



Ministry of Health & Family Welfare
Government of India



Frequently Asked Questions on Immunization

(For Program Managers)
2017



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SECTION: 1

IMMUNITY AND VACCINES



1. What is immunity?

Ans. Immunity refers to resistance against infection caused by microorganisms (bacteria and viruses) and their products (toxins). Physiologically immunity is of two types:¹

- ➡ **Humoral immunity** in which antibodies produced by B-cells cause destruction of extracellular microorganisms and prevent the spread of intracellular infections.
- ➡ **Cell-mediated immunity** is an immune response that does not involve antibodies, rather involves the activation of phagocytes, antigen-specific cytotoxic T-lymphocytes and the release of various cytokines in response to an antigen.



2. What is immunization?

Ans. Immunization is the process whereby 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.²



3. Do the children have natural immunity against diseases?

Ans. Babies are born with natural immunity against some diseases, which they get from their mothers (in utero) and by breastfeeding in the early days of their life. But as they grow, this immunity gradually decreases. Immunization further enhances their immunity and protects them against vaccine-preventable diseases.



4. How do vaccines protect from disease-causing organisms?

Ans. Vaccines contain either weakened or killed versions of viruses or bacteria, or an antigenic substance prepared from the causative agent, or a synthetic substitute. Once administered in the body by injection, mouth or by aerosol, stimulate the immune response to produce "**antibodies**" targeting those infectious agents, thereby producing protection against infections. Each vaccine provides immunity against a particular disease; therefore, a number of vaccines are administered to children and pregnant women to protect them from many vaccine-preventable diseases.³

¹Section 1: General aspects of vaccination (Vaccine Immunology) at http://www.who.int/immunization/documents/Elsevier_Vaccine_immunology.pdf

²Health Topics: Immunization (WHO) at <http://www.who.int/topics/immunization/en/>

³Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officers, 2016

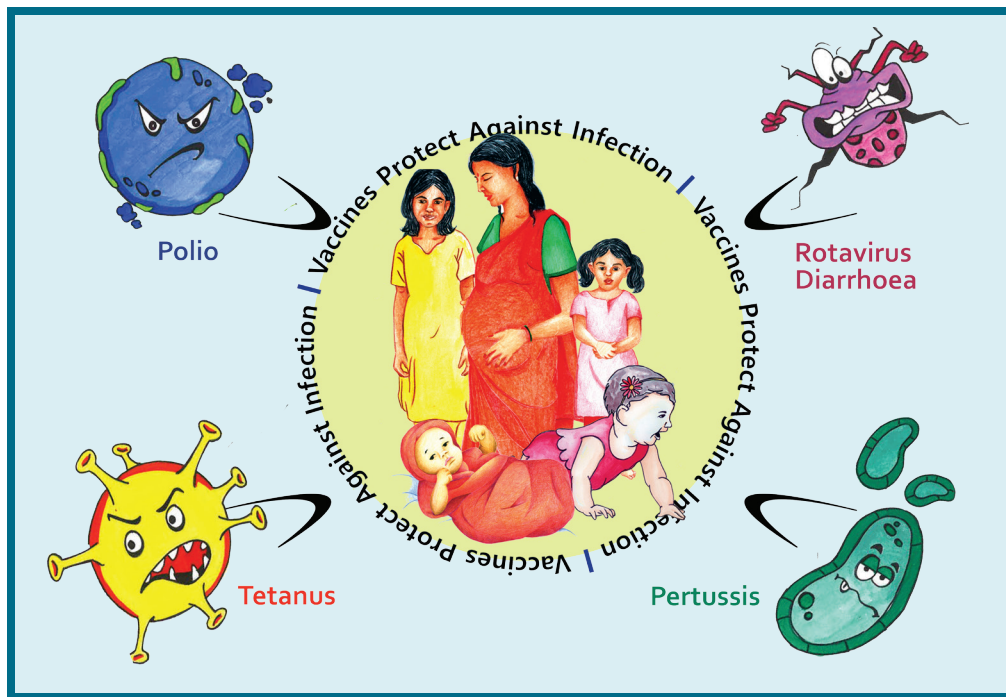


Figure 1: Vaccines protect against infection



5. What is the duration of immunity provided by immunization?

Ans. The duration of immunity varies with different diseases and different vaccines. Life-long immunity is not always provided by either natural infection or vaccination. The protection provided by vaccines decreases gradually over time. Therefore, booster doses are sometimes recommended for certain vaccines, at specific age groups.



6. When does the process of child immunization start?

Ans. Immunization process starts when a child is in utero. Immunity developed from TT vaccine given to pregnant women passes to her child and protects from neonatal tetanus. Immunity against some infections, like measles, is transferred to child as passive immunity and protects from infection for some period after birth. Under National Immunization Schedule, **BCG, OPV, and Hep B** vaccines are given to child immediately after birth.



7. Why is timely vaccination important?

Ans. Age of administration of vaccines is decided by medical and public health experts after careful study of disease epidemiology and protective efficacy of different vaccines. Vaccines ensure best protection when they are given at the right time. India's National Immunization Schedule has been designed to protect children since birth, and at the ages when they are vulnerable to specific vaccine-preventable diseases.

The recommended age for vaccination by different vaccines aims to achieve the best immune protection to cover the period in life when vulnerability to disease is highest. When children are not vaccinated at all or get vaccinated beyond the recommended age, they remain unprotected and may get infected from a vaccine-preventable disease.



8. What are the various types of vaccines?

Ans. Vaccines can be categorized on the basis of their composition, which also decides its mechanism of action once introduced into the body. Broadly, there are four types of vaccines:⁴

Vaccine Type	Description	Examples
Live-Attenuated Vaccines	Contains live form of disease- causing agents (virus or bacteria), that have been weakened under laboratory conditions. These agents replicate in the body of vaccinated individual and cause a mild form of self-limiting disease, followed by long lasting immunity.	BCG, Oral polio vaccine (OPV), Measles/ Measles- Rubella (MR), Rotavirus and Japanese encephalitis (JE) vaccines
Inactivated (or killed) vaccines	Contain inactivated form of disease causing agent (virus or bacteria). They cannot replicate but induce an immune response leading to protection against specific disease. These vaccines require multiple doses to induce, and booster doses to maintain immunity.	Pertussis, Haemophilus influenza type B (Hib) and Inactivated Poliovirus Vaccine (IPV)
Recombinant (or sub-unit) vaccines	Contain genetically modified form of disease causing agent, which produce antigenic proteins in vaccinated individual, thus inducing immunity.	Hepatitis B vaccine
Toxoid vaccines	Contain inactivated form of toxins produced by disease causing agent, which elicit immune response producing immunity against the disease.	Diphtheria and Tetanus toxoid (TT) vaccines

Table 1:Types of vaccines



9. Why do private providers offer some vaccines that are not available in Government's programme?

Ans. Government's immunization programme serves to a wider community, while private providers serve only to families that approach to them for services. Universal Immunization Programme (UIP) implemented by Ministry of Health & Family Welfare (MoHFW), Government of India includes vaccines recommended by **WHO and National Technical Advisory Group on Immunization (NTAGI)**. Its objective is to control transmission of diseases having public health significance that can lead to high mortality and morbidity among the community.

Private providers, on the other hand, follow immunization schedule recommended by Indian Academy of Paediatrics (IAP). It includes some vaccines that are not of public health significance and do not pose threat to a larger community. Therefore, vaccines provided in government's programme are fewer as compared to those provided by private providers.

⁴Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officers, 2016



10. Is there any difference in the vaccine quality provided by private practitioners and those provided at the government health facilities?

Ans. Both government and private sectors have same regulatory mechanisms and all vaccines are procured from government approved manufacturers. All vaccines are approved by **Central Drugs and Standards Control Organization (CDSCO)** which is the National Regulatory Authority (NRA). Drug Controller General of India (DCGI) heads the CDSCO and grants permission to conduct clinical trials; registers and controls the quality of vaccines.⁵



11. What is the difference between vaccine efficacy, effectiveness and efficiency of vaccines?

Ans. These three terms are generally used interchangeably though there is difference in the exact meaning in reference to immunization programme:

- ➡ **Vaccine efficacy** refers to percentage reduction in disease incidence in a vaccinated group compared to an unvaccinated group, under optimal conditions. Example: "single dose of measles vaccine is about 85% efficacious when administered below one year of age".⁶
- ➡ **Vaccine effectiveness** refers to the benefit it actually provides to the beneficiaries, not under the optimal conditions.
- ➡ **Vaccine efficiency** on the other hand, denotes ratio of outputs and inputs, i.e. overall gains made in immunization programme through reduction in VPD-related mortality and morbidity against the resources invested into the programme. These terms are generally used in reference to health economics. Example: "high coverage achieved in UIP has a positive economic and social effect, and so it is an efficient health programme."



12. Do all vaccines have same efficacy?

Ans. No. Different vaccines have different efficacies in terms of producing immunity and duration for which the immunity will last. Efficacy depends on many factors, including;

- ➡ The type of vaccine
- ➡ Age at which vaccine is administered
- ➡ Number of doses of the vaccine administered
- ➡ Gap between administration of two doses
- ➡ Administration of booster doses
- ➡ Correct route of administration
- ➡ Potency of vaccines.

⁵National Vaccine Policy, Ministry of Health & Family Welfare, Government of India, April 2011

⁶Introduction of Measles-Rubella Vaccine, Operational Guidelines 2017



13. What is the meaning of terms disease control, elimination, eradication and extinction?

Ans. Meaning of these terms is as follows:⁷

- ➡ **Disease control** is the reduction of disease incidence, prevalence, morbidity or mortality to a locally acceptable level. Control is achieved by deliberate efforts, and continued intervention measures are required to maintain the status. Example: Diarrhoeal Diseases.
- ➡ **Disease elimination** is reduction to zero of number of cases of a specified disease occurring over a period, in a defined geographical area. Example: Maternal and Neonatal Tetanus and Poliomyelitis.
- ➡ **Disease eradication** is permanent reduction to zero of the worldwide incidence of infection caused by a specific agent. Eradication is achieved by deliberate efforts, but continued intervention measures are no longer needed. Example: Smallpox.
- ➡ **Disease extinction** is the stage when a specific infectious agent causing a disease no longer exists in nature or in the laboratory. No disease has been made extinct so far.



14. Why some diseases may only be controlled, while a few others can be eradicated?

Ans. Availability of an effective vaccine is one of the most effective methods of preventing an infection from a disease. However, every disease-causing organism has a specific epidemiological pattern by which it spreads among the susceptible population. This involves geographic spread, availability of potential reservoirs, transmissibility, route of transmission, and natural resistance to re-infection, which decides whether a disease can be eradicated or not. Therefore, some diseases can be only be controlled by implementing effective control measures, while there are few which can be eradicated with no threat of re-introduction of infectious agent into the human population.

For example, small pox has been eradicated by use of an effective vaccine while maternal and neonatal tetanus has been eliminated.



15. What are the criteria for considering a disease a candidate for eradication?

Ans. Deciding whether a disease is a candidate for eradication depends on seven main factors;⁸

- ➡ No known animal reservoir
- ➡ No long-term carrier of the causative organism
- ➡ Lifelong immunity, after recovery from the disease
- ➡ Case detection is simple
- ➡ People with subclinical infection do not transmit the disease
- ➡ Availability of highly effective vaccine that confers long-term protection, and
- ➡ Global cooperation and commitment

Example of such diseases includes smallpox.

⁷Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, December 31,1999/48 (SU01);23-7 at <https://www.cdc.gov/mmwr/preview/mmwrhtml/su48a7.htm>

⁸Donald R. Hopkins, Disease Eradication, N Engl J Med 2013;368:54-63.DOI: 10.1056/NEJMr1200391 at <http://www.nejm.org/doi/pdf/10.1056/NEJMr1200391>



16. Which diseases have been successfully eliminated/ eradicated by use of vaccines in routine immunization?

Ans. Use of vaccines in India's Universal Immunization Programme (UIP) has resulted in successful eradication/elimination of three diseases from the country. These are smallpox (1977), poliomyelitis (2014) and maternal and neonatal tetanus (2015).



17. Is it true that individual vaccination also ensures protection of community at large? What is herd immunity?

Ans. **Yes.** It is true that individual vaccination against a disease-causing pathogen can protect even those individuals in a community who have not been vaccinated against that disease or pathogen. A population with a high number of members with immunity to a particular disease or pathogen may give protection from that infection to the small number of its non-immune members. This phenomenon is known as **"herd immunity"** or **"community immunity"** or **"population immunity"**. This is only achieved when a very high proportion of community members are vaccinated, so it is difficult for the disease-causing organism to spread to unprotected persons because there are few of those people left.

It is only true for diseases where there is a person to person transmission. Herd immunity makes it difficult for disease-causing organism to spread through cycle of infection, multiplication and circulation amongst the vulnerable population.

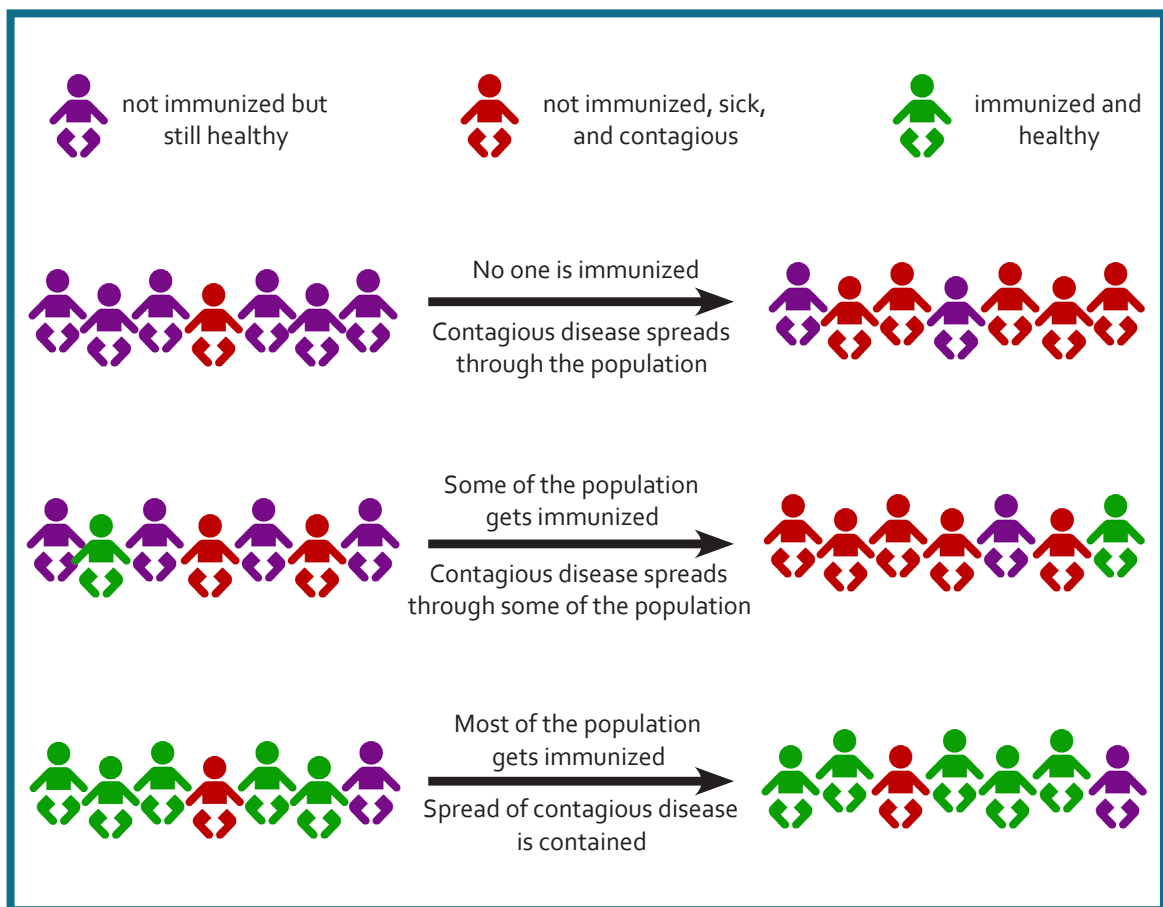


Figure 2: Depiction of herd immunity



18. What is the reason that some children suffer from vaccine-preventable disease though they have been vaccinated against that disease?

Ans. Vaccines have been used for decades and have proven to be effective. Like any other medicine, no vaccine is 100% efficacious. The immunity produced by vaccines varies from child to child. There may be children who do not develop sufficient protective immunity against a disease-causing pathogen due to malnutrition, repeated episodes of diarrhoea leading to diminished immunity or individual specific immune response to a vaccine.

Because of these reasons, some children suffer from vaccine-preventable disease despite receiving vaccination against it. However, in such cases the disease is of less severity than in children who have never been vaccinated.



19. What are vaccine hesitancy and vaccine confidence?

Ans. **Vaccine hesitancy** is the behaviour of parents, caregivers, or the community, who hesitate to get their children vaccinated in spite of immunization services being available and accessible. Inadequate immunization services due to non-availability of vaccines, absenteeism of vaccinators and long distances to vaccination centres contribute to this hesitancy. Other reasons for vaccine hesitancy are low perception of the benefits of vaccines, loss of wages, social beliefs, fear of AEFIs, inadequate IPC skills of health workers, geographical barriers.

Vaccine confidence is when parents, caregivers or the community understand the value of vaccination and voluntarily demand vaccination services as a right, whether these vaccinations are part of the RI schedule for their children or part of adult vaccinations such as TT for pregnant women. Vaccine confidence comes from adequate awareness about the benefits of vaccines, both to the individual and to the community, and the trust in the immunization service delivery system to be able to provide quality vaccination.⁹



20. Why have certain vaccines been introduced in selected states only?

Ans. Vaccines are introduced in National Immunization Schedule for diseases that lead to high mortality and morbidity among children. Certain vaccines are introduced in selected states due to the following reasons;

- ➡ Whenever new vaccines are introduced in UIP, then initially, they are rolled out in some states (phased-wise introduction) and gradually expanded across all states and districts of the country. For example, Rotavirus Vaccine and PCV.
- ➡ Secondly, diseases, like Japanese Encephalitis, are endemic in certain districts and states only (i.e. restricted to a certain place due to environmental conditions). For such diseases, vaccines are introduced only in those areas which are affected by them.
- ➡ There are initiatives by the state government to introduce additional vaccines in their routine immunization, which are not part of the National Immunization Schedule.

⁹Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officers, 2016



SECTION: 2

UNIVERSAL IMMUNIZATION PROGRAMME (UIP) AND NATIONAL IMMUNIZATION SCHEDULE (NIS)



21. What is the National Immunization Schedule under Universal Immunization Programme?

Ans. National Immunization Schedule is a vaccination plan that all children and pregnant women should follow and complete to ensure protection against vaccine-preventable diseases. This schedule includes **name of vaccine, recommended age/s of administration, total doses required, route and site of administration and volumes of doses.**

Vaccine	Dose	Recommended Age	Volume	Route and site of administration
Infants and Children				
BCG	Single	At birth	0.05 ml	Intradermal (LEFT upper arm)
Hepatitis B	Birth dose	At birth	0.5 ml	Intramuscular (Antero-lateral side of LEFT mid-thigh)
OPV	Zero dose	At birth	2 drops	Oral (mouth)
	First	6 weeks	2 drops	Oral (mouth)
	Second	10 weeks	2 drops	Oral (mouth)
	Third	14 weeks	2 drops	Oral (mouth)
	Booster	16-24 months	2 drops	Oral (mouth)
Pentavalent	First	6 weeks	0.5 ml	Intramuscular (Antero-lateral side of LEFT mid-thigh)
	Second	10 weeks	0.5 ml	Intramuscular (Antero-lateral side of LEFT mid-thigh)
	Third	14 weeks	0.5 ml	Intramuscular (Antero-lateral side of LEFT mid-thigh)
Rotavirus*	First	6 weeks	5 drops	Oral (mouth)
	Second	10 weeks	5 drops	Oral (mouth)
	Third	14 weeks	5 drops	Oral (mouth)
PCV*	First	6 weeks	0.5 ml	Intramuscular (Antero-lateral side of RIGHT mid-thigh)
	Second	14 weeks	0.5 ml	Intramuscular (Antero-lateral side of RIGHT mid-thigh)
	Booster	9 months	0.5 ml	Intramuscular (Antero-lateral side of RIGHT mid-thigh)
IPV	First	6 weeks	0.1 ml	Intradermal (RIGHT upper arm)
	Second	14 weeks	0.1 ml	Intradermal (RIGHT upper arm)
Measles/MR*	First	9-12 months	0.5 ml	Subcutaneous (RIGHT upper arm)
	Booster	16-24 months	0.5 ml	Subcutaneous (RIGHT upper arm)
JE*	First	9-12 months	0.5 ml	Subcutaneous (LEFT upper arm)
	Second	16-24 months	0.5 ml	Subcutaneous (LEFT upper arm)
DPT	First booster	16-24 months	0.5 ml	Intramuscular (Antero-lateral side of LEFT mid-thigh)
	Second booster	5-6 years	0.5 ml	Intramuscular (upper arm)
TT	First	10 years	0.5 ml	Intramuscular (upper arm)
	Second	16 years	0.5 ml	Intramuscular (upper arm)
Pregnant women				
TT	First	Earliest possible	0.5 ml	Intramuscular (upper arm)
	Second	4 week after 1st dose	0.5 ml	Intramuscular (upper arm)
	Booster	If received 2 TT doses in a pregnancy within the last 3 years	0.5 ml	Intramuscular (upper arm)

(1) If BCG is administered after one month of age, then dose will be 0.1 ml
(2) JE vaccine is given only in endemic districts.

Table 2: National Immunization Schedule

*Wherever applicable



22. Which vaccines are currently given to a child in India's Universal Immunization Programme and against which diseases these vaccines prevent?

Ans. Under India's Universal Immunization Programme 12 different vaccines are provided to beneficiaries free of cost, through government health system. These are – **BCG, OPV, Hepatitis B, Pentavalent, Rotavirus, PCV, IPV, Measles/MR, JE, DPT, and TT.**

Out of these, Rotavirus Vaccine, PCV and MR are being introduced in a phased-wise manner across different states. JE vaccine is given only in the districts where Japanese Encephalitis is endemic. The vaccines administered in UIP and the diseases prevented by them are as follows;

Vaccine	Disease Prevented	
BCG	Childhood Tuberculosis (or Primary Complex)	
OPV	Poliomyelitis	
Hepatitis B	Hepatitis B (affecting liver)	
Pentavalent	Diphtheria (<i>Gal Ghotu</i>), Pertussis (Whooping Cough, <i>Kaali Khansi/ Kukkar Khansi</i>), Tetanus (<i>Dhanustambh</i>), Hib infection (causing pneumonia and meningitis), and Hepatitis B	
Rotavirus*	Rotavirus diarrhoea	
IPV	Poliomyelitis	
Measles	Measles (<i>Khasra</i> or <i>Govar</i>)	
MR*	Measles and Rubella	
JE*	Japanese Encephalitis or Acute Encephalitis Syndrome (AES) or Brain Fever (<i>Dimagi Bukhar</i>)	
DPT	Diphtheria, Pertussis, and Tetanus	
TT	Tetanus (in new-born and pregnant women)	
PCV*	Pneumococcal Pneumonia	

Table 3: Vaccines and disease prevented

*Wherever applicable



23. What is the meaning of a fully immunized child?

Ans. A fully immunized child is one who has received all vaccines recommended in the National Immunization Schedule in required doses, before completing one year of age.

For the purpose of monitoring and evaluating the programme, a child below 1 year of age who has received one dose of BCG, Measles/MR along with 3 doses of OPV, Pentavalent Vaccine and two doses of IPV is said to be fully immunized. However, for the purpose of the programme and to ensure that the child is completely protected, all other vaccines applicable to a child below one year of age should be provided as per the immunization schedule, like PCV (3 doses), RVV (3 doses), JE (1 dose), wherever applicable.

Although, National Immunization Schedule recommends administration of birth dose of Hepatitis B and zero dose of OPV as soon as the child is born, this is not included in the criterion for a child to be categorized as fully immunized.



24. What is the meaning of a completely immunized child?

Ans. A child who has received all vaccines recommended for the first and second year in the National Immunization Schedule is said to be completely immunized.

- ➡ **First year:** One dose of BCG, Measles/MR* and JE vaccines*, 3 doses of OPV, Pentavalent vaccine, Rotavirus vaccine* and PCV*, and 2 doses of IPV
- ➡ **Second year:** Second dose of Measles/ MR* and JE vaccines*, and one booster dose of OPV and DPT

*Wherever applicable



25. What are left outs and drop outs?

Ans. From a service delivery perspective:

- ➡ **Left outs** are those children who have never been vaccinated or reached (thus remaining unimmunized);
- ➡ **Drop outs** are those children who started vaccination but did not complete the schedule (thus remaining partially immunized).

From behavioural perspective, a large percentage of dropouts is a serious problem because it reflects the poor perception of the parents/caregivers about the benefits of vaccination or of the immunization service delivery system, or both, combined with other barriers that forces them to place immunization on a lower priority.¹⁰

¹⁰Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officers, 2016



26. How new vaccines are introduced in UIP and how is immunization schedule decided?

Ans. The decision on inclusion of vaccines is taken by the Ministry of Health and Family Welfare, Government of India, on recommendation of **National Technical Advisory Group on Immunization (NTAGI)**.

Schedule for administration of different vaccines is decided based on the operational aspects of national immunization programme; and the recommendations provided by WHO-recommended schedules, vaccine position papers, as well as the **Strategic Advisory Group of Experts (SAGE)**.¹¹



Table 4: Steps for introduction of new vaccines in India

¹¹Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officers, 2016



27. Which vaccines have been introduced in recent years?

Ans. Vaccines introduced in Universal Immunization Programme during last few years are JE (2006), Hepatitis B (2007), Pentavalent (2011), IPV (2015) and Rotavirus Vaccine (2016). Pneumococcal Conjugate vaccine (PCV) and Measles-Rubella (MR) are the latest additions rolled out under UIP (2017).



28. Are there any vaccines given under Universal Immunization Programme that are banned by other countries?

Ans. No. There are no such vaccines in use in India's immunization programme that are banned in any other country. All vaccines being used are pre-qualified as effective and safe and recommended for use by WHO. All vaccines are approved by Central Drugs and Standards Control Organization (CDSCO) which is the National Regulatory Authority (NRA). Drug Controller General of India (DCGI) heads the CDSCO and grants permission to conduct clinical trials; registers and controls the quality of vaccines.¹²



29. If a child is brought late for a subsequent dose of multi-dose vaccines (for example, after more than the recommended one month), should the health worker restart the series from the first dose?

Ans. No. There is no need to restart the series or schedule again in case a child has received some doses of scheduled vaccines but is brought late for the subsequent doses. If the child is brought late, the health workers should give the next dose of the vaccine and motivate the parents to bring the child for the remaining doses at the recommended interval as per the immunization schedule.



30. What are the upper age limits for various vaccines?

Ans. According to National Immunization Schedule some vaccines have an upper age limit for administration and these vaccines should not be administered once that age limit is crossed.

The vaccines should be given till the following ages as per UIP guidelines:

- ➡ BCG: up to one year of age
- ➡ OPV: up to five years (OPV zero dose till 15 days of birth)
- ➡ Measles/MR: up to five years (in MR campaigns, vaccine is given to 9 months to 15 years age group)
- ➡ DPT: up to 7 years
- ➡ JE: up to 15 years

Only the above-mentioned vaccines have upper age limits. Efforts should be made to

¹²National Vaccine Policy, Ministry of Health & Family Welfare, Government of India, April 2011

ensure that all vaccines are given at the recommended ages, or closer to it.

For pentavalent, IPV, PCV and Rotavirus vaccines, if at least one dose is given before one year of age, then remaining doses can be administered and schedule must be completed irrespective of the age of child. If the first dose is not administered before one year of age, then these vaccines cannot be administered to the child under UIP.



31. Why are some vaccines not administered after a reaching a certain age?

Ans. Age of administration for different vaccines has been recommended in National Immunization Schedule taking into consideration maximum benefit in terms of immunity generation, reduction in disease incidence, and mortality and morbidity. The schedule has been designed to ensure protection against vaccine preventable diseases to children at ages when they are most vulnerable.

After attaining a certain age, children acquire natural immunity to some infections (like childhood tuberculosis), or cross vulnerable age period when a vaccine-preventable disease can be life threatening.



32. Why are booster doses required after receiving initial doses of some vaccines?

Ans. Immunity or protective effect generated by some vaccines gradually diminishes over time and increases vulnerability to target infections. For such vaccines, booster doses are administered after receiving initial doses as it boosts immunity and enhances protection level against specific vaccine-preventable disease. For example: DPT, OPV and PCV.



33. If a child has suffered from a vaccine-preventable disease in the past, will s/he still require vaccination against that disease?

Ans. **Yes.** Most vaccine-preventable diseases (for example, Diphtheria, Tetanus, Rotavirus diarrhoea, Hib pneumonia and JE) after an episode of full-blown infection and disease do not confer long-term immunity. Therefore, in these cases a child will still require all recommended doses of the vaccine as per the national immunization schedule.

Some vaccine-preventable diseases are caused by different strains of same pathogenic organism. In these cases, infection by one strain does not confer immunity against other strains and will require vaccination to ensure full protection. Example: Bivalent OPV as currently given in UIP provides protection against poliovirus types 1 and 3. Therefore, administration of this vaccine will still be required for a child who got infected by the type 1 poliovirus in past, as s/he is vulnerable for infection from type 3 poliovirus.



SECTION: 3

VACCINATION OF PREGNANT WOMEN



34. What vaccines are recommended for pregnant women in National Immunization Schedule?

Ans. In National Immunization Schedule, two doses of **Tetanus Toxoid (TT)** vaccine are recommended for all pregnant women. First dose is given as soon as the pregnancy is confirmed, and the second dose 4 weeks after the first dose.

However, if any pregnant woman has not received TT vaccination during her pregnancy, she should be given one dose of TT at the time of labour.



35. Why do pregnant women require vaccination against Tetanus?

Ans. Tetanus, also known as Lockjaw, is a life-threatening disease causing seizures and severe muscle spasms, often leading to death by respiratory failure. In new-borns, disease present as tightly closed mouth due to spasm of jaw muscles. As a result, they cannot take feeds, and in the majority of cases die.

Tetanus Toxoid (TT) vaccine is given to all pregnant women to protect them and their new-born babies from Tetanus. Due to sustained efforts over years, India has been successful in eliminating Maternal and Neonatal Tetanus, and to sustain this status administration of TT vaccine to all pregnant women need to be ensured.



36. Is it safe to give TT doses in all pregnancies?

Ans. **Yes.** Recommended doses of TT vaccine should be given to a woman every time she gets pregnant. Repeat doses only enhance immunity and do not cause any harm to the woman or her child.



SECTION: 4

NEW-BORN VACCINATION



37. What vaccines should be given to a new-born?

Ans. According to National Immunization Schedule, one dose each of three vaccines, **OPV, BCG and Hepatitis B**, should be given to new-borns irrespective of the place of delivery. This is recommended for all institutional and non-institutional deliveries, in both public and private sectors.



38. Is there any time limit for these vaccines recommended for new-borns?

Ans. **Yes.** Time limit for vaccines recommended for new-borns is as follows:

- ➡ **Hepatitis B (known as “birth dose”):** should be given within 24 hours of birth to protect the new-born from possible Hepatitis B infection that gets transferred from mother during delivery. If birth dose of Hepatitis B vaccine is given beyond 24 hours, then it will not provide this protection. However, maximum protection against Hepatitis B transmission is provided if the vaccine is given within 12 hours of birth.¹³
- ➡ **OPV (known as “zero dose”):** should be given within 15 days of birth, day of birth taken as day zero.
- ➡ **BCG:** should be given as early as possible after birth to provide maximum protection from childhood tuberculosis infection. BCG vaccine should not be given to the child beyond one year of age.



39. Why is the dose of polio vaccine that is given within 15 days of birth called the “zero dose”?

Ans. The dose of OPV given at birth is called the “zero dose” because:

- ➡ It is an “extra” dose that adds to the protection of the individual and the community
- ➡ It is given before the scheduled three primary doses

¹³Mortality and Morbidity Weekly Report, Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: Immunization of Infants, Children, and Adolescents, December 23, 2005/54 (RR16); 1-23



SECTION: 5

SIDE EFFECTS, ADVERSE EVENTS, AND CONTRAINDICATIONS



40. What are the side effects of vaccination?

Ans. All vaccines induce immunity by causing the recipient's immune system to react to the vaccine. Therefore, local reactions, fever and systemic symptoms can result as part of the immune response. In addition, some of the vaccine's components (e.g. aluminium adjuvant, stabilizers or preservatives) can also lead to reactions.¹⁴

The proportion of reaction occurrences likely to be observed with the UIP vaccines is as follows;

Vaccine	Local Adverse Events (pain, swelling, redness)	Fever (>38°C)	Irritability, malaise and systemic symptoms
BCG	90-95%	-	-
OPV	None	< 1%	< 1%
Hepatitis B	Adults: up to 15% Children: up to 5%	1-6%	-
HiB	5-15%	2-10%	-
Pertussis (DPT)	Up to 50%	Up to 50%	Up to 50%
Tetanus	~10%	~10%	~25%
Measles/MR	~10%	~5-15%	5% (Rash)
JE	< 1%	-	-
PCV	~10%	< 1%	-

Table 5: Common and minor vaccine reactions



41. If fever does not come after giving injectable vaccine, does this mean that vaccine has not been effective and needs to be re-administered? Is it necessary to get a fever after vaccination?

Ans. No. Though mild fever comes in majority of children who receive injectable vaccines, there are few children in which the immune response elicited by vaccine does not cause rise in body's temperature. This is normal in some children, and there is no need to re-administer vaccine if fever does not come after vaccination.

¹⁴Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officers 2016



42. Why is there pain and swelling at the injection site? How it can be managed?

Ans. In case of injectable vaccines (like Hepatitis B, pentavalent and IPV), infants may have redness, mild pain, and swelling at the injection site. This is mainly due to rupture of some muscle fibres by the needle getting injected into the muscle tissue. In addition, some of the vaccine's components (e.g. aluminium adjuvant, stabilizers or preservatives) can lead to local inflammatory reactions. These symptoms generally appear on the day after the injection is given and last from 1 to 3 days.

Cold compresses can be used to control swelling and redness. Health workers should recommend Paracetamol (syrup or tablet, in divided doses) for providing symptomatic relief to child.

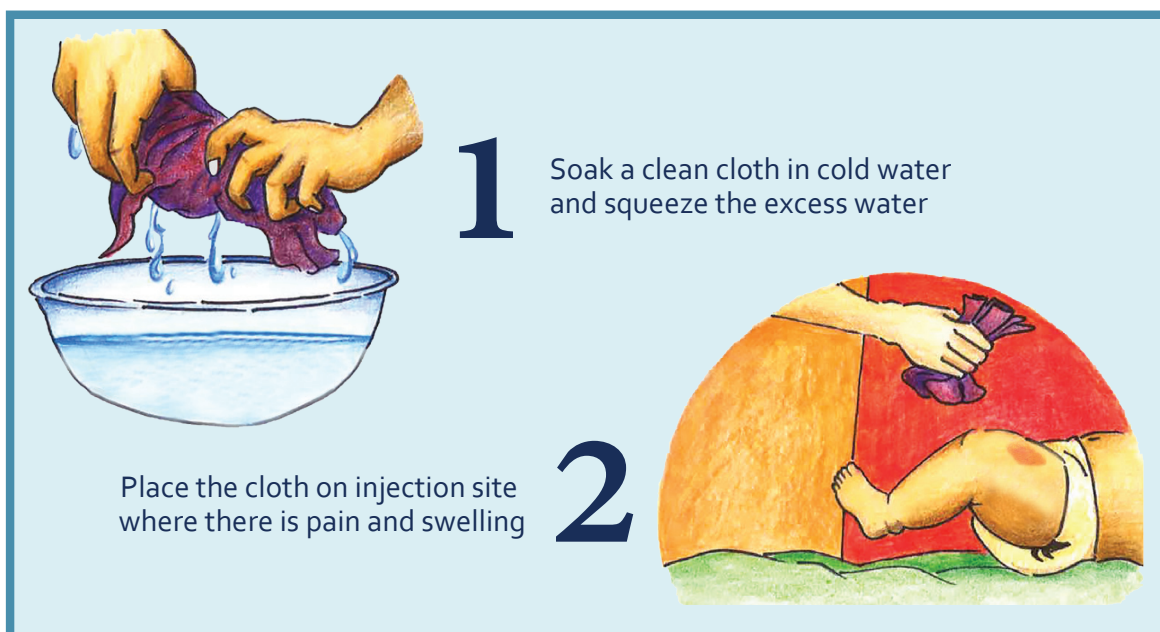


Figure 3: Using cold compresses for pain at injection site



43. Can a sick child be vaccinated? Is cough, cold and mild fever contra-indications for immunization?

Ans. **Yes.** A sick child suffering from mild illness can be safely vaccinated. Symptoms of mild illness (like cough, cold, mild fever or mild diarrhoea) are not contra-indications to vaccination. However, a child with moderate to severe illness requiring hospitalization (high grade fever, severe diarrhoea, etc.), should not be vaccinated during the acute phase.



44. Can vaccines, especially oral vaccines, be administered to a child with diarrhoea and vomiting?

Ans. Oral vaccines can be given to a child with mild diarrhoea. However, if a child has severe diarrhoea requiring hospitalization, oral vaccines should be given only after diarrhoea is controlled. Oral vaccines should not be given to child who is vomiting recurrently, until vomiting is controlled.



45. What is the meaning of Adverse Events Following Immunization (AEFI)?

Ans. Adverse events are any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The reported events may be a result of vaccine or immunization process, or they may be coincidental events that are not due to vaccine or immunization process but simply something that occurred soon after immunization.

Though, the occurrence is not due to a particular vaccine, but unless there is a thorough investigation to determine the cause, such occurrences are assumed to be due to vaccines and immunization. All cases of serious/severe AEFI should be reported and investigated as per guidelines. The cause-specific categorization¹⁵ of AEFIs is given in the following table;

1	Vaccine-product related reaction An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.	2	Vaccine quality defect-related reaction An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer. (Both 1 & 2 were earlier categorized as "Vaccine Reaction")
	3	Immunization error-related reaction An AEFI that is caused by an inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable. (formerly "Programme Error")	
4	Immunization anxiety-related reaction An AEFI arising from anxiety about the immunization (formerly "Injection Reaction")	5	Coincidental event An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.

Table 6: Cause-specific categorization of AEFIs

¹⁵Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officers 2016



46. Are there any medical conditions for which specific vaccines should not be given?

Ans. There are a few medical conditions for which vaccines should be delayed or should not be given. These are as follows:

- ➡ A child who has had a severe (allergic) reaction to earlier dose of any vaccine should not be given another dose of the same vaccine. This is an absolute contra-indication applicable for all vaccines.
- ➡ If a child has allergy to one conjugate vaccine (like DPT), any other conjugated vaccine (like PCV) should not be given (or may be given under medical observations) to the child.
- ➡ IPV should not be given to children allergic to streptomycin, neomycin or polymyxin B.
- ➡ Vaccination should be given only after medical advice if a child is allergic to egg proteins.
- ➡ Rotavirus vaccine should not be given to children who have history of intussusception, or abdominal surgery, or intestinal malformation.
- ➡ Live vaccines should not be given to immune-compromised children (e.g. HIV, Leukaemia), and those taking steroid therapy or immune-suppressant drugs.
- ➡ Vaccines should not be given to hospitalized or unconscious child, or those having convulsions.
- ➡ Immunization should also be withheld during moderate to severe acute illness, since vaccines may not elicit immune response in such conditions.



47. Can a child delivered by surgery (Caesarean section) or a child who has delivered prematurely also receive vaccination?

Ans. **Yes.** Vaccination should be provided to all children. It does not matter if:

- ➡ They are delivered by surgery or by normal delivery
- ➡ They are delivered at a private or government health facility or at home
- ➡ They are delivered before completing 9 months of gestation period (premature)
- ➡ Mother is suffering from any medical condition
- ➡ Has a low birth weight

The immunization schedule should start at birth irrespective of the age of gestation and weight of the child.

48. Why should the parents be asked to wait for some time after vaccination?

Ans. In rare cases, vaccines can lead to an allergic reaction or any other kind of adverse event. These events require early diagnosis and management. Therefore, it is advised that parents/caretakers are asked to stay at the session site for at least 30 minutes after receiving vaccination.

49. Can any vaccine, like OPV, lead to infertility or impotency?

Ans. No. All vaccines used in Universal Immunization Programme are pre-tested and recommended by WHO. All these vaccines are highly safe and effective, and are being used in many other countries besides India. No vaccine can lead to infertility or impotency, and this, like many other myths related to vaccines, is baseless and wrong.

50. Can Measles/MR vaccine lead to autism in children?

Ans. There is strong scientific evidence that measles/MR vaccination is not linked to autism, or any other conditions like inflammatory bowel disease or permanent neurological sequelae, which have been wrongly associated with this vaccine.¹⁶

51. Can vaccines cause allergy?

Ans. Vaccines are generally safe. However, some children may be allergic to certain vaccines or a component of vaccine (like antibiotic or preservative), and administration of vaccine in such children can result in allergic reaction, like itching, or appearance of red spots on the body, soon after immunization.

These cases need to be managed immediately by health workers and in some cases may require referral. To effectively identify these cases, health workers should advise parents/caregivers to wait for 30 minutes after vaccination.

¹⁶Measles vaccines: WHO Position Paper, April 2017



SECTION: 6

VACCINE HANDLING, ADMINISTRATION, AND INJECTION SAFETY



52. Can more than one vaccine be administered to a child at the same time?

Ans. **Yes.** More than one vaccine can be administered to a child at the same time. Different vaccines have different mechanism of generating immune responses in the body. Inactivated vaccines do not interfere with the effect of any other inactivated, live, or toxoid vaccines. Therefore, it is completely safe to administer more than one vaccine to a child at the same time. Doing this has no effect on efficacy of individual vaccines.

For example, the immunogenicity of the involved vaccines has been shown not to be significantly altered when PCV is co-administered with monovalent or combination vaccines against diphtheria, tetanus, pertussis (acellular and whole-cell vaccines), polio (inactivated and live oral vaccines), Hib, measles, rubella and rotavirus.¹⁷

Following precautions must be taken when more than one vaccine is to be administered to a child:

- ➡ Two or more vaccines should not be mixed in the same syringe.
- ➡ If two injectable vaccines are given on the same site, they should be given 2.5 cm (1 inch) apart.



53. Is there any benefit administering more than one vaccine at the same time?

Ans. From public health perspective, administration of more than one vaccine as per the schedule at the same time reduces the number of visits to the health facilities, thereby reducing drop outs. Also, giving multiple vaccinations during the same visit does not result in a higher incidence of adverse events.



54. What should be the interval between administrations of two doses of same vaccine as per the National Immunization Schedule?

Ans. There should be minimum 4 weeks of interval between administration of two doses of same multi-dose vaccine (like, Pentavalent and Rotavirus vaccines), except for PCV which is 2 months and JE vaccine which is 3 months. For booster doses, the recommended interval can be 6 months to more than one year after the primary doses.

¹⁷Pneumococcal vaccines WHO position paper – 2012 at <http://www.who.int/wer/2012/wer8714.pdf?ua=1>

Decreasing the interval between two doses of multi-dose vaccine may interfere with the antibody response and protection. Longer than normal recommended intervals between two subsequent doses of multi-dose vaccines normally does not impair the immunologic response. Therefore, interruption in the recommended schedule does not require a re-start from beginning.

Q 55. Why are vaccines in NIS administered at specific sites only?

Ans. Each vaccine is normally administered at the same, specific site on the body to maintain uniformity and to help determine vaccination history by asking from beneficiary or caretaker (in case immunization card is not available or lost). Specific sites of administration also help parents and caretakers recall previous vaccinations during the follow-up visits and household surveys.



Figure 4: Child with sites of multiple vaccines

*Wherever applicable

Q 56. Sometimes the same vaccine is of different colour in different vials. Does this have any effect on its efficacy?

Ans. No. All vaccines supplied for immunization programme undergo strict quality checks. There can be instances that colour of vaccine is slightly different in different vials, but this in no way affects the efficacy of vaccine.

Q 57. What should be done if child spits out or vomits immediately after taking vaccine orally?

Ans. If a child vomits immediately after taking vaccine orally, like OPV and rotavirus vaccines, then the vaccine dose should be given again. However, a repeat dose should be given after ensuring that child does not vomit it out again.



58. Why are some vaccines now being administered in thigh instead of buttocks?

Ans. Mid-thigh is the correct site for administering injectable vaccines in young children, especially up to five years of age. This site is recommended under UIP and therefore should be followed uniformly.

There are three reasons for administering some injectable vaccines in mid-thigh (anterolateral aspect). These are:

- ➡ Sciatic nerve, a major nerve for lower legs, passes through the buttocks (gluteal region). This nerve may get accidentally damaged in case of injection, leading to weakness or paralysis of lower limb.
- ➡ There is lot of fat in the buttocks. Vaccine gets deposited in this fat and either does not elicit or elicits a delayed or partial immune response.
- ➡ Antero-lateral aspect (front and outer part) of mid-thigh is preferred site for giving injection in children as it provides the largest muscle mass, leading to quick absorption of vaccine into the blood capillaries.



59. During 6th, 10th, 14th weeks and 9 months when more than one vaccine is to be administered on the same day, is there a definite sequence in which vaccines need to be given?

Ans. During 6th, 10th, 14th weeks and 9 months, when multiple vaccines are to be administered, it is preferable for health workers/ vaccinators to follow the sequence as given below, for the sake of programmatic consistency and uniformity;

6 Weeks	10 Weeks	14 Weeks	9 Months
1 OPV	1 OPV	1 OPV	1 Vit A
2 RVV*	2 RVV*	2 RVV*	2 Measles /MR*
3 fIPV	3 Penta	3 fIPV	3 PCV-B*
4 PCV*		4 PCV*	4 JE*
5 Penta		5 Penta	

*Wherever applicable

Table 7: Sequence of vaccination at 6, 10, 14 weeks and 9 months



60. What precautions should be taken at time of opening a vaccine vial?

Ans. Before opening vaccine vial, check the following;

- ➡ Label for type of vaccine, the label must be readable
- ➡ Expiry date
- ➡ Status of VVM
- ➡ Cap or bottle is not cracked
- ➡ The vaccine is not visibly frozen, in case the vaccine is freeze-sensitive

Note: Just after opening the vial (and reconstituting it, when applicable), health worker/ vaccinator should mention the date and time of opening on the vial.



61. What specific precautions should be taken during vaccine administration?

Ans. There are few specific precautions that should be taken by health workers/vaccinators. These are:

- ➡ Check the label for expiry date and the VVM label of the vaccine vials and diluents before use.
- ➡ Always use a new AD syringe for administering injectable vaccine.
- ➡ Always use a new syringe for reconstituting the vaccine (BCG, Measles/MR and JE vaccines).
- ➡ Ensure that the vaccine and diluents are of the same temperature and supplied by the same manufacturer (bundled) before reconstituting.
- ➡ Check expiry date and packaging of AD syringe before opening it.
- ➡ Never mix two or more injectable vaccines in the same syringe.
- ➡ Never use spirit, soap or liquid antibiotic to clean injection site. Water swab is adequate.
- ➡ Never rub or touch injection site after vaccine administration.



62. What are AD syringes?

Ans. AD or Auto Disabled syringes are specialized plastic syringes introduced in UIP for administering injectable vaccines. Once used, these syringes get locked, as the plunger cannot be withdrawn to refill the syringe with vaccine again. This avoids reuse or misuse of used syringes, and prevents transmission of infections from one child or a pregnant woman to another.

Care should be taken that under no condition different vaccines are withdrawn or mixed in the same syringe. Health workers/vaccinators must use a new AD syringe for every vaccine administered to a child. The syringe should be opened from the plunger-end and only when vaccine is to be administered.

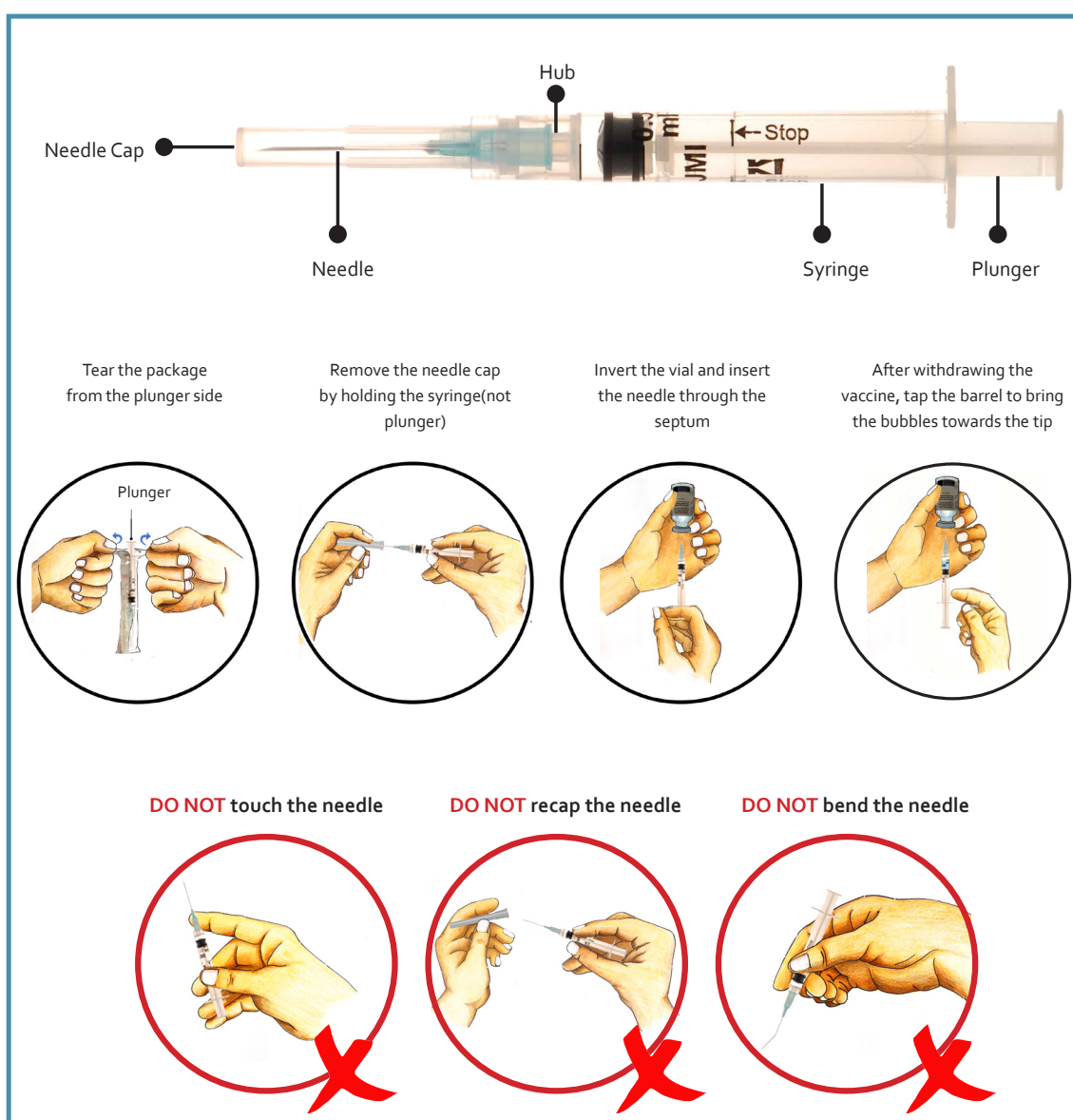
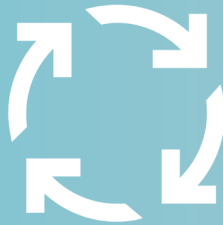


Figure 5: Using AD syringe



SECTION: 7

COLD CHAIN



63. What is “Cold Chain” for vaccines?

Ans. Cold chain is a system for storing and transporting vaccines at recommended temperatures from the point of manufacture till the point of use (administration to beneficiary). The system comprises of walk-in freezers, walk-in coolers, deep freezers, ice-lined refrigerators installed at different levels for the storage of vaccines, and refrigerated vaccine vans/ insulated vaccine vans, vaccine carriers and insulated cold boxes for transportation. Entire system is closely monitored to ensure delivery of potent and effective vaccines to the beneficiary.

The key elements of the cold chain are;

- ➡ **Personnel:** To manage vaccine storage and distribution (vaccine and cold chain handler at each cold chain point)
- ➡ **Equipment:** To store and transport vaccine and monitor temperature
- ➡ **Procedures:** To ensure correct utilization of equipment and ensure vaccines are stored and transported safely

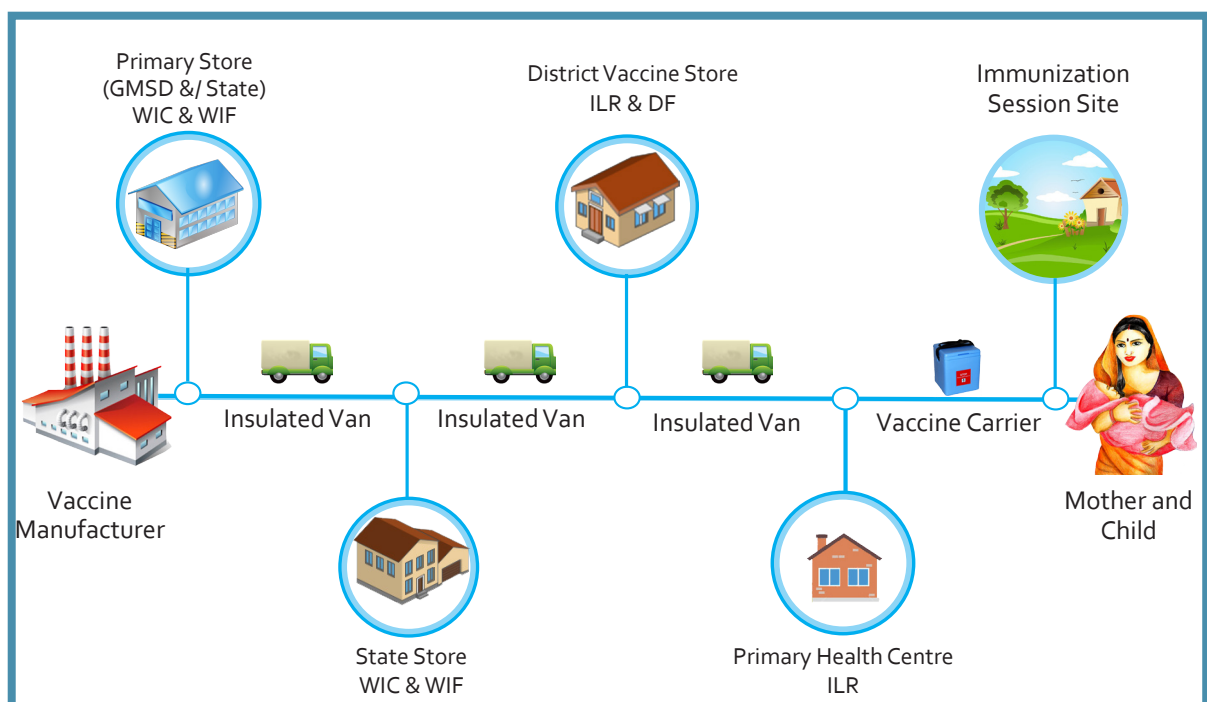


Figure 6: Storage and transportation of vaccines (Cold Chain System)



64. What is the recommended temperature for storage of vaccines at the health facilities and immunization session sites?

Ans. At health facilities and immunization session sites, all vaccines should always be stored at the recommended temperature between +2°C to +8°C.

Care should be taken to avoid keeping vaccines in conditions where the temperature is much lower (for example, freezers that are used for preparing ice), or where temperature is higher (for example, in direct sunlight). If a vaccine is not stored or transported at recommended temperature, there may be decline in potency and efficacy of the vaccine.



65. What should be the order from bottom to top for storing vaccines inside ice lined refrigerator?

Ans. The order of different vaccines from bottom to top inside an ice lined refrigerator should be;

OPV (bottom most), Measles/MR, BCG, JE, Rotavirus, TT, DPT, IPV, Pentavalent, PCV, Hepatitis B, followed by diluents (top most).

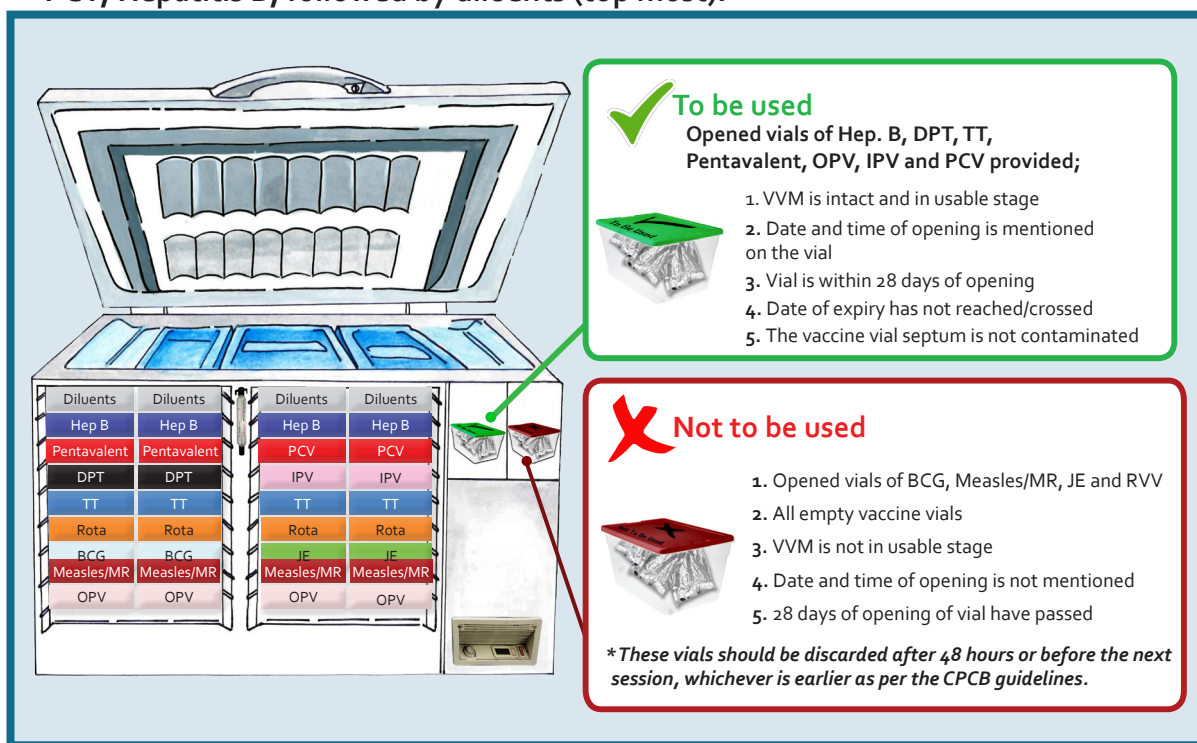


Figure 7: ILR with vaccine arrangement (Front view)



66. Can vaccines used in National Immunization Programme be stored in domestic refrigerator?

Ans. No. Vaccines used in immunization programme should not be stored in domestic refrigerator. This is because domestic refrigerators cannot maintain temperature in case of electricity supply failure, and also because different areas in the refrigerator may have different temperatures. In UIP, Ice Lined Refrigerator (Electrical/ Solar) and Deep Freezers are supplied for storage of vaccines.

However, in certain situations where there is assured 20-24 hours power supply, domestic refrigerators may be used. In these cases, vaccine vials should not be stored in freezer, chiller compartment, door, or basket of the refrigerator. If domestic refrigerators are used for storing UIP vaccines, diluents and ice-packs, then no other drugs, injections and non-UIP vaccines should be stored in it.

Q 67. What is a vaccine carrier?

Ans. Vaccine carrier is an insulated box used for transporting limited number of vaccine vials and diluents from cold chain point to outreach session sites, for storing vials at the session site, and to return back unused, partially used and completely used vials back to cold chain point on the same day. It is packed with four conditioned ice-packs and can maintain storage temperature of $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ for 12 hours, if not opened frequently. Vaccine carriers are used globally for the purpose of transporting vaccines to the point of use.
Note: Droppers and Syringes should not be kept in the vaccine carrier

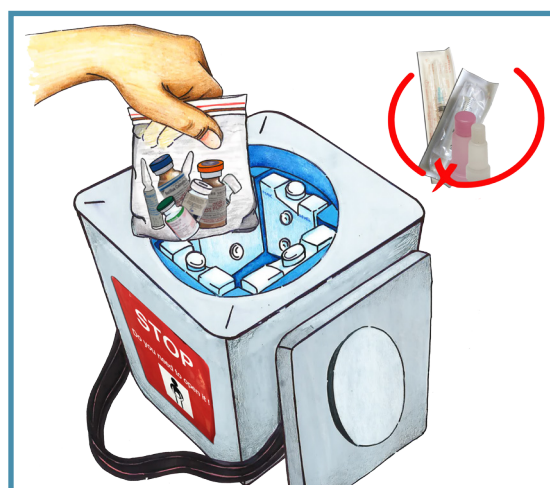


Figure 8: Vaccine carrier

Q 68. How should the health workers ensure that cold chain is maintained at the outreach session sites?

Ans. At outreach immunization session sites (villages and mohallas); health worker is responsible for maintaining appropriate cold chain for vaccines.

Health workers should ensure that once the vaccines are transported to the session sites, the vaccine carrier is placed in shade and not in direct exposure to sunlight. During the session, health worker should avoid opening vaccine carrier frequently as this breaks the cold chain for vials stored inside. To address this, health worker should take out one conditioned ice-pack outside the vaccine carrier and place non freeze-sensitive, opened vaccine vials on it, to maintain the recommended temperature.

Q 69. During an immunization session, can vaccine vials be placed on ice pack taken out from vaccine carrier?

Ans. As per guidelines, during an immunization session, health worker should take out one ice pack from vaccine carrier and place non freeze-sensitive, opened vaccine vials on it to maintain cold chain. This helps ensure that vaccine carrier is not opened again and again.

The vaccine vials that should be placed on ice pack are – BCG, Measles, OPV, Rotavirus and JE. BCG and Measles vials are placed in the pits provided on ice packs, while OPV, Rotavirus and JE are placed on the surface of ice pack.

The freeze-sensitive vaccine vials should NEVER be placed on ice pack. IPV, TT, DPT, PCV and Pentavalent vaccine vials should never be kept on the ice-pack.



Figure 9: Ice-pack with vials kept on it

70. What should be done if frozen vaccine vials are found at the health facility or session site?

Ans. Freeze sensitive vaccines (Hepatitis B, Pentavalent, IPV, DPT, TT and PCV); lose their potency if they freeze during storage or transportation. Therefore, if any of these vaccine vials are found to be visibly frozen, they should be discarded as per the guidelines.

A **“shake test”** should be performed at the health facility for any suspected frozen vaccine vial i.e. if temperature falls below 0°C or there are other frozen vials in the same box or there is any suspicious vial damaged due to freezing.

Vaccines, like OPV and Rotavirus vaccines do not lose their potency and efficacy on freezing, and these vaccines can be used again once they liquefy.

71. What else can be stored inside vaccine carrier during transportation and at session sites?

Ans. Vaccine carrier should only be used for transporting vaccines and diluents provided under UIP to session sites. It should have four conditioned ice packs to ensure appropriate temperature inside carrier. No other vaccine (non UIP), drug, food, or item should be kept inside vaccine carrier. State-specific vaccines, if are part of the Routine Immunization may be transported in the same vaccine carrier.

The droppers used for administration of oral vaccines and syringes should NOT be transported inside vaccine carrier as cold temperatures can cause them to crack.

Note: Hard frozen ice-packs should be used in vaccine carrier in case of Polio SIAs.

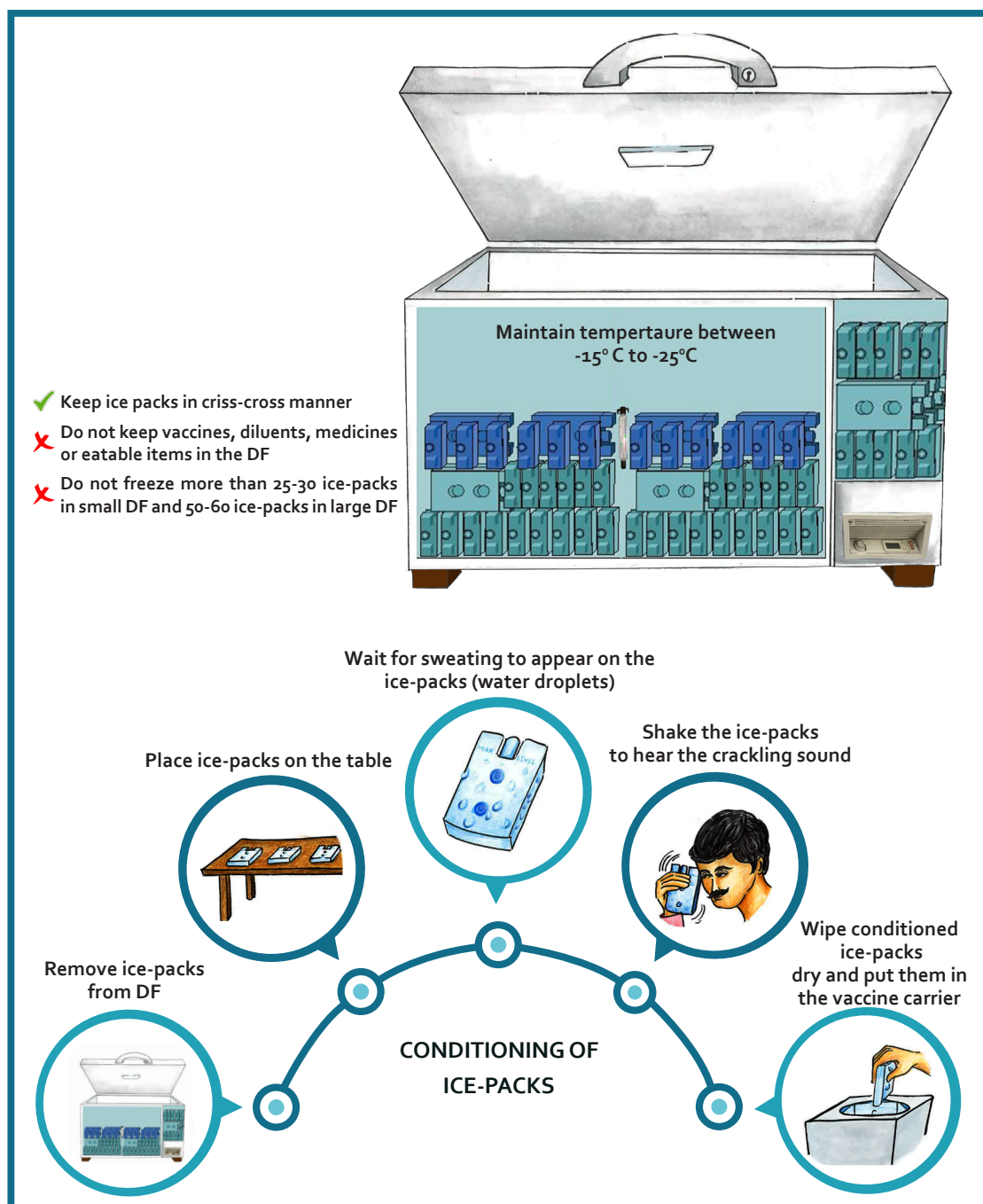


Figure 10: Freezing and conditioning of ice-packs



72. What is VVM? What does it signify?

Ans.

The inner square placed within the blue circle on the label or cap of the vial is called **Vaccine Vial Monitor** or **VVM**. A VVM is a temperature-time indicator (TTI) that contains heat-sensitive material that registers cumulative heat exposure between the time periods of exit from the manufacturing site till the time of use. The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly.

VVM does not measure vaccine potency. However, it gives information about the main factor that affects potency, i.e. heat exposure over a period of time. A darkened VVM implies that the vaccine might have negative effect on vaccine potency, and that this

vaccine if administered may not elicit the required immune response.¹⁸ VVM does not measure exposure to freezing temperature that also contributes to the degradation of freeze-sensitive vaccines.

Q 73. How is a VVM interpreted?

Ans. In VVM, the inner square (placed inside outer circle) changes colour gradually when exposed to high temperature. At the production facility, this square is white against the blue background of outer circle. As vial is exposed to heat at different points of time, the inner square begins to darken, and finally gets darker than colour of outer circle.

If the square is visible and lighter in colour, the vaccine is safe to use, though the vaccine in which the VVM is beginning to get dark should be used on priority. However, if the square is not visible or is darker in colour, the vaccine is NOT safe and should be discarded.

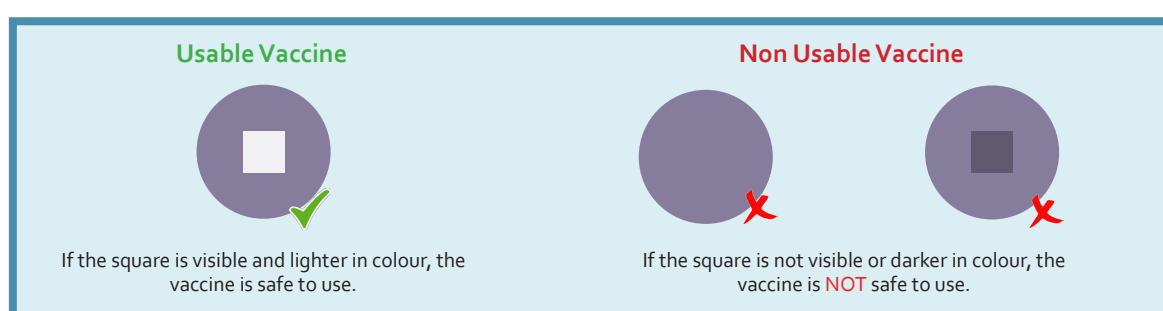


Figure 11: VVM different stages

In all vaccines, VVM is present on the label; but in freeze-dried vaccines (viz. BCG, Measles, and JE) and Rotavirus Vaccine Vial, VVM is present on the cap. The reason for putting VVM on cap is that once these vials are opened for reconstitution, they should be used within 4 hours. For such vaccines, time after reconstitution is more important for ensuring efficacy and safety, and therefore should be discarded after 4 hours irrespective of their VVM status.

Note: On all the vaccines, where the VVM is present on the label of the vial, an "Open Vial Policy" is applicable on them. However, in vaccines where the VVM is present on the cap of the vial, for e.g. BCG, Measles/MR, JE, Rotavirus vaccine vials, the "Open Vial Policy" is not applicable, and should be used within 4 hours of opening the vial.

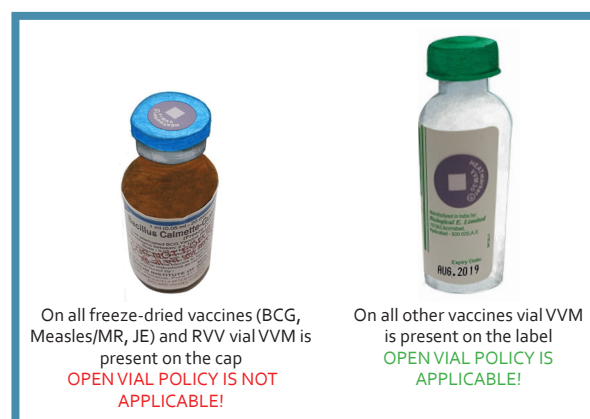


Figure 12: VVM placement on vials

Q 74. What are vaccine diluents?

Ans. A vaccine diluent is the liquid which is used to reconstitute a lyophilized (freeze-dried) vaccine (BCG, Measles/MR and JE). A vaccine diluent may be sensitive to heat or freezing, and may require transportation and storage in the cold chain.

¹⁸UNICEF: Handbook for Vaccine and Cold Chain handlers, 2015



75. What precautions should be taken regarding use of diluents?

Ans.

- ➡ ONLY the diluents supplied by the same manufacturer (bundled) along with vaccine are to be used as these are specifically designed for the needs of that vaccine, with respect to volume, pH level and chemical properties. No other diluents should be used even if they are chemically same.
- ➡ Diluents should be checked for expiry date, batch numbers and breakage (cracks and leaks). Care should be taken to ensure that freeze-dried vaccine (BCG, Measles/ MR and JE) are issued with corresponding diluents.
- ➡ Only the recommended volume of diluent must be used to reconstitute the vaccine.

"Bundling" ensures that vaccines are always supplied with diluents, AD syringes and reconstitution syringes, in corresponding quantities, at each level of the supply chain.

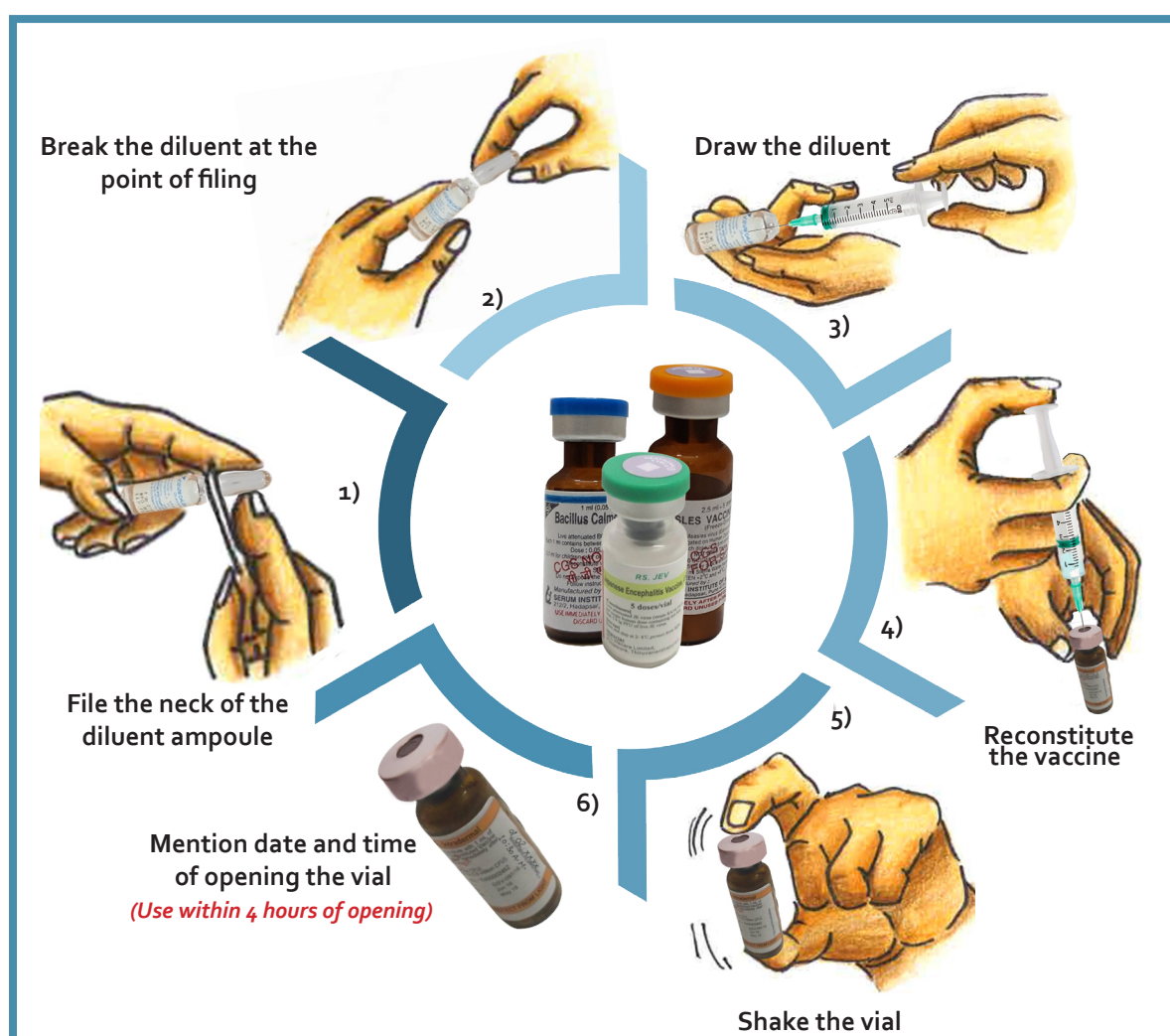


Figure 13: Procedure of reconstitution



76. Are diluents also to be stored in cold chain at recommended storage temperature?

Ans. **Yes.** Diluents also should be stored in the ILR at the last cold chain point. If the ILR has space constraints then the diluents may be stored outside ILR, but it must be ensured that they are kept in ILR at least 24 hours before use or issuing to sessions to ensure that vaccines and diluents are at same temperature (i.e. +2° to +8°C) during reconstitution. When mixed, the diluent and vaccine should be approximately at the same temperature; otherwise, it can lead to thermal shock that is, the death of some or all the essential live organisms in the vaccine.

The glass of diluent ampoules is too fragile and it should be stored in top of the ILR (above all the vaccines) to prevent cracking. Diluents should be transported along with the vaccines, in the vaccine carrier to the session sites.



77. What is “Open Vial Policy”?

Ans. To address the avoidable wastage and ensure optimal utilization of life-saving vaccines, Ministry of Health & Family Welfare, Govt. of India, has adopted a Multi-Dose Open Vial Policy (OVP). The policy underlines guidelines for the reuse and storage of open vaccine vials of specific types that contain a few doses at the end of a session, provided certain criteria are fulfilled.

Implementation of Open Vial Policy allows reuse of partially used multi dose vials of applicable vaccines under UIP in subsequent session (both fixed and outreach) up to four weeks (28 days) provided;

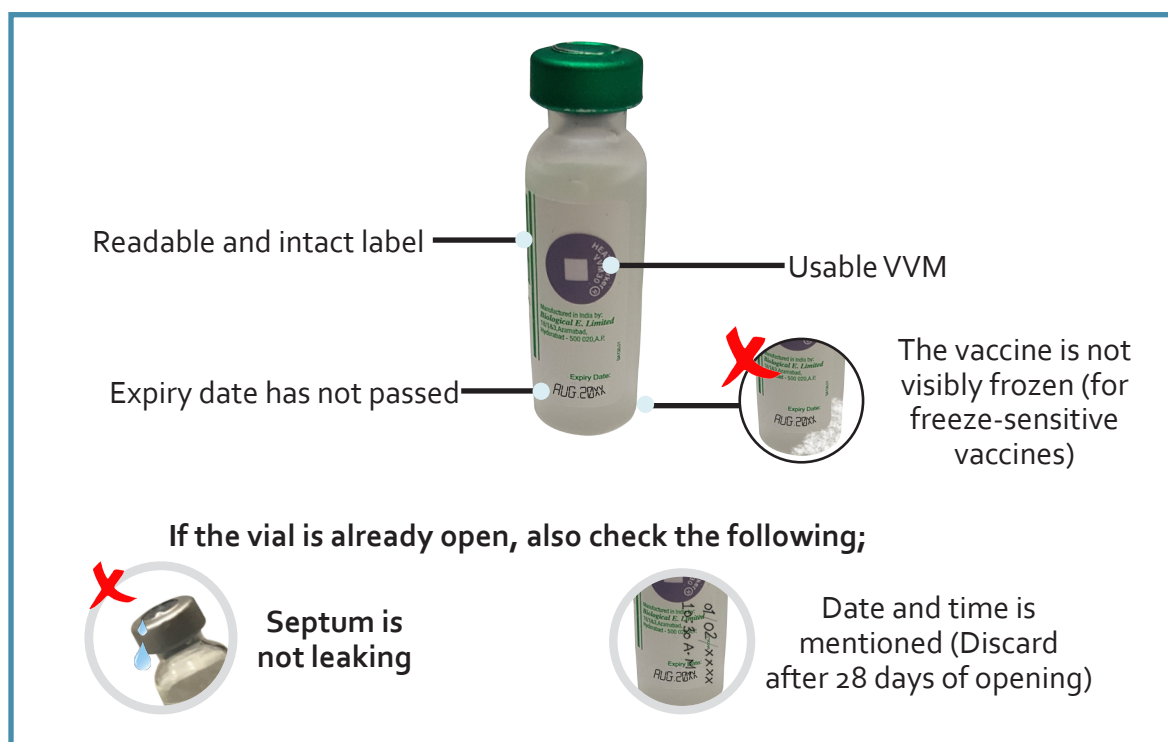


Figure 14: Points to be checked as per Open Vial Policy

- ➡ Expiry date has not passed
- ➡ Vaccines are stored under appropriate cold chain conditions both during transportation and storage
- ➡ Vaccine vial septum has not been submerged in water or contaminated in any way
- ➡ Aseptic technique has been used to withdraw vaccine doses
- ➡ VVM has not reached/crossed the discard point



78. Which are the vaccines on which “Open Vial Policy” applies?

Ans. Open Vial Policy is applicable on the open multi-dose vials of Hep B, OPV, IPV, PCV, DPT, TT and Pentavalent vaccine. The policy **DOES NOT** apply to freeze dried vaccines (BCG, Measles/MR and JE) and Rotavirus vaccines. These vaccines are to be used up to a maximum of 4 hours after opening.¹⁹
Note: All vaccines vials must be marked with date & time of opening the vial at first use.



79. What should be done with all returned vials (partially used vials, empty vials and unopened vials) of vaccines that cannot be reused during next session?

Ans. As per the “Open Vial Policy” guidelines, 2015, all vaccine vials (partially used vials, empty vials and unopened vials) should be returned to the last cold chain point on the same day. At the cold chain point, the cold chain handler should ensure appropriate segregation as “To be used” and “Not to be used”, as per the following instructions;

To be used

- ➡ Unopened vials, if the VVM is intact and in usable stage
- ➡ Partially used vials on which the open vial policy is applicable

Not to be used

- ➡ Unopened vials, if the VVM is not in usable stage
- ➡ Complete defacement of label of the vial
- ➡ No mention of date/ time of opening on the opened vials
- ➡ Open vials of BCG, Measles/ MR, JE and Rotavirus Vaccine
- ➡ Empty vaccine vials

All returned vials (to be used and not be used) should be kept in the ILR. The vials marked as not to be used should be discarded after 48 hours or before the next session whichever is earlier. After this period, these vials should be discarded as per biomedical waste management protocol. This is done to ensure availability of vaccine vial for investigation, in case any adverse event occurs during this period. In case of any reported AEFI they will not be discarded but retained for further investigation.

¹⁹Guidelines on Open Vial Policy for using multi-dose vials in Universal Immunization Programme, September 2015.



80. What should be done in case partially used vials are received without date and time on them?

Ans. If the date and time of opening is not mentioned on the opened vials, they should not be issued to any subsequent sessions. Such vaccine vials should be kept in the box **"Not to be used"** in ILR for 48 hours or before the next session, whichever is earlier and then must be discarded as per the guidelines.



81. What is "electronic Vaccine Intelligence Network (eVIN)"?

Ans. eVIN is a Government of India's initiative, launched in 2015, to support UIP by providing real-time information on vaccine stocks and flows, and storage temperature across all cold chain points of the country. In this system, cold chain handlers at all levels are provided with smart phones equipped with eVIN application for updating vaccine inventories. This is uploaded on a cloud server, which can then be viewed by programme managers at district, state and national level through online dashboards.

In addition, system also helps to track storage temperature of vaccines through SIM-enabled temperature loggers, which record temperature data every ten minutes and update the server every hour via GPRS. In case of temperature breach, the logger alarms and sends email and SMS alerts to responsible cold chain technicians and managers.



SECTION: 8

BIO-MEDICAL WASTE MANAGEMENT



82. What should be done with partially and fully used vaccine at the session site?

Ans. As per the “Open Vial Policy” guidelines, 2015, all vaccine vials (partially used vials, empty vials and unopened vials) should be returned to the last cold chain point on the same day. The health workers should segregate the vaccine vials as under;

To be used

- Unopened vials, if the VVM is in usable stage
- Partially used vials on which the open vial policy is applicable

Not to be used

- Open vials of BCG, Measles/ MR, JE and Rotavirus Vaccine
- Empty vaccine vials
- Vaccines with unusable VVM

The vials should be kept separately in properly sealed zipper pouches/bags in the vaccine carrier under the cold chain (reverse cold chain) and ensure carrier is picked up by the alternate vaccine delivery (AVD) mechanism to deliver at the designated vaccine/cold storage point.



83. How should the used syringes and needles be discarded at the session site?

Ans. At the session site, health workers or vaccinators should cut the needle of the AD Syringe immediately after administering the injection using the hub cutter that cuts the plastic hub of the syringe and not the metal part of the needle. The waste should be segregated as follows:



Hub-cutter:

- The cut needles that will get collected in the puncture-proof container of the hub cutter.
- The broken vials/ diluent ampoules (sharps) may also be put in the container of the hub-cutter, depending on the capacity of the hub cutter or may be stored in a separate puncture proof container.

**Red bag:**

- ➡ Plastic part of syringes (after cutting the needle)

**Black bag:**

- ➡ Needle caps/ wrappers

The red, black bags and the hub-cutter should be sent to the PHC for disinfection and disposal by the designated person at the PHC.

**84. How should the immunization waste be managed at the PHC?**

Ans. At the PHC,

- ➡ The black bag (containing the needle caps and wrappers) should be disposed as municipal waste.
- ➡ The collected material in the red bag (plastic part of the syringe) should be autoclaved. If unable to impart autoclaving, boil the waste in water for 10 minutes or provide chemical treatment (treating the waste in hypochlorite solution for 30 minutes). The autoclaved, boiled or chemically disinfected syringes should be sent for recycling.
Note: All returned vials that cannot be used (reconstituted, empty and unbroken vaccine vials and vaccine vials with unusable VVM) should be kept in the ILR and should be discarded using the same protocol after 48 hours or before the next session, whichever is earlier.
- ➡ The collected material in the hub cutter (cut needles, broken vials and ampoules) should also be autoclaved, boiled or chemically disinfected and should be disposed off in a safety pit/ tank.
- ➡ The hub cutter should be washed properly with sodium hypochlorite before reuse.

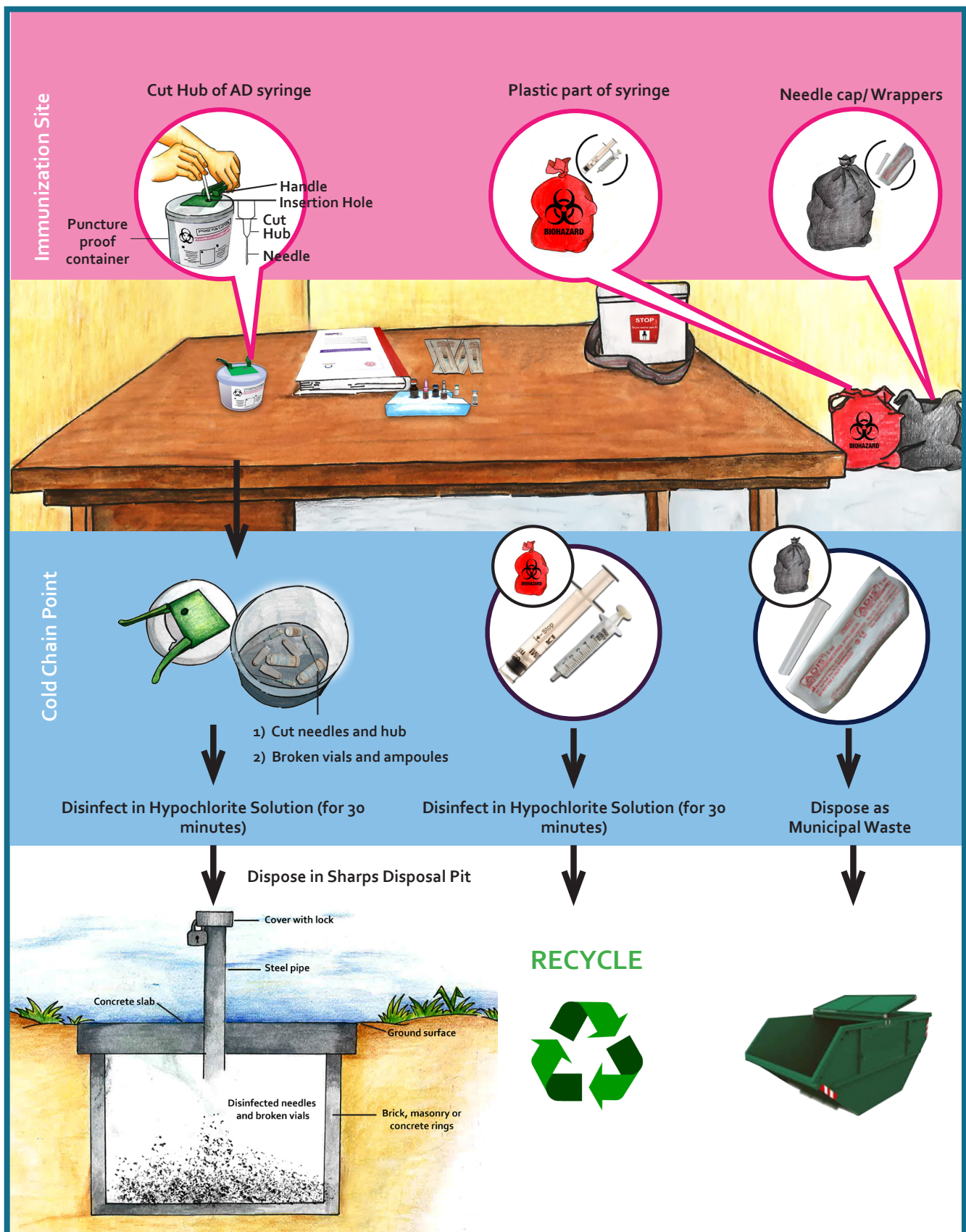


Figure 15: Bio-medical waste management



SECTION: 9

IMMUNIZATION CAMPAIGNS



85. What is Mission Indradhanush?

Ans. Mission Indradhanush is a health initiative launched by Ministry of Health & Family Welfare (MoHFW), Government of India, in December 2014, with the ultimate goal to ensure full immunization with all available vaccines for children up to two years and pregnant women. The mission is based on 4 guiding principles – identify (the unimmunized), validate (vaccination status), plan (for vaccine delivery), vaccinate (the unimmunized).

Government of India has identified 201 high focus districts across 28 states in the country that have the highest number of partially immunized and unimmunized children, and Mission Indradhanush targets these districts through intensive efforts and special immunization drives to improve the routine immunization coverage in the country.



86. What is Intensified Mission Indradhanush?

Ans. Fourth phase of Mission Indradhanush (2017-18) has been named as **Intensified Mission Indradhanush (IMI)**. It aims to rapidly build up immunization coverage by December 2018 and sustain thereafter through routine immunization.

IMI will be implemented in 108 districts across 16 states, 52 districts across 8 north eastern states, and 17 urban areas across 8 states, with special focus on children up to 2 years of age and pregnant women. This intensified mode will be characterized by better convergence with other departments besides health, intensive monitoring by health ministry and partners, prioritization of urban areas, and rewards on achievement of targets.



87. Should vaccines be given to children who come from other states where it has not been introduced?

Ans. **Yes.** Vaccines should be given to children as per the guidelines irrespective of their original state or place of residence, or the length of stay. Example, if a three-year child comes to a JE endemic state for a month from another place where JE vaccination is not provided under UIP. This child should be given one dose of JE vaccine while s/he is residing in the endemic state where vaccine is provided under UIP.



88. If a child has received all doses of a vaccine through routine immunization. Will s/he still require additional doses during a campaign?

Ans. **Yes.** Even if the child has received the age-specific and recommended vaccines in routine immunization, s/he should be given “additional” doses of the vaccine during the campaigns such as pulse polio or measles/MR campaigns. Also, if a child has received doses of a vaccine during a campaign, s/he should complete the vaccine schedule through routine immunization as well.

These additional doses during campaigns can be given/ administered irrespective of days since last dose was received. For example, if a child has received second dose of OPV three weeks before, s/he can still receive an additional dose during the pulse polio campaign.



89. Why is vaccine against rubella being introduced into UIP?

Ans. MR/MMR vaccines have been in use in private sector for a long time. Now, Rubella vaccine is being introduced in UIP as Measles-Rubella (MR) vaccine to prevent rubella infection in children and young adults.

Rubella is a viral disease, and during pregnancy this infection can cause abortion, stillbirth and may also lead to multiple birth defects in the new-born (like blindness, deafness, heart defects, development delays, and many other lifelong disabilities), known as Congenital Rubella Syndrome (CRS). This condition is a significant public health problem, as India accounts for around one-third of all children born worldwide with CRS.

Introduction of MR vaccine in UIP is an interim strategy to ensure measles elimination and rubella control in South-East Asia Region by 2020. The measles vaccine is safe, effective and inexpensive and the administration of a combined measles rubella vaccine can eliminate measles and rubella, as well as benefitting country budgets with cost savings. In order to reach the goal of measles elimination and control rubella, governments will need to:

- ➡ Achieve and maintain 95% population immunity against measles and rubella within each district through routine immunization and/or supplementary campaigns.
- ➡ Develop and sustain a sensitive and timely case-based measles and rubella/CRS surveillance system and an accredited measles and rubella laboratory network.²⁰



90. If rubella vaccine aims to prevent infection in pregnant women and subsequent birth defects in new-borns, why boys are also being vaccinated with this vaccine?

Ans. Both boys and girls are equally susceptible and at risk of getting rubella infection. Boys who get infected may cause transmission of rubella virus to unvaccinated children and young adults, so both boys and girls should be vaccinated with MR vaccine during MR campaigns and in routine immunization.

²⁰Strategic plan for Measles Elimination and Rubella and Congenital Rubella Syndrome Control in the South-East Asia Region 2014–2020

Q 91. Why is Measles Rubella (MR) vaccination campaign being conducted?

Ans. MR vaccination campaign is a special campaign to vaccinate all children in the age group of 9 months to less than 15 years with one additional dose of MR vaccine, irrespective of their previous vaccination status with measles vaccine. This wide age-range campaign has been recommended by the NTAGI as this will provide a second opportunity for those children who were left out due to either vaccine failure or failure to vaccinate. This will ensure attainment of high levels of population immunity by reaching wide age group, including children missed under routine immunization program.²¹

The purpose to conduct MR campaign is to boost the immunity, protect children from infection, and eliminate transmission of these disease-causing agents from the community by vaccinating 100 percent target children with MR vaccine. Further, follow-up campaigns may be required to sustain high population immunity against both measles and rubella besides maintaining high routine immunization coverage for both the antigens.

Q 92. Is MR vaccine being used during the campaigns safe for children?

Ans. **Yes.** The Measles-rubella (MR) vaccine used in campaigns as well as immunization programme is a live attenuated vaccine and safe and effective. The vaccine being used is WHO pre-qualified and is used in India, along with several other neighbouring countries like Bangladesh, Sri Lanka, Nepal, and Myanmar. Some children may have transient, self-limiting, low fever and mild rash, which is due to the immune response elicited by the vaccine, and should not be a cause of concern.



²¹Introduction to Measles-Rubella Vaccine National Guidelines 2017



SECTION: 10

VITAMIN A

93. Is Vitamin A also a vaccine?

Ans. No. Vitamin A is not a vaccine. It is a micronutrient required by body for growth and development. It also helps in maintaining immunity and supports good vision.

94. What are the signs of Vitamin A deficiency in children?

Ans. Night blindness is the first sign of Vitamin A deficiency, and in this condition affected children have poor vision in darkness but can see normally when adequate light is present. There are other signs which can be detected by medical officer at any health facility.

95. What is the schedule for giving Vitamin A?

Ans. Total 9 prophylactic doses of Vitamin A are given to children. First dose is given along with measles vaccine at 9 months (completed), second dose with measles at 16-24 months, and 3rd to 9th dose biannually till the age of 5 years. Minimum difference of 6 months must be ensured between any two subsequent doses of vitamin A.

First dose of vitamin A syrup is 1 ml or 1,00,000 IU (half spoon), and second to ninth dose is 2 ml or 2,00,000 IU (full spoon).

96. How is Vitamin A administered to children?

Ans. Vitamin A is available as syrup in dark coloured bottles. The syrup should be given with spoon (having dose markings) provided with the bottle.

97. Can Vitamin A be given along with other orally administered vaccines?

Ans. **Yes.** Vitamin A can be given along with other orally administered vaccines, like OPV and Rotavirus Vaccine. However, they should not be mixed.



98. What precautions are required with Vitamin A?

Ans. Health workers need to take some precautions while using and administering vitamin A. These are:

- ➡ Vitamin A bottle once opened should be used within 8 weeks. Therefore, date of opening a bottle should be clearly mentioned on its label.
- ➡ Bottles should be kept away from direct sunlight.
- ➡ Vitamin A syrup must only be administered with spoon (having dose markings) provided with the bottle.
- ➡ Expiry date and date of opening the bottle should be checked before administration.

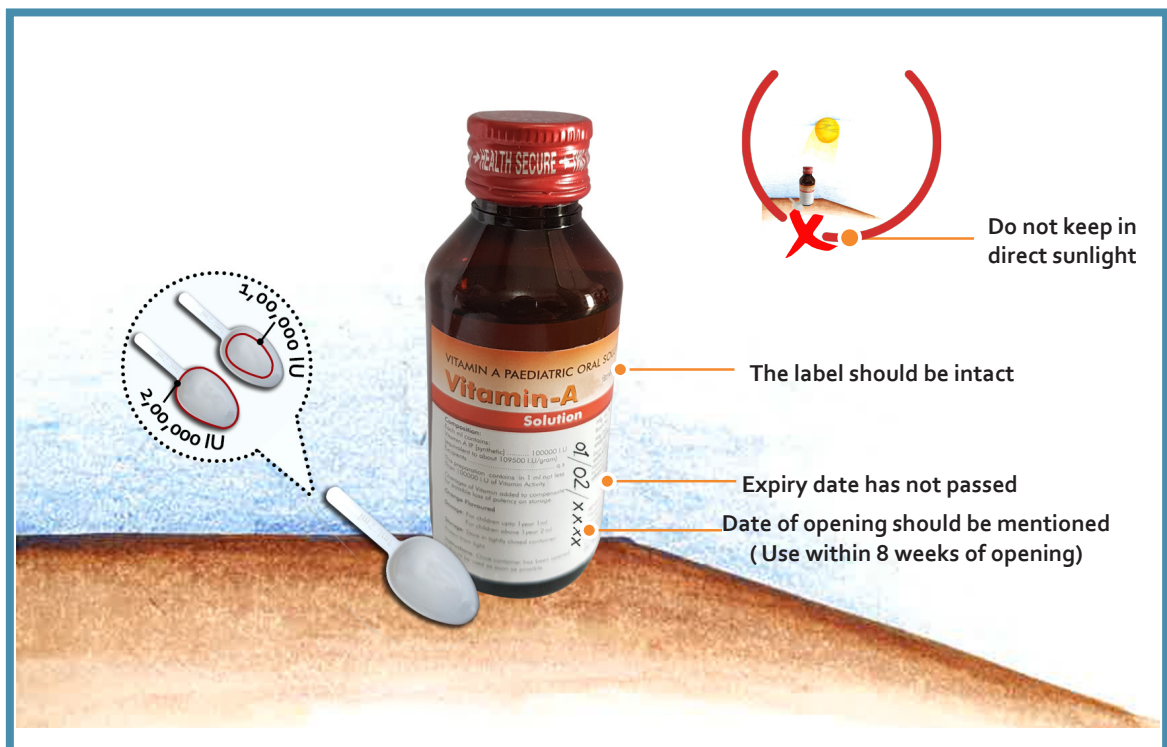


Figure 16: Vitamin-A and formulation



99. What is the therapeutic treatment schedule for children with clinical signs of Vitamin A deficiency?

Ans. In children having clinical signs of vitamin A deficiency, it is recommended to administer 200,000 IU (2 ml) of vitamin A immediately after diagnosis, followed by another dose of 200,000 IU (2 ml), 1-4 weeks later.



100. Why Vitamin A is given during measles outbreak?

Ans. Vitamin A supplementation is recommended for children who are infected during the measles outbreak. This markedly reduces measles associated mortality among the affected children. Utilization of Vitamin A is impaired during measles infection, irrespective of the total body stores of the vitamin. Vitamin A should be given to all measles cases,

irrespective of whether it has previously been administered prophylactically or given as routine immunization.²²

Recommended Vitamin A dosage schedule for measles treatment is as follows:

Age	Immediately on diagnosis	Next day
Infants < 6 months	50,000 IU	50,000 IU
Infants 6-11 months	1,00,000 IU	1,00,000 IU
Children >12 months	2,00,000 IU	2,00,000 IU

Table 8: Vitamin A dosage during a measles outbreak

²²Measles surveillance and outbreak investigation, Field Guide; Department of Family Welfare, New Delhi, November 2005



SECTION: 11

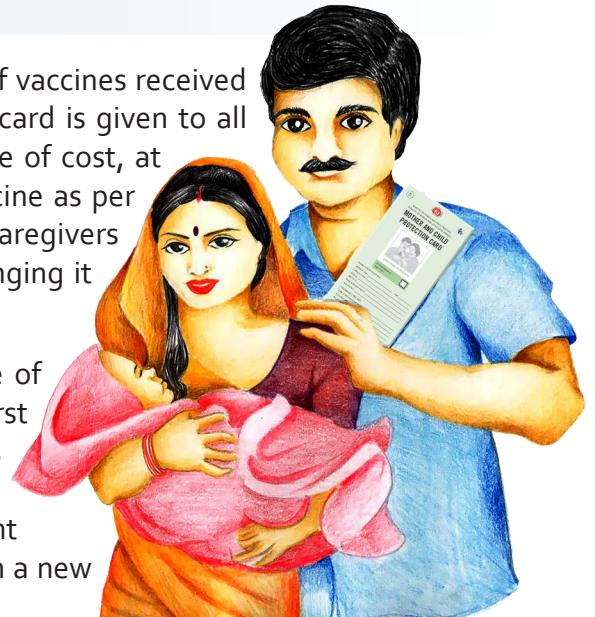
PROGRAM PLANNING AND IMPLEMENTATION



101. What is immunization component of Mother and Child Protection (MCP) card?

Ans. MCP card is a document mentioning the record of vaccines received (date and age), and dates for vaccines due. This card is given to all beneficiaries (pregnant women and children), free of cost, at first contact or at time of administering first vaccine as per schedule. Health workers should emphasize to caregivers the importance of keeping this card safe and bringing it along every time they come for vaccination.

MCP card is given to a pregnant woman at time of confirmation of pregnancy and administration of first dose of TT vaccine, and the same card continues till complete vaccination (including boosters and vitamin A doses) of her child. However, if a pregnant woman has not received or has lost her card, then a new card may be issued to her child.



102. What should be done if parents/caretakers have lost or have not brought MCP card along with them for vaccination?

Ans. In these situations, beneficiaries should never be denied for vaccination. If MCP card is lost, then health workers should re-issue a new card after filling the old entries from their facility register. Health worker should explain to parents/caregivers about importance of keeping MCP card safe for ensuring timely and complete vaccination.

In case, parents have forgotten to bring the card, then health worker should refer to her records and give the next vaccine due to the beneficiary.



103. What should be done if due vaccine is not available at the health facility or session site?

Ans. In such a situation, the health worker should administer all available and scheduled vaccines to the child and advice to return in the next immunization session. Health workers should put the name of the child in “**missed-dose tracking**” and ensure that the child receives the scheduled vaccines in the next session. However, the parents/caretakers can also take their children to higher level health facility for getting the scheduled vaccines.



104. What are the specific roles and responsibilities of health worker, ASHA, and Anganwadi worker in UIP?

Ans. All these three cadres of health functionaries share responsibility to: generate awareness regarding benefits of immunization, remove false beliefs in the community concerning immunization and vaccines, and ensure that timely vaccination is given to all beneficiaries.

ASHA workers play a specific role by preparing due list of beneficiaries to be immunized during a session and updating it on a monthly basis, mobilizing them to come to the session site where immunization services are being provided, and support health worker in organizing the session. She maintains a record of all immunization beneficiaries and updates it by adding vaccines administered to individual beneficiaries on the session day.

Anganwadi worker also plays an important role by mobilizing beneficiaries, supporting health workers in organizing sessions, and communicating important messages to parents and caretakers. Immunization of adolescent girls and boys is also a responsibility of Anganwadi workers.

Health worker administers vaccines, maintains cold chain, ensures injection safety, updates records, and prepares reports for submission to higher levels. They are also responsible for providing support to ASHA, Anganwadi workers, and other frontline functionaries in fulfilling their responsibilities.





105. What are the four key messages that must be given to parents after each vaccination?

Ans. As per the national guidelines, the four key messages that need to be delivered by health worker to parents and caregivers are:

- ➡ What vaccine was given, and what disease it prevents
- ➡ What minor adverse event could occur, and how to deal with them
- ➡ When and where to come for the next visit
- ➡ To keep the immunization card safe and to bring along for the next visit

After vaccination, the health workers should ensure that the parents/ caregivers wait for at least 30 minutes at the session site. Parents should be advised to immediately inform the ASHA/ AWW/ANM/MO of nearest health facility, in case of any problem faced by the child or mother even after 30 minutes.

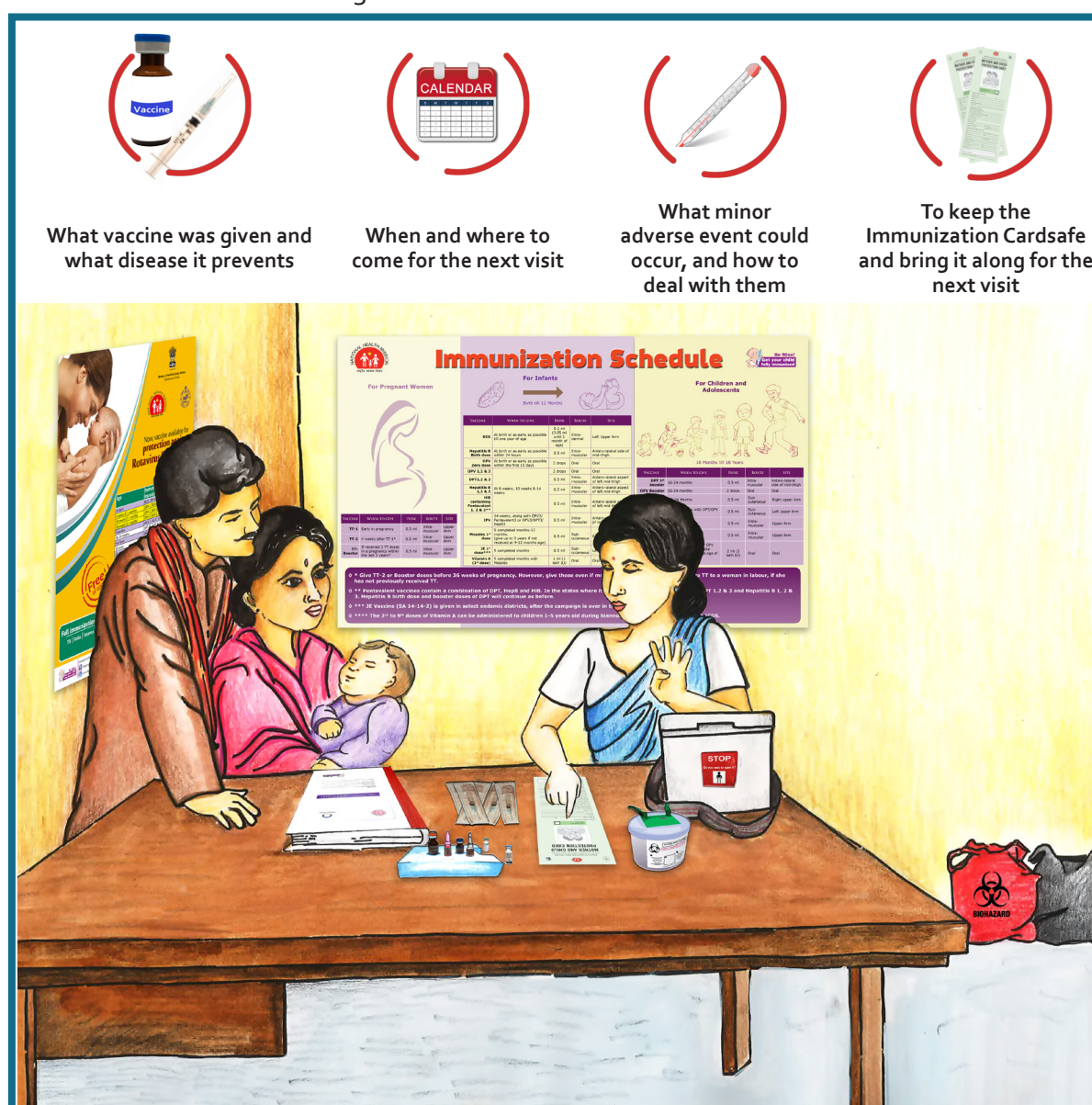


Figure 17: Four key messages



106. What is routine immunization microplanning?

Ans. RI microplanning is the basis for the delivery of UIP services to a community. The availability of updated and complete micro-plans at a planning unit (urban/rural) demonstrates preparedness of a unit and directly affects the quality of services provided. Micro-plans are prepared for a one year period but must be reviewed every quarter.²³

According to national guidelines for immunization programme, all government health facilities should prepare monthly plans for immunization service delivery to each and every outreach area (i.e. villages, slums, other habitations, etc.) situated within their catchment zones. These plans should be realistic, based on number of beneficiaries identified from house to house survey, developed jointly by health workers and frontline functionaries, and should be updated on quarterly basis. ASHA worker is given incentive for conducting a house to house survey.

These plans for immunization service delivery are known as micro-plans as they include specific details like – weekday and exact location of session, estimated number of beneficiaries, estimate of vaccines and syringe requirement for a session, names of vaccinator and other service providers (ASHA and Anganwadi worker), timing of session (from – to), name of person responsible for vaccine delivery, name of supervisor, etc.



107. Why is head count and house to house survey important for improving immunization coverage?

Ans. These are important activities undertaken to improve immunization coverage. These activities provide details of all beneficiaries (children and pregnant women) in a specific area, ensuring that no beneficiary is missed out. This further helps in developing complete due lists for session days, and correct estimates of injection load, outreach sessions required, and requirement per session of different vaccines and syringes.



108. Is it useful to monitor vaccine consumption, wastage, and coverage achieved?

Ans. Vaccines are life-saving and involve lot of financial and human resources in purchase, distribution and administration. Therefore, monitoring of vaccine consumption and wastage, and matching it with the immunization coverage will help to ensure their optimum utilization.

²³Ministry of Health and Family Welfare, Government of India, Immunization Handbook for Medical Officer 2016

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