Ministry of Health & Family Welfare
Government of India

NATIONAL HEALTH MISSION

World Health Organization

unicef

ROTARY INTERNATIONAL

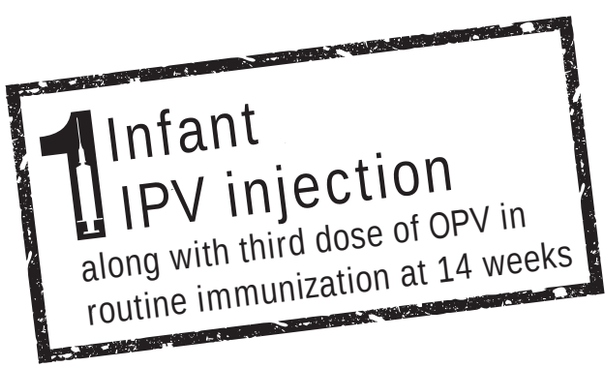
Operational Guidelines for Introduction of

INACTIVATED POLIOVIRUS VACCINE (IPV)

1 Infant
IPV injection
along with third dose of OPV in routine immunization at 14 weeks

Operational Guidelines for Introduction of

INACTIVATED POLIOVIRUS VACCINE (IPV)



NATIONAL HEALTH MISSION

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FOREWORD

India was certified polio free along with ten countries of WHO South-East Asia Region on 27 March 2014. India has not reported any polio case since 13 January 2011. This has been a hard won victory for the country's health system. In 2013, the Executive Board of the World Health Organization (WHO) approved the targets, goals, and timelines of the Polio Eradication and Endgame Strategic Plan (PEESP) 2013-2018 which lays out the strategy for achieving a world free from polio. India has endorsed this strategic plan and is committed to its objectives. This strategy includes the introduction of at least one dose of IPV into the routine immunization schedule followed by a globally synchronized withdrawal of type 2 vaccine viruses from immunization programmes in all 'OPV only' using countries.

Based on recommendations of India Expert Advisory Group (IEAG) and National Technical Advisory Group on Immunization (NTAGI), the Government of India (GoI) has decided to introduce inactivated polio vaccine (IPV) into routine immunization schedule in October 2015 simultaneously across the entire country. The introduction of IPV is critical to achieving high population immunity against type-2 poliovirus to protect our children and to prepare the platform for the upcoming tOPV to bOPV switch.

These operational guidelines are the culmination of efforts of Ministry of Health and Family Welfare (MoHFW) and the World Health Organization, India with excellent support from other partner agencies notably UNICEF, BMGF, Rotary and CORE.

In addition to the introduction of IPV, these guidelines and the trainings, will also contribute immensely to strengthening the routine immunization delivery mechanism.

It is expected that states will use the operational guidelines to disseminate uniform understanding across all levels and conduct quality training of medical officers, health workers including data managers and cold chain handlers.

The importance of training cannot be overemphasised and each state should ensure that all the trainings are completed before the introduction of the vaccine. Quality trainings with special attention to the Frequently Asked Questions (FAQs) will be the cornerstone that will ensure a successful introduction of IPV across the country.

This document encompasses the key activities and timelines necessary to guide the introduction of IPV in India. This document also provides relevant information and evidence that is required for policy makers.

I wish this document would be fruitfully used by all concerned stakeholders to carry forward the agenda of IPV introduction in India.

(Dr. Rakesh Kumar)

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LIST OF ACRONYMS

AD	auto-disable (syringe)
AEFI	adverse events following immunization
AHS	Annual Health Survey
ANM	auxiliary nurse midwife
ASHA	accredited social health activist
AWW	*anganwadi* worker
BCG	*Bacillus Calmette-Guerin* vaccine
bOPV	bivalent oral poliovirus vaccine
cMYP	comprehensive multi-year plan
CHC	community health centre
CBOs	community-based organizations
cVDPV	circulating vaccine-derived poliovirus
DHS	District Health Society
DIO	district immunization officer
DLHS	District Level Household Survey
DPT	diphtheria-pertussis-tetanus
DTFI	district task force for immunization
EPI	Expanded Programme on Immunization
FAQs	frequently asked questions
GPEI	Global Polio Eradication Initiative
Hib	*Haemophilus influenzae* type b
HMIS	health management information system
IAP	Indian Academy of Paediatrics
ICDS	Integrated Child Development Services
ILR	ice-lined refrigerator
IMA	Indian Medical Association
IEC	information, education and communication
IPHA	Indian Public Health Association
IPV	inactivated poliovirus vaccine
JE	Japanese Encephalitis
LHV	lady health visitor
M&E	monitoring and evaluation
MCP	mother-child protection (card)
MCTS	mother and child tracking system
MO	medical officer

MoHFW	Ministry of Health and Family Welfare
NHM	National Health Mission
NGOs	nongovernmental organizations
NPSP	National Polio Surveillance Project
OPV	oral polio vaccine
PHC	primary health centre
RI	routine immunization
SAGE	Strategic Advisory Group of Experts on Immunization
SIA	supplementary immunization activities
STFI	state task force for immunization
tOPV	trivalent oral poliovirus vaccine
ToT	training of trainers
TT	tetanus toxoid
UIP	Universal Immunization Programme
VAPP	vaccine-associated paralytic polio
VDPV	vaccine derived poliovirus
VVM	vaccine vial monitor
WHO	World Health Organization
WPV	wild poliovirus

1 BACKGROUND

The Global Polio Eradication Initiative (GPEI) was launched in 1988 when the forty-first World Health Assembly adopted a resolution for the worldwide eradication of polio. The goal of the GPEI is to complete the eradication and containment of all wild, vaccine-related and Sabin polioviruses, such that no child ever again suffers paralytic poliomyelitis. Since then, the global programme has developed evidence-based strategies and timely interventions which resulted in significant reduction in the number of polio-endemic countries from more than 125 in 1988 to 3[1] in 2015.

1.1 Brief epidemiology of polio

Poliomyelitis (or polio in short) is a viral infection caused by the poliomyelitis virus, an enterovirus belonging to the Picornaviridae virus family, and has three serotypes (type 1, type 2 and type 3). Poliovirus usually affects children under 5 years of age who are unvaccinated or under-vaccinated. Most children who are infected will show only minor symptoms but as many as one in 200 infected children will be paralyzed. The virus can also affect or be carried by adolescents and adults.

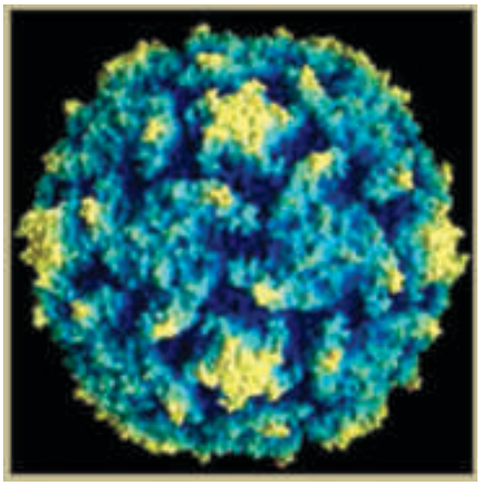


Figure 1: Image of wild poliovirus

The poliovirus enters the body through the mouth, often with food or drinking water that is contaminated with faecal matter from a person who carries the poliovirus. The virus multiplies at the site of implantation in the throat and gastrointestinal tract and is passed through faeces. The virus is usually present in the throat and stool before the onset of illness. The virus invades local lymphoid tissue, enters the bloodstream, and then may infect cells of the central nervous system.

Polioviruses are spread by faecal-oral route of transmission. Infection can be inapparent (without symptoms) in approximately 72% of cases; in about 24% it causes mild disease with transitory fever, discomfort, somnolence, headache, nausea, vomiting, constipation, and sore throat, in various combinations; it manifests as aseptic meningitis in about 4% of cases; and on rare occasions (<1%) it presents as paralytic poliomyelitis. The incubation period for paralytic poliomyelitis is commonly 7–14 days (range 3–35 days).

Polio is a crippling and potentially fatal infectious disease. There is no cure, but there are safe and effective vaccines. Therefore, the strategy to eradicate polio is based on preventing infection by immunizing every child to stop transmission and ultimately make the world polio free. Type 2 wild poliovirus has been eliminated in the world – the last wild type 2 poliovirus was detected in India in 1999. In this final stage of polio eradication, only type 1 and type 3 wild polioviruses continue to circulate in endemic areas. Both are highly infectious and both cause paralytic polio. Type 1 is the most pervasive strain of poliovirus and type 3 is at very low levels.

[1]WHO data as of 2 June 2015; http://www.polioeradication.org/Portals/0/Wild_poliovirus_list_2010-2015_02JUN.pdf

1.2 Global scenario

Since the launch of GPEI in 1988, polio cases have decreased by over 99%, from an estimated 350 000[2] cases then, to 26[3] reported cases in 2015 (as shown in Figure 2). The reduction is the result of the global effort to eradicate the disease. In 2015, only 3 countries (Afghanistan, Nigeria and Pakistan) remain polio-endemic, down from more than 125 in 1988.

As long as a single child remains infected, children in all countries are at risk of contracting polio. Failure to eradicate polio from these last remaining countries could result in as many as 200 000[4] new cases every year, within 10 years, all over the world. In most countries, the global effort has expanded capacities to tackle other infectious diseases by building effective surveillance and immunization systems.

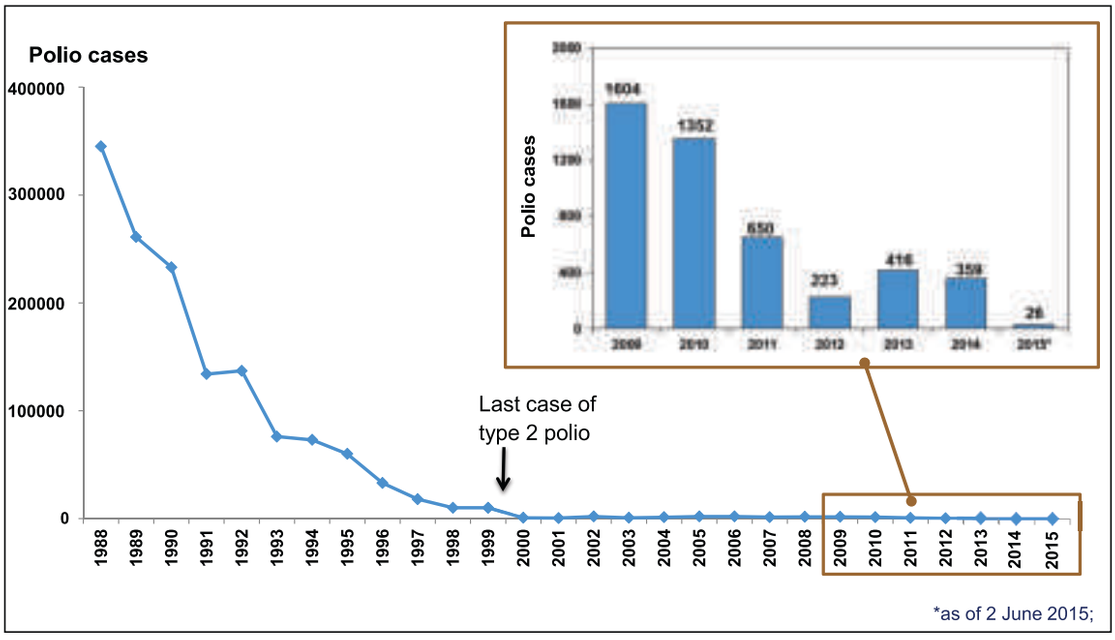


Figure 2: GPEI accomplishment – significant decline in wild polioviruses cases worldwide, 1988-2015

1.3 Indian scenario

India's battle against polio can be cited as the biggest public health achievement ever. The country was once recognized as the world's epicentre of polio, with an estimated annual incidence of 200 000–400 000 cases annually during the 1970s. In India, vaccination against polio started in 1978 with Expanded Programme on Immunization (EPI). By 1984, it was successful in covering around 40% of all infants, giving 3 doses of oral polio vaccine (OPV) to each. In 1985, the Universal Immunization Programme (UIP) was launched to cover all the districts of the country. In 1995, following the launch of Polio Eradication Initiative of the World Health Organization (WHO), India launched Pulse Polio Immunization Programme along with UIP, which aimed at 100% coverage.

[2]Global Polio Eradication Initiative; History of polio. Available from:http://www.polioeradication.org/Polioandprevention/Historyofpolio.aspx
[3]WHO data as of 2 June 2015; http://www.polioeradication.org/Dataandmonitoring/Poliothisweek/Wildpolioviruslist.aspx
[4]http://www.searo.who.int/thailand/factsheets/fs0005/en/

India accounted for nearly half of the world's total polio cases in 2009 when it reported 741 cases. The number of cases came down to 42 in 2010, a 94% reduction over the previous year. No polio cases have been reported from the historic reservoir states of Uttar Pradesh since April 2010 and Bihar since September 2010. The last case of paralytic polio due to wild poliovirus (WPV) in the country was reported from Howrah district of West Bengal on 13 January 2011[5].

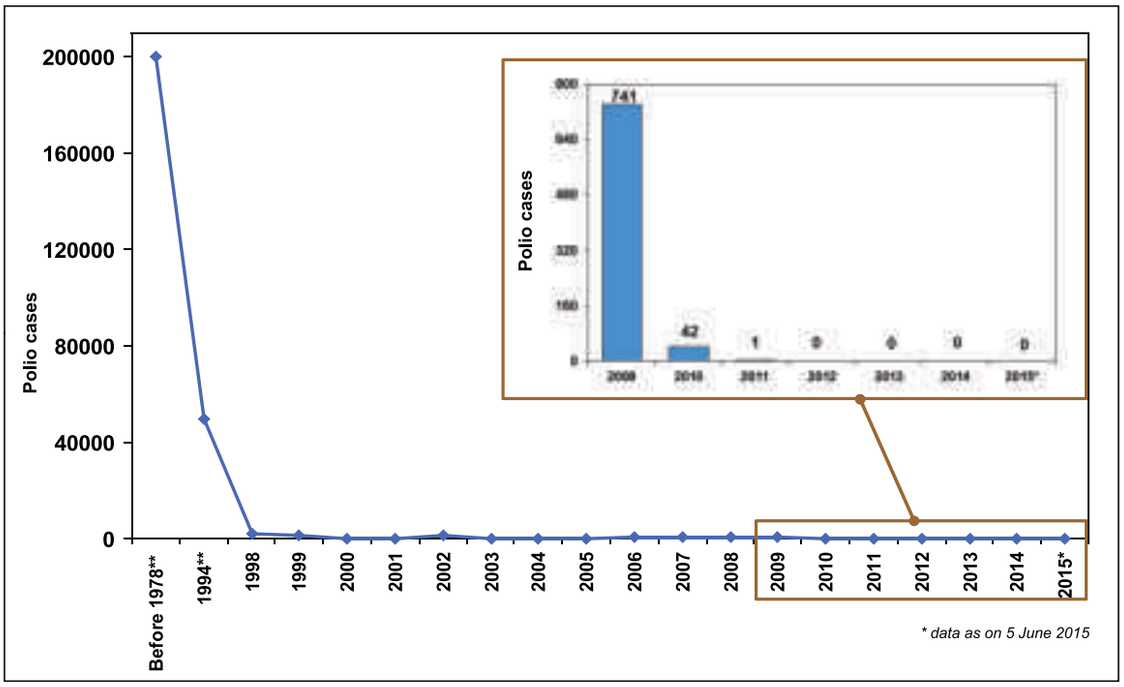


Figure 3: Polio trend in India,1988-2015

Having made unprecedented progress in stopping WPV transmission, India was removed from the list of polio-endemic countries in 2012. India's successful interruption of poliovirus for three years led to WHO South-East Asia Region being certified as polio free in March 2014. This was a historic milestone in the global effort to end polio and one of the greatest public health achievements in India.

The remarkable progress in polio eradication is an outcome of continuous operational improvement, adoption of best strategies and use of appropriate vaccines. Aggressive use of bivalent oral poliovirus vaccine (bOPV – type 1 & 3) in the high risk areas has immensely contributed in containing the poliovirus by successfully sustaining the high levels of population immunity achieved previously to type 1 poliovirus even while improving immunity against type 3 poliovirus. India is now guarding itself against the risk of polio resurgence from endemic countries (Afghanistan, Nigeria and Pakistan) and re-infected countries such as Cameroon, Equatorial Guinea, Ethiopia, Iraq, Kenya, the Syrian Arab Republic and Somalia, which poses a substantial threat to the continuing success of the polio programme. India also faces the risk of paralysis from vaccine derived polioviruses (VDPVs) in areas with low population immunity.

[5]**http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3734678/#ref51**

As India continues its efforts to raise population immunity against polio through continuing polio campaigns and intensive routine immunization activities, enhanced poliovirus surveillance and regular serosurveys against poliovirus in the highest risk areas since 2007–2012 help to identify areas at the risk of poliovirus importation and emergence of circulating vaccine-derived poliovirus type 2 (cVDPV2).

At present, the Government of India is committed to sustaining its polio-free status until global certification of polio is achieved and implementing the polio endgame strategy, which involves risk-free withdrawal of oral polio vaccine from the programme in a phased manner. The global polio endgame strategy entails introduction of inactivated poliovirus vaccine (IPV) in the routine immunization schedule prior to switch from trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV) to boost population immunity against the risk of cVDPV type 2 emergence. The Government of India plans to introduce IPV across the country in October 2015.

The Government of India endorses the global polio endgame strategy and is moving steadily towards implementing this strategy. The National Vaccine Policy 2011 and the comprehensive Multi-Year Plan (cMYP) 2013–2017 have also envisioned the introduction of new vaccines, including IPV.

2 TYPES OF POLIO VACCINES

The development of effective vaccines to prevent paralytic polio was one of the major medical breakthroughs of the 20th century. Both orally administered, live attenuated oral polio vaccines (OPV) and inactivated poliovirus vaccines (IPV) are being widely used across the world to prevent poliomyelitis. These vaccines have stopped transmission of polioviruses from most countries and have reduced the worldwide incidence of polio from 350 000 cases in 1988 to just 26 cases in 2015[6].

High levels of vaccination coverage must be maintained to stop poliovirus transmission and prevent outbreaks from occurring. The GPEI is constantly assessing the optimal use of the different vaccines to prevent paralytic polio and stop poliovirus transmission in different areas of the world.

2.1 Oral poliovirus vaccine (OPV)

The OPV, developed in 1961 by Albert Sabin, is a live vaccine prepared from attenuated (reduced virulence) viral strains. It was licensed in 1961 as a monovalent vaccine (mOPV) followed by a trivalent version (tOPV) licensed for use in 1963. OPV provides both humoral and mucosal intestinal immunity. Mucosal intestinal immunity provided by OPV helps to prevent infection with wild poliovirus. This intestinal immune response to OPV is the main reason why mass campaigns with OPV can rapidly stop person-to-person transmission of wild poliovirus. Three types of oral polio vaccines (described in the section below) were used in the polio campaigns worldwide depending upon the targeted population.

Figure 4: Child receiving polio drops

2.1.1 Monovalent oral poliovirus vaccine (mOPV)

mOPV contains live, attenuated poliovirus of single type – type 1 (mOPV1), type 2 (mOPV2) or type 3 (mOPV3). The vaccine gives protection against the poliovirus of the specific type. mOPV vaccines are recommended for use in supplementary immunization campaigns in areas where only WPV type 1 or type 3 alone is circulating. It is not recommended as a substitute for OPV in routine immunization programmes. mOPV2 stockpiles are secured with WHO for release to countries in response to any cVDPV2 after the tOPV-bOPV switch.

An Indian study showed that two doses of mOPV1 and mOPV2 protect about 90% of children and mOPV3 provides immunity to about 84% children[7].

2.1.2 Bivalent oral poliovirus vaccine (bOPV types 1 and 3)

bOPV consists of live, attenuated poliovirus strains of type 1 and type 3. It simultaneously targets the two types of wild poliovirus (type 1 and type 3) and was developed to improve the efficiency and impact of vaccination campaigns in areas where both types of poliovirus co-circulate.

[6]WHO data as of 2 June 2015

[7]Sutter RW, John TJ, Jain H, Agarkhedkar S, Ramanan PV, Verma H, et al. Immunogenicity of bivalent types 1 and 3 oral poliovirus vaccine: a randomized, double-blind, controlled trial. Lancet. 2010;376:1624–5.[PubMed]

A recent Indian study showed that bOPV given as per the EPI schedule protects about 99% of children from both polioviruses type 1 and 3[8].

2.1.3 Trivalent oral poliovirus vaccine (tOPV)

tOPV contains live attenuated poliovirus strains of all three poliovirus types. This is the most common form of OPV used in the routine and supplementary immunization activities in low and middle-income countries globally because of cost, ease of administration, and excellent oral and intestinal (gut) immunity. Presently, tOPV is the only oral polio vaccine used in the routine immunization in OPV-using countries. Many countries also give tOPV in supplementary immunization activities (SIAs).

As per a recently conducted study in India, tOPV given as per the EPI schedule protects about 99%, 98% and 91% of children from polioviruses type 1, 2 and 3 respectively[9].

Facts about OPV

- Taken orally as drops
- Easily administered
- Provides excellent gut (intestinal) immunity which helps prevent infection with wild virus
- Main preventive measure against polio

2.1.4 Risks associated with the use of oral polio vaccine

Although OPV is the vaccine of choice for polio eradication as it provides both humoral and intestinal immunity, a major concern about OPV is that it is a live attenuated virus vaccine and has ability to revert to a form that can cause paralysis. On very rare occasions, OPV can lead to vaccine-associated paralytic polio (VAPP) or vaccine-derived poliovirus (VDPV), especially in areas of low routine immunization coverage.

- **Vaccine Associated Paralytic Poliomyelitis (VAPP):** VAPP is an extremely rare event caused by a strain of poliovirus that has genetically changed in the intestine from the original attenuated vaccine strain contained in OPV. It is associated with a single dose of OPV administered to a child or can occur in a close unvaccinated or non-immune contact of the vaccine recipient who is excreting the mutated virus. It is estimated that OPV may cause VAPP in approximately 1 in 2.7 million doses of OPV administered. An estimated 250–500 VAPP cases occur globally every year (with 25–30 cases per year in India) of which more than 40% are caused by type 2 component of tOPV.

- **Vaccine Derived Poliovirus (VDPV):** As we are aware that oral polio vaccine contains a live, attenuated vaccine-virus. When a child is vaccinated, the weakened vaccine-virus replicates in the intestine and enters into the bloodstream, triggering a protective immune response in the child. Like wild poliovirus, the child excretes the vaccine-virus for a period of six to eight weeks. Importantly, as it is excreted, some of the vaccine-virus may no longer be the same as the original vaccine-virus as it has genetically altered during replication. This is called a vaccine-derived poliovirus.

[8,9] Comparative evaluation of immunogenicity and reactogenicity of bivalent oral poliovirus vaccine (bOPV) and trivalent oral poliovirus vaccine (tOPV) in the standard EPI schedule, with or without inactivated poliovirus vaccine (IPV) administration at DTP3 contact: A randomized controlled trial; Protocol No.: PBL/CR/2012/04/CT/bOPV (Unpublished)

So on very rare occasions, strain of poliovirus in OPV may change and revert to a form that may be able to cause paralysis (VDPV) in humans. There are three types of vaccine-derived polioviruses

1. circulating vaccine-derived poliovirus (cVDPV)
2. immunodeficiency-related vaccine-derived poliovirus (iVDPV)
3. ambiguous vaccine-derived poliovirus (aVDPV).

Types of VDPVs

(a) cVDPVs (circulating VDPVs) are associated with sustained person-to-person transmission and considered to be circulating in the community under conditions of low population immunity

(b) iVDPVs (immunodeficiency-related VDPVs) reported in immunodeficient patients who have prolonged infections after exposure to OPV

(c) aVDPVs (ambiguous VDPVs) currently have unclassifiable source (i.e., a single isolate from a healthy or non-immunodeficient person; environmental isolate without an associated AFP case)So on very rare occasions, strain of poliovirus in OPV may change and revert to a form that may be able to cause paralysis (VDPV) in humans. There are three types of vaccine-derived polioviruses:

Among the three types, cVDPV causes the sustained circulation. cVDPVs occur where there is low routine immunization or supplementary immunization coverage. This is a major risk factor for cVDPV emergence as there will be low population immunity in the area. A fully immunized population will be protected against both vaccine-derived and wild polioviruses. cVDPV outbreaks have the ability to become endemic, can spread in any under-vaccinated communities, and can be imported into other countries.

Remember

Once polio has been eradicated, use of the oral polio vaccine will need to be stopped to prevent re-establishment of poliovirus transmission due to vaccine-derived polioviruses. These vaccine-related cases are big challenge for the scientific community if the polio-eradication goal is to be achieved, and there is a need for prompt action to combat the issue. Switching to IPV is one option for this post-OPV era.

Due to the risk of cVDPVs, OPV must be phased out to secure a lasting polio-free world. This is because on very rare occasions, if a population is under-immunized, there are enough susceptible children for the excreted vaccine-derived polioviruses to begin circulating in the community. It is important to start with the removal of type 2-containing OPV (the trivalent OPV to bivalent OPV switch) because presently the type 2 component contained in trivalent OPV accounts for more than 90% of all cVDPV cases. There have been 43 cases of paralysis due to VDPVs since 2009 in India, of which 40 were due to type 2 VDPVs. The lower the population immunity, the longer these viruses survive. The longer they survive, the more they replicate, change, and exchange genetic material with other enteroviruses as they spread through a community.

2.2 Inactivated poliovirus vaccine (IPV)

Inactivated poliovirus vaccine (IPV) was developed in 1955 by Dr Jonas Salk. IPV is given by injection and is available only in trivalent form. IPV consists of inactivated (killed) poliovirus strains of all three poliovirus types (poliovirus types 1, 2 and 3). IPV is given intramuscularly using sterile injection equipment and procedures, and needs to be administered by a trained health worker. The IPV produces antibodies in the blood to all three types of poliovirus. It is highly effective in preventing paralytic disease caused by all three types of poliovirus. In the event of infection, these antibodies prevent the spread of the virus to the central nervous system and protect against paralysis. As IPV is not a live vaccine, it carries no risk of VAPP and VDPV. IPV provides excellent humoral immunity but does not provide mucosal intestinal immunity. However, studies in India shows that IPV given to OPV primed children boosts the mucosal intestinal immunity. IPV is one of the safest vaccines in use.

Facts about IPV

- Given through injection
- Currently IPV is used in most high-income countries due to its excellent safety profile and high efficacy.
- IPV is highly effective in producing immunity to poliovirus and protection from paralytic poliomyelitis.
- In countries still using OPV, it is given in addition to OPV
- Strengthens the immune system and provides further protection from polio.

2.3 Comparison of OPV and IPV

Oral polio vaccine (OPV)	Inactivated poliovirus vaccine (IPV)
• Inexpensive	• More costly than OPV
• Easy to administer (orally)	• Requires injection (can be administered only by health worker)
• Good humoral and mucosal intestinal immunity	• Very good humoral (blood) immunity,
• Confers transmission to contacts and secondary vaccination	• Does not confer transmission to contacts, thus, provide no secondary vaccination
• Rarely, can cause VAPP or VDPV	• No risk of VAPP or VDPV

3 THE POLIO ERADICATION ENDGAME STRATEGY AND RATIONALE OF INTRODUCING IPV INTO ROUTINE IMMUNIZATION

On 26 May 2012, the World Health Assembly declared the completion of poliovirus eradication to be a programmatic emergency for global public health and called for the development of a comprehensive polio endgame strategy. In response to this directive, the Global Polio Eradication Initiative (GPEI) developed this Endgame Strategic Plan 2013-2018.

Figure 5: Polio Endgame Strategic Plan

This plan has four objectives:

1. To detect and interrupt poliovirus transmission, including VDPVs;
2. To strengthen immunization systems and withdraw OPV;
3. To contain poliovirus and certify interruption of transmission; and
4. To plan how to utilize the legacy of the fight against polio.

The timeline is based on the epidemiology of polio globally, the recent rate and trend in OPV campaign quality improvements in the remaining polio-infected areas, new understanding of the risks posed by vaccine-related polioviruses, and the recent development of new strategies and tools for managing post-eradication risks.

The overall goal of this plan is to complete the eradication and containment of all wild, vaccine-related and Sabin polioviruses, such that no child ever again suffers paralytic poliomyelitis and also to plan for the backbone of the polio effort to be used for delivering other health services to the world's most vulnerable children.

Under this endgame plan to achieve and sustain a polio-free world, the use of oral polio vaccine must eventually be stopped worldwide, starting with OPV that contains type 2 poliovirus (OPV type 2). At least one dose of inactivated poliovirus vaccine (IPV) must be introduced into the routine immunization schedule as a risk mitigation measure before the proposed tOPV-bOPV switch.

The endgame planning document also frames the process for planning the polio 'legacy', building on the polio programme's achievements and experience, to sustain a polio-free world after programme closure and to ensure that the assets, learning, capacities and workforces developed in the fight against polio are applied to other major public health challenges.

3.1 The polio endgame strategy

The plan addresses the endgame through three distinct steps (Figure 6):

- **Step 1. Introduction of IPV in routine immunization by October 2015:** By end 2015, introduce at least 1 dose of IPV into all routine immunization systems, at least 6 months before the switch from tOPV to bOPV (containing poliovirus types 1 and 3).

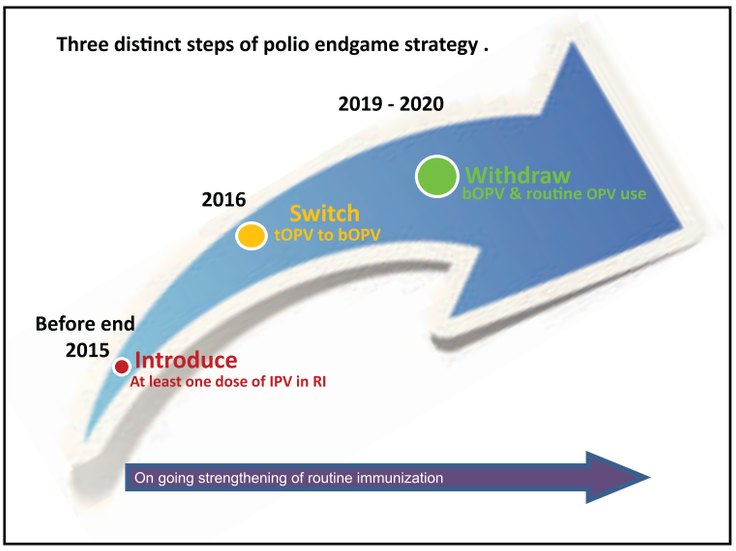


Figure 6: Steps of the polio endgame strategy

- **Step 2. tOPV-bOPV switch by April 2016:** From 2016, switch from tOPV to bOPV (which does not contain type 2 Sabin virus) in routine immunization and polio campaigns.

- **Step 3. Withdrawal of routine OPV use:** Plan for the eventual withdrawal of all OPV in routine use by 2019–2020.

3.2 Rationale for the introduction of IPV into routine immunization programme

The primary purpose of introducing IPV into routine immunization is to boost population immunity against type 2 poliovirus during and after the planned global withdrawal of OPV2 and switch from tOPV to bOPV. The vaccine will also facilitate the interruption of transmission with the use of monovalent OPV type 2 in the case of outbreaks, hasten eradication by boosting immunity to poliovirus types 1 and 3, and mitigate the risk of emergence and transmission of cVDPV2.

The primary purpose of the IPV dose is:

- To maintain immunity against type 2 poliovirus during and after the planned global withdrawal of OPV2 and switch from tOPV to bOPV.
- To boost both humoral and mucosal immunity against poliovirus types 1 and 3, which may also hasten the eradication of these WPVs.
- To reduce VAPP risks

Evidence indicates that one dose of IPV may reduce risk by protecting individuals against paralytic polio should they be exposed to cVDPV2 or WPV2 or by enhancing the population immunity that can be achieved through use of mOPV2 in the setting of an outbreak of type 2 poliovirus post OPV2 cessation. Because a proportion of the population will already be immune as a result of having received IPV, the immunity levels reached after a dose of mOPV2 will be higher than the immunity levels reached with a single dose of mOPV2 in a completely susceptible population.

3.3 Withdrawal of type 2 component of oral polio vaccines (OPVs): Switch from trivalent OPV (tOPV) to bivalent OPV (bOPV)

The endgame strategy plan mandates that all countries must eventually stop use of OPV beginning with removal of the type 2 component of tOPV through a globally synchronized switch to bOPV (containing only types 1 and 3) for routine immunization and all supplementary immunization activities. The global tOPV-bOPV switch, expected to occur in April 2016, has to be a globally coordinated process because any use of tOPV after April 2016 could jeopardize polio eradication by generating circulating vaccine-derived polioviruses from the type 2 component of the vaccine.

Although no wild poliovirus type 2 has been recorded over the past years, the risk of paralytic polio disease due to the type 2 component of OPV now outweighs its benefits. This switch is necessary because replacing tOPV with bOPV is the key to ensuring the eradication of type 2 polio Sabin virus, which in turn will reduce the risk of new cVDPV type 2 outbreaks after OPV type 2 cessation, if a cVDPV2 appears.

Primary objectives of switch

- Successfully recall tOPV and introduce bOPV in April 2016
- Minimize tOPV wastage after switch
- Ensure all children are vaccinated (avoid tOPV stock-outs before and bOPV stock-outs after the switch)
- Validate that the country is free of tOPV

Once the switch is made, tOPV will no longer be used anywhere in the world, and manufacturers will no longer supply tOPV. Selected high risk countries will conduct SIAs with tOPV in the months leading up to the switch.

3.4 In the endgame, polio eradication activities and strengthening routine immunization will be mutually beneficial

- IPV will be introduced through routine immunization delivery systems. The use of routine immunization as the primary way to deliver IPV will be critical to secure a polio-free future and to help sustain the gains made by the eradication efforts.

- Strengthening routine immunization is necessary to achieve and maintain high population immunity against polioviruses, especially type 2, after OPV type 2 is withdrawn. The magnitude, number and length of both WPV and cVDPV outbreaks are closely correlated with weaknesses in routine immunization systems.

- This is an opportunity for the global polio eradication initiative to use its infrastructure to contribute more systematically to strengthening routine immunization systems.

- One of the goals is to improve infant routine immunization coverage in a group of focus countries, which have some of the lowest routine immunization coverage levels in the

4 INTRODUCTION OF IPV IN ROUTINE IMMUNIZATION PROGRAMME IN INDIA

4.1 Global scenario

IPV was licensed in 1955 for use as a stand-alone and combination vaccine and was the only polio vaccine available until licensure of OPV in 1961–1962. IPV has been successfully used in many European countries over many years.

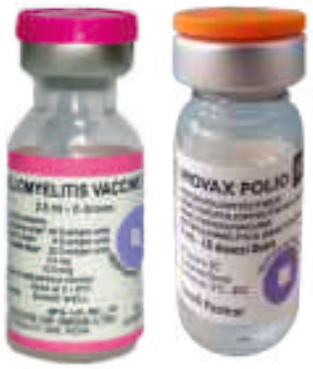


Figure 7: IPV vials (5-dose and 10-dose)

As the incidence of wild polio diminishes across the world, the optimal use of different available vaccines (both OPV and IPV) in different settings is constantly being assessed to prevent the risk of paralytic polio associated with continued routine use of OPV and stop poliovirus transmission.

Although previously most polio eradication efforts were centred on campaigns, WHO now recommends that at this stage in polio eradication, at least one dose of IPV should be added to the national immunization schedule of countries where currently only OPV is being used. In polio-endemic countries and in countries at high risk of wild poliovirus importation and subsequent spread, WHO recommends an OPV birth dose (zero dose) followed by a primary series of 3 OPV and at least 1 IPV doses.

Routine vaccination with IPV alone should be used only in countries with high immunization coverage (>90%) and at low risk of wild poliovirus importation and spread. In the regions of the world where wild poliovirus has been eliminated, moving to an IPV or IPV/OPV sequential schedule will reduce or eliminate the risk of VAPP and outbreaks of cVDPVs, as well as increase the likelihood of countries agreeing to stop administering OPV after eradication is achieved.

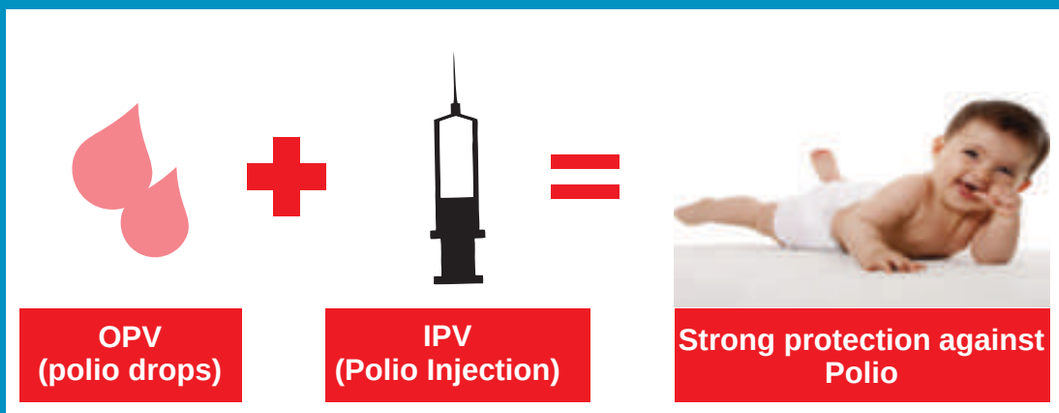
Remember

IPV is not replacing OPV, it is a pre-requisite for tOPV-bOPV switch.

New evidence now demonstrates that adding a dose of IPV is even more effective at stopping the virus and protecting children, than using OPV alone. Introducing IPV is a key element of the endgame plan and global readiness to manage risks associated with OPV type 2 withdrawal. The endgame plan calls for the introduction of IPV in all OPV-only using countries by the end of 2015. The primary role of IPV will be to maintain immunity against type 2 poliovirus while removing OPV type 2 globally.

Solid evidence exists supporting closing of immunity gaps and substantial boosting of antibody titres to types 1 and 3 (in addition to type 2 as described previously) when IPV is administered after OPV. To complete eradication and get the benefits of both, IPV and OPV should be used together. IPV should be used with OPV in routine schedules to increase immune responses and to decrease the circulation of wild poliovirus in countries in which transmission has not been stopped.

When IPV is administered after a few doses of OPV, the IPV not only enhances protection against paralytic disease but also boosts intestinal immunity, even more than an additional dose of OPV would provide. Thus, combining IPV with OPV provides the advantages of both vaccines: strong intestinal immunity and antibody protection against all three serotypes. This combination gives both the child and the child's community the best protection.



4.2 Indian scenario

In 2013, the India Expert Advisory Group recommended that the Indian Council of Medical Research (ICMR) expert group should study the proposal for the inclusion of IPV in India. The expert group met and the Standing Technical Committee then reviewed the available evidence and strategy of endgame plan. The following recommendations of the India Expert Advisory Group were endorsed by the National Technical Advisory Group on Immunization (NTAGI) in June 2014:

Remember

- IPV will be introduced across all Indian states/union territories in October 2015.
- Most of the vaccines in India since 1985 have been introduced in phases such as hepatitis B or pentavalent vaccine.
- After 30 years, IPV is the vaccine that is planned to be introduced pan-India in one go, i.e. without any phased approach.

- India should work towards a withdrawal of OPV2 from the immunization programme and comply with timelines of the globally synchronized tOPV to bOPV switch.
- India should introduce a single, full dose of IPV into the routine immunization schedule in all states, to be given at 14 weeks of age with DPT3-containing vaccines; and
- Routine immunization needs to be strengthened to ensure high coverage with all vaccines, including IPV.

These recommendations are far reaching in their vision as they give a new direction to India's polio eradication programme and reemphasize the importance and need to strengthen the routine immunization service delivery mechanism.

1 Infant
IPV injection
along with third dose of OPV in routine immunization at 14 weeks

Based on recommendations of the Indian Academy of Paediatrics (IAP), IPV is being used in the private sector, in addition to OPV schedules for a decade.

The vaccine is now planned to be introduced in the national immunization schedule in October 2015. With the roll out planned for the third quarter, India is within the timeline required for initiation of procurement procedures that will ensure vaccine availability. Catch-up strategies for IPV vaccination are not recommended for children born before the IPV vaccine introduction date because these children would have already started the OPV vaccination schedule and would therefore be protected against type 2 poliovirus. The primary purpose of the IPV dose is to maintain immunity against type 2 poliovirus during and after the planned global withdrawal of OPV2 and switch from tOPV to bOPV.

4.3 Rationale for introducing at least one dose of IPV with OPV schedule prior to OPV2 cessation

Introduction of at least one dose of inactivated poliovirus vaccine (IPV) into routine immunization schedule is a strategy to mitigate the potential risk of re-emergence of type 2 poliovirus following the withdrawal of Sabin type 2 strain from oral polio vaccine (OPV). Combined and sequential schedules of OPV and one dose of IPV have generated high seroconversion rates, and a number of studies have shown use of both vaccines simultaneously induces better immune responses than either vaccine alone[10].

A WHO Position Paper on polio vaccines (published on 28 February 2014) confirms that WHO no longer recommends an OPV-only vaccination schedule. For all countries using OPV only, at least one dose of IPV should be added to the schedule

One dose of IPV closes the immunity gap against type 2 poliovirus: A study conducted in Cote d'Ivore demonstrated that in previously tOPV vaccinated infants who were seronegative had seroconversion rates against type 2 poliovirus of 100% after one dose of IPV versus 53% after tOPV[11]. A similar study in Moradabad, India demonstrated that a single dose of IPV among children who had previously been immunized with tOPV but were seronegative substantially improved seropositivity rates against types 2 and 3 wild poliovirus (100% and 91% seroconversion, respectively)[12].

One dose of IPV and OPV result in additive immunity: Studies in Baltimore and Buffalo in the United States showed that equivalent serologic responses were seen after two doses of IPV, two doses of OPV, and a dose of IPV followed by a dose of OPV[13].

One dose of IPV boosts intestinal immunity: A recent study conducted in India found that in infants and children (aged 6–11 months, 5 and 10 years) with a history of multiple doses of OPV, a single dose of IPV boosted intestinal mucosal immunity and reduced the prevalence of poliovirus excretion (depending on age group) by 39–76% after an OPV challenge, compared to no polio vaccination[14].

[10] **http://www.who.int/wer/2014/wer8909.pdf**

[11] **Moriniere BJ, Van Loon FPL, Rhodes PH, Patriarca PA, Moriniere BJ, Klein-Zabban M-L, et al. Immunogenicity of a supplemental dose of oral versus inactivated poliovirus vaccine. The Lancet. 1993;341(8860):1545–50.**

[12] **Estivariz CF, Jafari H, Sutter RW, John TJ, Jain V, Agarwal A, et al. Immunogenicity of supplemental doses of poliovirus vaccine for children aged 6-9 months in Moradabad, India: a community-based, randomised controlled trial. Lancet Infect Dis. 2012 Feb;12(2):128–35.**

[13] **Faden H. Results of a clinical study of polio vaccine: the Buffalo experience. Pediatr Infect Dis J. 1991 Dec;10(12):973–5.**

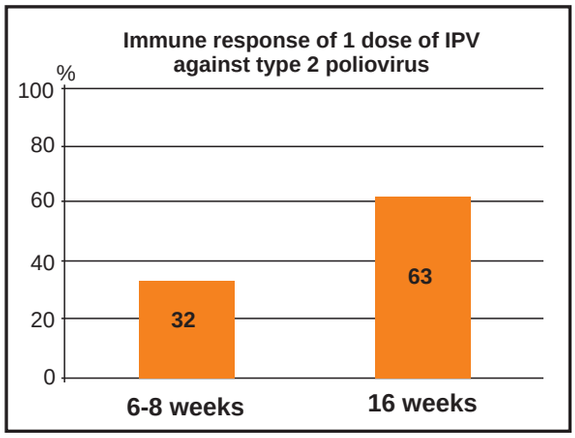
4.4 Rationale for introducing single dose of IPV at 14 weeks

IPV administration is recommended at 14 weeks of age because it provides the optimal balance between vaccine efficacy and early protection. If one dose of IPV is used, it should be given from 14 weeks of age because this is the age point when maternal antibodies have diminished and immunogenicity is significantly higher.

SAGE Recommendation:
In November 2013, the SAGE made a formal recommendation on the immunization schedule. Based on a detailed review of evidence, one dose of IPV be added when the third dose of DPT3 is given, i.e., at 14 weeks or at a contact soon thereafter.

4.4.1 Administering IPV earlier than 14 weeks of age is not recommended because

- Immunogenicity is significantly higher after 14 weeks than at earlier age points: Studies have shown that IPV is substantially less effective against type 2 poliovirus when it is given to newborns and infants 6-10 weeks old.
- Evidence suggests that a dose of IPV given at DPT1 contact protects only 32-39% of infants aged 6-8 weeks against poliovirus type 2. In contrast, if the dose is given at DPT3 contact when the infant is 16-weeks-old (4 months), it protects about 63% of infants. Most notably, seroconversion was higher when IPV was administered at 4 months of age (63%) in a recent study from Cuba compared to older studies where IPV was given at 6-8 weeks of age (32%-39%)[15].



- The higher seroconversion at 4 months of age is likely related to lower circulating maternal antibodies and hence reduced interference with immune response compared to that observed at younger ages.
- The scientific rationale for administering IPV with DPT3 is that IPV performance is negatively affected by the higher levels of maternally-derived antibody at younger ages when DPT1 and 2 are typically administered, even after taking into account the potentially lower vaccine coverage due to dropout rates between DPT1 and DPT3.
- Protection against VAPP: The last line of evidence supporting efficacy against paralysis relates to data demonstrating elimination of VAPP from Sabin strains in countries that introduced IPV at 3 months of age before the first dose of OPV[16]. The hypothesis was that IPV induced sufficient humoral immunity thus preventing paralysis from Sabin strains that revert to a neurovirulent form.

[14]**World Health Organization, unpublished data, presented [Internet]. [cited 2014 Apr 21]. Available from:** http://www.who.int/immunization/sage/meetings/2012/november/3__SAGE_WG_Scientific_Evidence22Oct2012.pdf

[15]Estivariz CF, Pallansch MA, Anand A, Wassilak SG, Sutter RW, Wenger JD, et al. Poliovirus vaccination options for achieving eradication and securing the endgame. Curr Opin Virol. 2013 Jun;3(3):309–15.

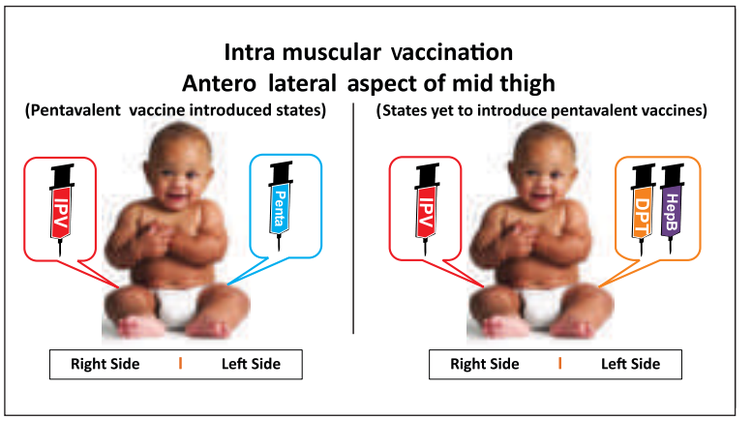
[16]Sutter RW, Kew OM, Cochi SL, Aylward RB. 28 - Poliovirus vaccine—live. In: Plotkin SA, Orenstein WA, Offit PA, editors. Vaccines (Sixth Edition) [Internet]. London: W.B. Saunders; 2013. p. 598–645. Available from:
http://www.sciencedirect.com/science/article/pii/B9781455700905000355

4.4.2 Risks associated with introducing IPV later than 14 weeks include

- Administering IPV at later immunization visits (e.g., 9 months measles visit) is not recommended because it leaves children unprotected for a longer period of time. Children entering the routine immunization programme late should be given IPV at the first immunization contact after 14 weeks of age.
- The purpose of IPV is to give infants protection against type 2 vaccine-derived polioviruses (VDPVs) after the switch from tOPV to bOPV. This IPV dose will be the only protection an infant will receive against type 2 poliovirus. The child is therefore vulnerable until vaccinated. Waiting until 9 months to administer IPV would mean leaving a large pool of susceptible hosts (all children aged 0–8 months) to be infected by or to transmit type 2 VDPV.
- Reaching fewer children due to significant dropout rates between the 14 weeks visit and 9 months of age.

4.5 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. The NTAGI recommends the administration of a 0.5 ml of IPV by intramuscular route at 14 weeks, along with third dose of OPV and pentavalent or third dose of OPV, DPT and HepB. There will be no change in the current OPV schedule.



The vaccine shall also be administered to all children of more than 14 weeks of age who are still eligible for third dose of OPV and pentavalent or third dose of OPV, DPT and HepB. This will ensure that children who are brought late for the third dose of OPV and pentavalent or third dose of OPV, DPT and HepB also get an opportunity to receive the IPV dose maximum up to 1 year of age.

4.6 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 IPV.

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. (2) DPT vaccine can be given up to 5-6 years (not beyond 7 years) of age (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. (4) Measles vaccine can be given up to 5 years of age (5) JE vaccine can be given up to 15 years of age. (6) IPV vaccine should be given at 14 weeks along with other due vaccines. In delayed cases, IPV can be given maximum up to 1 year of age.
6 weeks	OPV1/Pentavalent1 or OPV1/DPT1/HepB1	OPV1/Pentavalent1 or OPV1/DPT1/HepB1	
10 weeks	OPV2/Pentavalent2 or OPV2/DPT2/HepB2	OPV2/Pentavalent2 or OPV2/DPT2/HepB2	
14 weeks	OPV3/Pentavalent3 or OPV3/DPT3/HepB3	IPV, OPV3/Pentavalent3 or IPV/OPV3/DPT3/HepB3	
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)	
5-6 years	DPT second booster dose	DPT second booster dose	
10 years	TT	TT	
16 years	TT	TT	

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.

4.7 Key facts about IPV

Type	Inactivated (killed) poliovirus vaccine (IPV) with types 1, 2 and 3 antigens
Formulation	IPV may contain formaldehyde, as well as traces of streptomycin, neomycin or polymyxin. Some formulations of IPV contain 2-phenoxyethanol (0.5%) as preservative. IPV formulations do not contain thiomersal (incompatible with IPV antigenicity).
Composition	Each dose contains (active ingredients, produced in VERO cells) • Poliovirus type 1 strain Mahoney (inactivated) - 40 D antigen Unit • Poliovirus type 2 strain MEF-1 (inactivated) - 8 D antigen Unit • Poliovirus type 3 strain Saukett (inactivated) - 32 D antigen Unit Other components: 2-phenoxyethanol, formaldehyde Medium 199 Hanks diluent solution; IPV may contain traces of streptomycin, neomycin or polymyxin B

Presentation and dosage form	• IPV is a liquid vaccine. • No reconstitution is required. • In UIP, IPV will be available in 5-dose or 10-dose vials.
Storage temperature	• IPV is freeze-sensitive vaccine. It should be stored at temperatures ranging between +2°C and +8°C in the basket of an ice-lined refrigerator (ILR). • Do not freeze IPV • It is important to use conditioned ice packs to prevent freezing during transportation. • The Shake Test is not applicable to IPV vaccine. Discard the vial/s if there is any doubt of vaccine getting frozen.
Age group for vaccination	The IPV in UIP is recommended for infants along with third dose of OPV at 14 weeks (3½ months) to maximum upto 1 year of age.
Dosage and route	• 0.5 ml using auto-disable (AD) syringe available in programme. • Intramuscular in anterolateral aspect of mid-thigh (right thigh)

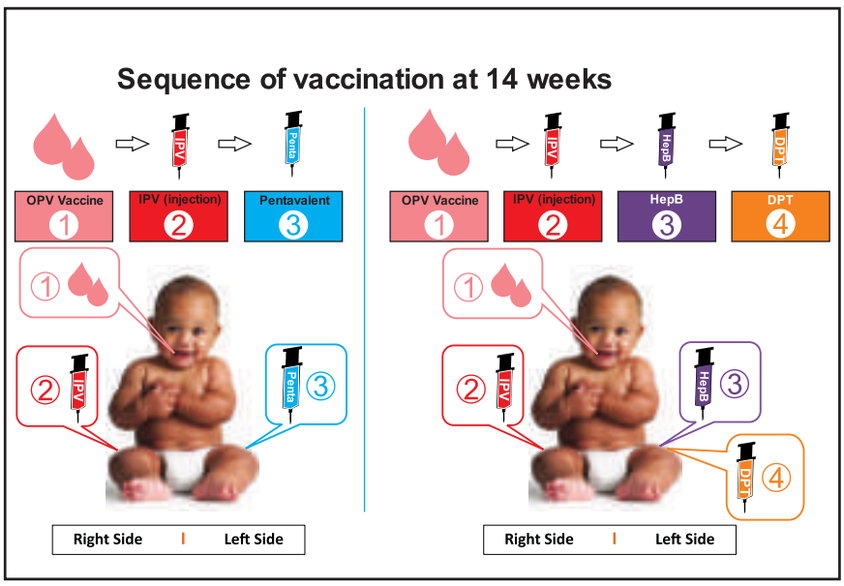
Instructions to parents for correctly holding the baby for an intramuscular injection

- **IPV will be administered as an intramuscular injection in anterolateral aspect of mid thigh**
- **One of the baby's arms embraces the parent's back and is held under the parent's arm.**
- **The other arm and legs are firmly controlled by the parent's hand**
- **Give penta on left thigh and IPV on right thigh**

Immunogenicity, efficacy and effectiveness	• The immunogenicity of IPV schedules depends on the age at administration, in addition to the number of doses, due to interference by maternal antibodies. • IPV can reduce the quantity and duration of virus shedding in stool samples, which may contribute to a reduction in transmission.

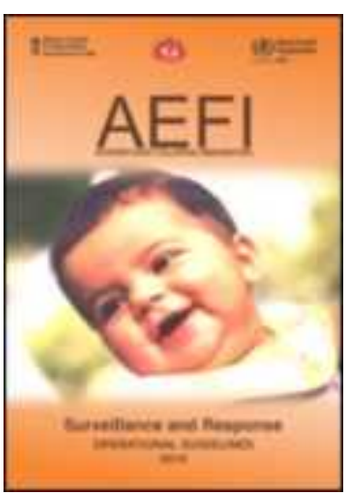
Co-administration with other vaccines

- IPV can be administered at the same time as the other vaccines in the programme. However, different syringes and different sites (minimum distance of 2.5 cm between injection sites) should be used.
- IPV can be administered to prematurely born infants (i.e., <37 weeks gestation) at the recommended age concurrent with other routine vaccinations.
- At 14 weeks contact, vaccinate child in the following sequence:



Adverse events following immunization

- IPV is a very safe vaccine in humans, whether used alone or in combination with other vaccines.
- No serious adverse events have been reported with IPV. Minor local reactions, such as redness and tenderness, may occur following IPV.
- Introduction of IPV (or any other new vaccine) may coincide with an increased reporting of adverse events following immunization (AEFIs) in the states and districts. Such AEFI cases, inclu ding those following administration of IPV, if any, should be reported as per the Government of India's revised “AEFI Surveillance and Response Operational Guidelines”. Increased reporting of AEFIs should not be interpreted as an issue with the vaccine/vaccination, it could well be a result of sensitive and improved surveillance due to extensive training of health workers at all levels. The health authorities should make all efforts to manage the adverse event (if any) followed by investigation of AEFIs as per guidelines.



Contraindications	• IPV should not be administered to children with a documented/known allergy to streptomycin, neomycin or polymyxin B, or with a history of an allergic reaction following a previous injection of IPV.

Open vial policy	• Open vial policy is applicable to IPV. • The guideline, when followed correctly, ensures effective utilization of vaccines and minimizes wastage • Vaccine vials opened in a fixed or outreach session can be used at more than one immunization session for up to four weeks, provided o the expiry date has not been reached; o the vaccine vial monitor (VVM) has not reached the discard point; o vaccines are stored in appropriate cold chain conditions, both during transportation and in the cold chain storage point; o vaccine septum has not been submerged in water or contaminated in any way. • The states need to have a robust alternate vaccine delivery mechanism to ensure effective implementation of the open vial policy.

4.8 Challenges

The introduction of a new vaccine into any routine immunization schedule poses challenges at various levels. In India, the health system provides a strong infrastructure for delivering these services to all parts of the country.

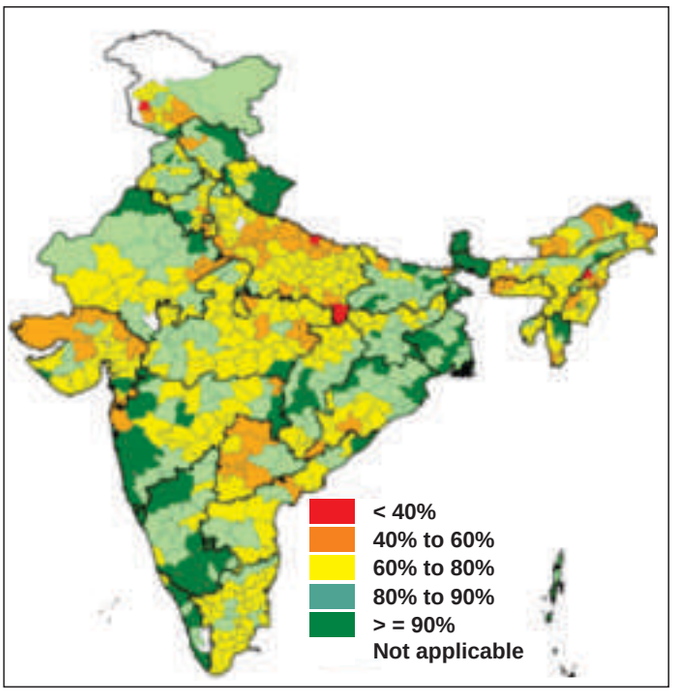


Figure 8: DPT3 coverage, India, DLHS 4/AHS 3

As shown in figure 8, the coverage in India for DPT3 as determined by various surveys/evaluations is around 70%. While the goal for any immunization program is to vaccinate every child, the current estimated coverage of DPT3 allows for the introduction of IPV. Variations in coverage exist between states and districts. Routine immunization strengthening is a major activity being undertaken through special frontline worker trainings, which are focused on improving mobilization of children to sessions. These interventions will contribute to improving the coverage further and hence increase the number of children administered IPV.

5 OPERATIONALIZATION OF IPV INTRODUCTION IN INDIA

5.1 Preparedness assessment for IPV introduction in India

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. This initially involves top-down macroplanning at the state level, followed by bottom-up microplanning and detailing precise logistic and financial needs for each district and sub-district, starting from the more peripheral levels and moving towards the higher levels. Timely trainings/orientation/media briefing and information sharing with community helps in smooth launch at the level of health care service providers, mobilizers and community settings.

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.

5.1.1 New vaccine preparedness assessment

The MoHFW, Government of India, has very recently developed and disseminated state- and district-level preparedness assessment checklists prior to pentavalent introduction. These checklists have been developed to support the state and district programme managers in assessing critical information prior to introduction of the new vaccine.

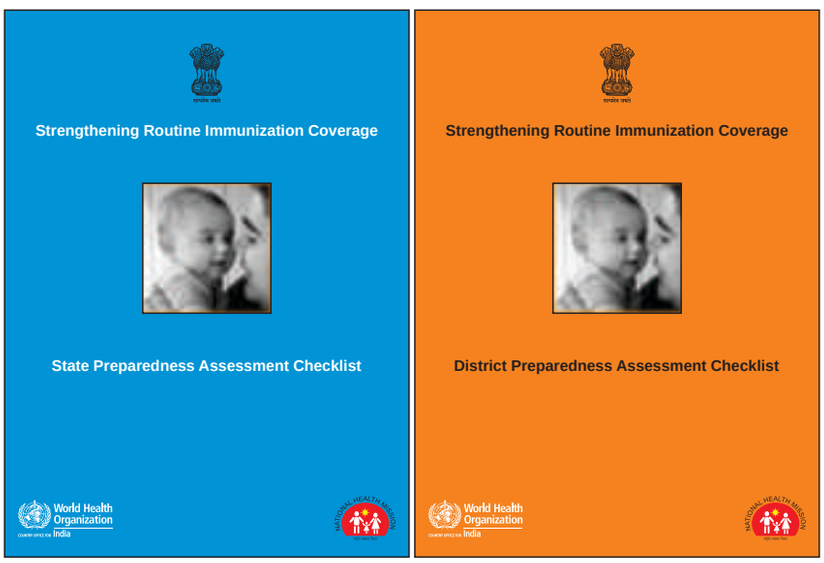


Figure 9: State and district preparedness assessment checklists to strengthen routine immunization coverage

These checklists help in assessing and identifying strengths and weaknesses at state, district and block levels to take corrective actions for effective and successful introduction of any new vaccine such as Hib-containing pentavalent vaccine or IPV in the UIP in respective states. WHO and UNICEF assisted MoHFW in reviewing the preparedness based on information provided by the states in the checklist. Table 1 lists the 14 components incorporated in the checklists.

Table 2: Components of state & district preparedness assessment checklists

1. Human resources vitals	2. Background information
3. Microplanning status	4. Training status
5. Recording & reporting practices	6. Vaccine coverage and wastage
7. Vaccine management, transport and logistics	8. Waste management and injection safety
9. Monitoring and evaluation	10. AEFI
11. Mobilization	12. Advocacy and communication
13. Surveillance	14. Cold chain maintenance
15. General impressions	16. Additional remarks/comments

5.2.1. Vaccine calculation

The annual number of IPV doses needed is the product of the target population, one dose per child and wastage factor.

Every beneficiary will require just one dose at 14 weeks or in delayed cases maximum up to 1 year of age. Considering the standard vaccine wastage rate of 10% for 5-dose vials and 10-dose vials and buffer stock of 25%, the annual vaccine requirement in the first year can be calculated as follows:

(Number of beneficiaries X Number of doses X wastage factor) + (number of beneficiaries X 0.25)

Vaccine stores at all levels (state, regional, district, primary health centers (PHCs), community health centers, other cold chain storage points) need to forecast their vaccine needs for the stipulated time period to ensure that the right amount of vaccines, logistics and cold chain equipment are available to vaccinate all eligible infants at a given time in a given area. Each of these levels should monitor the stock of vaccine and syringes in order to assess the lead-time and re-ordering levels.

5.2.2. Wastage rate and buffer stock

IPV introduction recommends indicative wastage values of 10% for both 5-dose vials and 10-dose vials. The buffer stock recommended is 25% for the first year of vaccine introduction and in subsequent years, the data on coverage and vaccine utilization can be analyzed and appropriate buffer stocks calculated for the following years. All efforts should be made to minimize vaccine wastage at all levels.

The open vial policy is recommended for IPV. The buffer stock is meant for managing sudden and unexpected shortages. The amount of buffer stock recommended is generally 25% of the annual requirement. Buffer stock is supplied only in the first year of vaccine introduction.

$$\text{Wastage rate} = \frac{\text{doses supplied - doses administered}}{\text{doses supplied}} \times 100$$

Summary: Wastage permissible for all vaccines in routine immunization

Vaccine	Maximum acceptable wastage
BCG	50% and the wastage multiplication factor for calculation is 2.0
Measles and JE	25% and the wastage multiplication factor for calculation is 1.33
IPV, OPV, Pentavalent Hepatitis B, DPT, TT	10% for all vaccines eligible for reuse under the open vial policy The wastage multiplication factor for calculation is 1.11

5.2.3. Estimating vaccine and syringes needed

The auto-disable (AD) syringes (0.5 ml) available under the UIP are to be used to administer IPV as well. As each AD syringe is packed separately, hence, maximum permissible wastage rate for AD syringes equal to vaccine doses supplied including wastage. IPV is a liquid vaccine, hence no requirement of reconstitution syringe.

5.2.4 Cold chain space and inventory

The cold chain infrastructure in India is a wide network of cold chain stores consisting of government medical supply depots (GMSD), state, regional/divisional vaccine stores, and district and PHC/CHC vaccine storage points. The cold chain network in the country has been the backbone to ensure that right quantity and right quality of vaccine reaches the target population.

In states that have introduced the pentavalent vaccine, cold chain space availability has increased due to the reduced requirement of DPT and hepatitis B vaccines. With this freed capacity, there is no constraint envisaged on the cold chain capacity for storage of IPV.

The cold chain inventory should be regularly reviewed and status of the same should be updated in the National Cold Chain Management Information System (NCCMIS).

5.2.5 Cold chain monitoring

IPV is heat and freeze sensitive vaccine and loses its potency when exposed to temperatures outside the range recommended by the manufacturer. Its capacity to produce neutralizing antibodies is destroyed by both heat and freezing. The heat impact on vaccines is cumulative. Proper storage of vaccines and maintenance of the cold chain during storage and distribution are essential to prevent the loss of potency. Once a vaccine loses its potency, this cannot be regained. Damaged vaccines should be discarded according to the guidelines.

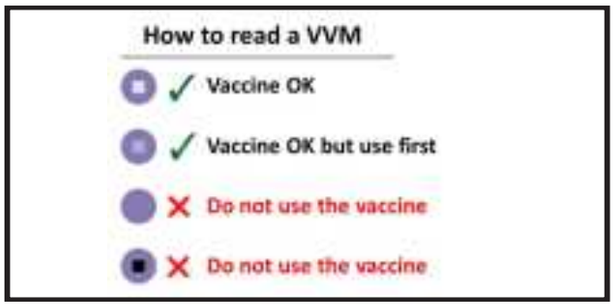


Figure 10: Interpretation of VVM

All IPV vaccine vials have a vaccine vial monitor (VVM). The VVM registers cumulative heat exposure, and changes from light to dark. Before use, check the VVM on each vaccine vial. If inside square is the same colour, or darker than the outer circle (stage 3 or 4), do not use the vaccine. The colour of VVM on IPV vial changes faster than the other vaccines.

5.2.6 Vaccine storage

To ensure efficacy of the vaccines, proper storage and packing are essential. The following are recommended for vaccine storage:

- In top-opening refrigerators (ice-lined): store IPV and other freeze-sensitive vaccines on top.
- IPV could be damaged if placed in direct contact with frozen ice packs that were inadequately conditioned, therefore water ice packs should be conditioned before use.

Vaccine/Diluent storage in ILR

Figure 11: Vaccine/diluents storage in ILR

5.2.7 Conditioning of water ice packs

In order to ensure correct storage of vaccines, the following procedure should be followed

- Ensure that the insulated vaccine carriers are clean before use and at end of the day.
- Use a packing table, and remove water ice packs from freezer and place on table to defrost. Packs are ready to use when there are physical signs of thawing; no ice and drops of water on surface, and liquid is observed inside.
- Dry the packs and line the walls of the insulated vaccine carrier with them.
- Place the vaccines inside and ensure that the container is properly closed.
- Allowing ice packs to thaw means that the initial freezing temperature is lost, so the temperature in the insulated carrier does not drop below 0°C.
- Properly conditioned water ice packs constitute the best method to maintain the temperature of the insulated carriers and cold boxes.
- There should be sufficient ice packs to ensure that the vaccines are totally surrounded during transportation.

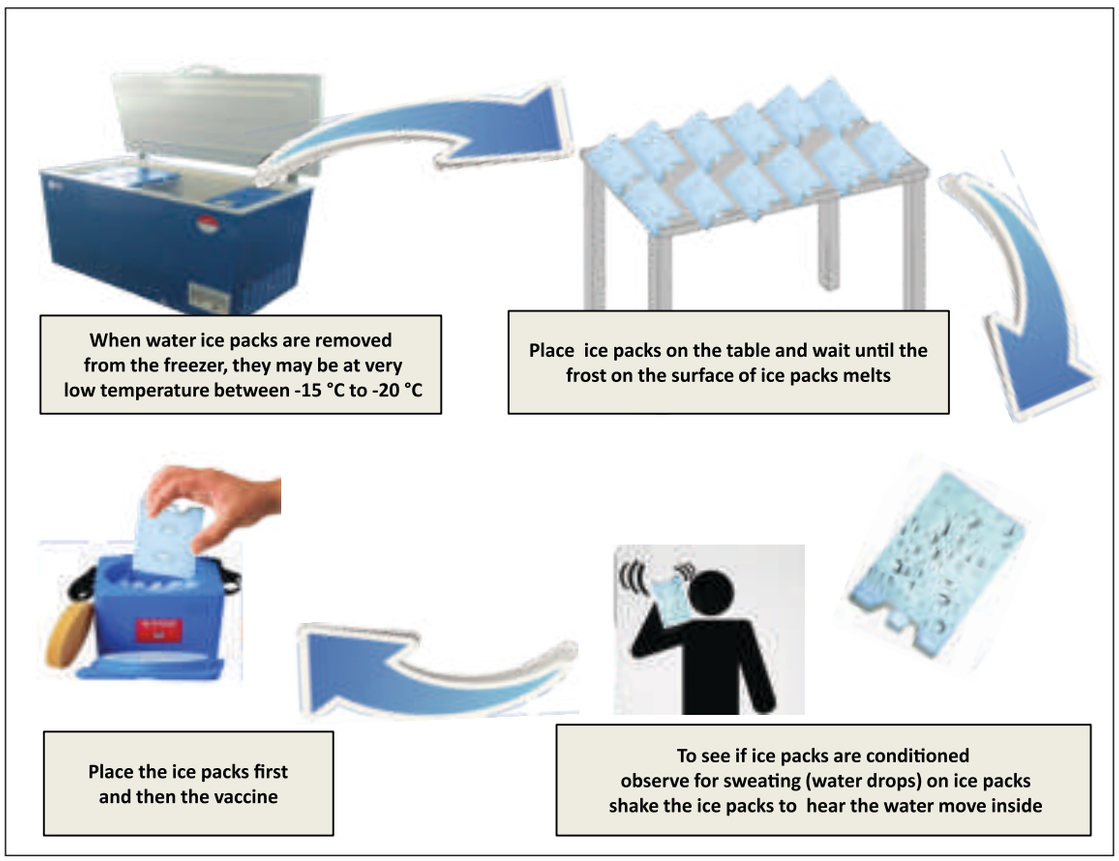


Figure 12: Conditioning of ice packs

5.2.8 IPV stock management (inventory control)

The inventory system should ensure that units with the nearest expiry date are used first in a system known as FEFO (first-expired, first-out). A maximum of 1 month is recommended for storage of IPV in a health facility. Expiry date should always be checked whenever a vial is opened. Never use vaccines after the expiry date. The heath worker should remember that writing date is mandatory on vial once it is opened.

6 TRAINING FOR HEALTH CARE STAFF

The successful introduction of IPV vaccine will largely depend upon the training conducted for all levels of health functionaries. Health-care providers are not only responsible for handling and administering the vaccine but are also a major source of information for parents and the community. A good training gives confidence to the health workers to introduce new vaccines

All sessions must be interactive. Methodology should include PowerPoint presentations, role plays, exercises and interactive discussions. Each batch should not have more than 40 participants. In large states/districts more than one batch may have to be planned. Trainers should be patient listeners to any feedback from the trainees.

Remember

- IPV introduction sensitization training should be conducted as per guidelines.
- The trainings on IPV introduction should not be clubbed/tagged with other ongoing training or review meetings.
- All trainings will have some common and some cadre-specific messages. Key tips/messages for participants have been incorporated into respective agendas.without any apprehension and ambiguity.

Health-care personnel who require training include district immunization officers (DIOs), medical officers (MOs), cold chain handlers, supervisors, data managers and frontline health workers. The officials and staff of the Department of Women and Child Development such as child development project officers (CDPOs), integrated child development services (ICDS) supervisors and anganwadi workers also need to be trained at the same time. In addition, plans should be drawn up to orient the faculty of paediatrics and preventive and social medicine departments in medical colleges as well as professional bodies (IAP, IMA) involved in immunization service delivery.

6.1 Training approach for IPV introduction

Cascaded trainings are envisaged for building capacity of all cadres of staff involved in routine immunization. These trainings will be conducted beginning at least four months before IPV introduction. Training activities will commence at the national level, with a one-day orientation of state level officers on IPV introduction. Each state where IPV is to be introduced is expected to conduct five training workshops (one-day to half-day duration each). This excludes IPV advocacy and launch workshop.

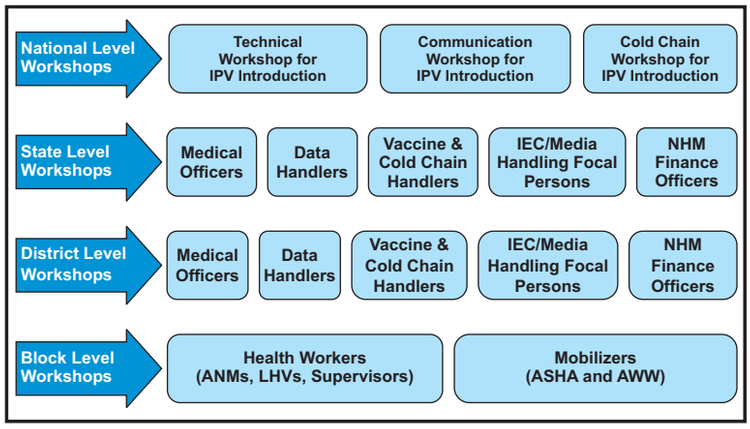


Figure 13: Training plan for IPV introduction

Subsequently, these state level officers will conduct trainings in their respective states, beginning with a state level training for district level officials. Further, the district level officers will conduct district-level training for block medical officers of their district. These medical

officers will, in-turn, be responsible for training health workers, including ANMs, supervisors and cold chain handlers.

Instructions for health workers on administering IPV

Step 1: Check and write the following details of IPV before opening the vial.
- Date and time of opening the vial as per open vial policy
- Manufacturer name
- Manufacturing date
- Expiry date
- Batch number
- VVM status

Step 2: Before administration of IPV, check the age of the beneficiary.
- Single dose of IPV should be given alongwith third dose of OPV and Pentavalent or third dose of OPV, DPT and HepB. In delayed cases IPV can be given maximum up to 1 year of age.

Step 3: Administer 0.5 ml of the vaccine with AD syringe.
Remember IPV is a liquid vaccine so no reconstitution is required.

Step 4: Administer the vaccine as an intramuscular injection in the anterolateral aspect of the mid-thigh (right side).

Step 5: Immediately cut the used AD syringe using the hub cutter.

Step 6: Dispose of the cut syringe and other immunization waste as per waste disposal guidelines.

Step 7: Record the IPV dose in the revised MCP/immunization card, tally sheets, registers, etc.

It is important to ensure sensitization of paediatricians/medical practitioners through involvement of Indian Medical Association (IMA), Indian Academy of Pediatrics (IAP) and Indian Public Health Association (IPHA).

Every opportunity should be utilized for sensitization of new vaccine introduction (IPV). For example, state/district task force meetings and medical officers' trainings are ideal to discuss IPV introduction topics. The state, district and sub-district programme managers should remember that trainings should exclusively be held as per timelines recommended in this guideline.

Training materials will be developed based on findings from post-introduction evaluation of pentavalent vaccine and a preparedness assessment that will be conducted before the introduction of IPV. These will include standardized power-point presentations from operational guidelines, handouts/information kits for medical officers and health workers that include FAQs on IPV. These materials could be translated in the local language and be used appropriately in individual states. The FAQs on IPV should be widely used for dissemination of information, especially to medical officers, frontline health workers and mobilizers.

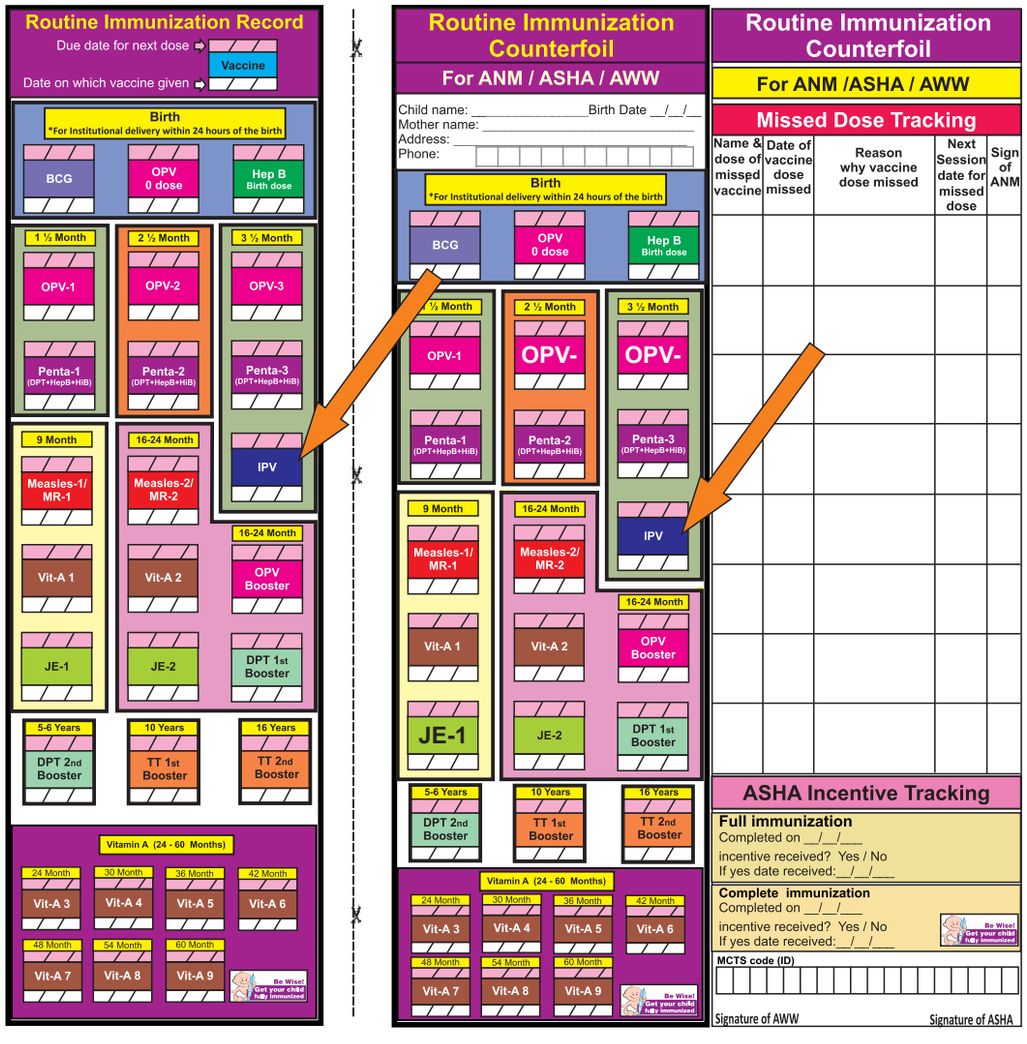
6.2 Reporting and recording of IPV in routine immunization programme

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.

In HMIS, IPV will find its place under the heading Child Immunization (M6) number of infants from 0 to 11 months subhead. Position of IPV in this format will be under the DPT3 coverage. Do not record IPV under any other heading.



7 IPV INTRODUCTION ACTIVITIES AT STATE, DISTRICT AND BLOCK LEVELS

7.1 State-level IPV introduction activities

The following activities should be undertaken at the state level for the successful introduction of IPV in the national programme.

Key messages

- IPV supply shall either be in 10 dose or 5 dose vials.
- Assess cold chain space accordingly.
- IPV is a freeze-sensitive vaccine and is to be stored in ILR (+2°C and +8°C).
- As of now, introduction of IPV does not mean that OPV is to be stopped.
- One dose administration of IPV at 14 weeks of age and in delayed cases maximum up to one year only.
- Vaccine should only be introduced in the districts that have completed the recommended trainings.
- Refrigerator mechanics to visit all vaccine storage points at least once before IPV introduction.
- State and district task forces to monitor open vial policy implementation.

7.1.1 State task force for immunization (STFI)

- STFI should be convened periodically to steer key messages for all activities for introduction of IPV vaccine in the state, including commitment and support from various departments and stakeholders.
- Issues identified for smooth introduction of the vaccine should be addressed during meetings of the STFI and the State Health Society (SHS).
- States should make best use of lessons learnt from the polio programme to strengthen routine immunization. Opportunity like new vaccine introduction should be used to highlight issues that need attention for corrective action.
- WHO (National Polio Surveillance Project (NPSP), UNICEF and other key routine immunization partners involved in immunization at state and district levels are expected to proactively support the authorities in providing quality information/monitoring data at STFI and district task force for immunization (DTFI) levels for appropriate actions.

7.1.2 Assess district preparedness

The state needs to assess the preparedness of districts using standardized checklists. Quantitative data should be reviewed, compiled and reflected in the state preparedness checklist. In case the State has undertaken preparedness assessment exercise recently for pentavalent vaccine then the same should be reviewed to visit the areas needing attention. If the same is not available then the state preparedness checklist with necessary annexures should be completed and submitted to the state oversight team – Mission Director, National Health Mission (NHM) and Director, Family Welfare. The assessment should be completed as per timeline. Following this the state preparedness checklist needs to be forwarded for review at the national level to the Deputy Commissioner, Immunization Division, Nirman Bhawan, New Delhi.

7.1.3 Track high-priority districts

Assign state observers to track planning, preparation, launch and implementation of IPV in the state with a special focus on districts identified under Mission Indradhanush. They should visit these districts and provide oversight to activities for introduction of IPV, including participation in DTFI and assessment of district preparedness using checklists.

7.1.4 Strengthening routine immunization micro-plans

- All high-risk areas (HRAs) identified in polio microplans and all additional sessions planned under mission Indradhanush should be incorporated into the RI microplans. Ensure all vulnerable sections are provided an equal opportunity to avail services.
- Monitor completeness of all components of microplanning.

7.1.5 Indenting and delivery of vaccine and logistics

- Ensure availability of required doses of IPV vaccine and other logistics. Official communications from the state should include the following key messages and the same should be reiterated at regular intervals.
- IPV supply from Government of India will either be in 10 dose or 5 dose vials,
- Assess cold chain space for both options, i.e., with 10-dose IPV vials and with 5-dose IPV vials.
- Following IPV introduction both OPV and IPV will simultaneously be in use in the immunization program. Introduction of IPV does not mean that OPV is to be stopped
- One dose administration of IPV at 14 weeks of age and in delayed cases, maximum up to one year only.
- Vaccine should only be introduced in the districts that have completed recommended trainings. To ensure smooth launch and merger of IPV in routine immunization programme, all cold chain handlers and frontline health workers should be trained before IPV introduction.
- IPV is a freeze-sensitive vaccine. To avoid freezing of vaccine ensure that all vaccine storage (cold chain) points are visited by refrigerator mechanic at least once prior to the introduction so that necessary repairs or maintenance can be undertaken well in time. Also remember, the VVM of IPV changes faster than any other vaccine.

7.1.6 Training workshops for health workforce at state-level

- This is a critical activity and needs timely planning and implementation. Conducting these training of trainers (ToT) workshops will create a pool of master trainers who will in turn ensure that the officials concerned at all levels are sensitized well in time prior to introduction. The state immunization officer will be responsible for planning and conducting state-level training workshops as per timelines. Key development partners such as WHO, UNICEF and others should proactively support the states and districts in planning, sensitization of health officials and monitoring the quality of training.
- Five training workshops similar to the ones that were conducted before pentavalent introduction need to be conducted at the state level. Details are given in table below.
- Sensitization workshop for district NHM finance officials (DPM and DAM) at district level will help to garner funding support for IPV introduction as per guidelines. The support will largely be in ensuring completeness of training of frontline health workers and mobilizers. Details are given in Table 3.

Table 3: State-level training workshops/TOTs

S.No.	Trainees	Trainers	Duration	Timeline
1	**Medical officers** DIO and 2 MOs per district (3 persons per district). Also include surveillance medical officers (SMOs) of WHO-NPSP, UNICEF district coordinators, and others such as state programme manager (NHM), state information education and communication (IEC) consultant, state ASHA coordinator, state cold chain officer, state data manager, state monitoring and evaluation (M&E) coordinator (NHM), state finance and accounts manager (NHM) (1-2 officials per organization dealing with cold chain to be invited from agencies such as WHO, UNICEF, UNDP, CORE, CARE, others).	SIO with support from state cold chain handler, HMIS and MCTS coordinators , IEC consultant and partners – WHO NPSP, UNICEF, others	One day for each workshop	Within 3 weeks after completion of national level workshop
2	**Data handlers** Districts to identify and nominate least 2 persons per district. District level HMIS and MCTS coordinators, district computer assistant to DIOs, district M&E focal person (NHM), focal person responsible for immunization reports in CMO office. Immunization data handlers (1-2 data handlers per organization to be invited from agencies such as WHO, UNICEF, UNDP, CORE, CARE, others).	State Immunization Officer (SIO), state HMIS and MCTS coordinator, state M and E focal person/coordinator, representatives from partner organizations such as WHO NPSP, UNICEF, ITSU and others		
3	**Vaccine and cold chain handlers** District to nominate at least 2 persons per district). District refrigerator mechanic, vaccine storekeeper in charge of immunization programme at district level. 1-2 officials per organization dealing with cold chain to be invited from agencies such as WHO, UNICEF, UNDP, CORE, CARE, others.	State Immunization officer (SIO), state cold chain officer (CCO), representatives from partner organizations such as WHO NPSP, UNICEF and others		
4	**IEC/media handling focal persons** Districts to identify and nominate at least 2 persons dealing with media and IEC for sensitization at state level. 1-2 officials per organization dealing with IEC/media handling to be invited from agencies such as WHO, UNICEF, UNDP, CORE, CARE, others.	SIO with support from WHO, UNICEF and other partners, State IEC consultant, media officer, partners		
5	**NHM finance officers** State-level workshop to orient the district-level NHM finance officials (DPM and DAM) on the guidelines related to funding support for the introduction, especially launch, media sensitization, block-level frontline health worker and mobilizer trainings, IEC materials, ASHA incentives, etc.	SIO with support from WHO, UNICEF and other partners		Preferably, before the start of district workshops in the state.

Notes: 1. Refer to related annexures for agendas and tips for trainers.
2. Submit district-wise fortnightly progress on training status to the GoI on the first and fifteenth of each month.

7.1.7 Dissemination of guidelines/revised formats/IEC materials

- Disseminate relevant guidelines and training material during training to each category of staff for introduction of pentavalent vaccine
- Ensure printing of IEC materials (as per prototypes) in local languages in adequate numbers
- Ensure that all the updated reporting and recording tools including immunization component in mother-child protection (MCP) card, registers, due lists, etc. are printed and disseminated in time. Appropriate translation in local languages should be undertaken if required. Ensure use of this updated material in the sensitization workshops at all levels.

7.1.8 Tracking beneficiaries (leftouts and dropouts)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro planning and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure it is a time-bound activity and gets completed in 1–2 weeks
- State health authorities and partners should intensively monitor this activity and share findings at all relevant platforms
- Implementation of immunization tracking bag (one per session site). ASHA or AWW of that area to be made responsible for this. ANM to provide oversight and cross check counterfoils to ascertain reasons for dropouts.

7.1.9 Intensify monitoring and supervision

- Intensify supervision and monitoring of programme at district, block, session and house-to-house levels through government functionaries and partners. Use standardized RI monitoring formats provided by MoHFW.

7.1.10 Communication planning

- Concentrated effort is required at the state level to build partnership for immunization. This includes involvement of all government sectors, Panchayat system, NGOs, media, IAP, IMA and other appropriate organizations. The state IEC Bureau/ State IEC wing under NHM in coordination with WHO, UNICEF and other partners should convene a partners meeting to map partner resources and assign key mobilization activities. The state must develop a detail communication plan for creating public awareness using various communication channels such as mass media, mid media and interpersonal communication. Ensure timely printing and distribution of IEC materials (as per prototypes) in local languages and in adequate numbers. (For details see chapter 8)

7.2 District-level IPV introduction activities

The following activities should be undertaken at the district level for successful introduction of IPV into UIP:

7.2.1 District task force for immunization (DTFI)

- DTFI should be convened periodically to steer all activities for introduction of pentavalent vaccine in the district, including obtaining commitment and support for introduction of this vaccine from various departments and stakeholders. Issues identified in activities essential for smooth introduction of IPV in the district should be addressed during meetings of the DTFI and the District Health Society (DHS).
- Districts should make best use of lessons learnt from the polio programme to strengthen RI. Make best use of this new vaccine introduction opportunity to highlight issues that need attention for corrective action.
- WHO, UNICEF and other key RI partners at district level are expected to proactively extend support in providing quality information/monitoring data to DTFI for guiding and taking appropriate actions.

- Ensure district cold chain vaccine storekeeper and refrigerator mechanic attend the DTFI meeting.
- Representatives of urban local bodies should be invited in DTFI.

7.2.2 Assess district preparedness

- The district needs to assess the preparedness of the blocks using standardized checklists. The qualitative and quantitative block /planning unit data should be compiled and reflected in the district preparedness checklist. In case the district has undertaken preparedness assessment exercise recently for pentavalent vaccine then the same should be reviewed to visit the areas needing attention.

7.2.3 Track high-priority blocks

- Senior district health officials have to be identified and deployed to visit and provide oversight to activities for introduction of IPV in high-priority blocks and urban areas, including participation in DTFI and assessment of district preparedness using checklists. In Mission Indradhanush districts, the DTFI should review the existing observer plan and see if the same observers could be deployed as observers for IPV introduction as well.

Key messages

- IPV supply from GoI will be either in 10 dose or 5 dose vials.
- Assessment of cold chain space should be completed before introduction of IPV.
- IPV is a freeze-sensitive vaccine and is to be stored in ILR (+2°C and +8°C)
  As of now, introduction of IPV does not mean that OPV is to be stopped.
- One dose administration of IPV at 14 weeks of age and in delayed cases maximum up to one year only.
- Do not introduce IPV until all blocks have completed the recommended trainings.
- Refrigerator mechanics to visit all vaccine storage points at least once before IPV introduction.
- Cold chain sickness rate in each district should be less than 2%.
- District task forces to monitor open vial policy implementation.

7.2.4 Strengthen RI microplans

- All high-risk areas (HRAs) identified in polio microplans and all additional sessions planned under mission Indradhanush should be incorporated into the RI microplans. Ensure all vulnerable sections, high risk groups are provided an equal opportunity to avail services.
- For improved microplanning, ANMs/ ASHAs/AWWs should undertake a headcount survey for estimation of beneficiaries by using standardized tools. This has to be a time-bound activity (1–2 weeks) and has to be intensively monitored by government functionaries and partners. DTFI to monitor the completeness of microplans.

7.2.5 Indenting and delivery of vaccines and logistics

- Ensure availability of required doses of IPV vaccine and other logistics. Official communication from the district should include the following key messages and the same should be reiterated at regular intervals.
- IPV supply from Government of India will either be in 10-dose or 5-dose vials,
- Assess cold chain space with both options, i.e., 10-dose IPV vials and 5-dose IPV vials.
- Following IPV introduction both OPV and IPV will simultaneously be in use in the immunization program. Introduction of IPV does not mean that OPV is to be stopped
- One dose administration of IPV at 14 weeks of age and in delayed cases, maximum up to one year only.

- Vaccine should only be introduced in the districts that have completed recommended trainings. To ensure smooth launch and merger of IPV in routine immunization, all cold chain handlers and frontline health workers should be trained before IPV introduction.
- IPV is a freeze-sensitive vaccine. To avoid freezing of vaccine ensure that all vaccine storage (cold chain) points are visited by refrigerator mechanics at least once prior to the introduction so that necessary repairs or maintenance can be undertaken well in time. Monitor the frequency and outcomes of visits and share the feedback in DTFI. DHS and DTFI are responsible for providing support to issues requiring attention.

7.2.6 Training workshops for the health workforce at district level

- Prepare a training calendar to train the health workforce.
- Conduct district-level ToTs to create a pool of trainers at district and block levels. The DIO will be responsible for ensuring timely completion of training as per guidelines. Key development partners such as WHO, UNICEF and others are expected to proactively support the district in planning and sensitization to the workshop activities including monitoring the quality of training.
- The district and block level pool of trainers are expected to follow the cascading approach for sensitizing the health work force at district and block levels. These include training of identified block/urban planning unit MOs, cold chain handlers, data handlers, health workers and supervisors (ANMs, lady health visitors (LHVs) and health supervisors) and community mobilizers (ASHAs, AWWs and link workers).
- Do not forget to train the staff posted in big government hospitals.
- Five training workshops similar to the ones done for pentavalent vaccine introduction need to be conducted at the district level.
- Sensitization workshop for Block NHM finance officials (BPM and BAM) at district level will help to garner funding support for IPV introduction as per guidelines. The support will largely be in ensuring completeness of training of frontline health workers and mobilizers. Details are given in Table 4.

Table 4: Summary of district training workshops/TOTs

S.No.	Trainees	Trainers	Duration	Timeline
1	**Medical officers** Blocks to identify and nominate the names of at least 4 officials (2 MOs + 2 others as nominated by block MO) per block/urban planning unit. Nominations to be forwarded to DIO. Other participants to be invited include district programme manager NHM, district IEC consultant, district ASHA coordinator, district cold chain handler, district data manager, district M&E coordinator (NHM), district accounts manager (NHM)	Master trainers: DIO and 2 MOs trained at state level	One day for each workshop	Within 2 weeks after completion of state-level workshop
2	**Data handlers** Block/planning unit to identify and nominate at least 2 data handlers involved in immunization data entry (HMIS and MCTS data) per block/planning unit. Nomination to be forwarded to DIO.	Master trainers: DIO and 2 MOs trained at state level. Include HMIS and MCTS staff trained at state level.		Within 3 weeks after completion of state-level workshop
3	**Vaccine and cold chain handlers** Block/planning unit to identify and nominate at least 2 persons per vaccine storage point. Nominations to be forwarded to DIO	Master trainers: DIO and 2 MOs trained at state level along with district cold chain handler, refrigerator mechanic trained at state level		
4	**IEC/media handling focal persons** Blocks to identify and nominate at least one person dealing with media and IEC. Nominations to be forwarded to DIO.	DIO with support from WHO, UNICEF and other partners, district IEC consultant, media officer, partners		At least 2 weeks prior to the launch
5	**NHM finance officers** District-level workshop to orient the block-level NHM finance officials (BPM and BAM) on the guidelines related to funding support for the introduction, especially launch, media sensitization, block-level frontline health worker and mobilizer training, IEC materials, ASHA incentives, etc.	SIO with support from WHO, UNICEF and other partners		Preferably, before the start of any district workshops in the district.

Notes: 1. Refer to related annexures for agenda and tips for trainers.
2. Submit fortnightly progress on training status of each level of functionaries to the State Immunization Officer.

7.2.7 Dissemination of guidelines/revised formats/IEC material

- Disseminate relevant guidelines and training material to the participants in the workshops
- Ensure that the district has an adequate number of printed IEC materials (as per prototypes)
- Ensure that all the updated reporting and recording tools such as MCP cards, registers, due lists, etc. are printed and disseminated to blocks/planning units in time. Ensure that these materials are discussed and used in the sensitization workshops.

7.2.8 Tracking beneficiaries (left outs and dropouts)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro planning and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure it is a time-bound activity and gets completed in 1–2 weeks.
- State health authorities and partners should intensively monitor this activity and share findings at all relevant platforms.
- Implementation of immunization tracking bag (one per session site). ASHA or AWW of that area to be made responsible for this. ANM to provide oversight and cross check counterfoils to ascertain reasons for dropouts.

7.2.9 Cold chain

Ensure cold chain assessment is undertaken prior to the IPV launch. Key issues and gaps identified should be followed up.

7.2.10 Intensify monitoring and supervision

- IPV introduction needs to be monitored and supervised at all levels. Based on GoI guidelines intensify supervision and monitoring of RI at district, block, session and house-to-house levels through government functionaries and partners. Use standardized formats provided by MoHFW.
- DTFI should use the RI monitoring data to review IPV implementation at field level.
- Monitoring IEC and mobilization activities is critical for smooth acceptance of IPV in the programme. Corrective action on mobilization monitoring data will lead to increase in coverage and help reduce dropouts and left outs in the community.

7.2.11 Communication planning

- The district health department in coordination with other department and partner agencies the CMOs should plan and conduct IEC and social mobilization activities focusing on high risk areas. The Local mobilization activities should include special efforts in reaching the dropouts. The district IEC/Social mobilization plan must fortify the communication gap and best utilization of available resources. Ensure timely development and distribution of IEC materials.

7.3 Block-level IPV introduction activities

The following activities should be undertaken at the block level for the successful introduction of Hib-containing pentavalent vaccine into UIP:

7.3.1 Strengthen RI micro-plans

- Revise microplans. All high-risk areas identified in polio microplans should be incorporated in the routine immunization microplans. Sessions planned in Mission Indradhanush should be included in the RI Microplan.

- Undertake head count for estimation of beneficiaries by ANMs/ASHAs/AWWs for improved microplanning. Use standardized tools. Ensure that this is a time bound activity (1–2 weeks) and that it is intensively monitored by government functionaries and partners. MO in charge to monitor and provide oversight to this activity.
- DTFI to monitor progress.

Key messages

- Cold chain handlers and ANMs should be made aware that IPV supply from GoI will either be in 10 dose or 5 dose vials.
- MOIC to ensure that cold chain storage points in block should have adequate cold chain space for IPV introduction.
- IPV is a freeze-sensitive vaccine and is to be stored in ILR (+2°C and +8°C).
- As of now, introduction of IPV does not mean that OPV is to be stopped.
- One dose administration of IPV at 14 weeks of age and in delayed cases maximum up to one year only.
- Do not introduce IPV vaccine until all blocks have completed the recommended trainings.
- Refrigerator mechanics to visit all vaccine storage points in the block at least once before IPV introduction.
- Ensure timely release of funds through Block Programme Manager and Block Accounts Manager (NHM)
- Medical officer in-charge to strictly implement and monitor open vial policy.

7.3.2 Indenting and delivery of vaccines and logistics

- Ensure availability of required doses of IPV vaccine and other logistics. Official communications from the Block Medical Officer in charge should include the following key messages and the same should be reiterated in ANM monthly review meetings.
- IPV supply from Government of India will either be in 10 dose or 5 dose vials,
- Introduction of IPV does not mean that OPV is to be stopped.
- One dose administration of IPV at 14 weeks of age and in delayed cases maximum up to one year only.
- For smooth launch and merging IPV in routine immunization programme ensure 100 percent training of cold chain handlers and front line health workers are trained before IPV introduction.
- IPV is freeze sensitive vaccine; to avoid freezing of vaccine ensure that all vaccine storage (cold chain) points in the block are visited by refrigerator mechanic at least once prior to the introduction so that necessary repairs or maintenance can be undertaken well in time. Monitor the frequency and outcomes of visits and share the feedback in DTFI. DHS and DTFI are responsible to provide support for issues requiring attention

7.3.3 Block training workshops for training ANMs/ASHAs/AWWs

- ANMs/LHVs/health supervisors: The district should plan to train all the ANMs at district or block level.
- Cadre-wise attendance should be monitored closely. Provide block attendance feedback to CMO/DIO, so that the same can be shared in the DTFI.
- Mobilizers (ASHAs and AWWs) are to be trained at block level by trained block level officials.
- WHO, UNICEF and other partner agencies are expected to support the PV introduction activities at district /block level, including monitoring the quality of training.
- Details of training at block level are given in Table 5

Table 5: Block-level training workshops/TOTs

S.No.	Trainees	Trainers	Duration	Timeline
1	Health workers (ANMs, LHVs, health supervisors	District and block master trainers (DIO and 2 MOs trained at state level + 2 block level MOs trained at district level). They will be supported by other trained officials such as district/block level data handlers, district vaccine and cold chain	One day for each workshop	Within 3 weeks of completion of the district-level workshop
2	Mobilizers (ASHAs and AWWs)	District and block master trainers DIO and 2 MOs trained at state level + 2 block level MOs trained at district level. They will be supported by other trained officials such ASHA coordinators at the district level and others	Half day for each workshop	

Notes: 1. Refer to related annexures for agenda and tips for trainers.
2. Submit fortnightly progress on training status of each level of functionary to DIO.

7.3.4 Dissemination of guidelines/revised formats/IEC materials

- Disseminate relevant guidelines and training materials to the participants during the training workshop.
- Ensure printed IEC materials are shared with the participants. Ensure appropriate display of IEC materials.
- Ensure that all the updated reporting and recording tools including immunization component in MCP cards, registers, due lists, etc. are shared during the training workshops.

7.3.5 Tracking beneficiaries (leftouts and dropouts)

- Undertake headcount for estimation of beneficiaries by ANMs/ ASHAs/AWWs for improved micro planning, due listing and tracking.
- Use standardized tools for microplanning and estimation of beneficiaries. Ensure it is a time-bound activity and gets completed in 1–2 weeks.
- State and district observers and partners should intensively monitor head count activity and share findings at all relevant platforms.
- Implementation of immunization tracking bag (one per session site). ASHA or AWW of that area to be made responsible for this. ANM to provide oversight and cross-check counterfoils to ascertain reasons for dropouts.
- Share the due list formats and revised immunization component in the MCP card. Demonstrate the use of counterfoil using immunization tracking bag with a focus on “missed dose tracking”.

7.3.6 Intensify monitoring and supervision

- Strengthen monitoring and supervision through LHVs and health supervisors. Explain preparation of supervision plan based on priority and use of standardized formats.
- MO in charge and other nodal officials identified should supervise the IPV implementation in the routine immunization sessions.
- Blocks/planning units should be receptive to feedback from independent agencies for corrective action.

7.3.7 Communication planning

- The Block MOICs should plan IEC and mobilization activities for greater community participation. Facilitate and coordinate all available human resource such as mobilizers and NGO volunteers to create awareness and enabling environment. List high risk pockets and plan mobilization activities with mobilizers/volunteers. The communication plan must include strategic use of communication channels such as announcements

from mosque/temples and meetings with local influencers, for example community leaders, panchayat members, local practitioners, teacher to mobilize families to bring their children for immunization. Ensure including the names or mobilizers/volunteers/influencers in the micro plans. Distribute IEC materials well in advance as per guidelines.

7.4 Role of partner agencies

The technical and monitoring support of partner agencies such as WHO, UNICEF and Rotary continues to be of significance in strengthening of health systems and programmes in India. The technical support provided by WHO, UNICEF and other partner agencies such as CORE, RMNCHA, ITSU, IAP and IMA for the introduction of IPV vaccine demonstrates the value addition to the process.

7.4.1 WHO

- Shall provide technical expertise in the development of plans for IPV introduction at national and state levels;
- Provide recommendations on customization of the preparedness checklists and support the district and state governments in completion of these checklists;
- Assist in the review of information derived at the state and national level;
- Monitor training activities and implementation at the block/district levels with feedback to DTFI and STFI;
- Track the progress in implementation of actions in strengthening RI and sharing of the findings at district, state and national levels; and
- Share feedback and recommendations to guide further strategies in IPV introduction.

7.4.2 UNICEF

- Shall develop a communications strategy and its timeline for IPV introduction at both the national and state levels;
- Provide assistance in information dissemination through its network;
- Provide regular feedback and recommendations; and
- Assist in the development of behavioural change communication (BCC) for IPV introduction.

7.4.3 Rotary International

- Will support advocacy at state and district level;
- Assist with IEC activities; and
- Support activities for mobilization of religious groups in support of IPV.

7.4.4 State and local organizations

- Other organizations such as IMA, IAP and civil society bodies will be identified as per state requirements. These organizations can play an important role in information dissemination and advocacy at various levels.
- Their involvement at district and state task force meetings can be encouraged based on decisions by state and district health department needs.
- Their capacities and roles can be reviewed at local level.

8 COMMUNICATION, ADVOCACY AND SOCIAL MOBILIZATION

8.1 Communication strategy and plan

The launch of IPV vaccine is a critical step forward in the global eradication of polio and transitioning from oral polio vaccines. This is the first time after 1985 that a single vaccine is being introduced across the entire country at the same time. It is therefore very important for all stakeholders – the public and policy makers alike to understand the value addition of improving children's immunity against polio that IPV in addition to OPV will bring.

Key Communication Tasks

- Raise awareness of all stakeholders on the importance of IPV use.
- Promote confidence in the vaccination schedule, its safety and effectiveness.
- Address rumours and misinformation.
- Improve vaccination coverage.
- Enhance detection and reporting of possible AEFI.

A well planned communication strategy has been developed to ensure that launch of IPV builds upon the gains of India's long drawn out battle against polio and the country continues to remain polio free.

The objectives of the IPV communication plan are:

1. Positive and correct positioning of IPV introduction into the routine immunization schedule.
2. Facilitate community acceptance of IPV in addition to OPV.
3. Strengthening of capacity of health workers in inter personal communication for effective delivery of IPV and routine immunization.
4. Building an enabling environment through positive media reporting and involvement of key stakeholders and influencers.

The key components of the communication strategy are as follows:

1. Building an enabling environment for IPV:
   - Launch of IPV at the state and district levels: Launch ceremony with participation from the state government, polio partners, development partners, nongovernmental organizations (NGOs) and media
   - Media briefings through specialized IPV related media kit, which will be provided.
   - Release of IPV IEC materials, operational guidelines, etc.
2. Advocacy with key stakeholders such as public representatives, government, private medical networks and doctors, religious leaders, media, etc.
3. Social mobilization for IPV by engaging panchayati raj institutions, religious leaders, social and community groups, women's groups, self-help groups, milk cooperatives, agriculture produce committees, youth clubs, NGOs, community based organizations (CBOs) and network of polio influencers
4. Community mobilization to create awareness and demand for IPV:
   - Training of master trainers on IPV introduction – ToTs at state/district and block levels.
   - Cascade training of frontline workers on frequently asked questions (FAQs) related to IPV.
   - Micro-planning and tracking of children due for IPV along with DPT3/Pentavalent3.
   - Mothers meetings for IPV introduction.
   - Influencer meetings and mosque announcements.

5. Ensuring visibility for the IPV introduction through an IEC/IPC package:
   - Posters for IPV introduction
   - Banners/hoardings
   - FAQs for health work force including ANM, ASHA, AWW, social mobilization network, etc.
6. AEFI communication plan

8.2 Launch of IPV vaccine

A successful launch of IPV will include mass media components as well as capacity building of health workers in interpersonal communication to respond to queries posed by the community. Other related government departments, local media and NGOs should also be briefed and brought on board, so that they may also spread the message and motivate the community to benefit from immunization.

A well-publicized launch ceremony should be planned for IPV introduction to improve general awareness about UIP and specific knowledge related to IPV vaccine introduction. The state and district task forces on immunization should steer the planning, coordination, implementation and monitoring of the programme.

Steps to be undertaken for the launch events:

1. **Preparatory phase:**
   - Identify and brief key guests and invitees including public representatives, government, professional bodies, media, NGO partners, religious leaders, etc.
   - Identify suitable venue and date in consultation with officials concerned.
   - Prepare materials for launch event from prototypes provided.
   - Prepare talking points for key speakers.
   - Prepare agenda for the event from the prototype provided.
   - Identify photographer and equipment required for the launch.

2. **Event:**
   - Check event venue prior to the event and ensure equipment is in working order.
   - Ensure orderly and timely conduct of the event.
   - Ensure folders with materials are available for all participants.
   - Ensure release of IEC materials for IPV launch.
   - Prepare press release based on the draft provided.

LAUNCH KIT: A standardized launch kit has been developed for the IPV introduction which will be provided to the state government containing the following:

1. Prototypes for backdrop/banner
2. Prototypes for standee
3. Draft agenda for event
4. PowerPoint slides/other materials for use
5. Operational guidelines for IPV
6. Frequently asked questions on IPV
7. Draft press release

8.3 Briefing media

It is important to ensure that the media is well briefed about the IPV launch and has access to the correct information so that wrong or incorrect reporting in mass media is minimized.

These simple steps can be followed at the state and district level for briefing of media:

1. **Preparatory phase**
   - Identify spokespersons at state and district levels. These can be the SIO/CMO/District Magistrate. Ensure the spokespersons have the requisite media skills. Organize media skills training for spokespersons if necessary on IPV facts.
   - Prepare list of state and district media staff covering health issues, with the latest contact numbers, emails and official addresses; editors of major newspapers and TV channels, radio; district-wise list of local cable operators.
   - Prepare key message sheets on immunization and share with spokespersons.
   - Prepare a press release from the prototype press release that has been provided in the media kit.

2. **Implementation phase**
   - Organize media briefing with key reporters on IPV introduction using PowerPoint slides and media kit that is provided
   - Hold media collaboration workshops; include state-level journalists.
   - Keep them regularly informed of all immunization related developments through faxes and emails.

3. **Monitoring and evaluation phase**
   - Track reporting on IPV introduction through media (newspapers, TV, radio) for tonality of reporting.
   - In case of negative or incorrect reporting, ensure that the reporter has access to correct information. Maintain news clippings of news reports by publication, date and placement

Media toolkit: A standardized media kit has been for the IPV introduction, which will be provided to the state government for dissemination containing the following:

1. Background note on IPV introduction
2. Frequently asked questions on IPV
3. Draft press release
4. Compendium of radio messages for local FM channels on IPV
5. Format for maintaining media reports on IPV

8.4 Advocacy

Advocacy is a well-defined process based on demonstrated evidence to influence decision makers, stakeholders and audiences to support and/or implement policies or actions related to the advocacy goal which in this case is to ensure that IPV is introduced smoothly into the routine immunization schedule and is accepted well by the community.

Advocacy with these groups is important for promoting immunization and IPV introduction.

1. Local public representatives (MPs, MLAs, members of legislative councils, zila panchayat chairman and members, ward members for urban areas)
2. Key officials of the government and medical fraternity at the state, district and block levels:
   - State level: Chief secretary, principal secretary health, Mission Director, National Health Mission, directorate of health and family welfare, state immunization officers, medical colleges, eminent private pediatricians/experts, medical institutions and networks (such as the IAP – Indian Academy of Pediatrics; IMA – Indian Medical Association; IAPSM – Indian Association of Preventive and Social Medicine)
   - District and block level: district magistrates, chief development officers, block development officers, chief medical officers, district immunization officers, medical officers, private practitioners, etc.
3. Influencers such as religious leaders, teachers, self-help groups
4. NGOs and CBOs
5. Media

Prepare an advocacy plan to reach out to the relevant groups using tools and materials. Assess your existing resources and adapt them with IPV related messages. Document the proceedings with action points for the future. Keep IMA informed and prepare and share PowerPoint/IEC materials on IPV with IAP/IMA members.

Table 6: Indicative planning matrix for advocacy activities

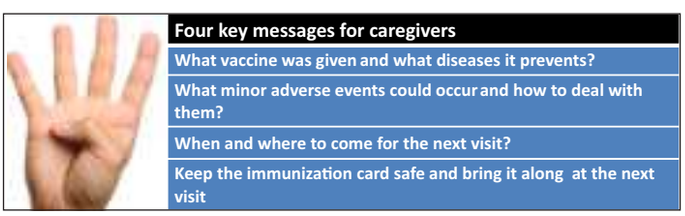
Indicative planning matrix for advocacy activities				
S. no.	**Audience**	**Desired action**	**Modalities of engagement (activities)**	**Tools required**
	Policy makers (state/ district/block)	• Review and support for IPV introduction	• Meetings/briefing sessions • Launch workshop • Exposure visits • Debriefing on IPV	• Advocacy kits • Briefs • Reports
	Medical officers/ institutions (IMA, IAP, IAPSM, private doctors/ experts)	• Orientation about Polio Endgame and IPV introduction	• Workshop • Meetings/briefing sessions	• PowerPoint slides • Background material on IPV introduction • Operational guidelines • Detailed FAQs for responding to any AEFI • Fact sheets • Brochure
	Public representatives Influencers: religious leaders, teachers, self-help groups groups, NGOs, CBOs	• Awareness about IPV introduction • Knowledge about benefits of IPV + OPV • Advocacy with the community about full immunization, IPV + OPV	• Meetings/briefing sessions • Community meetings	• Brochure • FAQs • Fact sheets
	Media	• Awareness about IPV introduction • Knowledge about benefits of IPV + OPV • Positive reporting	• Media briefings/workshop	Media kit containing: • Press release • Background material on IPV launch • Compendium of messages for radio

ADVOCACY TOOLKIT: You need to develop your own toolkit using the materials that have been provided in the launch and media toolkits. Make sure that you adapt the IPV materials to the audience that you are advocating with so that correct information reaches the audience in the correct format.

8.5 Community engagement and social mobilization

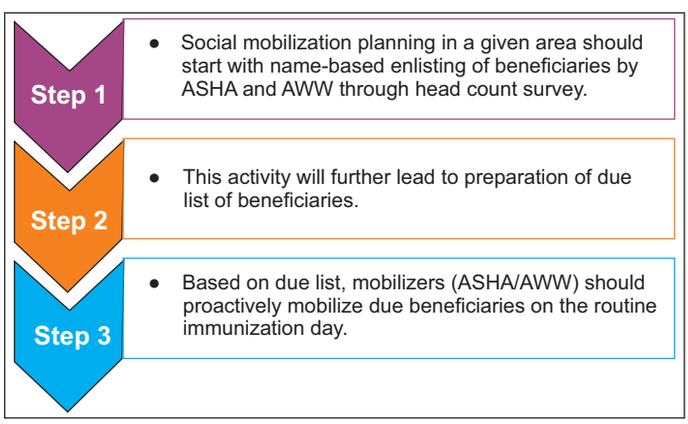
Community engagement and social mobilization is a critical activity that has been responsible for the success of the polio programme in India. This entails creating dialogue with communities, answering their questions and clearing misconceptions if any. Social mobilization utilizes the influencers within the community to convince and move refusal or resistant communities/families towards behaviour change.

Social mobilization can make a huge difference in reaching out to all the left outs (children not vaccinated at all) and dropouts (children that started the vaccination but missed subsequent doses).



The frontline worker is the keystone of community engagement and it is important to ensure that the auxiliary nurse midwives (ANMs), AWWs, ASHAs and community volunteers are well trained before the IPV launch. Health workers, if properly trained and informed, can motivate and generate community interest in the UIP and the new vaccine. They are the main source of information for the general public. It is therefore critical to ensure that all ASHAs, AWWs and link workers are trained on key aspects of IPV, including the four key messages

Steps for social mobilization



1. **Preparatory phase**
   - Update the beneficiary due list for 14-weeks-old (3½ months) infants who are due for IPV and OPV/Pentavalent or IPV and OPV/DPT/HepB.
   - Preparation of due list for IPV as part of the RI activities

2. **Mobilization for RI**
   - Mothers' meetings for RI and discussion about IPV introduction at 14 weeks (3 ½ months) age.
   - Influencer meetings on IPV introduction before launch, monthly meetings thereafter to discuss any refusal cases.
   - Mosque announcements prior to RI session in the village.

3. **Service delivery**
   - Mobilization of beneficiaries for RI session.
   - Ensuring of IPV along with OPV3/Pentavalent3 or with OPV3/DPT3/HepB3 for infants 14 weeks (3½ months) of age.
   - Ensuring updating of Immunization card with IPV information.
   - Ensuring delivery of the four key messages including 30 minute waiting after the immunization.

8.6 IEC materials and resources for IPV launch

The polio programme in India has a very distinctive branding. For the IPV launch, the IEC materials build upon the existing polio campaign. The following package of materials have been developed for the IPV launch in India:

1. **IEC/IPC package**
   - Booth / Session site Posters for IPV introduction
   - Banners / hoardings
   - Brochure- FAQs for community / mothers / care-givers
   - Booklet: FAQs for frontline workers (SMNet, ASHAs)

2. **Training resources**
   - Media kit for training of media personnel
   - Training curriculum for training of frontline workers

8.7 AEFI communication plan

An Adverse Event Following Immunization (AEFI) is an unfortunate event. Most AEFI sound much more serious than they are, because of poor communication within the system. To handle an AEFI effectively, it is best to be prepared in advance. Internal communication is most important during an AEFI. Be ready to respond promptly and effectively in case of occurrence of any AEFI.

- Set up a communication plan between the AEFI committee members and those working on the ground.
- All ANMs/ASHAs/AWWs and MOs must:
  - o Be sensitized to recognize and report AEFI promptly.
  - o Know what to do in the event of an AEFI and the location of the nearest AEFI treatment centre.
- Develop single-page reference material for ANMs/ASHAs on what to do during an AEFI, who to contact, etc.
- Organize infection prevention and control training for ANMs and ASHAs on what to say to parents about AEFI, during vaccination sessions, or during door-to-door IPC.
- Ensure district AEFI committee is functional and involved .
- If an AEFI occurs, get information out as quickly as possible. The public needs to know that you share their concerns, that the situation is being investigated and that you will keep them informed.
- Have a trusted spokesperson identified in advance to deliver messages during an AEFI. This spokesperson may not necessarily be the senior-most person in the district.

- Ensure that this spokesperson has been trained in media handling during AEFI. If not organize media-handling skills training in advance.
- Call partners meetings and discuss how messaging must be communicated during an unfortunate AEFI.
- Demand for information increases from many quarters – be prepared with information!
- Coordination is crucial – take charge! Prepare a coordination plan. Constantly update it when people move out of the system and new people come in.
- Workload increases – keep advances resources ready to quickly access the resources!

8.7.1 Media communication guidelines during AEFI

During an AEFI, the media likes a quick response, accuracy and simplicity, statistics with explanation, context (part of a wider picture), comments or explanation from the highest authority, and multiple sides of the story.

The AEFI committee/immunization programme managers may follow the guidelines given below for effective management of media during a crisis:

- Prepare a media database of journalists (print and electronic media) and regularly update.
- Identify in advance an appropriate spokesperson and share contact details of spokesperson(s) with all concerned focal points at the district, state and national levels. The spokesperson should have had the media training and should be articulate and technically competent to handle the questions that arise.
- An information package may contain the following documents both in hard copy and electronic files:
  - Frequently Asked Questions (FAQs) on IPV;
  - Fact sheet or a technical brief on IPV; and
  - Contact addresses of spokespersons (experts) that media can talk to.
- Media release: The draft media release must specifically answer who, what, when, where, why, and what action is being taken.
- Mention the name and contact details of the AEFI Committee (on the top), and the name and contact details of the spokesperson. The AEFI Committee may also recommend another name such as a medical expert) for further details should journalists have more questions (at the end).

Important AEFI Messages

- Benefit of immunization in preventing disease is well proven.
- It is very risky not to immunize (risk of disease and complications).
- Before the introduction of vaccines, vaccine-preventable diseases caused millions of death and/or disability. That situation would return without continued use of vaccines.
- Vaccines do cause some reactions, but these are rarely serious and hardly ever cause long-term problems (have data ready and available to substantiate this fact).
- We have well-established immunization safety surveillance in place. Immunization safety is very important, and even the slightest suspicion of a problem is investigated.
- The AEFI is currently being investigated, but is likely to be coincidental/due to a local problem (depending on type of event), and the immunization programme must continue to keep the population safe from disease.

9 MONITORING AND SUPERVISION

A team of national and state observers shall supervise and monitor all activities in the pre-launch period across the country. Special focus states (where routine immunization coverage requires to be strengthened), pre-identified high-focus districts (Mission Indradhanush) and polio high-risk districts shall be prioritised. These teams shall guide and evaluate the progress and share their findings with the state task force and national task force (Immunization division, MoHFW) at the national level for further action. It is recommended that introduction activities should start 3–6 months prior to the scheduled introduction of the vaccine.

9.1 Supervision and monitoring of implementation

Oversight of the implementation activities is crucial at all levels. Supervision should focus on bringing the gaps identified through the state and district preparedness assessment checklists.

9.1.1 National level

Review of the state preparedness checklists and assessment of progress achieved in addressing the identified issues at regular intervals will contribute to effective implementation and also have the added benefit of strengthening the RI system in each state.

Field visits by national observers will provide real-time information. The observers must visit the health facilities at all levels to assess the preparedness of states prior to introduction. The observers must share their observations with the district and state level officials for further action (if any).

9.1.2 State level

Review of the preparedness checklists of the districts must be done by the SIO. It is recommended that a state team be formed to oversee the implementation process. Officers from various departments can also be involved in the state-level trainings to enable participation in monitoring.

Field visits by the state immunization officer and state observers (assigned for high-priority districts) must focus on checklist findings and visit the district training sessions. Issues identified must be shared with state and district task forces for corrective actions.

9.1.3 District level

In addition to officers of the health department, officials from Integrated Child Development Services (ICDS) department should also be involved in block-level monitoring of training. Child development project officer and local administrative officers should be invited by block MOs to observe training of ASHAs and AWWs at the PHC level.

9.2 Monitoring the process of IPV vaccine implementation

Standardized data collection formats and operating procedures have been developed by the GoI to monitor the provision of RI services at immunization session sites and community level coverage of all antigens offered through UIP to detect coverage gaps. The introduction of IPV vaccine in the UIP provides an opportunity to strengthen the overall monitoring of RI programme. The GoI mandated intensified RI monitoring strategy should be used for IPV related monitoring as well. Appropriate information may be collected on the status of implementation through all components of RI monitoring.

9.2.1 Session site monitoring

This captures information on vaccine supply and the availability of logistics, functioning of alternate vaccine delivery (AVD) system, injection practices of ANMs, injection safety and waste disposal, record keeping and inter-personal communication of service providers.

9.2.2 District and block level monitoring

This provides information on coverage, vaccine stocks, wastage rates, etc.

9.2.3 Household monitoring

This uses convenience sampling in the community surrounding RI session sites to assess the coverage of RI antigens of children under 35 months of age.

The existing mechanisms such as the task force for immunization, other interactions and review meetings should be used for feedback and information sharing for appropriate corrective measures and follow-up.

9.3 Monitoring supply of vaccines and logistics

Available records must be examined for supply, utilization and balance of vaccines and AD syringes and verified physically to see whether there is a logical association between vaccines and AD syringes supplied and used.

If the following are found, there is a need to explore and address the reasons:

- The utilization of the vaccine and AD syringes shows a pattern of rapid increase or decrease week after week;
- Doses consumed for vaccines that are provided at the same time (IPV, OPV3/Pentavalent3 or IPV, OPV3/DPT3/HepB3) differ widely from each other for the same period.

If there is any mismatch between the reported number of doses and AD syringes used, the vaccinators, doctors, store in-charge and supervising authorities concerned must be consulted to determine the reason for the variation or mismatch. If their reply is found convincing and realistic, no action is required other than appreciating them. If the reply points towards problems or irregularities in work/management, solutions need to be discussed with the persons concerned. The senior authorities should be informed well in time.

9.4 Monitoring the cold chain

IPV vaccine should be stored between +20C and +80C. It is damaged by freezing as well as at higher temperatures. Therefore, strict attention to condition of water ice packs and the maintenance of cold chain is essential.

9.5 Monitoring immunization safety

IPV vaccine is a safe and effective vaccine; however, as with any new vaccine added to the programme, adequate attention should be paid to ensure that sensitive surveillance for AEFIs is in place. Any suspected AEFI thought to be associated with IPV should be reported in the prescribed GoI format, including hospitalizations, deaths and any other severe or unusual medical event or event clusters. If an AEFI occurs, measures should be taken to check the compliance with safety strategies from the existing supervisory checklists and explanations sought for deviations from safety norms such as recapping, non-use of hub cutters and other incorrect practices.

9.6 Lessons learnt from the introduction of injectable pentavalent vaccine – Post introduction evaluation (PIE)

The introduction of any new vaccine into the immunization programme is an opportunity to strengthen health systems and improve the reach of immunization services to disadvantaged populations. WHO recommends that a post introduction evaluation (PIE) of new vaccines be conducted within 6–12 months of introduction of a new vaccine. The aim of such evaluation is to assess community acceptance and its impact on the existing immunization system, to derive lessons for necessary corrective measures. Although a PIE is done in the context of new vaccine introduction, the exercise provides a broad overview of the performance of the immunization programme and thus boosts the confidence to further scale up and introduce new and underutilized vaccines in the programme.

A PIE of pentavalent vaccine was conducted in Tamil Nadu and Kerala in 2012, and a similar PIE was conducted in Goa, Gujarat, Haryana, Jammu & Kashmir, Karnataka and Puducherry in 2013 to evaluate the status of pentavalent vaccine and measles-containing vaccine second dose.

The detailed findings of PIE in these eight states have been given in the annexure 1. The national and state governments should plan to conduct PIE of IPV within 6–12 months of vaccine introduction.

10 FREQUENTLY ASKED QUESTIONS (FAQs) FOR INACTIVATED POLIOVIRUS VACCINE

1. What is IPV?

IPV refers to the inactivated poliovirus vaccine. IPV consists of inactivated (killed) poliovirus strains of all three poliovirus types and is given as an injectable vaccine.

2. What is OPV?

OPV refers to oral polio vaccine. OPV is a live vaccine and is orally administered.

3. How is IPV different than OPV?

Characteristics	IPV	OPV
Type	Killed (Inactivated)	Live Vaccine
Route	Intra-Muscular (Right Thigh)	Orally
Dose	0.5 ml Injectable	2 drops
Schedule	One dose	Birth dose, 3 primary doses and one booster
Booster	No	Yes
Freeze sensitive	Yes	No
Heat sensitive	Yes	Yes
Remember : IPV and OPV when used together provide lifelong protection to the children from polio paralysis		

4. Is IPV a new vaccine?

No, IPV is not a new vaccine. IPV was developed by Dr Jonas Salk. It is also called as the "Salk vaccine". IPV was licensed in 1955. IPV is being used as part of the national immunization programme in many countries across the world.

5. Is IPV safe?

Yes, IPV is one of the safest vaccines. It protects children against all three types of poliovirus.

6. Will IPV replace OPV?

No, IPV (injection) will not replace OPV (polio drops). IPV is to be administered in addition to third dose OPV in the same visit.

7. Is IPV a part of national immunization programme in other countries?

Yes, IPV is being used as part of national immunization programme in many countries across the world. 30 countries are already using IPV and OPV as part of their national immunization schedule. 126 countries including India will be introducing at least one dose of IPV in their national immunization schedule shortly.

Summary

By introducing IPV in routine immunization along with existing vaccination schedule of OPV, it will strongly help and ensure that:

- Polio-free countries like India are better protected against polio re-infection or re-emergence
- All children are better protected from all polio disease
- Eradication of all three strains of poliovirus transmission will be accelerated

8. Why is IPV now being introduced when India has already eradicated polio?

Although polio has been eradicated in India, the threat of re-emergence and reinfection due to poliovirus remains at large. For completing polio eradication and elimination of all polio disease

in the world, a strategic plan has been developed by the global experts to secure a lasting polio-free world. This plan includes use of IPV in combination with OPV. Using IPV and OPV together will provide additional protection to the child and the community against polio.
As part of the global polio eradication plan, 126 countries, including India, are introducing at least one dose of IPV along with OPV in the national immunization schedule.

9. Why should IPV be given along with OPV?

The child and the community are better protected against polio when IPV and OPV are given together. IPV together with OPV provide additional protection to the child and prevents re-emergence and re-infection to poliovirus.

10. Is it safe to give IPV and OPV together?

Yes, it is absolutely safe to give IPV and OPV together. There are many countries that are already giving OPV and IPV as part of their RI schedule.

11. After receiving IPV and OPV through routine immunization, does the child still need to take OPV doses through Pulse Polio campaigns?

Yes, even after receiving IPV and OPV doses in routine immunization, the child must be given OPV doses during Pulse Polio campaigns also. This will boost the child's immunity and will continue to protect the child against Polio.

12. After receiving IPV and OPV through routine immunization, does the child still need to take OPV booster doses as per routine immunization schedule?

Yes, even after receiving IPV and OPV doses in routine immunization, the child must be given OPV booster doses as per RI schedule.

13. Which government health facilities in our country will provide IPV?

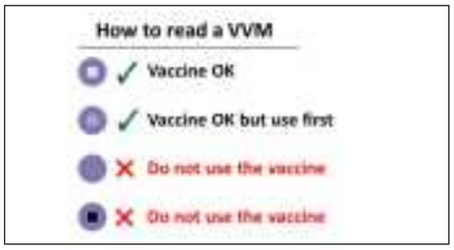
IPV is an injectable vaccine and will be provided free of cost through routine immunization sessions. IPV will be provided in all government hospitals, dispensaries, PHCs, CHCs, sub-centres and outreach session sites. IPV will not be given in a house-to-house campaign mode.

14. Is IPV expensive? What is the cost of each dose? Remember

IPV is an expensive vaccine. Each dose of IPV costs more than Rs. 120. A 5-dose vial costs Rs. 600 and a 10-dose vial costs Rs. 1200.

15. How many doses of IPV will be there in one vial?

IPV vaccine will be supplied to states in 5-dose or 10- dose vial presentation. The health worker must check for the vaccine details before using the vaccine vial. The health worker must check for the vaccine details before using the vaccine vial.



16. Will both 5-dose and 10-dose IPV vials have vaccine vial monitor (VVM) on their label?

Yes both the 5-dose and 10- dose IPV vaccine vials will have a vaccine vial monitor (VVM) on their labels. If the VVM reaches the discard point then do not use the vaccine. Just before opening the vial do not forget to mention the date and time of opening the vial. Remember that open vial policy is applicable to IPV vaccine

17. Will Open Vial Policy be applicable to IPV?

Yes, Open Vial Policy is applicable to IPV. Do not forget to write the date and time of opening of vial on the label. As per guidelines, IPV may be used up to 28 days after opening, provided that the criteria for the multi-dose vial policy are fully met.

18. What is the eligible age for IPV?

The child between 14 weeks (3½ months) and one year of age coming to RI session site to receive third dose of OPV will be eligible for IPV.

19. When should IPV be administered as per routine immunization schedule?

In states that have introduced pentavalent vaccine, IPV should be administered to a child along with third dose of OPV and pentavalent vaccine. States that have not yet introduced pentavalent vaccine will provide IPV along with third dose of OPV, DPT and HepB as part of routine immunization.

Open Vial Policy

Vaccines opened in a fixed or outreach session can be used at more than one immunization session up to 4 weeks provided:

- Expiry date has not passed
- VVM has not reached discard point
- Vaccines stored at appropriate cold chain conditions: both during transport & storage in cold chain storage point
- Vaccine septum has not been submerged in water or contaminated in any way
- Aseptic technique used to withdraw all doses
- If any adverse event happens – Do not use the opened vial, retain the vial for investigation.

National Immunization Schedule

Pregnant Women	TT
• Early in pregnancy	
• 4 weeks after 1st dose	

If pregnant women have received 2 doses of TT within last 3 years, then only one booster dose is given.

Ideally TT2 or booster dose should be given before 36 weeks of pregnancy. However, it may be given even if more than 36 weeks have passed.

States without Pentavalent vaccine							
For infants	BCG	OPV	IPV	HepB	DPT	Measles	JE
• At Birth	✓	✓		✓			
• 6 Weeks		✓		✓	✓		
• 10 Weeks		✓		✓	✓		
• 14 Weeks		✓	✓	✓	✓		
• 9 Months						✓	✓

States with Pentavalent vaccine*						
BCG	OPV	IPV	Penta	HepB	Measles	JE
✓	✓			✓		
	✓		✓			
	✓		✓			
	✓	✓	✓			
					✓	✓

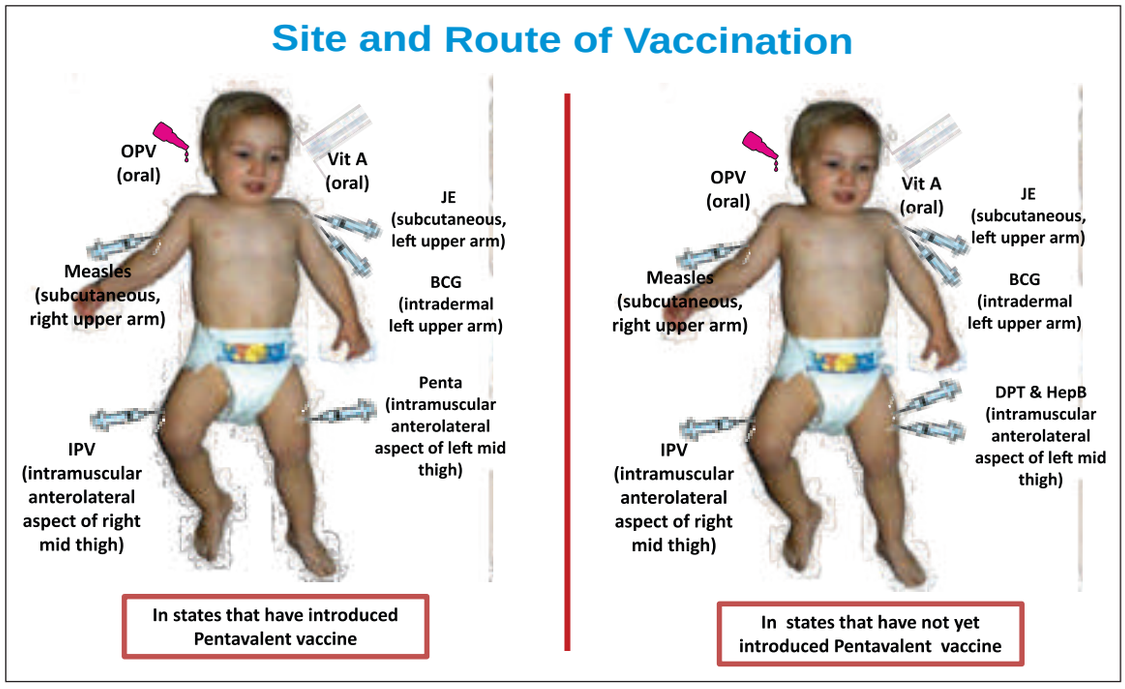
For children	DPT Booster	OPV Booster	Measles	JE	TT Booster
• 16-24 Months	✓	✓	✓	✓	
• 5-6 Years	✓				
• 10 Years					✓
• 16 Years					✓

- IPV should be given at 14 weeks, in delayed cases it can be given maximum upto 1 year.
- A child that has already received OPV3/Penta3 or OPV3/DPT3/HepB3 is not eligible for IPV.
- *A child whose vaccination schedule has been started with DPT/Hep B will receive subsequent doses of DPT/Hep B and not pentavalent vaccine.
- A zero dose child who presents after first birthday without any dose of DPT/Penta vaccines will complete the schedule with DPT+Hep B and not pentavalent vaccine.
- If a child receives atleast one dose of pentavalent vaccine before his/her first birthday, the child should complete the schedule with pentavalent vaccine at the earliest opportunity.

20. What are the route, dose and site of IPV injection?

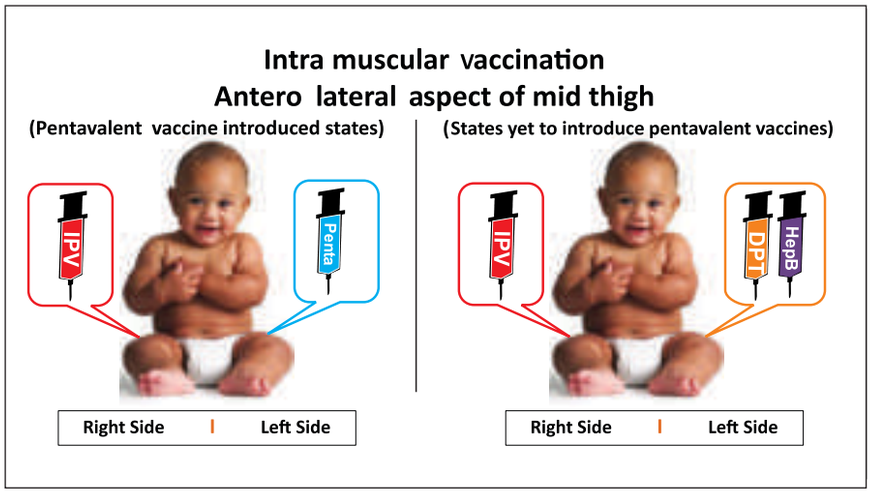
IPV is to be administered intramuscularly (I/M) as a single dose (0.5 ml) in the anterolateral aspect of right mid-thigh. IPV will be administered using AD syringe.

- If child requires more than one injection, for example Penta or DPT/HepB then these have to be administered in the anterolateral aspect of left mid-thigh.
- If two vaccines are to be administered simultaneously then ensure that the distance between two sites is at least 2.5 cm (1 inch). Sites of other intramuscular vaccination are mentioned below.



21. What should be the site for administration of Penta or HepB and DPT following introduction of IPV in the programme?

As per revised RI schedule, only IPV will be administered in the anterolateral aspect of right mid-thigh where in all doses of Penta or HepB and DPT will be administered in the anterolateral aspect of left mid-thigh.



22. Why should IPV be given in the right side in anterolateral aspect of mid-thigh only?

Site for an injection is fixed to maintain uniformity across the country. Uniformity helps ANMs to remember and safely provide multiple vaccinations. It also helps ANM in seeking vaccination history in case of loss of MCP card. Fixing the sites for vaccination helps in better recall by the caregiver during follow up visits, evaluation surveys and adverse events, etc.

We are already practicing such kind of uniformity for administering other UIP vaccines such as BCG (left upper arm); Measles (right upper arm) and JE (left upper arm).

IPV will be given in anterolateral aspect of right mid-thigh and pentavalent or HepB and DPT will be given in the anterolateral aspect of left mid-thigh.

Remember

- Pentavalent vaccine has already been introduced in 20 states/UTs. This vaccine will shortly be introduced in the remaining 16 states/UTs.
- DPT and HepB will continued to be given intramuscularly at 6, 10 and 14 weeks in states that have not yet introduced pentavalent vaccine. This means that the child coming for the third dose of OPV in such states will receive three injections (IPV in the right thigh, DPT and HepB in the left thigh).
- Following pentavalent vaccine introduction, the number of injections at 6, 10 and 14 weeks will reduce.
- The child coming for third dose of OPV in pentavalent introduced states will then receive only two injections (IPV and Penta) instead of three (IPV, DPT and HepB).

23. Will IPV injection be given to a child coming earlier than 14 weeks?

No, IPV injection will not be administered to a child coming earlier than 14 weeks. As per RI schedule third dose of OPV is provided at 14 weeks of age hence IPV cannot be given before 14 weeks of age.

24. Why is IPV administered with third dose of OPV at 14 weeks (3 ½ months)?

IPV administration is recommended at 14 weeks of age because the protection response of the IPV vaccine is significantly higher after 14 weeks than at an earlier age.

25. What should be the vaccination schedule for a child coming later than 14 weeks of age (delayed cases)?

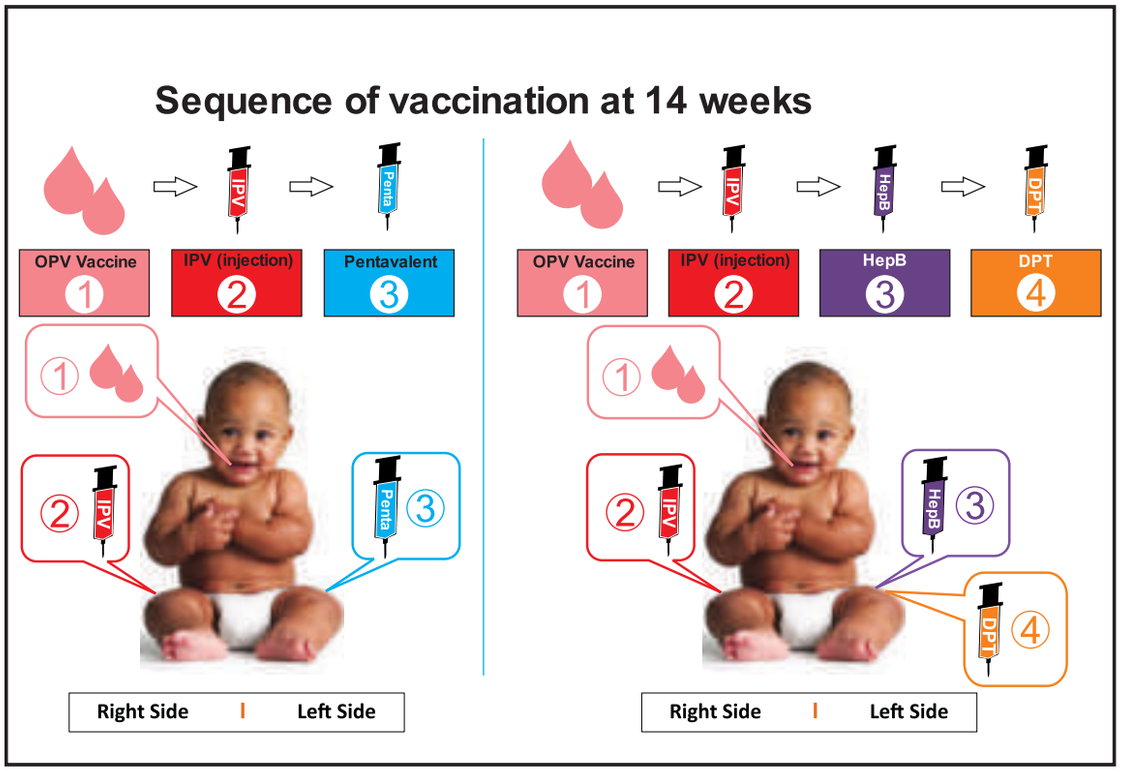
As per the national immunization schedule the child should get one dose of IPV at 14 weeks along with third dose of OPV and Pentavalent or HepB/DPT. In case of those children where vaccination is delayed beyond 14 weeks the child should be administered the due dose as soon as possible but not later than one year.

Remember

In delayed cases (beyond 14 weeks), one dose of IPV should be given as soon as possible up to maximum one year of age. Remember vaccination results are the best when given at the recommended age.

26. What sequence should be adopted for administering vaccines to a child coming for third dose of OPV?

Please refer to the following sequence for administering all vaccines at 14 weeks contact.



27. Is there any booster dose for IPV?

No, there is no booster dose of IPV. As per national immunization schedule only one dose of IPV is to be administered with third dose of OPV.

28. Is it safe to given multiple vaccinations to a child in one visit?

Yes, it is safe to give multiple vaccinations to a child in one visit as per national immunization schedule. If multiple due vaccines are not given then the vaccine must be given in the next session or minimum four weeks apart.

If more than 2 injections are to be given in the same thigh then the distance between the two injections should be at least 2.5 cm (1 inch).

29. What is the benefit of giving multiple vaccinations to a child in one visit?

There are several benefits of giving multiple vaccinations to a child in one visit.

- There is no contraindication for giving multiple vaccination (if due) in one visit
- The caregiver does not have to come repeatedly for vaccination
- Better compliance at the level of caregiver.
- Reduces ANM workload

30. Does the child need some special care after IPV injection?

No, the child does not need any special care after IPV vaccination. As per RI guidelines,

after administering any vaccine, the health worker should observe the child for at least half an hour at the session site. In case of fever, paracetamol can be given in recommended doses.

31. Does IPV have any side effects?

No, IPV does not have any side-effects. Like every injection prick there might be slight redness or tenderness which generally goes away in a day or two.

32. Are there any contraindications for use of IPV?

IPV should not be administered to children with a documented or known allergy to streptomycin, neomycin or polymyxin B, or with a history of a previous allergic reaction after IPV injection.

33. Can IPV be given to a sick child?

Yes, IPV can be safely administered to a child with minor to moderate illness. If the child is, or seems to be, severely sick then it is better to wait and ask the parents to consult the doctor and thereafter bring the child when he/she gets better.

34. Can IPV be given to a premature infant (born before 37 weeks gestation)?

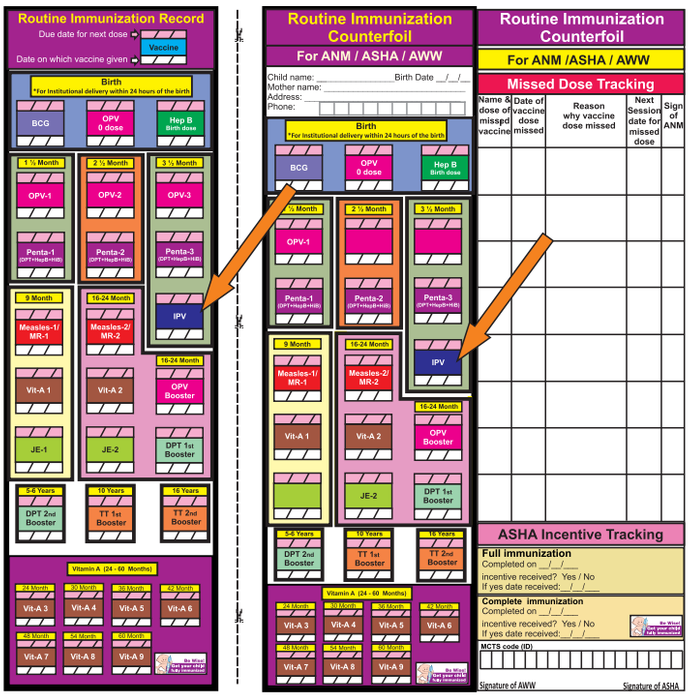
Yes, IPV can be administered at 14 weeks after the birth of the premature child.

35. Can IPV be given to an immunodeficient child?

Yes, IPV can be safely administered to a child with immunodeficiency (e.g., HIV/AIDS, congenital or acquired immunodeficiency, sickle cell disease).

36. Where will the IPV dose be recorded in the MCP card?

IPV has to be recorded separately in the MCP card along with the other vaccines due at 14 weeks (3½ months). The new MCP card has provision for recording the IPV vaccination.



37. What should you do if you find a frozen IPV vial?

- IPV is a freeze sensitive vaccine. If you find a frozen vial of IPV do not use the vaccine.
- Remember freeze thawed IPV vaccine cannot be tested for freezing. Shake test is not applicable to IPV.
- Suspected frozen vials of DPT, Pentavalent, TT, Hep-B vaccines can be tested for freezing through Shake Test procedure.

Remember

- IPV is a freeze sensitive vaccine.
- All vaccines come with VVM – Check the VVM before the use.
- As part of open vial policy, all partially used vaccines should be sent back to the vaccine storage point the same day.IPV is an expensive vaccine. Each dose of IPV costs more than Rs. 120. A 5-dose vial costs Rs. 600 and a 10-dose vial costs Rs. 1200.

38. Which all vaccines should be kept on an ice pack at the immunization site?

As per RI guidelines, the health worker is expected to take out one ice pack at the session site and use the same after opening the heat sensitive vaccine.

- On Ice Pack- BCG and Measles (place them in the holes on ice pack), OPV and JE vaccine should be placed on the surface of the ice pack.
- Remember – IPV, HepB, TT, DPT and Penta should never be kept on the ice pack.

39. What are the four key messages that every health worker must give to the caregiver after vaccination?

Remember that a vaccinator's task is not complete till she delivers the four key messages to caregiver (refer to the picture).

Four key messages for caregivers
What vaccine was given and what diseases it prevents?
What minor adverse events could occur and how to deal with them?
When and where to come for the next visit?
Keep the immunization card safe and bring it along at the next visit

40. Let us assume if one of the two vaccines OPV or IPV is not available at session site, and a child due for third dose of OPV comes to the session site for vaccination?

In such a condition, the health worker should give all vaccines that are available and advice the caregiver to come back in the next session for receiving the dose missed today due to non-availability.

41. Will IPV be a part of ASHA's full immunization incentive?

Yes, IPV will be a part of the national immunization schedule. The ASHA will be eligible for the full immunization incentive only if the child has received all vaccinations (within one year) as per the schedule

Remember

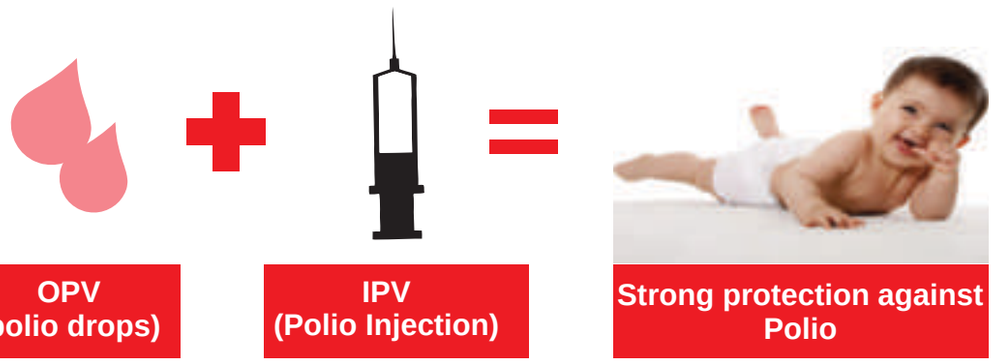
ASHA is eligible for the full immunization incentive only if child has received all vaccines due in the first year as per the national immunization schedule and this now includes IPV.

Some anticipated scenarios following IPV introduction.

SCENARIO	WHAT YOU SHOULD DO
1. Child coming is less than 14 weeks of age	• Do not give IPV. • IPV injection will not be given to a child coming earlier than14 weeks. As per RI schedule third dose of OPV is provided at 14 weeks of age hence IPV cannot be given before 14 weeks of age. • Utilize this opportunity to provide other due vaccination (if any) • Give four key messages
2. Child coming at 14 weeks of age is completely unimmunized (has not received any) vaccinations	• Verify that the child has not received any vaccinations • Give vaccination as below - Give first dose of OPV - Give BCG (left upper arm) - First dose of Penta in left thigh (Pentavalent States) - First dose HepB and DPT in left thigh (States where Pentavalent vaccine has not been introduced) • Give four key messages
3. Child coming is more than 14 weeks of age but less than one year of age and has received birth dose and all vaccinations due at 6 weeks.	• Verify if the child is more than 14 weeks of age and has received all due vaccines at 6 weeks of age. • As per RI schedule third dose of OPV is provided at 14 weeks of age hence IPV can be given. • In such case give second dose of OPV along with second dose of penta or HepB and DPT • If the child is 9-12 months of age then give Measles and JE (if applicable). • The caregiver should be given four key messages.
4. Child coming at 14 weeks of age has received birth dose and all vaccinations due at 6 and 10 weeks.	• Verify if the child is more than 14 weeks of age and has received all due vaccines at 6 and 10 weeks of age • In such cases give third dose of OPV with IPV followed by - third dose of Penta (Pentavalent States) - third dose of HepB and DPT (States where Pentavalent vaccine has not been introduced)

5. Child coming is more than 14 weeks but is less than one year of age and has received birth dose and all vaccinations due at 6, 10 and 14 weeks	• Verify if the child is more than 14 weeks and less than one year of age and has received all due vaccines at 6, 10 and 14 weeks of age • In such cases where third dose of OPV has already been given then do not give IPV. • Remember that we do not give IPV to a child that has already received OPV3 earlier. • If the child is 9-12 months of age then give Measles and JE (if applicable). • The caregiver should be given four key messages.
6. Child coming is more than 14 weeks of age and less than one year of age has received all due doses of OPV as per RI schedule. The child has also received OPV through all campaigns. The child however has not received any injectable vaccine so far.	• Verify all doses of OPV have been given as per immunization schedule • In such cases do not give IPV. • Remember IPV should be given only with third dose of OPV. • In such cases give BCG followed by - first dose of Penta (Pentavalent States) - first dose of HepB and DPT (States where Pentavalent vaccine has not been introduced) - If the child is 9-12 months of age then give Measles and JE (if applicable). • The caregiver should be given four key messages.
7. Child coming has received IPV vaccination by a private practitioner.	• Verify if the child has actually received IPV through private practitioner. • Verify the age at which IPV was given: - If IPV has been given before 14 weeks then give one dose of IPV along with OPV. - If IPV has been given at 14 weeks or later then do not give IPV. • Utilize this opportunity to provide other due vaccination (if any) • Give four key messages.

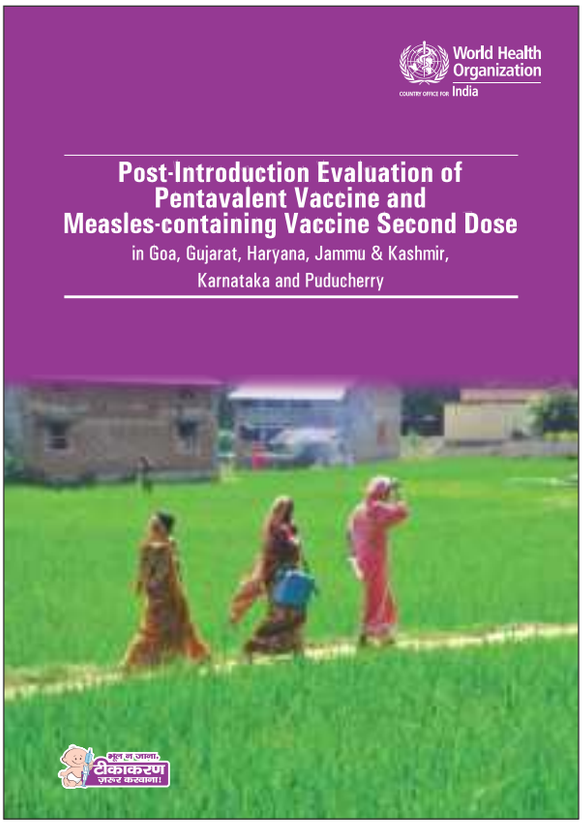
IPV Key Messages for the community:



- Children are still at risk of polio till such time as it is not eradicated from the world.
- Just one dose of IPV with third dose of OPV to your child in routine immunization at 14 weeks of age gives additional protection against polio
- IPV is available free of cost at the RI session site

Annexure 1

Key findings and recommendations of post-introduction evaluation (PIE) of pentavalent vaccine in India



Recent findings from the post-introduction evaluation (PIE) of pentavalent vaccine and measles-containing vaccine second dose (MCV-2) suggested the following:

- Begin early preparations for roll out of new vaccine – at least three to four months in advance of the actual vaccine launch.
- Organize a state-level official launch ceremony under strong political leadership, with the engagement of media, to increase programme visibility and boost confidence among public about the new vaccine. Districts should also organize launches for greater public awareness.
- Fill up staff vacancies at all levels particularly in high-risk areas.
- Revise existing RI microplans to include high-risk areas and migratory/non-migratory settlements identified under the polio programme and new microplans should be prepared using bottom-up approach to ensure inclusion of all components.
- Provide good quality training to health staff at all levels prior to the introduction of new vaccine on all aspects of vaccine delivery – from operations to appropriate use of communications channels.
- Revise reporting and recording tools such as MCP cards, registers, tally sheets etc. before introduction.
- Strengthen cold chain & vaccine management to avoid vaccine stock-outs and wastage. Cold chain handlers should also be trained.
- Maintain supportive supervision and appropriate oversight with a feedback mechanism.
- Ensure availability of information, education and communication (IEC) material in adequate quantities to raise awareness among community.
- Utilize data generated from programme implementation, including monitoring, for action. State and district task forces for immunization should regularly review this data to assess performance of the immunization programme and monitor routine immunization (RI) activities. The task forces should also review preparedness for vaccine introduction.

Remember
It will be important to ensure that these recommendations are acted upon during the IPV introduction process in states and UTs.

Annexure 2

IPV training workshop for medical officers at state/district level

Agenda: IPV training workshop for medical officers at state/district level	
Activity	Person/s responsible*
Registration	
Objectives of the workshop and opening remarks (15 minutes) • Make the participants feel special and important since they are master trainers for introduction of a new vaccine in the state. They must understand that they are playing a key role in strengthening of the health system, particularly the immunization programme in the state. • Only the officials that have been trained on IPV introduction will impart trainings. • All sessions must be interactive. Methodology should include PowerPoint presentations, role-plays, exercises and interactive discussions. Trainers should be patient listeners to any feedback from the trainees. • Trainings will be imparted as per guidelines. Trainers need to follow the timelines as per operational guidelines. • Delay in trainings may lead to delay in IPV introduction. It is a matter of national pride that we complete our trainings at all levels in time and be at ahead or at par with global agenda of polio endgame strategy. • Each batch should not have more than 40 participants. In large states/districts more than one batch may have to be planned.	
Role of participants attending the training workshop for IPV introduction (10 minutes) • Explain the objectives of the workshop to participants (why they have been called and what is expected from them).	
Global and national update on polio eradication (10 minutes) • The participants must be informed about the countries with ongoing transmission. • The threat of importing wild poliovirus in our country.	
Overview of Polio Endgame Strategy (15 minutes) • The trainer should stress more on IPV introduction in Oct 2015. • The participants must be informed that tOPV will be replaced with bOPV in routine immunization April 2016. They should understand that bOPV is the same vaccine that was introduced in SIAs in our country in 2010. • The rationale behind the use and more important how IPV will support switching to bOPV.	
Introduction to IPV vaccine (15 minutes) **Basic facts about IPV** • Key messages: vaccination saves lives; IPV is safe and effective; it is being introduced across all states in India in October 2015. Touch base on the use of IPV vaccine in other countries as standalone and combination vaccine and in our country through private sector since more than 5 years. Availability of IPV in UIP programme as a liquid formulation in 10 dose and 5-dose vial. • Let participants know that IPV vaccine is expensive. The cost of each dose is between `120 to `150. Each 10-dose vial approximately costs `1200 and a 5-dose vial is `600. Participants should understand the implications of reporting inflated/incorrect coverage. They should know that IPV is both freeze as well as heat sensitive vaccine. Open vial policy applicable to IPV.	

Revised National Immunization Schedule

- Discuss the existing vaccination schedule.
- Emphasize as to how ANM will convince the parents for one dose of IPV at 14 weeks.
- Keep watch on third dose of OPV, Penta or DPT and HepB coverage since IPV will be given as just one dose with third dose of OPV, at 14 weeks.
- Remember – IPV introduction should not lead in drop of coverage of any other vaccine (Penta, DPT, HepB) at 14 weeks.

National Immunization schedule with IPV inclusion; FAQs related to scenarios (20 minutes)

- Discuss the existing vaccination schedule.
- Emphasize on third dose of OPV, Penta or third dose of DPT and HepB coverage since IPV will be given as just one dose with third dose of OPV at 14 weeks.
- Make them understand the revised schedule.
- Reporting of coverage: Do not forget to explain the IPV related scenarios that ANM is expected to face in immunization session.
- Reiterate as to when to give and when not to give IPV vaccination. Discuss how ANM has to deal with children coming for vaccination later or earlier than recommended age.

Vaccine and cold chain management of freeze and heat sensitive IPV (15 minutes)

- Demonstrate to participants where to report IPV coverage in HMIS. Also, make them understand the fields in HMIS where AEFI data and vaccine stock positions are to be entered.
- Storage of IPV vaccine in ILRs should be between +2 – 8°C. Explain how the space required in ILRs will be used for IPV in view of IPV replacing Hep B and DPT vaccines. Explain about the freeze sensitive nature of the injectable IPV. Explain them that these are heat sensitive as well.
- Emphasize the need for the open vial policy. This will not be possible without the back up of a strong alternate vaccine delivery (AVD) plan.
- Emphasize on minimizing vaccine wastage. Explain to them that the state should review vaccine wastage on a monthly basis and districts should review wastage session wise/on a monthly basis.
- Review the existing alternate vaccine delivery mechanism. Participants should bring the AVD microplan of their district. Two well performing and two poor-performing districts should share the AVD plans with their SWOT (strengths, weakness, opportunities and threats) analysis.
- This is a freeze-sensitive vaccine. Explain to the participants that the shake test will not be applicable to IPV.
- Are they aware of the National Cold Chain Management Information System (NCCMIS) software?
- Explain to them the value of this tool and indicators generated. Review the status of NCCMIS and provide the password if required. NCCMIS will help them know inventory as well as break down status of cold chain equipment.
- Review the status of the NCCMIS. The cold chain handlers should be aware about the cold chain inventory including the equipment that stands broken down. Is district or the cold chain point in the district prepared for storage of this new vaccine? This is more important in states that have not yet introduced IPV vaccine.
- They should understand the appropriate time to reorder vaccines (lead time).
- Ensure that vaccine handlers in the district are aware of the contact details of the refrigerator mechanic/person/agency responsible for cold chain repair and preventive maintenance. Details of visit and job undertaken related to cold chain equipment must be documented in the temperature logbook for that particular equipment (when visited – date and time, what was found, what was repaired, outcome of visit and any other instructions given to the vaccine handler of that cold chain point).

Dealing with health workers: IPV related FAQs (30 minutes)

- Coverage trends after IPV vaccine introduction: participants must ensure that ANMs are fully aware of IPV and are comfortable administering IPV along with third dose of OPV, Penta or third dose of DPT and HepB vaccination at 14 weeks.
- They should know the value of giving IPV with OPV.

Introduction to the revised immunization component of the MCP card and counterfoil (20 minutes)

- Update participants on IPV specific modifications in reporting and recording tools - MCP cards, tally sheets, MCH registers, HMIS/MCTS formats.
- Introduce them to the revised MCP cards with emphasis on counterfoil use. Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/due list registers, tools, etc.).
- Emphasize the usefulness of tracking tools: estimation of beneficiaries, due list registers, tally sheets, tracking bags and counterfoils, etc.

Understanding "full immunization" and "complete immunization" (20 minutes)

- Provide clarity on the terms "full immunization" and "complete immunization".
- Disseminate the information regarding ASHA incentives (enlisting of beneficiaries, Updating due list, mobilization of beneficiaries to session site, full immunization, complete immunization)
- Resensitize them about entitlements of ASHA specific to Immunization (`100 for estimation of beneficiaries once in 6 months, `100 for updating due list per month, `150 per session for mobilization to session site, `100 for each fully immunized child, and `50 per for each completely immunized child). Remember to mention that now IPV is included as part of full immunization incentive.
- Clarity on incentive message to ANM/AWW/ASHA – IPV included as part of full immunization incentive.
- Brief participants regarding communication sent from state NHM to districts and blocks to ANMs because it has been observed that ANMs and ASHAs are most of the time not aware of their entitlements especially the support to enlisting of beneficiaries, due list preparation etc.

Entry of IPV coverage in HMIS and MCTS portals (15 minutes)

- Coverage trends after IPV vaccine introduction: participants must ensure that ANMs are fully aware of IPV and are comfortable administering IPV along with third dose of OPV, Penta or third dose of DPT and HepB vaccination at 14 weeks. They should know the value of giving IPV with OPV.
- Importance of due list preparation for tracking beneficiaries (drop outs and left outs)

Understanding importance of session-wise coverage reports

- This will help programme managers at all levels and also vaccine and data handlers at vaccine storage points to understand vaccine coverage, utilization, wastage, etc.

Use of coverage monitoring chart

- Message to participants – Following IPV introduction the MO incharge should compare monthly data of third dose of OPV, Penta and IPV coverage. Check the monthly and cumulative coverage data.
- MOs should fix responsibility of the person who will be required to update and display the same every month.

Understanding evaluated, administrative and monitoring coverage trends of third dose of OPV and Penta or third dose of DPT, HepB in view of IPV introduction (30 minutes)

- Importance of due list preparation for tracking beneficiaries (drop outs and left outs)

The 'tOPV to bOPV' switch in April 2016 and other calendar events (20 minutes)

Vaccine safety (AEFI) and immunization waste management (20 minutes)

Communication and Media management (30 minutes)

Anticipated issues and proposed solutions (20 minutes)

- Listen to participants regarding anticipated issues and challenges. Ask them the possible solutions. The feedback should be reviewed and do able solutions should be projected for approval from STFI/DTFI and/or State and district health society.
- Review monitoring and supervision mechanism at state/district level. Questions to be reviewed by programme manager:
  - Who are involved in RI monitoring in the districts/block?
  - Are they aware of standardized RI monitoring formats approved by the GoI?
  - Is monitoring happening as per these formats?
  - Has there been any data entry for monitored sessions?
  - Is any data analysis available and shared with district or block?

What to do after this workshop: role in sensitizing the health workforce, timelines for completing IPV trainings (30 minutes)

- Ask them to bring out possible issues that they visualize that they might face during the new vaccine introduction.
- Explain to them what they have to do when they go back to their districts.
- These officials must know that as master trainers they will have to further conduct training at block/planning unit level.
- The master trainers will have to take the help of other officials that have been trained at the state level such as NHM finance officials, data handlers (HMIS and MCTS coordinators, district computer assistants to DIOs, district M&E focal person/coordinators (NHM), focal person responsible for immunization reports in CMO office), cold chain handlers (district vaccine store keeper, district cold chain handlers) and district IEC focal persons.
- Ensure there is a plan to monitor IPV planning, trainings, introduction and implementation of IPV vaccine.

Interaction about way forward (15 minutes)

- Reiterate the “remember” messages.
- The master trainers must ensure that a timeline for training is prepared and followed for training the health workforce involved in the immunization programme.

Wrap up

- Let participants know that partner agencies have been requested to monitor planning and implementation of IPV introduction activities.
- Also they should ensure that no district/block should introduce IPV until all their health workers have been trained.

Approximate total time: 6 hours

*Person/s responsible for conduct of training to be decided at the local level

Annexure 3

IPV vaccine training workshop for data handlers at state/district level

Agenda: IPV vaccine training workshop for data handlers at state/district level	
Activity	Person/s responsible*
Registration • Each batch should not have more than 40 participants. In large states/districts, more than one batch may have to be planned.	
Objective of the workshop and opening remarks (15 minutes) • Explain the objectives of the workshop to participants (why they have been called and what is expected from them). • Make the participants feel special and important since they are master trainers for a new vaccine introduction in the state. • They must understand that the coverage data reports that they collate and compile actually helps in measuring the progress of the programme. • They should know that their data drives the programme, their data drives action.	
Basic facts about IPV vaccine (15 minutes) • Key messages: vaccination saves lives; IPV is safe and effective; it is being introduced across all states in India in October 2015. Touch base on the use of IPV vaccine in other countries as standalone and combination vaccine and in our country through private sector since more than 5 years. Availability of IPV in UIP programme as a liquid formulation in 10-dose and 5-dose vial. • Brief them about global and national update on polio including polio endgame strategy. • Let participants know that IPV vaccine is expensive. The cost of each dose is between ` 120 to ` 150. Each 10-dose vial approximately costs ` 1200 and a 5-dose vial is ` 600. Participants should understand the implications of reporting inflated/incorrect coverage. • Briefly explain them about They should know that IPV is both freeze as well as heat sensitive vaccine. Open vial policy applicable to IPV. • Discuss the existing vaccination schedule and lay emphasis on third dose of OPV, Penta or third dose of DPT and HepB coverage since IPV will be given with third dose of OPV,Penta contact at 14 weeks.	
Current and revised vaccination schedule (20 minutes) • Interactive discussion on current UIP schedule • Lay emphasis on third dose of OPV, Penta or third dose of DPT and HepB contact • Ask CCH how many children get vaccinated with Pentavalent doses and corroborate on IPV (DPT if pentavalent vaccine dose is not yet introduced) • CCH should also be aware that ANM is not supposed to vaccinate a child with IPV who has already received third dose of OPV at 14 weeks or later. However, if any child less than one year who is has not yet received third dose of OPV is eligible for IPV along with third dose of OPV, ANM should give third dose of OPV and single dose of IPV. A child beyond one year of age is not eligible for IPV and hence ANM should not give IPV.	
Understanding "full immunization" and "complete immunization" (20 minutes) • Provide clarity on the terms "full immunization" and "complete immunization". Ensure that all entitlements of ASHA specific to Immunization are clearly explained to participants (` 100 for estimation of beneficiaries once in 6 months, ` 100 for updating due list per month, ` 150 per	

session for mobilization to session site, ` 100 for each fully immunized child, and ` 50 per for each completely immunized child). Remember to mention that now IPV is included as part of full immunization incentive.
- Explain them about the evaluation survey.
- Discuss the Full Immunization and complete immunization status at national, state and district level such as Annual Health survey, District level household survey, any other evaluated coverage if available.
- They should know how important is to analyze physical and financial progress.

Analyzing trends of third dose of Penta, OPV, DPT and Hep B coverage in view of IPV introduction (20 minutes)
- Understanding importance of session-wise coverage reports: this will help programme managers at all levels and also vaccine and data handlers at vaccine storage points to understand vaccine coverage, utilization, wastage, etc.
- Ask them to explain as to what analysis they would like to present in ANM meeting and MO meeting.

Use of coverage monitoring chart (30 minutes)
- Check out to see if coverage monitoring chart is being prepared in their state/district/blocks, demonstrate tool for analysis.
- MOs should fix responsibility of the person who will be required to update and display the same every month.
- Understanding the importance of session-wise coverage reports: this will help programme managers at all levels and also vaccine and data handlers at vaccine storage points to understand vaccine coverage, utilization, wastage, etc.
- Use of coverage monitoring chart: explain how to make it, what data to use, importance of monthly and cumulative coverage data, etc. Check out to see if coverage monitoring chart is being prepared in their state/district/blocks, demonstrate tool for analysis.

Update on revised data entry tools and logistic requirements (30 minutes)
- Introduce them to the revised MCP cards with emphasis on counterfoil use.
- Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/due list registers, tools, etc.).
- Emphasize the usefulness of tracking tools: estimation of beneficiaries, due list registers, tally sheets, tracking bags and counterfoils, etc.

Entry of IPV in HMIS and MCTS portals (15 minutes)
- Demonstrate to participants where to report IPV coverage in the HMIS.
- Also, make them understand the fields in the HMIS where the AEFI data and vaccine stock positions are entered.

Assessing immunization performance (15 minutes)

Key indicators for review
- Are they aware of monitoring RI in districts/blocks?
- Are they aware of standardized RI monitoring formats approved by the GoI?
- Is monitoring happening as per these formats?
- Has there been any data entry for monitored sessions?
- Has any analysis been shared with the district or block?
- Are any partners involved in RI monitoring? If yes, is monitoring data being used for corrective action?

NCCMIS status (15 minutes)

- Are they aware of NCCMIS software? Explain to them the value of this tool and the indicators generated. Review the status of NCCMIS and provide the password if required.

FAQs on IPV (15 minutes)

Role of trainers at various levels (30 minutes)

- Actions required in training the data handlers.
- Ask them to bring out possible issues that they might face during the new vaccine introduction.
- Explain to them what they have to do when they go back to their districts. These officials should know that as master trainers they need to further conduct training at block/planning unit level. The master trainers will have to take the help of other officials that have been trained at the state level such as the HMIS and the MCTS coordinators, district computer assistants to DIOs, district M and E focal person (NRHM), focal person responsible for immunization reports in CMO office, district vaccine store keeper, district cold chain handlers and district IEC focal persons.

Wrap up and reiterate the "remember" messages

Approximate total time: 4 hours

*Person/s responsible for conduct of training to be decided at the local level

Annexure 4

IPV training workshop for vaccine and cold chain handlers at state/district level

Agenda: IPV training workshop for vaccine and cold chain handlers at state/district level	
Activity	Person/s responsible*
Registration	
Objectives of the workshop (15 minutes) • Proper maintenance of ILR along with correct positioning of IPV in ILR. • Conditioning of ice packs and distribution as per calculations done. • Adherence to open vial policy and follow EEFO.	
Opening remarks (15 minutes) *Interactive Training session* *Trainer introduces himself/herself and encourages cold chain handlers to introduce and talk about their work experience.* • Cold chain handlers are the custodians of all vaccines used under universal immunization program. A motivated cold chain handler will ensure that all guidelines are followed for safe handling of all vaccines including IPV and will accountable for the same. • IPV stands for "Inactivated Poliovirus Vaccine" which is an injectable vaccine. IPV is given as single dose 0.5 ml intramuscular in right mid-thigh (anterolateral aspect) along with third dose of OPV at 14 weeks. IPV enhances protection to the children against all types of polio. • IPV is highly freeze sensitive as well as heat sensitive, costly and the stocks is limited. Shake test is not applicable to IPV to detect freezing. Hence, special care has to be given by cold chain handler regarding IPV to prevent damage due to freezing or avoidable wastage factors. • Meticulous handling of IPV by cold chain handler can avert AEFI occurrences in the field.	
Basic facts about IPV vaccine (30 minutes) • IPV stands for as "Inactivated Poliovirus Vaccine" and is an injectable vaccine. • IPV will be available in UIP programme in a liquid formulation. • IPV is safe and effective; its use will accelerate global polio eradication. • IPV is in use in private sector since 10 years. • It is being introduced across all states/union territories in India in October 2015. • IPV is available in UIP programme in a liquid formulation (10- & 5-dose vials) • IPV vaccine is expensive. - 10-dose vial is approximately `1200 - 5-dose vial is approximately `600. • IPV is both freeze as well as heat sensitive vaccine. Shake Test is not applicable to IPV. • Open vial policy applicable to IPV	
Current and revised vaccination schedule (15 minutes) • Interactive discussion on current UIP schedule. • Lay emphasis on third dose of OPV/Penta/DPT & HepB contact • Ask cold chain handler how many children get vaccinated with Pentavalent doses and corroborate on IPV (DPT if pentavalent vaccine dose is not yet introduced) • CCH should also be aware that ANM is not supposed to vaccinate a child with IPV who has already received third dose of OPV at 14 weeks or later. However, if any child less than one year who is has not yet received third dose of OPV is eligible for IPV along with third dose of OPV, ANM should give third dose of OPV and single dose of IPV. A child beyond one year of age is not eligible for IPV and hence ANM should not give IPV.	

Storage of vaccines in ILRs and; explain freeze sensitivity of IPV vaccine (30 minutes)

- Storage of IPV vaccine in ILRs should be between +2 – 8°C.
- Explain with pictures on positioning of IPV in ILR along with other UIP vaccines and make them understand the freeze and heat sensitivity of vaccines.
- IPV is both freeze and heat sensitive.
- Repeat that shake test is not applicable on IPV.
- Make sure alternate-back up CCHs are attentive and interact and make sure he/she is well abreast on the handling of all vaccines including IPV.

Update on revised data entry tools and logistic requirements (30 minutes) (MCP cards/counterfoil, tally sheets, MCH registers, HMIS/MCTS formats)

- Identify cold chain handler who is aware of the contents of revised MCP cards/counterfoil, tally sheets.
- Show the revised MCP cards/counterfoil, tally sheets and pass it through the group and make them aware.
- Show them the contents of MCH registers and HMIS/MCTS formats.
- Identify the space/column for filling information on IPV.

How to calculate vaccine wastage, emphasizing on IPV vaccine? (15 minutes)

- IPV is costly, freeze and heat sensitive as well. Shake test is not applicable. Discuss what could be the avoidable wastage factors in the field including vaccine storage point. Then interact how these can be avoided in their experience.
- Give scenario of IPV expenditure by ANM/session and ask cold chain handler to identify the highest wastage.
- Assess if the CCH is aware of all the AVD persons/mechanism working in their planning unit. Enquire if there is any AVD person who does not deliver the vaccines to the field on time/does not return the vaccines at the end of session to the vaccine storage point.
- Encourage cold chain handler to highlight ANM/sessions with high wastage rate and AVD with callous approach on handling of vaccines and bring it to the notice of medical officer.
- The five important details for all vaccines/diluents including IPV must be written in the vaccine stock register and displayed in cold chain room. CCH should urge ANMs to mention the same in their tally sheet. The details to be recorded are:
  1. Name of the manufacturing company
  2. Batch number
  3. Expiry date
  4. Manufacturing date
  5. VVM status

Preventive maintenance mechanism and responding to chain equipment complaints (20 minutes)

- Review the status of the NCCMIS.
- Assess if the cold chain handler and vaccine handler is aware of the contact details of the refrigerator mechanic/person/agency responsible for cold chain repair and preventive maintenance.
- Cold chain handler should document details of visit and job undertaken related to cold chain equipment in the temperature logbook for that particular equipment.
- Details such as when visited-date and time, what was found, what was repaired, outcome of visit and any other instructions given to the vaccine handler of that cold chain point.
- CCH should ensure:

- ILR/deep freezer should be placed 1 feet away from the wall, on a wooden platform and connected with a recommended stabilizer.

- Temperature recording twice daily in recommended logbook.
- Remind MO to cross check recording of temperature physically and countersign the logbook weekly.
- Door should not be opened frequently.
- Defrost monthly and/or as required.
- Must prepare to keep the vaccine in alternate arrangement when ILR is taken up for defrosting and recorded accordingly in temperature lob book.
- Position the vaccines as per recommended guidelines.
- Diluent should be kept in ILR 24 hours prior to use (for reconstitution vaccines).
- Only conditioned ice packs have to be used (ask one cold chain handler to explain/demonstrate).

Strengthening reporting and recording of vaccine and cold chain equipment (NCCMIS) (15 minutes)

- Review mechanism of monitoring and supervision
- Ensure that vaccine handlers in the district are aware of the contact details of the refrigerator mechanic/person/agency responsible for cold chain repair and preventive maintenance. Details of visit and job undertaken related to cold chain equipment must be documented in the temperature logbook for that particular equipment (when visited – date and time, what was found, what was repaired, outcome of visit and any other instructions given to the vaccine handler of that cold chain point).
- Reiterate the "remember" messages.

Initiatives taken by state to strengthen cold chain supervision and monitoring (15 minutes)

Reiterate " remember" messages (15 minutes)

Role of participants as trainers in sensitization training (15 minutes)

Wrap up

Approximate total time: 4.5 hours

* Person/s responsible for conduct of training to be decided at the local level

Annexure 5

IPV training workshop for IEC/media handling focal persons

Agenda: IPV training workshop for IEC/media handling focal persons	
Activity	Person/s responsible*
Registration	
Objectives of the workshop and opening remarks (10 minutes) **Expected role of participants in the programme** • Responsibility of training of IEC and media handling focal personnel at district and block level	
Understanding immunization status at national, state and district levels (20 minutes) **Situational analysis:** • Global and national polio eradication status. • Explain "full immunization" and "complete immunization". • Current RI status (evaluated/ reported coverage. • Brief about where and why we are missing children. • Current strengths and challenges in immunization program at state and district level. • Explain about national and state level efforts to increase immunization coverage in high focus areas/districts – Mission Indradhanush, etc. • Mobilization efforts, incentives available for ASHA.	
Brief on preparedness for IPV introduction, State efforts to improve the gaps (10 minutes) • Explain about state preparedness plan for IPV introduction. • Trainings from state to block level staff.	
Basic facts related to polio endgame strategy (20 minutes) including introduction of IPV in national immunization programme • Briefly explain polio endgame strategy and forthcoming events. • How would current vaccination schedule change after introduction of IPV introduction? • Rationale for IPV introduction.	
Key FAQs (refer to operational guidelines) (20 minutes) • Take them through FAQs. • No need to go through scenarios and response.	
Address additional questions asked by media/participants (20 minutes) • Participants should be encouraged to ask questions; facilitator to note these questions on the flip chart and then address them one by one.	
Increasing visibility of the RI program in state with a focus on IPV introduction (20 minutes) • Demonstrate the new IEC prototypes developed for IPV introductions. • Share state specific instructions on IEC and communication including budget guidelines (if any).	
Role of media, (print, electronic and social) in IPV introduction (20 minutes) • Disseminate state specific instructions. • Plans for advocacy through print, electronic media (FM radio, TV, etc.) and social media.	

Risk communication (15 minutes)

- Explain that IPV is a safe vaccine; it is in use in many countries and in India it has been in use for more than a decade.
- Most of the queries are answered in FAQs.
- Handling an AEFI crisis – refer MoH communication guidelines for building vaccine confidence around AEFI)

Writing a press release (45 minutes)

- Participants should be informed about writing a press release for IPV introduction.
- Essentials of a press conference
- Key points to remember for conducting a press conference including essential documents needed during the conference.

Setting up mechanisms to monitor communication specific activities in the districts and blocks (30 minutes)

- Monitoring state IEC/ behaviour change communication (BCC) efforts.
- Discuss and disseminate IEC specific questionnaire for supervision and monitoring IPV introduction activities.

Anticipated challenges and issues (20 minutes)

- Suggestions and solutions.

Carry home messages based on IPV operational guidelines (15 minutes)

- Complete trainings as per timelines.
- 2 participants per state/district to be invited for the trainings. At block level only focal person for IEC and communications to be trained.
- The participants being trained will be responsible for conducting training workshops for the next level (district/block).
- Identify key persons from print and mass media. Ensure contact details are available. Invite for the media brief when planned by state/district task force.
- Trained personnel will be responsible for facilitating the launch of vaccine at respective levels including the media briefing, press release, etc.

Wrap up

Approximate total time: 4.5 hours

*** Person/s responsible for training to be decided at the local level.**

Annexure 6

IPV training workshop for National Health Mission (NHM) programme and finance officers at state/district/block level

Agenda: IPV training workshop for National Health Mission (NHM) programme and finance officers at state/district/block level	
Activity	Person/s responsible*
Registration	
Objectives of the workshop and opening remarks (15 minutes) • Make the participants feel special and important since they are master trainers for training for finance managers at district and block level. • Will help in informing the policy and decision makers. • With clarity on project implementation plan matters their support will be critical for smooth introduction of trainings and other activities with NHM funding support. • They must understand that they their contribution will be instrumental in strengthening of the health systems at state/district level.	
What is the need to train NHM finance officers? • It is extremely important to train NHM finance officials. • These officials should be trained on priority basis as this has direct impact on supporting all other IPV introduction trainings and other activities at all levels. • Trainers /trainees must realize that IPV introduction is a matter of national pride that we complete our trainings and other activities at all levels in time and be at ahead or at par with global timelines of polio endgame strategy.	
Role of attending participants in IPV introduction activities at state/district and block level (15 minutes) • Role of NHM programme and finance officers in state and district task forces will be critical to the programme. • Support from state and district health society will be critical in areas needing attention especially budgetary needs. • Understanding and supporting cascade-training plan from state to district to blocks by NHM will be the key to introduction.	
Global and National update on polio eradication and overview of Polio Endgame Strategy (15 minutes) • The 'tOPV to bOPV' switch in April 2016 and other calendar events. • Inform about national and global implications/repercussions in case of missing/delaying timelines.	
Introduction to IPV vaccine in National Immunization schedule (15 minutes) **FAQs related to IPV** • Touch base with basic understanding of vaccine and schedule and those that are important for the attending participants.	
Cost of IPV vaccine (15 minutes) • Nature of vaccine (freeze sensitive). Implications due to a compromised cold chain; alternate vaccine delivery. • Let participants know that IPV vaccine is expensive. The cost of each dose is between `120	

to `150. Each 10-dose vial approximately costs `1200 and a 5-dose vial is `600. Participants should understand the implications of reporting inflated/incorrect coverage. They should know that IPV is both freeze as well as heat sensitive vaccine. Open vial policy is applicable to IPV.

Understanding Immunization PIP (Part C) (20 minutes)

- Supporting immunization activities from Part A and Part B project implementation plan (IEC, infrastructure, HR, etc.)

Status of NHM support for IPV introduction (20 minutes)

- Printing of revised MCP card and counterfoil as per prototype and SOPs
- Printing of revised (IPV included) tally sheets, due list formats, MCH registers and monthly reporting formats.
- Not printing the MCP cards and other tools will create confusion at all levels.
- Tracking bag (one per session per ANM) as per prototype and SOPs. Emphasize on the usefulness of tracking tools and procuring tracking bags for ANMs.
- Support required from NHM for printing training material in local languages.
- Release of project implementation plan (Part C) immunization funding especially cold chain, trainings, alternate vaccine delivery, supervision at all levels, immunization waste management.
- IPV launch plan and support from NHM at state/district level.
- IEC activities support to IPV introduction.
- Supervision and monitoring plan (mobility support in terms of training, vehicle and stay support for state and district observers).

Supporting adverse event following immunization AEFI activities (20 minutes)

- Brief about the AEFI system in country (committees, causality assessment committees, etc.).
- Participants should understand that before introduction of any new vaccine the district /blocks, the AEFI management kits should be available with all the recommended drugs at appropriate health facilities.
- Finance managers should identify the source of funding for supporting an AEFI activity, if it occurs at any point of time in the programme. These could include management of child in government or private facility (if required), transportation of vaccine to lab for testing, meeting of district and state AEFI committees, causality assessment, media management, etc.).
- Close the session by reiterating that IPV is safe and has been in use around the world since many years and its use in India for more than 10 years in private sector.

Understanding "full immunization" and "complete immunization" (30 minutes)
Ensure participants have clarity on ASHA incentives, which include

- Enlisting of beneficiaries (house to house survey).
- Updating due list (they should understand that enlisting of beneficiaries will actually form the basis of preparation of due list for tracking beneficiaries (drop outs and left outs).
- Mobilization of beneficiaries to session site.
- Full immunization (IPV included as part of full immunization incentive).
- Complete immunization.

Increasing incentive awareness among ASHAs

- NHM network should percolate clarity on ASHA incentive message to ANM/AWW/ASHA through DPMs/DAMs and BPMs/BAMs and other health staff.
- NHM should send communication right up to the level of ASHA regarding inclusion of IPV as part of full immunization incentive along with other vaccines as per national immunization schedule.

Status of available funds under Part C Immunization project implementation plan fund utilization and status of utilization of Part A and Part B of funds identified for supporting immunization activities (30 minutes)

- Update on any state specific immunization initiative being supported by NHM (Immunization field volunteer, etc.).
- Issues and challenges for action by state/district task force and/or state/district health society.

Understanding coverage trends of third dose of OPV and Penta or DPT, HepB in view of IPV introduction (15 minutes)

- Inform them about how to measure progress of IPV introduction in relation to coverage of third dose of Penta/OPV or DPT/HepB/OPV.
- Reiterate again that their role timely disbursement of immunization incentives will be very important and hence they must review the utilization district wise at state level and block wise at district level and subcentre wise at block level.

Anticipated issues and proposed solutions (15 minutes)

- Issues and challenges (if any) for action by state/district task force and/or state/district health society.

What to do after this workshop? (30 minutes)
Summarize the key take home messages

- Training of finance officials, monitoring fund utilization especially ASHA incentives, review cold chain preventive maintenance at state and district including review mechanism of cold chain handlers.

Interaction about way forward (15 minutes)

Wrap up

Approximate total time: 4.5 hours

* Person/s responsible for conduct of training to be decided at the local level

Annexure 7

IPV training workshop for ANMs, LHVs and health supervisors at block level

Agenda: IPV training workshop for ANMs, LHVs and health supervisors at block level	
Activity	Person/s responsible*
Registration	
Objectives of workshop and opening remarks (10 minutes) • Explain participants why they have been called, and what is expected from them. • Ask them to bring out possible issues that they visualize that they might face during the new vaccine introduction.	
Basic facts about IPV vaccine (20 minutes) • IPV is safe and effective vaccine. • IPV being used in many countries for more than 50 years and in India for past 10 years. • It is being introduced across all states/union territories in India in October 2015. • Availability of IPV in UIP programme as a liquid formulation in 10-dose and 5-dose vial. • IPV will be given as just one dose at third dose of OPV, Penta contact at 14 weeks. • Dose of IPV is 0.5 ml, intramuscular at right anterolateral thigh. • IPV is expensive vaccine. The cost of each dose is `120-150. - A 10-dose vial cost `1200 and 5-dose vial cost `600. • IPV is both freeze and heat sensitive vaccine. - Proper care needed during transport and during the immunization session. • Open vial policy is applicable to IPV.	
Handling IPV during immunization session (15 minutes) • The details for all vaccines/diluents including IPV must be written before starting the vaccination session that day. ANM must mention the five important details as under: 1. Name of the manufacturing company 2. Batch number 3. Expiry date 4. Manufacturing date 5. VVM status • IPV is both freeze and heat sensitive vaccine. - Use conditioned of icepack; avoid exposure to sunlight/heat; check VVM.	

- ANMS should be fully aware of IPV and are should be comfortable to give IPV along with third dose of OPV, Penta or DPT and HepB vaccination at 14 weeks. They should know the value of giving IPV with third dose of OPV.
- Explain the IPV related scenarios that ANM is expected to face in immunization session.
  - Reiterate as to when to give and when not to give IPV vaccination.
- Discuss how ANM has to deal in children coming for vaccination later or earlier than recommended age.
- Do not forget to explain that all children younger than 1 year who have already received a third dose of OPV will not be given IPV however any child who is coming for third dose of OPV dose should not be denied a dose of IPV.
- A child more than one year of age that has not earlier been vaccinated at 14 weeks or later (before one year) is not eligible for the IPV vaccine. Go through with different scenarios that the ANMs may face following IPV in their immunization sessions.

FAQs on IPV vaccine (20 minutes)

- Discuss FAQs in detail (interactive session with all participants).

Introduction to the immunization component of the MCP card (30 minutes)

- Introduce them to the revised MCP cards with emphasis on counterfoil use.
- Ask all ANMs to make one entry in the card and counterfoil.

Improving microplanning (20 minutes)

- Emphasize on including polio HRA as part of the microplan and estimation of beneficiaries concept.
- Discuss process to undertake field survey.
- Preparation and updating of beneficiary due list.

Use of immunization tracking bag and due list for tracking (30 minutes)

- Use of immunization tracking bag.
- Exercise on placing immunization card in tracking bag after IPV vaccination.

Update regarding revised logistics (30 minutes)

Registers/MCP cards/tally sheets, MCH registers, HMIS/MCTS formats/IEC material

- Importance of session-wise coverage reports: this will help programme managers at all levels and also vaccine and data handlers at vaccine storage points to understand vaccine coverage, utilization, wastage, etc.
- Sensitize them on revisions done in the reporting tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers, etc.).
- Sensitize them to revisions done in the reporting and tracking tools (registers/MCP cards/vaccine distribution registers/vaccine stock registers/due list registers, tools, etc.).

Where does an ANM enter data for IPV vaccination in the HMIS and MCTS registers/formats? (15 minutes)

- Demonstrate where to report IPV coverage in HMIS format.
  - Also, make them understand the fields in HMIS where AEFI data and vaccine stock positions are to be entered.
- Emphasize the usefulness of tracking tools: estimation of beneficiaries, due list registers, tally sheets, tracking bags and counterfoils, etc.

Discuss about how coverage of DPT, hepatitis B and IPV vaccine will change when IPV vaccine is introduced (20 minutes)

Importance of ensuring open vial policy for DPT, TT, hepatitis B and IPV vaccine is in place through alternate vaccine delivery (15 minutes)

- Open vial policy applicable to IPV. Emphasize on minimizing vaccine wastage. Explain them that the vaccine storage points will be closely watching the IPV implementation including vaccine wastage.
- Explain how monitoring will intensify for vaccines distribution and return of unused/partial vaccines on the day of immunization

Vaccine safety (AEFI) and immunization waste management (20 minutes)

- Explain reporting/management guidelines
  - What to do in case of AEFI?
  - When & where to report AEFI?

What to do after this workshop: their role in sensitizing the social mobilizers: ASHAs and AWWs (30 minutes)

Provide clarity on the terms “full immunization” and “complete immunization.” Ensure that all entitlements of ASHA specific to Immunization are clearly explained to participants (`100 for estimation of beneficiaries once in 6 months, `100 for updating due list per month, `150 per session for mobilization to session site, `100 for each fully immunized child, and `50 per for each completely immunized child). Remember to mention that now IPV is included as part of full immunization incentive.

Wrap up

Approximate total time: 6 hours

* Person/s responsible for conduct of training to be decided at the local level

Annexure 8

IPV training workshop for ASHA, AWW and link workers at block level

Agenda: IPV training workshop for ASHA, AWW and link workers at block level	
Activity	Person/s responsible*
Registration	
Objectives of the workshop and opening remarks (10 minutes) • Make the mobilizers feel special and important. • They should understand that it is because of them that the country has made progress in polio eradication, maternal and neonatal tetanus elimination, and reduction of morbidity and mortality due to other vaccine preventable diseases. • Explain to them that immense progress has been made in RI, but to reach the beneficiaries who have not yet been reached will require special efforts and initiatives. • Make them feel accountable for their area of work. • Inform them about the IPV vaccine introduction in their state and the expectation from them to improve coverage related to all vaccines, with emphasis on IPV vaccine. • They should understand the value of timely tracking of beneficiaries using tracking tools such as tracking bags, counterfoils and due lists. • Make them feel accountable for the vaccine used and vaccine wasted at their level. • Focus on introduction of IPV and the expectation in regard to recording and reporting of immunization coverage related to all vaccines, with emphasis on IPV.	
Basic facts about IPV vaccine (10 minutes) • IPV is safe and effective vaccine. • IPV being used in many countries for more than 50 years and in India for past 10 years. • It is being introduced across all states in India in October 2015. • Availability of IPV in UIP programme as a liquid formulation in 10-dose and 5-dose vial. • IPV will be given as just one dose with third dose of OPV at 14 weeks. • Dose of IPV is 0.5 ml, intramuscular at right anterolateral thigh. • IPV is expensive vaccine. The cost of each dose is `120-150. o A 10-dose vial cost `1200 and 5-dose vial cost `600. • IPV is both freeze and heat sensitive vaccine. o Use conditioned icepack. o Avoid exposure to sunlight/ heat. o Check VVM. • Open vial policy is applicable to IPV. • Mobilizers must understand clearly about what to do with children coming for vaccination later or earlier than recommended age. • They should know the value of giving IPV with OPV.	
Introduction to the immunization component of the MCP card; filling and using the counterfoil and its use through tracking bag; understanding "full immunization" and "complete immunization" (30 minutes) • Introduce them to the revised MCP cards with emphasis on counterfoil use. • Ask all ANMs to make one entry in the card and counterfoil.	

Improving microplanning, emphasizing on estimation of beneficiaries by ASHAs/AWWs in their catchment area (10 minutes)

- Emphasize on including polio HRA as part of the microplan and estimation of beneficiaries concept.
  - o Discuss process to undertake field survey.
  - o Preparation and updating of beneficiary due list.
- Let them know that they have to undertake a very important and critical survey related to estimation of beneficiaries for improving the microplans.
- Ask them about the possible issues that they visualize that they might experience in the estimation of beneficiaries (survey).

Use of immunization tracking bag and helping to prepare due lists for tracking (30 minutes)

- Use of immunization tracking bag.
- Exercise on placing immunization card in tracking bag after IPV vaccination.

New IEC materials related to IPV vaccine and how to display them (10 minutes)

- Show the IPV vaccine/RI related material available.
- Discuss how effectively these can be used.

Key messages regarding IPV vaccine that ASHAs/AWWs must understand for improving vaccine coverage in the field. Emphasize on IPV vaccine messages (30 minutes)

- Make ASHAs know what important messages need to be percolated in the community regarding IPV

Four key messages for caregivers
What vaccine was given and what diseases it prevents?
What minor adverse events could occur and how to deal with them?
When and where to come for the next visit?
Keep the immunization card safe and bring it along at the next visit

- Critical messages related to IPV should be provided in addition to the four key messages.
  - o Explain their role in case any minor event or an AEFI case is reported.
  - o Reiterate the “remember” messages.

Concept of full immunization" and "complete immunization" & mobilizers incentive for immunization (10 minutes)

- Provide clarity on the terms "full immunization" and "complete immunization".
- Ensure that all entitlements of ASHA specific to immunization are clearly explained to participants:
  - `100 for estimation of beneficiaries once in 6 months.
  - `100 for updating due list per month.
  - `150 per session for mobilization to session site.
  - `100 for each fully immunized child.
  - `50 per for each completely immunized child.

Remember to mention that now IPV is included as part of full immunization incentive.
Interaction about way forward (15 minutes)

- Explain to them what they have to do when they go back to their village/area of work.

Wrap up

Approximate total time: 3 hours

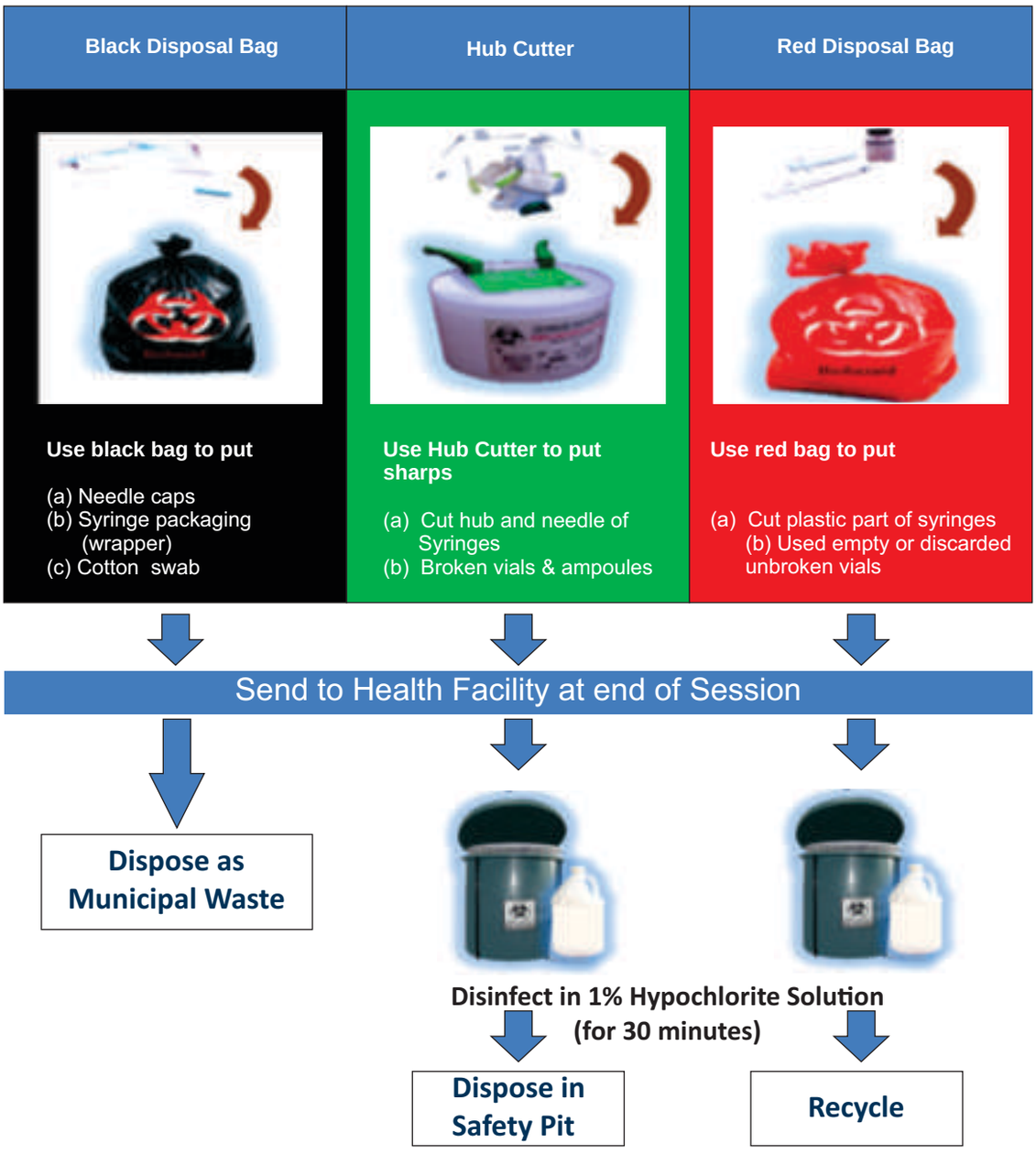
* Person/s responsible for conduct of training to be decided at the local level

Annexure 9

Waste management

The existing immunization Central Pollution Control Board (CPCB) guidelines for biomedical waste disposal will be applicable to IPV, including segregation of immunization waste at source and its treatment and disposal.

The principles followed are segregation of waste at source (at the session site), transportation to the PHC or CHC, treatment of sharps and potentially biohazardous plastic waste, disposal of sharps and treated plastic waste through proper recycling.



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