POLIO GLOBAL ERADICATION INITIATIVE

Aide Mémoire

Use of fractional-dose inactivated polio vaccine (fIPV) in supplementary immunization activities (SIAs)

Purpose

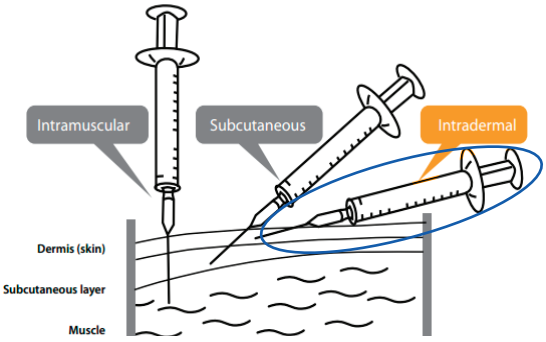
Summarize operational considerations for use of fIPV in SIAs as a quick reference for field staff.

What you need to know about fIPV

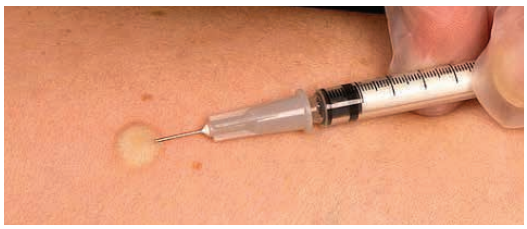
- Intradermal (ID) administration of a fractional dose of IPV (fIPV) is safe, effective and immunogenic.[1] [2]
- fIPV can benefit children previously vaccinated for polio AND zero-dose children. For children who have previously received oral polio vaccine (OPV), fIPV will help to "boost" their immunity.[1]
- fIPV can be given alone or at the same time as any OPV vaccine. Accelerated routine immunization with fIPV is recommended to enhance eradication of wild poliovirus (WPV), and reduce the risk of emergence of VDPVs.
- fIPV may be used for VDPV2 outbreak or event response in settings where immunity is already high and recommended by global technical experts. In most instances, especially in low-immunity settings, mOPV2 remains the vaccine of choice.

How to administer fIPV

- **Overview:** intradermal injection of fIPV is shallow, given directly into the dermis layer of the skin
  - **The dose of fIPV is 0.1 mL or 1/5th of a full dose**
- **Technique**
  - Angle of syringe should be *close to flat on the skin* (10–15 degree angle, as circled below)



  - Vaccine should be administered ***slowly*** **and formation of a "bleb" observed** (5–10 mm diameter) (circular "bulge" that forms as skin is stretched by injected fluid).



- Do not repeat the vaccination, even if no bleb is observed after injection.
- **Finger mark** vaccinated child on the left finger immediately after injection.

**If dual antigen campaign: fIPV + mOPV2, two different pre-designated fingers to be marked*

Presentation & packaging of fIPV

- **Several manufacturers supply IPV in both single and multiple full-dose vials** (exact label may vary).
- **Full-dose IPV vials are also used to supply fIPV:**
  - 1-dose vial (0.5 mL) → 4-5 fIPV doses (0.1 mL each)
  - 5-dose vial (2.5 mL) → up to 25 fIPV doses (0.1 mL each)
  - 10-dose vial (5 mL) → up to 50 fIPV doses (0.1 mL each)

What you need to know about fIPV vials

- **Cold chain is essential.** Always store at 2–8 °C.
- **IPV is freeze sensitive; discard any vial suspected to have undergone freezing.**
- **Do NOT use the "shake test"** *as not effective for IPV*
- **Check the VVM** before each use and discard vial if colour of the square is the same as or darker than the surrounding circle.[3]
- **Mark the vial with the time and date of opening**. Vaccine can be used up to 28 days after opening vial if stored appropriately and VVM has not expired.

The septum of a multi-dose vial tolerates multiple punctures; there should be no leakage if the vial is upside down. If leakage is observed, note and discard.

Injection device options

	Advantages	Training suggestions
AD syringes* (0.1 mL)	Simple & standard syringe, low cost, less solid waste	How to administer ID injections
Adapters + AD syringes* (0.1 mL)	Correctly positions needle, simple & standard syringe, additional waste	How to apply adapter, how to administer ID injections
Jet injectors	No skin puncture, clinically equivalent immune response, specialized device rather than syringe	Two-part training: "injector" to administer, and "assistant" to load each injection

*ONLY 0.1 mL auto disable (AD) syringes, **DO NOT USE 0.05 mL**

1 11th Meeting of SAGE Polio Working Group: conclusions and recommendations. 19–20 January 2015 (**http://www.who.int/immunization/sage/meetings/2016/april/1_11th_Meeting_SAGE_Polio_Working_Group_January_2016.pdf).**

2 Use of fractional dose IPV in routine immunization programmes: considerations for decision-making. March 2017; (**http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/fIPV_considerations_for_decision-making_March2017.pdf?ua=1**), accessed 10/04/2017.

3 WHO. What is VVM and how does it work? **(http://www.who.int/immunization_standards/vaccine_quality/What%20is%20VVM%20and%20how%20does%20it%20work.pdf).**

Operations during fIPV campaign

- **Vaccination site selection**
  - Fixed health facility (existing health facilities designated to hold SIA sessions, with functional cold chain: refrigerator/freezer)
  - Outreach surge sites (temporary sites, in operation for ≥1 SIA session, rely on vaccine carriers and cooling packs for cold chain)
  - Mobile teams (used for difficult-to-access populations, positioned as needed, rely on vaccine carriers and cooling packs)
- **Workforce planning and essential functions** Core roles include the following:
  - vaccinator: inject vaccine, manage vaccination site including waste management
  - team assistant(s): record vaccinations on tally sheet, do finger-marking
  - social mobilizers: mobilize communities, direct children to vaccination site, address hesitant families
  - supervisors & monitors: ensure high quality and coverage during SIA, identify and resolve issues of team performance, missed children, vaccine supply or cold chain
  - always consider how to maintain smooth work flow and crowd control.
- **Number fIPV vaccinations/day per vaccinator**
  - Adjust micro-plans and expected number of children to local circumstances.
  - **≥ 100 children/day** is reasonable for a fixed or outreach vaccination site.

Training

See Tools and library at **www.polioeradication.org**

Standard WHO multi-dose vial policy (MDVP) [4]

should be observed. Partly used vials may be used for up to 28 days if properly handled and maintained, according to MDVP and national immunization policy.

Vaccine for outreach sites & mobile teams

- Fixed health facilities can act as "hubs" for distribution, if sufficient space and resources.
- Re-stock vaccine carriers and replenish **cooling packs** for daily redistribution.
- Ensure there is adequate refrigerator space to store vaccine and **cooling packs** overnight.
- **DO NOT use ICE PACKS** for IPV as the vaccine temperature could become too cold (<2 °C).

Waste management

- Safe disposal of injection materials is essential.
- Disposal methods must be clearly communicated and all personnel trained in safe practices.
- If adapters are used, they must be left attached to the syringe after immunization and disposed of in a safety box. **Never reuse adapters**.

Adverse events following immunization (AEFI)

- Country standard reporting form must be completed for any suspected serious event.

Monitoring and evaluation

- **Employ IM/LQAS to monitor children immunized** using standard methods.
- **Acceptability & safety of fIPV**
  - acceptable to the target population, health-care providers and SIA personnel
  - investigate and verify serious AEFIs
  - needle-stick injuries or other occupational health concerns of SIA personnel.
- **Vaccine accountability indicators**
- **Operational challenges**
  - Wastage *per vial* is expected to be less than 10% (≥45 fIPV doses per 10 full-dose vials).
  - Overall campaign wastage expected is ≤15% (opened & unopened vial wastage).
  - Vaccine management (MDVP, freeze prevention, cold chain maintenance, etc.).
- Multiple antigen campaign implementation:
  - *Coordination & implementation of fIPV with OPV or other vaccines, including maintenance of separate cold chains where warranted for vaccines with different requirements.*

NOTE: Country engagement and government leadership, rapid, iterative decision-making and proactive communication during campaigns are crucial for ensuring optimal coverage.

Additional references on fIPV

- Anand A et al. Early priming with inactivated poliovirus vaccine (IPV) and intradermal fractional dose IPV administered by a microneedle device: a randomized control trial. Vaccine. 2015 33:6816–22.
- Bahl S et al. Fractional-dose inactivated poliovirus vaccine immunization campaign – Telangana State, India, June 2016. MMWR Morb Mortal Wkly Rep. 2016;65:859–63.
- Jafari H et al. Efficacy of inactivated poliovirus vaccine in India. Science. 2014;345(6199):922–5.
- Resik S et al. Priming after a fractional dose of inactivated poliovirus vaccine. N Engl J Med. 2013;368:416–24.

4 WHO. Multi-dose Vial Policy (MDVP), Revision 2014. Sept 2014 **(http://apps.who.int/iris/bitstream/10665/135972/1/WHO_IVB_14.07_eng.pdf)**.