



FAQs on tOPV to bOPV switch & IPV roll out in India

Q. What is the switch date from tOPV to bOPV in India?

A. The Ministry of Health and Family Welfare, Government of India (GoI) has decided April 25, 2016 as National Switch Date for switching from tOPV to bOPV all over the country. After the switch date, only bOPV will be used both in routine immunization (RI) as well as polio campaigns. No supplies of tOPV will be accepted from 1st March 2016 onwards in government supplies chains and after 1st April 2016 in private market. After switch date, remaining tOPV will be removed from cold chain and disposed off as per National Switch Plan. National Validation Day has been decided as 9th May, 2016.

Q. What is expected from the practicing pediatricians?

A. All pediatricians/practitioners/IAP members will need to participate in the 'switch process' and ensure the following:

- 1-Destroy all the available stock of tOPV in their premises on 25th April 2016;
- 2-To avoid wastage, do not overstock tOPV and order only as much of tOPV as required for their clinical use till 24th April 2016;
- 3-Cooperate with designated authorities for validation purposes.

Q. How to destroy tOPV on/after 25th April 2016?

A. tOPV to be destroyed only at DISTRICT HQ under direct supervision of Sr. Official, who will issue certificate under his/her signature to state. For returning of tOPV for destruction, there is 'no need to maintain cold-chain'. Use anyone of the following method as per availability:

- Use medical waste incinerator under supervision;
- Autoclave for 30 minutes under supervision;
- Boil tOPV vials in plain water for 10 minutes under supervision;

Q. What are the key dates related to 'switch'?

A. Here are the key dates pertaining to 'switch':

- **April 1st:** tOPV would not be available after this date.

- **April 11th:** bOPV would be available in private market but it is not to be opened or used before 25th April.
- **April 25:** Polio Switch Day, when tOPV would be completely withdrawn and replaced by bOPV in both routine immunization and polio campaigns.
- **9th May:** National Validation Day when India would be declared free of tOPV.

Q. What are the GoI objectives/compulsions to launch IPV in India?

A. The main objective of GoI's initiatives is to enhance population immunity against type-2 poliovirus just prior to proposed switch from trivalent-OPV to bivalent-OPV (type1 and 3) in April 2016 so that the risks associated with the complete removal of type-2 vaccine virus can be mitigated. These risks include future outbreaks of cVDPV type 2 emerged during or shortly after OPV type 2 withdrawal, importation of cVDPVs, or outbreak occurring due to break in bio-containment process in laboratories storing viruses. The decision to employ only a single dose of IM-IPV and two doses of intradermal IPV is only an interim arrangement owing mainly to the limited supply and availability of IPV, globally.

Q. Why IAP is recommending four doses of IPV in their immunization schedule?

A. The main aim of existing IAP ACVIP guidelines on polio immunization is to provide almost 100% protection against VAPP along with the best possible humoral and mucosal protection against polioviruses to an individual child in office practice setting. Ideally, to get best sero-protection, IPV should be started at least at 8 weeks of age and 2 doses at 8-week interval should be given to neutralize interference caused by maternal antibodies if given earlier. Since, immunization schedules in India are started at 6 weeks, this is the reason why three priming doses at 6, 10, and 14 weeks are recommended by IAP.

Q. Is there any change in the focus of existing IAP recommendations on polio immunization?

A. Considering the recent initiatives taken by the GoI as described in this document, the IAP ACVIP will have to add another objective, i.e. to provide protection against type-2 poliovirus to naive children born post-switch. IPV would be the only source of providing type-2 immunity to children after April 2016. So our focus would be protection against VAPP along with provision of protection against type-2 poliovirus by maximizing type 2 population immunity. Since the threat of cVDPV type-2 emergence would be greatest, at least for one year following tOPV to bOPV switch, our latter objective would need to override the former for the time being. However, the scarcity/non-availability of IPV in the private sector has created confusion amongst practitioners and further complicated the existing scenario.

Q. How will IPV be launched in India?

A. IPV will be rolled out in India in phased out manner. Six states, i.e. UP, Bihar, Madhya Pradesh, Gujarat, Punjab and Assam have already rolled out IPV (as full dose, intramuscular given along with 3rd dose of DTP at 14 weeks or first contact afterwards) from 30th November, 2015. These states constitute roughly 65% of India population. Remaining states/UTs will roll out IPV in a phased manner from late May 2016.

Q. In which states of the country IPV will be launched by an intradermal route of administration?

A. In six states, i.e. Orissa, Andhra Pradesh, Telangana, Tamil Nadu, Kerala, Karnataka, Maharashtra and Puducherry IPV will be given in fractional dose (0.1ml instead of 0.5 ml) by intradermal route at 6 and 14 week from April, 2016.

Q. Earlier, the GoI was supposed to launch IPV in full-dose, intramuscular route at 14 weeks all over the country. Why is there a change in the approach now?

A. This change in approach is driven mainly by scarcity of IPV. Had India implemented full-dose, IM IPV all over India, IPV would have been out of stock by mid-2017. In mini-IEAG, held on March 26, 2016, the GoI took a decision to roll-out IPV in all the remaining states/UTs prior to switch date (i.e. April 25, 2016) in 2-dose fractional dose by intradermal route.

Q. Why is there a scarcity of IPV in India?

A. As per the information available through Ministry of Health & Family Welfare, Government of India (GoI), the main reason behind shortage of IPV in India is the failure of major producers of IPV globally to supply adequate quantity of the vaccine to India. M/s Sanofi Pasteur and M/s Bilthoven, the two major producer of IPV globally, have continued to encounter difficulty in scaling up their bulk production for IPV at their manufacturing units. This means limited bulk is available for supply to India for filling at M/s Shantha Biotech and M/s Serum Institute of India (SII). All the IPV from M/s GSK, the other major international producer of IPV, is being used for production of their combination vaccines. On the other hand, there is increased demand of IPV for supplementary immunization activities (SIAs) in two endemic countries, Pakistan and Afghanistan, and also from other countries introducing IPV in their routine immunization (RI) this year. Around 36 countries are going to introduce IPV between February and September 2016. Further, there is stockpiling of IPV for outbreak response in case of any outbreak occurring in future with type 2. This is to be noted that the GoI has initially demanded approximately 28.1 million doses of IPV, however, it has received only 10.3 million doses so far. Because of global shortage, only 50% of the estimated requirement of IPV till March 2018 is secured.

Q. How to administer IPV by intradermal route?

A. IPV will be administered in a similar way as BCG vaccine is given. 0.1 ml of vaccine from a multi-dose vial will have to be administered using BCG needle and syringe at right deltoid muscle in upper arm. So, 50 doses (i.e. 25 children can be vaccinated from a single 5.0 ml multi-dose vial.

Q. What is the exact technique of administering ID-IPV?

A. The skin is stretched between thumb and forefinger and sterile needle (25 G or 26 G) inserted at the 10-15 degree angle with bevel upwards for about 2 mm into superficial layers of the dermis (almost parallel with the surface). Raised blanched bleb showing tips of hair follicles is a sign of correct injection. A bleb of around 7mm represents 0.1ml injection. The site of injection is at insertion of the deltoid muscle into the humerus. Sites higher on the arm are likely to lead to keloid formation. Do not squeeze or scratch the site and also do not use ointments, oils, or herbs on the site after injection. Also, do not rub/massage the injection site and do not put a sticking plaster over the injection site.

For details, please visit following YouTube video for demonstration:

<https://www.youtube.com/watch?v=F3EDggy99v0>

Q. How to store IPV vials in refrigerator?

A. It should be stored between +2°C and +8°C in the refrigerator (or in the basket of ILR) along with other vaccines such as DPT and Penta. IPV is a freeze-sensitive vaccine. The 'Shake Test' is not applicable to IPV vaccine. One should discard the vial/s if there is any doubt of vaccine getting frozen.

Q. For how long an open IPV vial be stored?

A. Opened IPV multi-dose vials can be kept and used for up to 28 days after opening, provided the expiry date has not passed, the vaccine is appropriately handled and stored, and the VVM indicates that vial can be used. Remember: opened vials should be used first before opening additional vials.

Q. What are the GoI eligibility criteria for administration of single dose of IM full dose IPV at 14 weeks?

A. Any child who is coming at 14 weeks (not beyond 1 year) and if he/she has not received any/no primary series of vaccination, IPV is administered. If all primary series vaccines already received before IPV introduction, IPV is not administered. *(Please remember, this is for pediatricians working in government sector)*

Q. What are the GoI eligibility criteria for administration of two doses of ID-fIPV?

A. A 6 week to one year old child brought to session site for OPV1 / Penta 1 within 1 year of age is eligible for first fractional dose of IPV. If the child has failed to take the first dose of OPV and Penta within 1 year of age, then this child is neither eligible for Penta nor IPV.

A child who has received first fractional dose of IPV along with OPV1 / Penta 1 is eligible to receive second fractional dose of IPV when the child is brought to session site to receive OPV3/Penta3 (within or after 1 year of age). *(Please remember, this is for pediatricians working in government sector)*

Q. In case of shortage of IPV, does the private sector use only bOPV without IPV?

A. Considering the current situation, following scenarios are possible:

- 1-IPV is available but in limited quantity with irregular supply in the private market;
- 2-IPV is not available at all in private market.

For Scenario 1, IAP ACVIP advises its membership to use alternative schedule as suggested by the committee earlier in which primary schedule is started at 8-weeks instead of 6 weeks and completed with two doses of IPV administered at an interval of 8-weeks, instead of three.

For Scenario 2, following options would be available:

1-Use OPV (tOPV till April 2016 and bOPV thereafter) to complete polio immunization schedule;

2-Refer children to government health facilities to get immunized at 8 and 16 weeks with IPV (IM or ID) as per IAP ACVIP alternative schedule;

3-Procure IPV vials from government health facilities and immunize at your own facility with ID-fIPV at 8 and 16 weeks;

4-Advice parents to follow GoI immunization schedule *in toto* for polio immunization and refer them to government health facilities for the same.

Q. Which is the best option to adopt?

A. The option 1 would be untenable and hazardous since it will leave children vulnerable against type 2 polio without any immunity against type 2 poliovirus especially those born post-switch. Option 2 would be unfeasible since central or state government would not agree to 'accommodate' IAP schedule. Regarding the option 3, arrangements can be made with state/district-level government health department to provide IPV vials for intradermal vaccination at private health facilities. However, one has to furnish the record of the children vaccinated at their clinics to the designated local public health authority. This option however may not be available at all the places. The option 4 would be the other feasible option considering the current scenario. Though it would be contradictory to IAP ACVIP stated objective, i.e. the provision of complete protection against VAPP, but for the next one year at least, our main focus should be provision of immunity against type 2 poliovirus.

Q. What is IAP's stand on Intradermal IPV doses?

A. In view of existing literature available the current stand of IAP ACVIP that it does not as yet approve the use of 'intradermal fractional-dose IPV' (ID-f IPV) for office-practice. However, considering the extraordinary situation in context of extreme shortage of IPV and the urgent need of providing immunity against type-2 poliovirus, the committee is willing to provisionally accept immune-protection accorded by two ID-fIPV doses as moderately effective given at 6 and 14-week of age against type-2 polioviruses provided another full dose of IM-IPV is offered at least 8 week interval of the second dose of ID-fIPV. The committee still maintains that for routine immunization (RI), at least two-doses of IPV starting from at

least 8 weeks of age and maintaining an interval of at least 8 weeks between them are necessary to provide adequate immune protection against all types of polioviruses.

Q. At what ages the fractional-dose, intradermal fIPV be given at private facility?

A. As stated above, the GoI wants to give at 6 and 14 weeks along with 1st and 3rd doses of OPV and Penta (i.e. along with OPV1/Penta1, and OPV3/Penta3). However, it would be better to vaccinate at 8 and 16 weeks as per IAP recommendations and described above.

Q. If in case IPV is available in the private hospitals, is it OK to complete the course with intramuscular IPV after an initial intradermal IPV?

A. Yes. As explained in the document, IAP ACVIP is willing to accept immune responses provided by two-doses of ID-fIPV as moderately effective. Hence, if a child has received one dose of ID-fIPV at 6 weeks, two more full doses of IM-IPV should be offered at least 8 weeks after the first dose. The minimum interval between the 2nd and 3rd dose should also be at least 8 weeks. However, if a child had already received two doses of ID-fIPV at 6 and 14 weeks, one more dose of IM-IPV should be given at least 8 weeks after the last dose of fIPV.

Q. If IPV is available in private market, and a child has only received a single dose of IM-IPV at 14 weeks or later through public health facility, should two more doses of IPV be given to complete primary immunization?

A. No, only a single dose of IM-IPV at least 8 weeks after the first dose should be given.