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FAQs

Frequently Asked Questions in Pediatric & Adolescent Practice

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CHAPTER 4

Immunization

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CHAPTER OUTLINE

1. National Immunization Schedule
2. Indian Academy of Pediatrics Immunization Timetable
3. Expanded Program on Immunization Vaccines
4. Non-expanded Program on Immunization Vaccines
5. Cold Chain
6. Safe Immunization Practices
7. Adverse Effects Following Immunization
8. Vaccine-preventable Disease Surveillance

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1. NATIONAL IMMUNIZATION SCHEDULE

Q1. What is the national immunization schedule?

Table 4.1 National immunization schedule

Age	*Vaccination*
Birth	BCG, OPV, Hepatitis B
6 weeks	DPT1, OPV1, Hepatitis B1, Hib1
10 weeks	DPT2, OPV2, Hepatitis B2, Hib2
14 weeks	DPT3, OPV3, Hepatitis B3, Hib3
9 months	Measles 1st dose
16–24 months	DPT booster 1, OPV booster, Measles 2nd dose, Rubella
5–7 years	DPT booster 2
10–16 years	TT

Note: Changes in NIP; Birth dose of Hepatitis B vaccine introduced; Penta Vac (DTPw-Hib-HB) combo introduced @ 6, 10 and 14 weeks; MR vaccine recommended at 16–24 months; Monovalent indigenous Rotavac 116E proposed @ 6 and 14 weeks; A single dose of IPV along with 3rd dose of DTPw (Penta vac) proposed: HPV vaccine for girls and Td vac for both boys and girls proposed.

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2. INDIAN ACADEMY OF PEDIATRICS IMMUNIZATION TIMETABLE

Q2. What is Indian academy of pediatrics (IAP) immunization timetable 2014?

I. IAP recommended vaccines for routine use

Table 4.2 The IAP immunization timetable 2014

Age (completed weeks/months/years)	*Vaccines*	*Comments*
Birth	BCG OPV0 Hep-B1	Administer these vaccines to all newborns before hospital discharge
6 weeks	DTwP1 IPV1 Hep-B2 Hib1 Rotavirus1 PCV1	**DTP:** • DTaP vaccine/combinations should preferably be avoided for the primary series • DTaP vaccine/combinations should be preferred in certain specific circumstances/conditions only • No need of repeating/giving additional doses of whole-cell pertussis (wP) vaccine to a child who has earlier completed their primary schedule with acellular pertussis (aP) vaccine-containing products **Polio:** • All doses of IPV may be replaced with OPV if administration of the former is unfeasible • Additional doses of OPV on all supplementary immunization activities (SIAs) • Two doses of IPV instead of 3 for primary series if started at 8 weeks, and 8 weeks interval between the doses • No child should leave the facility without polio immunization (IPV or OPV), if indicated by the schedule **Rotavirus:** • 2 doses of RV1 and 3 doses of RV5 • RV1 should be employed in 10 and 14 weeks schedule, instead of 6 and 10 weeks • 10 and 14 weeks schedule of RV1 is found to be far more immunogenic than existing 6 and 10 weeks schedule.
10 weeks	DTwP2 IPV2 Hib2 Rotavirus2 PCV2	**Rotavirus:** • If RV1 is chosen, the first dose should be given at 10 weeks.
14 weeks	DTwP3 IPV3 Hib3 Rotavirus3 PCV3	**Rotavirus:** • Only 2 doses of RV1 are recommended at present. If RV1 is chosen, the 2nd dose should be given at 14 weeks.

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6 months	OPV1 Hep-B3	**Hepatitis-B:** The final (third or fourth) dose in the Hep B vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose.
9 months	OPV 2 MMR-1	**MMR:** • Measles-containing vaccine ideally should not be administered before completing 270 days or 9 months of life • The 2nd dose must follow in 2nd year of life • No need to give stand-alone measles vaccine
9–12 months	Typhoid Conjugate Vaccine	• Currently, two typhoid conjugate vaccines, Typbar-TCV® and PedaTyph® available in Indian market • PedaTyph® is not yet approved; the recommendation is applicable to Typbar-TCV® only • An interval of at least 4 weeks with the MMR vaccine should be maintained while administering this vaccine • Should follow a booster at 2 years of age
12 months	Hep-A 1	**Hepatitis A:** • Single dose for live attenuated H2-strain Hep-A vaccine • Two doses for all killed Hep-A vaccines dose on [day 0 (elected date) and booster dose at 6 months] are recommended now
15 months	MMR 2 Varicella 1 PCV booster	**MMR:** • The 2nd dose must follow in 2nd year of life • However, it can be given at anytime 4–8 weeks after the 1st dose • The 2nd dose at 4–6 years recommended earlier is no more required. **Varicella:** The risk of breakthrough varicella is lower if given 15 months onwards.
16–18 months	DTwP B1/DTaP B1 IPV B1 Hib B1	The first booster (4th dose) may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose. **DTP:** • First and second boosters should preferably be of DTwP • Considering a higher reactogenicity of DTwP, DTaP can be considered for the boosters.
18 months	Hep-A2	**Hepatitis A:** 2nd dose for killed vaccines; only single dose for live attenuated H2-strain vaccine
2 years	Typhoid booster	• Either Typbar-TCV® or Vi-polysaccharide (Vi-PS) can be employed as booster; • Typhoid revaccination every 3 years, if Vi-polysaccharide vaccine is used • Need of revaccination following a booster of Typbar-TCV® not yet determined.

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4–6 years	DTwP B2/DTaP B2 OPV3 Varicella 2 Typhoid booster	**Varicella:** The 2nd dose can be given at anytime 3 months after the 1st dose.
10–12 years	Tdap/Td HPV	**Tdap:** It is preferred to Td followed by Td every 10 years. **HPV:** • Only 2 doses of either of the two HPV vaccines for adolescent/preadolescent girls aged 9–14 years • For girls 15 years and older, and immunocompromised individuals 3 doses are recommended • For two-dose schedule, the minimum interval between doses should be 6 months • For 3 dose schedule, the doses can be administered at 0, 1–2 (depending on brands) and 6 months

II. The IAP recommended vaccines for High-risk* children (Vaccines under special circumstances):
   1. Influenza vaccine
   2. Meningococcal vaccine
   3. Japanese Encephalitis vaccine
   4. Cholera vaccine
   5. Rabies vaccine
   6. Yellow fever vaccine
   7. Pneumococcal Polysaccharide vaccine (PPSV 23)

*High-risk category of children:

- Congenital or acquired immunodeficiency (including HIV infection)
- Chronic cardiac, pulmonary (including asthma if treated with prolonged high-dose oral corticosteroids), hematologic, renal (including nephrotic syndrome), liver disease and diabetes mellitus
- Children on long-term steroids, salicylates, immunosuppressive or radiation therapy
- Diabetes mellitus, cerebrospinal fluid leak, cochlear implant, malignancies
- Children with functional/anatomic asplenia/hyposplenia
- During disease outbreaks
- Laboratory personnel and healthcare workers
- Travelers
- Children having pets in home
- Children perceived with higher threat of being bitten by dogs such as hostellers, risk of stray dog menace while going outdoor.

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3. EXPANDED PROGRAM ON IMMUNIZATION VACCINES

BACILLUS CALMETTE-GUERIN VACCINE

Q3. What is recommendation for use of bacillus calmette-guerin (BCG) in individuals?

The recommended age of administration is at birth (for institutional deliveries) or at 6 weeks with other vaccines. Catch up vaccination with BCG is recommended till the age of 5 years. Routine tuberculin testing prior to catch up vaccination is not necessary.

BCG may be repeated once in children less than 5 years of age in the absence of a reaction/scar presuming that BCG has not been taken up (even though most patients with absent reactions/scars have shown *in vitro* evidence of cell mediated immunity against tuberculosis). Here again, tuberculin testing prior to administration of the second dose of BCG is not necessary.

Q4. What is the efficacy of BCG vaccines?

It has an efficacy of 75–86% for prevention of miliary and meningeal form of the disease. Protective efficacy for pulmonary tuberculosis is 50%.

Q5. If infant does not develop scar after BCG vaccination, should we repeat vaccination?

A raised blister will appear in most people vaccinated with BCG, but not everyone. If a child did not have this reaction to the vaccine, it does not mean that they have not responded to it. There's no need to vaccinate with BCG a second time. However some experts recommend re-vaccination only once after 3 months after the birth dose.

Q6. What is the treatment of BCG adenitis?

Subcutaneous administration of BCG is associated with an increased incidence of BCG adenitis. The injected site usually shows no visible change for several days. Subsequently, a papule develops after 2–3 weeks, which increases to a size of 4–8 mm by the end of 5–6 weeks. This papule often heals with ulceration and results in a scar after 6–12 weeks. The ulcer at vaccination site may persist for a few weeks before formation of the final scar. No treatment is required for this condition.

Q7. What is IAP ACVIP recommendation for BCG vaccination in individual use?

The recommended age of administration is at birth (for institutional deliveries) or at 6 weeks with other vaccines. Catch up vaccination with BCG is recommended till the age of 5 years. Routine tuberculin

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testing prior to catch up vaccination is not necessary. BCG may be repeated once in children less than 5 years of age in the absence of a reaction/scar presuming that BCG has not been taken up (even though most patients with absent reactions/scars have shown *in vitro* evidence of cell mediated immunity against tuberculosis). Here again, tuberculin testing prior to administration of the second dose of BCG is not necessary.

Q8. What is IAP ACVIP recommendation for BCG vaccination in public health perspective?

The IAP ACVIP believes that despite the poor efficacy of the current BCG vaccine against pulmonary TB, it is safe, has relatively high protective efficacy against miliary and meningeal TB, does not interfere with the efficacy of other vaccines given simultaneously, and is inexpensive. Considering a very high disease burden of TB in India, the committee recommends continuation of BCG vaccine in the national immunization program of India (UIP). However, the development of new, improved TB vaccine should remain a national priority.

Until an improved vaccine is available, efforts to control the spread of TB must rely on optimal use of the tools currently available: early diagnosis, directly observed therapy, appropriate preventive treatment and public health and infection control measures.

Q9. Who should not be given BCG vaccines?

The BCG vaccination should not be given to persons who are immunosuppressed (e.g. persons who are HIV infected) or who are likely to become immunocompromised (e.g. persons who are candidates for organ transplant).

The BCG vaccination should not be given during pregnancy. Even though no harmful effects of BCG vaccination on the fetus have been observed, further studies are needed to prove its safety.

POLIO VACCINES

Q10. What are the different vaccines available for polio?

There are two types of polio vaccines, first the inactivated polio vaccine (IPV) by Jonas Salk and other the live oral polio vaccine (OPV) by Albert Sabin. Both these vaccines contain all the three types of polioviruses.

Q11. What are the different types of OPV?

Different types of OPV are:

- *Trivalent OPV (tOPV):* tOPV used in national RI program for polio vaccination and in selective supplementary immunization activities (SIA) campaigns in pulse polio program, National Immunization Days (NIDs)

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- *Monovalent OPV (mOPV):* mOPV (mOPV1 for type 1 and mOPV3 for type 3), licensed in 2005 to enhance the impact of SIAs in the key remaining reservoirs of wild polio virus (WPV)
- *Bivalent OPV (bOPV):* bOPV (for type 1 and type 3), licensed in 2010 and used effectively in SIAs to break the chain of transmission of both type 1 and type 3 virus together in certain areas.

Q12. What are the contraindications of OPV?
Oral polio vaccine is contraindicated in patients with low immunity especially if inactivated polio vaccine (IPV) is available.

Q13. What are the salient features of IPV?
Inactivated polio vaccine is formaldehyde killed poliovirus, grown in monkey kidney cell or human diploid cells. Old IPV contained 20, 8 and 32 D antigen units of types 1, 2 and 3 polioviruses respectively. All currently used IPV vaccines are enhanced potency IPV (eIPV) which contain 40, 8 and 32 D antigen units of type 1, 2 and 3 respectively. Currently the term IPV means eIPV. The vaccine should be stored at 2–8°C. It is highly immunogenic. Its immunogenicity is dampened by the presence of maternal antibody in the very young infant, especially up to the age of 8 weeks.

Q14. How efficacious is IPV?
Seroconversion rates of IPV are 90–100% after two doses given after the age of 2 months and at 2 months interval or in the expanded program on immunization (EPI) schedule of three doses at 6, 10 and 14 weeks. A third dose, given after a suitable interval boosts the antibody levels and ensures the perpetuation of immunity for decades and more.

Q15. What are the demerits of IPV?
High cost, scarce availability—only 2 major manufacturers, injectable route— extra injections needed (monovalent use).

Q16. What should be schedule for polio immunization in children infected with human immunodeficiency virus (HIV)?
In HIV children, IPV is to be given at 6, 10, 14 weeks; 15–18 months, and 5 years. If indicated, IPV to be given to household contact. If IPV is not affordable or available, OPV should be given as OPV has been found to be generally safe in HIV infected especially in early stages.

Q17. What is the primary schedule for polio vaccination as per recent Indian Academy of Pediatrics Committee on Immunization (IAP ACVIP) recommendation?
As per the recommendation of IAP ACVIP timetable 2012, the polio vaccination schedule as depicted in Table 4.3.

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Table 4.3 Indian Academy of Pediatrics Committee on Immunization (IAP ACVIP) timetable 2014, the polio vaccination schedule

Birth	*OPV0*
6 weeks	IPV1
10 weeks	IPV2
14 weeks	IPV3
6 months	OPV1
9 months	OPV2
16–18 months	IPV B1
4½–5 years	OPV3

Abbreviations: OPV, oral polio vaccine; IPV, inactivated polio vaccine

Q18. What are the benefits of sequential schedule?
There are moderate level of scientific evidence that sequential immunization schedules starting with two or more doses of IPV and followed by two or more doses of OPV (at an interval of 4–8 weeks) induce protective immunological responses to all three polio virus serotypes in greater than or equal to 90% of recipients. Sequential schedules that provide IPV first, followed by OPV, can prevent VAPP while maintaining the critical benefits conferred by OPV (i.e. high levels of gut immunity). Data from several studies show that sequential schedules considerably decrease the risk of VAPP.

Q19. Is there any alternative schedule in IAP ACVIP timetable for primary vaccination of polio with two doses of IPV instead of three doses?
Yes, alternatively two doses of IPV can be used for primary series at 8 and 16 weeks. Though this schedule is immunologically superior to EPI schedule and the number of IPV doses is reduced, but will be more cumbersome due to extra-visits and incompatibility with combination formulations. Further, the child would be susceptible to WPV infection for the first 2 months of life considering the epidemiology of WPV in India till quite recently.

Q20. If IPV first, followed by OPV can prevent VAPP then why IAP ACVIP has retained birth dose of OPV before IPV in immunization timetable 2012?
Providing the first OPV dose at a time when the infant is still protected by maternally derived antibodies may, at least theoretically, also prevent VAPP. A birth dose of OPV is considered necessary to induce gut immunity in countries where the risk of poliovirus transmission is high.

Q21. What is catch-up schedule of polio vaccination as per IAP ACVIP?
Inactivated polio vaccine may be offered as "catch-up vaccination" for children less than 5 years of age who have completed primary

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immunization with OPV. IPV can be given as three doses; two doses at 2 months interval followed by a third dose after 6 months. This schedule will ensure a long lasting protection against poliovirus disease.

Q22. What are the recommendations for polio vaccination for travelers?

The IAP ACVIP (2014) has issued the following recommendations for travelers to polio endemic countries:

a. For those who have previously received at least three doses of OPV or IPV should be offered another dose of polio vaccine as a once-only dose before departure.
b. Nonimmunized individuals should complete a primary schedule of polio vaccine, using either IPV or OPV. Primary series includes at least three doses of either vaccine.
c. For people who travel frequently to polio endemic areas but who stay only for brief periods, a one-time only additional dose of a polio vaccine after the primary series should be sufficient to prevent disease.

Q23. What are the merits/demerits of OPV and IPV?

Table 4.4 The difference of both vaccines is as given below: Merits and demerits of OPV and IPV

OPV	*IPV*
Oral, ease of administration, suitable for mass campaign	Necessity of skilled personnel for injection
High systemic immunity except in developing countries	High systemic immunity
High gut immunity, pharyngeal immunity	Lower gut immunity but good oropharyngeal immunity
High efficacy (but suboptimal efficacy in tropical countries)	High efficacy
Risk of VAPP	No risk of VAPP
Risk of VDPVs	No risk of VDPVs
Contraindicated in immunodeficient individuals	The only polio vaccine recommended for immunodeficient individuals

Abbreviations: OPV, oral polio vaccine; IPV, inactivated polio vaccine; VAPP, vaccine-associated paralytic poliomyelitis; VDPV, vaccine-derived poliovirus

Q24. What is immunogenicity and vaccine efficacy of tOPV in developing country like India?

In developed countries like USA, greater than 95% seroconverted after three doses of tOPV (to all three types). Excellent mucosal immunity induced by OPV and invisible immunization of others due to vaccine virus spread were believed to be two factors contributing to such striking herd effect. A greater degree of vaccine virus spread

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and herd effect was anticipated in developing countries with poor hygiene and sanitation conditions.

When OPV was introduced in developing countries including India, suboptimal immunogenic efficacy of type 1 and 3 component was observed in several places. Studies conducted by Dr T Jacob John and his colleagues from Vellore, India, have demonstrated low immunogenicity of tOPV in India as early as in 1970s and 1980s. This was further confirmed by a comprehensive review of 32 studies from developing countries which shows low immunogenicity of tOPV for type 1 and 3 in developing countries.

Within India when it comes to Uttar Pradesh, per dose efficacy of tOPV is calculated to be just 9% per dose. Exact cause for poor efficacy of OPV is not known but warm climate, interference by Enteroviruses, high incidence of diarrhea and prevalence of malnutrition are some of the factors attributed for lower efficacy of tOPV.

Q25. How can IPV be used as a complementary to OPV?

The advantages of using IPV along with OPV can be as follows:

a. Excellent immunogenicity, efficacy and safety of IPV which guarantees individual protection.
b. The risk of VAPP with this combined OPV and IPV schedule is extremely low as the child receives OPV at the time when he/she is protected against VAPP by maternal antibodies. Subsequently, he/she is protected from VAPP by IPV.
c. Mucosal immunity as measured by stool excretion of virus after mOPV1 challenge is superior with combination of OPV and IPV as compared to IPV alone. IPV boost mucosal immunity very effectively in previously OPV vaccinated individuals.
d. Switch to IPV is part of end game strategy in post-polio eradication era in the form of at least one dose of IPV to be included in the routine EPI.

Q26. When there is no case of polio in India since January 2011, should still be OPV recommended to be given through SIAs?

Yes, because in 2014, polio remains endemic in three countries: Afghanistan, Nigeria and Pakistan. Until poliovirus transmission is interrupted in these countries, all countries remain at risk of importation of polio; hence, OPV to be administered to every child till the age of 5 years during all SIAs being conducted in that area as it is necessary to sustain high level of immunity against WPV till global success in polio eradication.

Q27. Why OPV should be given despite availability of IPV?

OPV use should be continued due to following reasons:

a. In concordance with the government policy of using OPV for polio eradication.

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b. Mucosal immunity as measured by stool excretion of virus after mOPV1 challenge is superior with combination of OPV and IPV as compared to IPV alone.
c. By not giving OPV we might create confusion in the minds of the parents whose children receive only IPV about the efficacy and safety of OPV and interfere with OPV uptake on the NIDs and Sub-National Immunization Days (SNIDs).

Q28. What's wrong if I use only IPV in my office practice?

As mentioned earlier, there is less than satisfactory response with IPV when used in 6, 10, 14 weeks schedule, particularly against types 1 and 2 serotypes. According to a study conducted by WHO in Gambia, Oman and Thailand, a three-dose schedule which combines OPV-IPV, demonstrated the highest seroconversion rates. This is the most quoted study put forward by groups advocating combined use of OPV and IPV. GOI has not recommended use of IPV in RI yet, but in coming years as a part of end game strategy, single dose of IPV will be part of RI.

Q29. What are the recommendations for adult polio vaccination?

Routine adult polio vaccination or boosters are not recommended considering the epidemiology of the disease in India. Vaccination with IPV is recommended for certain adults who are at greater risk of exposure to poliovirus like laboratory workers who handle specimens that might contain polioviruses, etc.

For unvaccinated adults, two successive injections of 0.5 mL can be given at intervals of preferably 2 months. A third dose (booster) may be administered 8–12 months after the second injection.

Q30. Which vaccine OPV or IPV induces better mucosal immunity? If OPV induces good mucosal immunity then why highly vaccinated children with OPV participate in wild polio transmission?

Mucosal immunity refers to the resistance to mucosal infection by wild polioviruses due to prior infection or immunizing experience. OPV induces a high nasopharyngeal and duodenal IgA response. Some more facts about mucosal immunity are:

- Immunoglobulin A (IgA) response is induced more readily by infection than by stimulation by nonreplicating antigen. Thus IgA is a marker of gut infection not necessarily mucosal immunity. Moreover, IgA is not the only medium of local mucosal immunity.
- It is not necessary that an OPV dose will cause infection every time if there is no uptake. This finding offers an explanation why repeated doses of OPV have to be given to the same children, with virtually 100% coverage, before wild virus transmission could be stopped in developing countries

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