaccine-derived poliovirus (VDPV)

How effective is the polio vaccine?

- In more than 95% of recipients, three doses of OPV produce immunity for all of the poliovirus types in the vaccine.
- IPV is also highly effective in preventing paralytic disease caused by all three types of poliovirus but induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces, risking continued circulation.

How safe is Polio Vaccine and what are its potential adverse effects?

Both OPV and IPV are extremely safe. With OPV, vaccine-associated paralytic polio (VAPP) can occur in approximately 1 in 2.7 million doses. VAPP usually occurs with the first dose of OPV, and this small risk declines further with subsequent doses. On rare occasions, over time, in areas of low vaccination coverage, the live attenuated (weakened) viruses contained in OPV can begin to circulate and regain the ability to cause paralytic cases. This is known as vaccine-derived poliovirus.

IPV is one of the safest vaccines in routine use. No serious adverse events have been linked to it. Mild events include injection site redness in less than 1% of those vaccinated, swelling in 3%–11% and soreness in 14%–29%.

Administration Summary

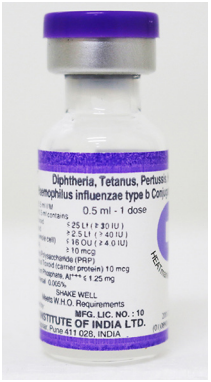
Type of Vaccine	Live,attenuated virus, oral (OPV), inactivated virus, injectable (IPV)
Number of Doses	Three to four doses
Schedule (OPV+IPV)	6, 10, 14 weeks Three OPV doses initiated from six weeks of age with minimum interval of four weeks; an IPV dose should be given from 14 weeks of age (with OPV dose).
(Sequential IPV-OPV)	1–2 doses of IPV starting from two months of age, followed by at least two doses of OPV; an interval of 4–8 weeks is required between all doses
(IPV only)	Three doses beginning at two months of age, with an interval of 4–8 weeks between doses
Special Precautions	Postpone vaccination if the child has moderate to severe illness (with temperature ≥39 °C)
Booster activities	Supplementary doses given during polio eradication
Contraindications	Known hypersensitivity (allergy) or anaphylaxis to a previous dose
Adverse Reactions	OPV – Rare vaccine-associated paralytic polio (VAPP) IPV – No known serious reactions; mild injection site reactions do occur
Dosage	OPV: two (2) drops into the mouth; IPV: 0.5 ml
Injection site	For IPV left upper thigh (outer part); OPV is given orally through mouth
Injection type	For IPV - intramuscular
Storage	OPV must be kept frozen from -15°C to -25°C. Do not freeze IPV. It should be stored from +2°C to +8°C.

TABLE 4
OPV and IPV Immunization Schedule for Children under One Year of Age

Age	Minimum Interval Between Doses	Dose
Six (6) weeks	Four (4) weeks	OPV1
10 weeks	Four (4) weeks	OPV2
14 weeks	Four (4) weeks	OPV3 and IPV

F.4 DPT-HepB+Hib Combination Vaccine (PENTA)

What is DPT-HepB+Hib vaccine (PENTA)?



DPT-HepB+Hib vaccine is called a pentavalent vaccine because it protects against five diseases: diphtheria, tetanus, and pertussis, hepatitis B, and *Haemophilus influenzae* type b. The vaccine may come in single or multi-dose vials. Do not useDPT-HepB+Hib as a birth dose.

What are the forms and presentation of Pentavalent vaccine?

Pentavalent vaccine is available in liquid suspension for injection which may be available in one (1) -, two (2)- and 10-dose vials.

How effective is Pentavalent vaccine?

Pentavalent vaccine is highly effective against five different diseases. However as Pentavalent contains vaccine aginst five different diseases some of the components need booster doses.

How safe is DPT-HepB+Hib vaccine and what are its potential adverse effects?

The number of cases of serious reactions to the DPT-HepB+Hib vaccine is similar to those of the other vaccines that contain DPT. If a serious reaction does occur, health workers should report the problem to supervisors immediately. Children who have a severe reaction should NOT receive additional doses of the vaccine. Mild reactions to the vaccine include: (i) soreness, redness, or swelling at the injection site, which resolves within one to three days; and (ii) fever.

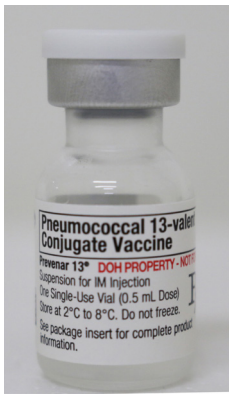
Administration Summary

Type of Vaccine	Pentavalent vaccine
Number of Doses	Three doses. PENTAVALENT vaccine is given as 3 dose infancy schedule however some vaccines such as Diphtheria and Tetanus need booster doses.
Schedule	Given at 6, 10, 14 weeks of age pentavalent1 starting at six weeks (minimum) with pentavalent2 and pentavalent3 at intervals of four weeks (minimum) after each dose.

Booster	**For Tetanus vaccine:** Total childhood schedule of five (5) doses (3 in infancy), another (Td) in early childhood (1–6 years), and another (Td) during adolescence (12–15 years) is required. A further dose in adulthood is likely to provide lifelong protection. **For Diphtheria vaccine:** Total childhood schedule of 6 doses is recently recommended by WHO. Three (3) doses in infancy, 4th dose at two years old and two other doses with Td vaccine at school age.
Contraindications	Anaphylaxis or hypersensitivity (allergy) after a previous dose
Adverse Reactions	Mild local and systemic reactions are common
Special Precautions	Do not use as a birth dose
Dosage	0.5 ml
Injection Site	Right Outer Upper Thigh
Injection Type	Intramuscular
Storage	Store between +2°C to +8°C. Never freeze the vaccine.

F.5 Pneumococcal vaccine

What is Pneumococcal vaccine?



A pneumococcal vaccine is a vaccine against *Streptococcus pneumoniae*. Types include: pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine.

What are the forms and presentations of Pneumococcal vaccine?

- Pneumococcal Conjugate Vaccine (PCV13) – contains serotypes 1, 3, 4V, 5, 6A, 6B, 7, 9F, 14, 18, 18C, 19A, 19F and 23F.
- Pneumococcal Polysaccharide Vaccine (PPV) – contains serotypes 1, 2 , 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F.

How effective is Pneumococcal vaccine?

Each pneumococcal vaccine protects against disease caused by the pneumococcal serotypes that it contains; it is unlikely to protect against serotypes that it does not contain. It does not protect against other bacteria that cause the same types of infections (pneumonia, meningitis, etc.) as pneumococcus. The usage of these vaccines resulted in a huge reduction in invasive pneumococcal disease.

How safe is Pneumococcal vaccine and what are its potential adverse effects?

Pneumococcal conjugate vaccine is safe and well tolerated in all target groups. No severe adverse events have been proven with use of these vaccines to date. Mild events include soreness at the injection site in about 10% of those vaccinated; fever has been reported in less than 1%.

Administration Summary

Type of Vaccine	Pneumococcal Polysaccharide and Pneumococcal Conjugate
Number of Doses	PCV - three doses for infants. PPV - one dose for adults.
Schedule	PCV - 6, 10 and 14 weeks of age for infants. PPV - At 60 and 65 years old for adults.
Contraindications	Anaphylaxis or hypersensitivity (allergy) after a previous dose
Adverse Reactions	Severe: none known Mild: injection site reactions and fever
Special Precautions	Postpone vaccination if the child has moderate to severe illness (with temperature ≥39 °C)
Dosage	0.5 ml
Injection Site	Anterolateral (outer) part of the left thigh (vastus lateralis) for infants, upper arm (deltoid) for adults
Injection Type	Intramuscular
Storage	Store between +2°C to +8°C

TABLE 5.
PCV and PPV Immunization

Type of Vaccine	Pneumococcal Conjugate (PCV)	Pneumococcal Polysaccharide (PPV)
Target Population	Infants under one year of age	Seior Citizes: 60 and 65 years old
No. of Doses	Three (3) doses	One (1) dose
Schedule	At 6, 10, and 14 weeks	At age 60 and 65 years old
Dosage	0.5 mL	0.5 mL

F.6 Measles-Rubella (MR) and Measles-Mumps-Rubella (MMR) Combination Vaccines

What are the MR and MMR vaccines?

In the Philippines, the NIP uses combination vaccines for measles, rubella (MR) and for measles, mumps, and rubella (MMR). MR and MMR vaccines are provided in powder form with diluents and must be reconstituted before they can be used. It is essential that only the diluent supplied with the vaccine be used. MR and MMR vaccines should be kept at +2°C– +8°C after reconstitution. Any remaining reconstituted vaccine must be discarded after six hours or at the end of the immunization session, whichever comes first.

What are the forms and presentations of Measles and Rubella containing vaccine?

Measles and Rubella containing vaccines are available as freeze dried vaccine to be mixed with the diluent. Formerly these vaccines used to be single antigen vaccines which contained only Measles or Rubella vaccine, however it is highly recommended to use vaccines that contain both Measles and Rubella with other antigen as per the need and availability such as Measles Rubella (MR), Measles Mumps Rubella (MMR) or Measles Mumps Rubella Varicella (MMRV).

How effective are the MMR and MR Vaccines?

Measles, Rubella and Mumps containing vaccines when given in required doses are highly effective. The usage of Measles and Rubella containing vaccine has decreased rates of the disease significantly in many countries in Asia and Africa.

How safe are MR and MMR vaccines and what are their potential adverse effects?

Both MR and MMR vaccines are very safe to use and may cause some rare adverse events as described below:

- Mild events are more common and include local injection site pain and tenderness, (5%–15%), fever and rash (in about 5%), which can occur five to 12 days after vaccination. Serious events are rare and include anaphylaxis in 1–3.5 per one million doses administered; severe allergic reaction in one per 100 000 doses; and, thrombocytopenia (decreased platelet count) in one per 30,000 doses.
- Rubella-containing vaccine may cause a temporary form of arthritis one to three weeks after vaccination in up to one in four post pubertal females (who have already reached sexual maturity).
- Mumps containing vaccine may cause parotid swelling (in 1%–2%).

Administration Summary

Type of Vaccine	Live attenuated viral
Number of Doses	Two (2) doses
Schedule	Childhood Dose of MMR: 9 months and 12 months
Booster	In Philippines, booster dose are given at school age children at grade 1 and grade 7.
Contraindications	For Measles Containing Vaccine(MCV) • Known allergy to vaccine components (including neomycin and gelatin) • Pregnancy • Severe congenital or acquired immune disorders, including advanced HIV infection/AIDS
Adverse Reactions	Mild: fever, rash 5–12 days following administration Serious: Thrombocytopenia (decreased platelets), anaphylaxis, encephalitis. Joint pain when rubella containing vaccine (RCV) is given to adult women; parotitis with mumps component.
Special Precautions	None
Dosage	0.5ml
Injection Site	Upper arm
Injection Type	Subcutaneous
Storage	Store between +2°C to +8°C.

TABLE 6.
MMR and MR Immunization

Type of Vaccine	Measles Mumps and Rubella (MMR)	Measles Rubella (MR)
Target Population	Infants under 15 months of age	School age children
No. of Doses	Two (2) doses	Two (2) doses
Schedule	9 months and 12 months	Grade1(5-6years old) and Grade7 (11-12 years old)
Dosage	0.5 mL	0.5 mL

F.7 Rotavirus Vaccine

What is Rotavirus vaccine?

A rotavirus vaccine protects children from rotaviruses, the leading cause of severe diarrhea among infants and young children. It contains genetically engineered live attenuated human rotavirus strains or hybrid human-bovine reassortment rotavirus strains.

What are the forms and presentations of Rotavirus vaccine?

- **Rotarix™**
  Rotarix is a monovalent, human, live attenuated rotavirus vaccine containing one rotavirus strain of G1P[8] specificity. ROTARIX is indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) when administered as a 2-dose series in infants and children.
- **RotaTeq™**
  RotaTeq is a live, oral pentavalent vaccine containing five rotavirus strains produced by reassortment.

What is the efficacy of Rotavirus vaccine?

Safety and efficacy trials in Africa and Asia found that the vaccines dramatically reduced severe disease among infants in developing countries, where majority of rotavirus-related deaths occur. The incidence and severity of rotavirus infections has dropped in countries that introduced the rotavirus vaccine. The vaccines may also prevent illness in non-vaccinated children by limiting exposure through the number of circulating infections.

How safe is Rotavirus vaccine and what are its potential adverse effects?

The available rotavirus vaccines are safe and well tolerated.

Mild adverse reactions include irritability, runny nose, ear infection, vomiting and diarrhea (in 5% or more of children vaccinated).

There is a low risk of intussusception or inversion of one portion of the intestine within another portion (about one to two per 100,000 infants vaccinated). Rotavirus vaccines are generally not recommended for infants with a history of intussusception.

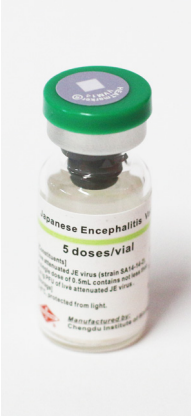
Administration Summary

Type of Vaccine	Live attenuated virus, oral
Number of Doses	Two (2) doses (Rotarix™); three (3) doses (Rotateq™)
Schedule	Six (6) and 10 weeks of age
Contraindications	• Severe allergic reaction to previous dose • Severe immunodeficiency (but not HIV infection) • History of uncorrected congenital malformation of gastro-intestinal (GI) tract.
Adverse Reactions	• Mild: irritability, runny nose, ear infection, diarrhoea, vomiting • Severe: intussusception
Special Precautions	• Should be postponed for acute gastroenteritis and/or fever with moderate to severe illness • Not routinely recommended if with a history of intussusception or intestinal malformations that possibly predispose to intussusception
Dosage	1 ml
Storage	Store between +2°C to +8°C

F.8 Japanese encephalitis (JE) vaccine

What is JE vaccine?

Japanese Enchephalitis vaccine protects people against viral enchepahilits caused by Japanese Enchephaltis virus (JEV). JEV is the leading cause of viral encephalitis in Asia.



What are forms and presentations of JE vaccine?

Four vaccines for preventing JE are currently available. Inactivated Vero cell derived vaccine, live attenuated vaccine, live recombinant vaccine and inactivated mouse brain derived vaccine.

The most commonly used one is live attenuated powered vaccine mixed with a diluent provided in a separate vial by the manufacturer. Before it can be used, JE vaccine must be reconstituted. The reconstituted vaccine must be discarded after six hours or at the end of the immunization session, whichever comes first.

How effective is JE vaccine?

JE vaccines are highly effective in preventing JEV infection. Several related studies demonstrate that vaccination is the best possible way to reduce the disease burden. Data on the population impact of vaccination programs show significant reduction in JE cases.

How safe is JE vaccine and what are its potential side effects?

JE vaccines are safe. High fever (in 5%–7% of those vaccinated); injection site reactions (redness, swelling: in less than 1% with some types of vaccine); and, low-grade fever, irritability, nausea and dizziness (rare) are the usual side effects.

Administration Summary

Type of Vaccine	Live attenuated virus vaccine
Number of Doses	One (1)
Schedule	Single dose administered at less than eight (8) months of age
Booster	The WHO states that the need for a booster in endemic settings has not been clearly established. However most of the countries have adopted the one (1) dose schedule.
Contraindications	• Known allergy to the vaccine or any of its components • Pregnancy • Any condition that results in a decreased or abnormal immune system response, including due to any infection (such as HIV), medication and/or congenital problems (since birth) • Acute diseases, severe chronic diseases, and chronic diseases with acute symptoms and/or fever • Encephalopathy (brain disease), uncontrolled epilepsy (seizures) or other diseases of the nervous system
Adverse Reactions	High fever (in 5%–7% of those vaccinated); injection site reactions (redness, swelling: in less than 1% with some types of vaccine); low-grade fever, irritability, nausea and dizziness (rare)
Special Precautions	• Medical history: caution needed for family or individual history of seizures or other chronic diseases, allergies and for women who are lactating • Postpone vaccination for at least three (3) months if the person has been given immunoglobulin
Dosage	0.5ml
Injection Site	Upper arm
Injection Type	Subcutaneous
Storage	Store between +2°C to +8°C

F.9 Tetanus Diptheria (Td) Vaccine

What is Td vaccine?

Td is the tetanus diphtheria toxoid vaccine. It is suitable for children older than five years old and adults, including pregnant women. Td has the added advantage of protecting against diphtheria and tetanus.

What are the forms and presentation of Td vaccine?

The vaccine can come in either as dT or DT. The capital or small letter D signifies the amount of diphtheria toxoid in vaccine either high or low.

How effective is the Td vaccine?

A three-dose course of Td provides protection against maternal and neonatal tetanus for at least five years. Five doses will protect women throughout their childbearing years. When given to women of childbearing age, vaccines that contain Td not only protect women against tetanus, but also prevent neonatal tetanus in their newborn infants and act as booster for diphtheria. When Td vaccine is given to a woman who is or who becomes pregnant, the antibodies that form in her body are passed to her fetus. These antibodies protect the baby against tetanus and diphtheria during birth and for a few months afterwards.

How safe is Td vaccine and what are its potential side effects?

- Mild reactions to Td vaccines include:
  - Soreness. About one in ten people who receive the vaccines have mild pain, redness, warmth, and swelling at the injection site for about one to three days after the injection. This mild reaction is likely to be more common after later doses than earlier ones, and may affect between 50% and 85% of people who receive booster doses.
  - Fever. About one in ten people may develop a mild fever after receiving the vaccines.
- Severe reactions, such as seizures, neurological complications, and anaphylaxis following Td vaccination are very rare.

Administration Summary

Type of Vaccine	Toxoid
Number of Doses	• Tetanus vaccine is given as five (5)-dose schedule. Three (3) doses in infancy as Pentavalent and two (2) doses in school age children as Td. • Children (Grade 1 and Grade 7) who had received three primary doses in the form of PENTA should receive at least two doses of Td • Pregnant women who had received three childhood DPT/PENTA doses should receive three doses of Td. • Pregnant women with no previous DPT/PENTA immunization or unreliable immunization information should receive 5 Td.

Schedule	After receiving primary doses during infancy (three doses in the form of PENTA), Td should be given to children 5-7 years old (Grade 1) and 12-15 years old (Grade 7). For pregnant women, Td vaccine should be given as early as possible upon onset of pregnancy. For the prevention of tetanus in women through their childbearing years and in newborns, women should receive five doses of tetanus toxoid. The table below shows the schedule by dose and the length of protection provided. Td can be used instead of TT to protect against both tetanus and diphtheria.
Contraindications	There are no contraindications to tetanus toxoid. It is safe to give at any time, even in the first trimester of pregnancy. However, PENTA, DT, and Td should not be given to individuals who have suffered a severe reaction to a previous dose.
Adverse Reactions	• Severe: rare anaphylaxis, brachial neuritis (inflammation of the nerves that control the shoulder, arm and hand) • Mild: injection site reactions and fever
Dosage	0.5 ml
Injection Site	Td is injected into the upper outer part of the arm
Injection Type	Intramuscular
Storage	Store between +2°C to +8°C. Never freeze.

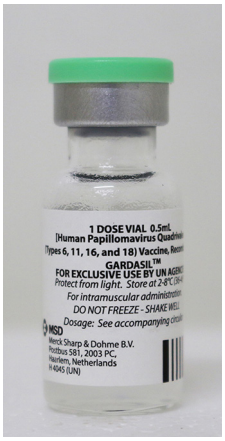
When vaccines containing tetanus toxoid are left standing for a long time, the vaccine separates from the liquid and looks like fine sand at the bottom of the vial. Shake the vial to mix the vaccine and liquid again before giving the vaccine. Td vaccine should never be frozen. The “shake test” will determine if the vaccine has been damaged by freezing. If the vaccine fails the shake test you must discard it.

TABLE 7.
Tetanus diphtheria Immunization Schedule

Dose	When To Give	Expected Duration of Protection for Woman
Td 1	As early as possible in pregnancy, or at first contact when a girl reaches childbearing age	May be very limited duration protection
Td 2	At least four weeks after Td1	One to three years
Td 3	At least six months after Td2 or in next pregnancy	Five years
Td 4	At least one year after Td3 or in next pregnancy	10 years
Td 5	At least one year after Td4 or in next pregnancy	All childbearing years

F.10 Human Papilloma Virus (HPV) vaccine

What is HPV vaccine?



HPV vaccine is primarily used for prevention of cervical cancer for women. Other benefits are prevention of ano-genital warts, vulvular, vaginal and anal cancer and penile intraepithelial neoplasia (pre-cancerous disease of the outer skin layer of the penis).

What are the forms and presentations of HPV vaccine?

There are three available HPV vaccines:

1. **Bivalent HPV vaccine**
   - contains types 16 and 18 L1 major capsid protein, self-assembled as intact, non-infectious virus-like particles (VLP's)
   - manufactured in insect cells, Baculovirus.
   - adjuvanted with ASO4 (Aluminum Hydroxide) plus monophosphoryl lipid A derived from Salmonella minnesota.

2. **Quadrivalent HPV vaccine**
   - Contains types 6, 11, 16, 18 L1 major capsid protein, self-assembled as intact, non-infectious virus-like particles (VLP's)
   - manufactured in yeast, Saccharomyces cereviseae
   - adjuvanted with propriety amorphous aluminium hydroxyphosphate sulphate.

3. **Nonavalent HPV vaccine**
   - contains types 6,11,16,18,31,33,45,52 and 58 purified viral L1 protein
   - manufactured in yeast, Saccharomyces cereviseae
   - adjuvanted with propriety amorphous aluminium hydroxyphosphate sulphate.

What is the efficacy of HPV vaccine?

- Studies of the quadrivalent vaccine were conducted in young women and men (16 through 26 years of age). Among persons not previously exposed to a targeted HPV type, the vaccine was nearly 100% effective in preventing cervical precancers, vulvar and vaginal precancers, and genital warts in women, as well as 90% effective in preventing genital warts and 75% effective in preventing anal precancers in men.
- Study of the bivalent vaccine among young women aged 15 through 25 years who were not previously exposed to a targeted HPV type showed 93% vaccine efficacy in preventing cervical precancers due to HPV 16 or 18. In all studies of the bivalent HPV vaccine, more than 99% of females developed an HPV 16 and 18 antibody response a month after completing the three-dose series.
- While promising, HPV vaccines do not replace other prevention strategies, such as regular cervical cancer screening using the Pap Smear test.

How safe is HPV vaccine and what are its potential side effects?

Potential side-effects and adverse events to the vaccine include:

- Local reactions: 84% experience mostly burning pain and swelling at the injection site.
- Fever: 10% of vaccine recipients
- Vasovagal syncope can occur among adolescents and adults after receiving the vaccine. If this happens:
  - › Clients should be observed for 15 minutes after receiving the vaccine.
  - › Recipients should always be seated during vaccine administration.

Administration Summary

Type of Vaccine	Recombinant
Number of Doses	Two (2) doses
Schedule	Routinely given to females nine to 10 years old. Given in two (2) doses six months apart
Contraindications	Persons with history of immediate hypersensitivity to yeast or to any vaccine component
Adverse Reactions	• Mild: injection site reactions; fever, dizziness, nausea • Severe: rare anaphylaxis
Special Precautions	• Postpone vaccination for pregnancy • Adolescents should be seated during injections and for 15 minutes afterwards since they sometimes faint
Dosage	0.5 ml
Injection Site	Upper arm (deltoid)
Injection Type	Intramuscular
Storage	Store between +2°C to +8°C. Protect from light.

F.11 Seasonal Influenza Vaccine

What is Influenza vaccine?

Most seasonal influenza vaccines are trivalent, containing two strains of influenza A and one strain of influenza B, chosen based on known circulating strains. The influenza vaccine, also known as flu shot, is an annual vaccination using a vaccine that is specific for a given year to protect against the highly variable influenza virus.

What are the forms and presentations of Influenza vaccine?

There are two different types of flu vaccines, trivalent and quadrivalent.
Trivalent vaccines protect against two influenza A viruses (an H1N1 and an H3N2) and an influenza B virus.

Quadrivalent vaccines protect against two influenza A viruses and two influenza B viruses.

How effective is the Influenza vaccine?

Seasonal influenza vaccines are usually effective if given during the right time according to the circulating strain in a particular setting. Vaccine effectiveness is dependent upon the extent of the match between the virus strains used to prepare the vaccine and those viruses in actual circulation.

Research has shown that when there is a good match between the virus strains chosen for the vaccine and those in circulation, the vaccine prevents influenza illness in approximately 70-90% of healthy adults.

How safe is Influenza vaccine and what are its potential side effects?

While there are side effects to the vaccine, they are usually minor. The safety is high. Side effects include runny nose and sore throat, which can last for up to several days. The flu vaccine in rare circumstances may cause an allergic reaction which needs immediate medical attention.

Common side effects are mild and temporary when compared to the burden of hospitalization and deaths during annual epidemics.

Administration Summary

Type of Vaccine	Inactivated influenza virus
Number of Doses	Usually one dose to be given annually
Schedule	Adults 60 years of age or older should get vaccine as it becomes available in the health center near you ideally before flu season.
Contraindications	Known hypersensitivity (allergy) or anaphylaxis to a previous dose or to a vaccine component such as egg protein

Adverse Reactions	• Mild: injection site reactions and fever • Severe: rare anaphylaxis, Guillain-Barré syndrome, oculo-respiratory syndrome
Special Precautions	May postpone vaccination in case of moderate to severe illness (with temperature ≥39 °C)
Dosage	0.5 ml
Injection Site	Upper arm (deltoid)
Injection Type	Intramuscular
Storage	Store between +2°C - +8°

G. Summary of Route of Administration, Injection Sites and Schedule

TABLE 8.
Summary of Vaccines by Route of Administration, Injection Site and Schedule

No.	Vaccine	Route of Administration	Injection Site	Schedule
1	BCG	Intradermal	Upper right arm	At birth
2	HepB	Intramuscular	Outer mid-thigh	At birth
3	OPV	Oral	Mouth	6-10-14 weeks
4	IPV	Intramuscular	Outer left upper thigh	14 weeks
5	PENTA	Intramuscular	Outer right upper thigh	6-10-14 weeks
6	PCV	Intramuscular	Outer left upper thigh	6-10-14 weeks
7	PPV	Intramuscular	Upper right arm	Adults 60 and 65 years old
8	Rotavirus Vaccine	Oral	Mouth	6-10 weeks
9	MMR	Subcutaneous	Upper right arm	9 months and 12 months
10	MR	Subcutaneous	Upper right arm	Grade 1 and 7
11	Td	Intramuscular	Outer, left upper arm	Grade 1 and 7 for children For child-bearing woman: Td1: As early as possible in pregnancy Td2: 4 weeks after Td1 Td3: 6 months after Td2 Td4: 1 year after Td3 Td5: 1 year after Td4
12	JE	Subcutaneous	Upper arm	9 months
13	HPV	Intramuscular	Outer, upper arm	Female: 9 – 10 years old
14	Influenza Vaccine	Intramuscular	Outer, upper arm	60 years old and above, annually

Intradermal = into the skin; Intramuscular = into a muscle; subcutaneous = under the skin