

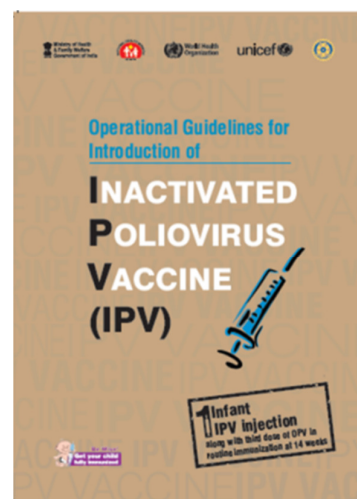
Addendum to IPV Introduction Guidelines based on Recommendations of India Expert Advisory Group (IEAG)

Background

India was certified polio-free along with 10 other countries of WHO South-East Asia Region on 27 March 2014 and has maintained its polio-free status for over 5 years now. However, India is still at the risk of wild poliovirus importation from areas where transmission is still ongoing. The country also possesses risk of Vaccine Associated Paralytic Polio (VAPP) cases and emergence of Vaccine Derived Polio Viruses (VDPVs). The country is maintaining high routine immunization and sensitive surveillance to prevent and rapidly detect importations and emergence of poliovirus until polio is completely eradicated globally.

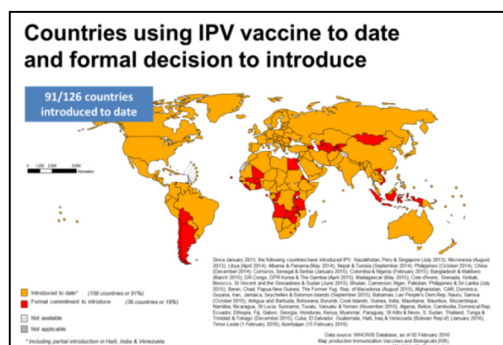
Global Polio Endgame Strategy

India is committed for the implementation of global polio endgame strategy that addresses the eradication of all polio disease, whether caused by WPV or VDPV to achieve a world free from polio. Polio Eradication Endgame Strategic Plan, 2013-18 (PEESP) provides global guidance for implementation of this strategy and was endorsed in May 2015 during World Health Assembly (WHA) represented by Ministers of Health of all 194 Member States including India. The strategy involves a switch from trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV) from the programme. This switch is associated with risk of time limited type 2 VDPV outbreaks because of silent transmission resulting from replication and mutation of type 2 vaccine virus in gut of recently immunized children. The risk of VDPV outbreak is related to low population immunity against particular serotype. The Strategic Advisory Group of Experts on Immunization (SAGE) to World Health Organization in its October 2015 meeting affirmed a two-week global tOPV to bOPV switch window between 17 April 2016 and 1 May 2016. Accordingly, the country has decided National Switch Date as 25 April 2016. To mitigate the risk of VDPV emergence, introduction of at least one dose of IPV was recommended by SAGE in 2012.



Global Status of IPV Introduction

As part of the PEESP recommendations, all 126 countries which, at the start of 2013 were only using OPV, were required to introduce at least 1 dose of the IPV into RI schedule as part of preparations for the switch. The level of commitment from all countries to meet this timeline has been exceptional and as of February 2016, 91 of the 126 countries have introduced IPV in their routine immunization



schedule. This rapid introduction across many countries along with introduction of IPV in SIA of few countries, as well as the requirement of maintaining a stockpile of IPV for post switch VDPV emergences led to global IPV vaccine shortages.

IPV Introduction in India

Based on recommendations of Strategic Advisory Group of Experts on immunization (SAGE), India Expert Advisory Group (IEAG) for polio eradication and National Technical Advisory Group on Immunization (NTAGI), the Government of India decided to introduce a single dose of IPV in Universal Immunization Programme.

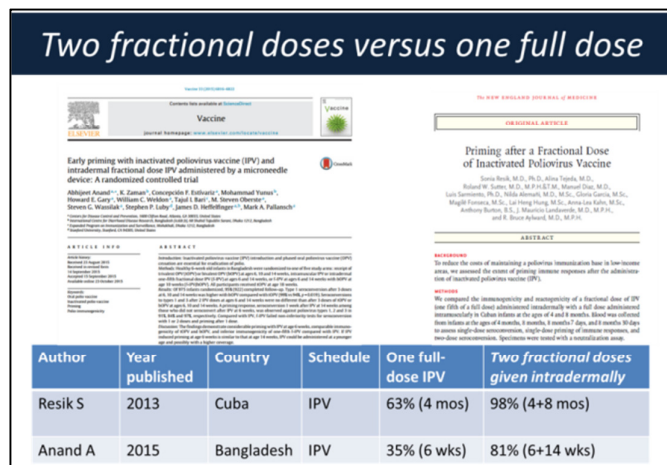
Government of India (GoI) requested Gavi to support the country with 40 million doses of IPV in the first year of introduction for the full birth cohort. However, Gavi agreed to provide support of 28.14 million doses for the first year of introduction (from October 2015-September 2016); initial supply timelines were changed frequently and quantity was not adequate to cover one full year birth cohort in a single go. Thus, it was decided to introduce IPV in the country in phases. In the first phase, IPV was introduced in six states (Assam, Bihar, Gujarat, Madhya Pradesh, Punjab and Uttar Pradesh) starting from 30 November 2015, and planned IPV introduction in remaining states/UTs before switch, i.e., from 1 April 2016.

Due to continued global IPV supply shortages, Ministry of Health & Family Welfare, Government of India, called for an IEAG meeting on 26 February 2016 to discuss the fallout of IPV supply situation. IEAG discussed various research studies that have been undertaken to assess the effectiveness of dose-reduction approach, i.e., use of fractional dose of IPV.

Data from studies to date in Cuba and Bangladesh were presented, demonstrating that “prime boost” model of fractional doses at 6 weeks and 14 weeks, offers better protection than a single full dose.

Various research studies (as shown in the figure with references in last section) suggests that although two fractional doses of IPV are much more immunogenic than a single full dose of IPV and adoption of such a schedule should alleviate supply shortage (60% antigen-sparing), but requires high-performing routine immunization system (limiting implementation), and national decision to use IPV off label.

IEAG also discussed that as per WHO Polio Position Paper (Weekly Epidemiological Record, scheduled for 25 March 2016 publication), “As an alternative to the intramuscular injection of a full IPV, countries can consider using fractional doses (1/5 of a full dose) via the intradermal route.

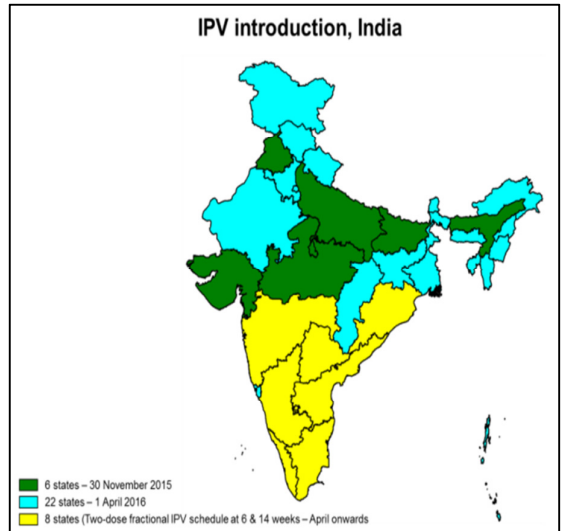


In view of these evidences and IEAG recommendations, GoI decided to introduce a schedule of two fractional doses of IPV (.1 ml each), administered at 6 weeks and 14 weeks, in 8 states/UTs. This schedule requires an off-label use.

The over-riding objective is to ensure administration of IPV to all infants (before or as early as feasible after the switch). While potentially more programmatically demanding and requiring an off-label use, the fractional dose has many advantages, as it will reduce costs, offer better immunogenicity than a single full dose of IPV, and help to ensure that all eligible infants in India receive IPV.

Thus, IPV introduction plan in country as follows:

- The vaccine already introduced in six high-risk states of Assam, Bihar, Gujarat, Madhya Pradesh, Punjab and Uttar Pradesh in November 2015.
- IPV is planned to be introduced in 22 state/union territories from 01 April 2016 before the national switch date, i.e., 25 April 2016.
- Two-dose fractional IPV schedule is proposed to be introduced in eight states/UTs (Orissa, Telangana, Andhra Pradesh, Tamil Nadu, Kerala, Karnataka, Maharashtra and Puducherry) before the national switch date, i.e., 25 April 2016.



Operationalization of Two-dose Fractional IPV Schedule

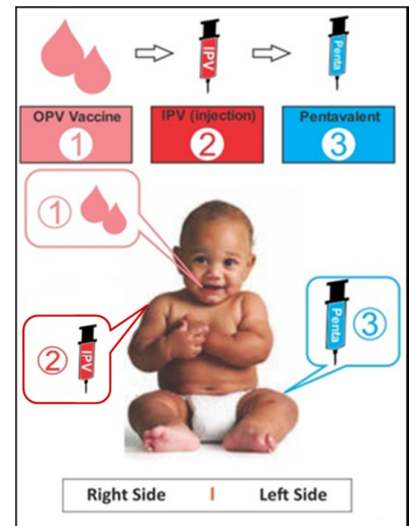
The introduction of IPV vaccine should be viewed as an opportunity to strengthen the overall RI service delivery in the states and districts. Introduction of any new vaccine in the programme requires meticulous planning at all levels.

The IPV introduction plan encompasses all components, including a programme assessment at all levels to determine what is required for the introduction. The introduction plan takes into account the timelines for successful completion including vaccine supply and estimated procurement requirements. The IPV introduction operational guidelines have been standardized for uniform understanding at all levels.

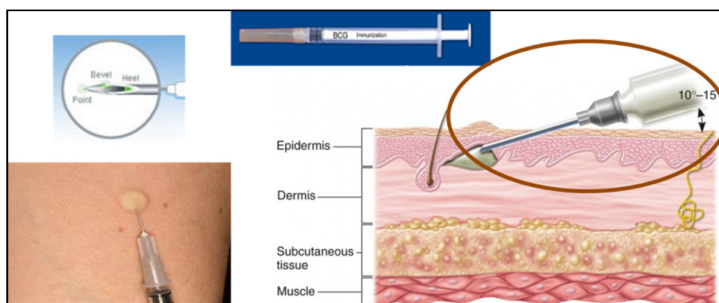
Eligibility criteria

- Any child coming after 6 weeks (1½ months) but within one year of age for first dose of OPV and pentavalent is eligible for the first fractional dose of IPV (dose 0.1 ml intradermal, right upper arm).

Sequence of vaccination at 6 & 14 weeks



- A child who has received the first fractional dose of IPV along with first dose of OPV and pentavalent is eligible to receive second fractional dose of IPV when the child is brought to session site to receive third dose of OPV and pentavalent.



Vaccination Schedule before and after IPV Introduction

As per the current routine immunization schedule in India, a child receives oral polio vaccine at birth followed by three OPV doses at 6, 10 and 14 weeks. Two fractional doses of IPV by intradermal route have been recommended to be given to a child at 6 and 14 weeks, along with first and third doses of OPV and pentavalent. There will be no change in the current OPV schedule. IPV will not be administered to a child coming before 6 weeks.

If the first fractional dose of IPV dose is delayed but administered within first year, the second fractional dose should be given along with third dose of OPV and pentavalent as soon as possible. The vaccine shall be administered to all children of more than 14 weeks of age who are still eligible for third dose of OPV and pentavalent. This will ensure that children who are brought late for the third dose of OPV and pentavalent also get an opportunity to receive the IPV dose maximum up to 1 year of age.

Age group for vaccination

The two fractional doses of IPV in UIP are recommended for children coming after 6 weeks (1½ months) to maximum up to 1 year of age.

Dosage and route

- Injection technique same as BCG but in right arm.
- Intradermal: Between layers of skin (Epidermis–Dermis)
- 0.1ml, using BCG syringe
- Needle at angle of 10–15 degree
- Keep beveled up while injecting the needle

Comparison of immunization schedule before and after IPV introduction

Table 1 describes the current immunization schedule (i.e. prior to IPV introduction) and immunization schedule after the introduction of two-dose fractional IPV schedule.

Table 1: Comparison of immunization schedule before and after IPV introduction

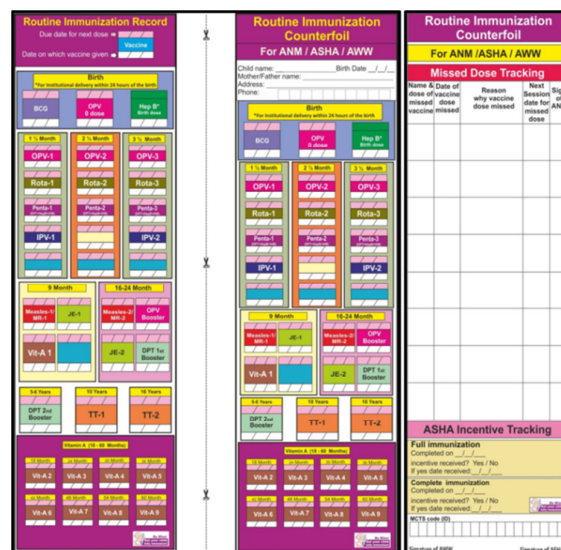
Age	Vaccination schedule before IPV introduction	After IPV introduction	Remarks
At birth	BCG, OPV-0, Hep B-birth dose	BCG, OPV-0, Hep B-birth dose	(1) BCG vaccine can be given up to 1 year of age.
6 weeks	OPV1, Pentavalent1	OPV1, IPV1, Pentavalent1	(2) DPT vaccine can be given up to 5-6 years (not beyond 7 years) of age
10 weeks	OPV2, Pentavalent2	OPV2, Pentavalent2	(3) Pentavalent vaccine should be given under 1 year of age. In delayed cases, due doses above 1 year of age can be given to a child only if a child has received at least one dose of pentavalent vaccine before his/her first birthday. Due doses should be given at a minimum interval of four weeks, at the earliest available opportunity.
14 weeks	OPV3, Pentavalent3	OPV3, IPV3, Pentavalent3	
9 months	MCV1, JE-1 (where applicable)	MCV1, JE-1 (where applicable)	
16-24 months	MCV2, DPT first booster dose, OPV booster dose, JE-2 (where applicable)	MCV2, DPT first booster dose, OPV booster dose, JE-2 (where applicable)	(4) Measles vaccine can be given up to 5 years of age
5-6 years	DPT second booster dose	DPT second booster dose	(5) JE vaccine can be given up to 15 years of age.
10 years	TT	TT	
16 years	TT	TT	(6) In delayed cases, IPV can be given. Maximum up to 1 year of age.

BCG: *Bacillus Calmette-Guerin*; DPT: diphtheria-pertussis-tetanus; HepB: Hepatitis B; Hib: *Haemophilus influenzae* type b; JE: Japanese Encephalitis; MCV: measles alone or MR/MMR; OPV: oral polio vaccine; TT: tetanus toxoid; IPV: inactivated poliovirus vaccine

Recording & reporting tools

All recording and reporting formats should be revised to include IPV. These revised formats should be distributed before introduction and ensure that during health workers' training, an exercise for filling the MCP card should be conducted.

Inclusion of IPV will be required in vaccine stock forms, immunization cards, due lists, tally sheets, monthly progress reports at all levels, maternal and child health (MCH)/immunization register, coverage monitoring charts, supervisory checklists, computer databases, immunization coverage surveys and evaluation formats as well as AEFI reporting formats.



The reporting of IPV vaccination will be done through existing reporting mechanisms such as the health management information system (HMIS) and the mother and child tracking system (MCTS). MoHFW is in process of updating the HMIS and MCTS portal to include IPV coverage reporting.

References

1. <http://www.sciencedirect.com/science/article/pii/S0264410X15013158>
2. http://www.who.int/immunization/sage/meetings/2013/april/3_nejmoa1202541.pdf