

# **Summary of Key Points**

## **WHO Position Paper on Polio Vaccine March 2016**



**World Health  
Organization**

# Background

- Poliomyelitis (polio) is an acute communicable disease of humans caused by poliovirus of serotypes 1, 2 or 3.
- Faecal-to-oral and/or oral-to-oral mode of transmission, depending on standard of sanitation.
- In the pre-vaccine era before 1960, virtually all children became infected.
- 1974: Oral poliovirus vaccine recommended as part of the Expanded Programme on Immunization.
- 1988: World Health Assembly resolved to eradicate polio globally by the year 2000.

# Epidemiology

- Globally, the last case of poliomyelitis caused by naturally circulating WPV type 2 (WPV2) occurred in India in 1999. Global eradication of WPV2 was certified in 2015.
- No case due to WPV type 3 (WPV3) has been detected since 10 November 2012.
- In 2015, Pakistan and Afghanistan remain endemic for transmission of WPV type 1 (WPV1).
- In 2015, 73 polio cases were reported, all due to WPV1. This represents the lowest number for any calendar year on record.

# Disease

- The incubation period is usually 7–10 days (range 4–35 days).
- Most people infected with poliovirus have no symptoms, with viral replication occurring in, and limited to, the alimentary tract or pharynx.
- Approximately 25% of those infected develop minor symptoms, usually fever, headache and sore throat.
- Paralytic poliomyelitis occurs when poliovirus enters the central nervous system and replicates in anterior horn cells (motor neurons) of the spinal cord and is experienced in <1% of poliovirus infections in children <5 years of age, varying with serotype and age.
- The typical clinical manifestation of paralytic poliomyelitis is acute flaccid paralysis affecting the limbs, principally the legs, usually asymmetrically; sensation remains intact. Persistent paralysis and resulting deformities are common sequelae.
- The case-fatality rates among paralytic cases range from 5% to 10% in children and from 15% to 30% in adolescents and adults, predominantly associated with bulbar involvement.

# Treatment and prevention

- No specific anti-viral drugs are available for poliomyelitis. Treatment consists of supportive, symptomatic care during the acute phase, including respiratory support in cases with respiratory muscle paralysis.
- For primary prevention, two types of poliovirus vaccines are available:
- Live attenuated oral poliovirus vaccine
- Inactivated poliovirus vaccine

# Oral poliovirus vaccine (OPV)

- OPV is administered as 2 drops (~0.1 mL), directly into the mouth.
- There have been several licensed formulations of OPV: (i) monovalent OPVs against type 1 (mOPV1), type 2 (mOPV2) or type 3 (mOPV3); (ii) bivalent OPV (bOPV) containing types 1 and 3; and (iii) trivalent (tOPV) containing types 1, 2 and 3.
- The eradication of indigenous WPV2 in 1999, coupled with the continuing emergence of neurovirulent circulating type 2 vaccine-derived polioviruses (cVDPV2s) as well as vaccine-associated paralytic poliomyelitis (VAPP), led to the recommendation that there should be coordinated global cessation of use of the type 2 component of OPV and a switch from tOPV to bOPV.
- The only serious adverse events associated with OPV are rare cases of VAPP, which can occur in vaccinated individuals or their contacts, and the emergence of vaccine-derived polioviruses.

# Inactivated poliovirus vaccine (IPV)

- IPV can be administered by subcutaneous or intramuscular injection. A fractional dose of stand-alone IPV can also be administered via the intradermal route although intradermal use is not currently licensed by any national regulatory authority.
- IPV is available either as a stand-alone product or in combination with one or more other vaccine antigens including DTP, hepatitis B, or Hib.
- IPV is considered very safe, whether given alone or in combination with other vaccines.
- IPV has been shown to be highly effective in stimulating circulating antibody responses to poliovirus in both high- and low-income country settings yet is less effective than OPV in inducing intestinal mucosal immunity among previously unvaccinated individuals.

# WHO position

- All children worldwide should be fully vaccinated against polio, and every country should seek to achieve and maintain high levels of coverage with polio vaccine in support of the global commitment to eradicate polio.
- WHO no longer recommends an OPV-only vaccination schedule. For all countries currently using OPV only, at least 1 dose of IPV should be added to the schedule.
- In polio-endemic countries and in countries at high risk for importation and subsequent spread, WHO recommends an bOPV birth dose (a zero dose) followed by a primary series of 3 bOPV doses and at least 1 IPV dose.



# Global tOPV- bOPV switch

- Indigenous wild poliovirus type 2 has not been detected since 1999. Immunity gaps resulting from insufficient use of tOPV with low vaccination coverage have led to increasing emergence of cVDPVs, with 26%–31% of cases of VAPP associated with the type 2 component in tOPV.
- It is therefore essential to switch from tOPV (containing type 1, 2 and 3 serotypes) to bOPV (containing only type 1 and 3 serotypes) in national immunization programmes and to coordinate the switch globally.
- In 2015 the World Health Assembly agreed that all Member States which currently use OPV should prepare for the global withdrawal of the type 2 component of OPV in April 2016.
- All stocks of tOPV should then be removed and destroyed from service delivery points and their removal confirmed to WHO.

# Vaccination with OPV plus IPV

- The primary series consisting of 3 bOPV doses plus 1 IPV dose can be initiated from the age of 6 weeks with a minimum interval of 4 weeks between the bOPV doses.
- If 1 dose of IPV is used, it should be given from 14 weeks of age (when maternal antibodies have diminished and immunogenicity is significantly higher) and can be co-administered with an OPV dose.
- The primary series can administered according to the regular schedules of national immunization programmes, for example at 6, 10, and 14 weeks (bOPV1, bOPV2, bOPV3+IPV), or at 2, 4, and 6 months (bOPV1, bOPV2+IPV, bOPV3 or bOPV1, bOPV2, bOPV3+IPV). Both OPV and IPV may be co-administered with other infant vaccines.
- For infants starting the routine immunization schedule late (age >3 months) the IPV dose should be administered at the first immunization contact along with bOPV and the other routinely recommended vaccines.

# Sequential IPV–OPV schedule

- In countries with high vaccination coverage (e.g. 90%–95%) and low importation risk (neighbouring countries and major population movement all having similarly high coverage) an IPV–bOPV sequential schedule can be used when VAPP is a significant concern.
- Where a sequential IPV–bOPV schedule is used, the initial administration of 1 or 2 doses of IPV should be followed by  $\geq 2$  doses of bOPV to ensure both sufficient levels of protection in the intestinal mucosa and a decrease in the burden of VAPP.
- For sequential IPV–bOPV schedules, WHO recommends that IPV be given at 2 months of age (e.g. a 3-dose IPV–bOPV–bOPV schedule), or at 2 months and 3–4 months of age (e.g. a 4-dose IPV–IPV–OPV–OPV schedule) followed by at least 2 doses of bOPV.
- Each of the doses in the primary series should be separated by 4–8 weeks depending on the risk of exposure to poliovirus in early childhood.

# IPV-only schedule

- An IPV-only schedule may be considered in countries with both sustained high immunization coverage and the lowest risk of both WPV importation and transmission.
- IPV is usually given by intramuscular injection as it is less reactogenic than when given by subcutaneous injection and may be included as a component of combination vaccines.
- A primary series of 3 doses of IPV should be administered beginning at 2 months of age. If the primary series begins earlier (e.g. with a 6, 10 and 14-week schedule) then a booster dose should be given after an interval of  $\geq 6$  months (for a 4-dose schedule).

# Switching to sequential schedules or exclusive use of IPV

- To mitigate the risk of undetected transmission, WHO recommends that endemic countries and countries with a high risk of WPV importation should not switch to an IPV-only or a sequential IPV–bOPV schedule at this time.
- The 3 bOPV+1 IPV schedule as currently recommended should be adopted and supplemental immunization activities should continue to support intensive efforts to eliminate poliovirus transmission.
- A sequential IPV–bOPV schedule or IPV-only schedule can be considered in order to minimize the risk of VAPP, but only after a thorough review of local epidemiology.

# Special populations, contraindications and precautions

- Polio vaccine (IPV or bOPV) may be administered safely to asymptomatic HIV-infected infants. HIV testing is not a prerequisite for vaccination.
- bOPV is contraindicated in severely immunocompromised patients with known underlying conditions such as primary immunodeficiencies, thymus disorder, symptomatic HIV infection or low CD4 T-cell values, malignant neoplasm treated with chemotherapy, recent haematopoietic stem cell transplantation, drugs with known immunosuppressive or immunomodulatory properties (e.g. high dose systemic corticosteroids, alkylating drugs, antimetabolites, TNF- $\alpha$  inhibitors, IL-1 blocking agent, or other monoclonal antibodies targeting immune cells), and current or recent radiation therapies targeting immune cells.
- These populations can safely receive IPV.



# Vaccination of travellers

- Before travelling abroad, persons residing in countries with active transmission of a wild or vaccine-derived poliovirus should have completed a full course of polio vaccination in compliance with the national schedule, and received one dose of IPV or bOPV within 4 weeks to 12 months of travel, in order to boost intestinal mucosal immunity and reduce the risk of poliovirus shedding.
- Travellers to infected areas should be vaccinated according to their national schedules.



# Vaccination of health-care workers

- All health-care workers worldwide should have completed a full course of primary vaccination against poliomyelitis.