

3.16 POLIOMYELITIS

Virology

Polioviruses are classified as enteroviruses in the family Picornaviridae.¹ They have an RNA genome, and are transient inhabitants of the gastrointestinal tract (GIT). There are 3 poliovirus serotypes, PV1, PV2 and PV3. The virus enters through the mouth, multiplies in the pharynx and GIT and is excreted in the stools for several weeks. The virus invades local lymphoid tissue, enters the blood stream and may then infect and replicate in cells of the central nervous system.²

Clinical features

Poliomyelitis is an acute illness following gastrointestinal infection by one of the 3 types of poliovirus. Transmission is through faecal-oral and, occasionally, oral-oral spread.³ The infection may be clinically inapparent. If symptoms occur, they may include headache, gastrointestinal disturbance, malaise and stiffness of the neck and back, with or without paralysis. Paralysis is classically asymmetrical. Paralytic polio is a complication of poliovirus aseptic meningitis, and may be spinal (79%), bulbar (2%) or bulbospinal (19%). The case-fatality rate in paralytic polio is 2 to 5% in children, 15 to 30% in adults and up to 75% in bulbar polio. The infection rate in households with susceptible young children can reach 100%. The proportion of inapparent or asymptomatic infection to paralytic infection may be as high as 1000:1 in children and 75:1 in adults, depending on the poliovirus type and social and environmental conditions.²

The incubation period ranges from 3 to 21 days. Infected individuals are most infectious from 7 to 10 days before to 7 to 10 days after the onset of symptoms. The oral vaccine virus may be shed in the faeces for 6 weeks or more,² and for up to several years in people with impaired immunity. Oral vaccine strains shed for many years may mutate into potentially neurovirulent strains.⁴⁻⁹

Epidemiology

The incidence of poliomyelitis has been dramatically reduced worldwide, but cases still occur in developing countries in the Indian subcontinent, the eastern Mediterranean and Africa.^{10,11} The World Health Organization (WHO) aimed to eradicate poliomyelitis by the year 2005 and, although not successful, is still hopeful this will be achieved by 2010 or soon after.¹² In 1994, the continents of North and South America were certified to be free of polio,¹³ followed by the Western Pacific region (including Australia) in 2000 and the European region in 2002.^{14,15} In countries where the disease incidence is low but transmission is still occurring, poliomyelitis cases are seen sporadically or as outbreaks among non-vaccinated individuals. In 2005, 12 countries previously declared polio-

free, including Indonesia, experienced outbreaks due to importations of wild poliovirus from one of the remaining endemic countries: Afghanistan, India, Nigeria and Pakistan.¹¹

In Australia, the peak incidence of poliomyelitis was 39.1/100 000 in 1938. There has been a dramatic fall in incidence since 1952, but epidemics occurred in 1956 and 1961–62. The last notified case of wild poliomyelitis in Australia occurred in 1977 due to an importation from Turkey, but 2 vaccine-associated cases were notified in 1986 and 1995.^{16,17} Because of the rapid progress in global polio eradication and diminished risk of wild virus associated disease, inactivated poliomyelitis vaccine (IPV) is now used for all doses of polio vaccine in Australia.^{3,18} This change was implemented because of concern about the risk of causing vaccine-associated paralytic poliomyelitis (VAPP), which is about 1 case for every 2.4 million doses of oral poliomyelitis vaccine (OPV) distributed.¹⁹ The advantage of using IPV is that it cannot cause VAPP.

Global eradication of polio

The WHO strongly supports the use of OPV to achieve global eradication of poliomyelitis, especially in countries with continued or recent circulation of wild-type poliovirus.²⁰ However, most countries which can afford IPV now use IPV in preference to OPV, in order to eliminate the risk of VAPP and also to reduce the risk of prolonged shedding of potentially neurovirulent strains of poliovirus by individuals with impaired immunity.³ A vaccine-derived poliovirus (VDPV) is derived from OPV but has a number of significant mutations due to long-term replication in an individual with impaired immunity (iVDPV) or through person-to-person transmission in areas of low polio vaccine coverage (circulating VDPV or cVDPV). Outbreaks of poliomyelitis due to cVDPV have been reported worldwide.⁶ People travelling to countries still using OPV are at risk of VAPP, as was reported for an unimmunised adult from the USA who travelled to Costa Rica in 2005.²¹ The WHO is planning for global OPV cessation, once the interruption of wild poliovirus transmission has been certified, to remove the incidence of VAPP and VDPVs.²² Further information is available from the WHO Polio Eradication website <http://www.polioeradication.org>.

Vaccines

- **IPOL** – Sanofi Pasteur Pty Ltd (IPV; inactivated poliomyelitis vaccine). Each 0.5 mL pre-filled syringe contains poliovirus 40D antigen units of type 1, 8D antigen units of type 2 and 32D antigen units of type 3 grown on monkey kidney cells, inactivated with formaldehyde; traces of phenoxyethanol as preservative, neomycin, streptomycin and polymyxin B.

Combination vaccines that include IPV

Formulations for children aged <8 years

- **Infanrix hexa** – GlaxoSmithKline (DTPa-hepB-IPV-Hib; diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliomyelitis vaccine-*Haemophilus influenzae* type b (Hib)). The vaccine consists of *both* a 0.5 mL pre-filled syringe containing 30 IU diphtheria toxoid, 40 IU tetanus toxoid, 25 µg pertussis toxoid (PT), 25 µg filamentous haemagglutinin (FHA), 8 µg pertactin (PRN), 10 µg recombinant HBsAg, 40 D-antigen units inactivated polioviruses type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett) adsorbed onto aluminium hydroxide/phosphate; phenoxyethanol as preservative; traces of formaldehyde, polymyxin and neomycin *and* a vial containing a lyophilised pellet of 10 µg purified Hib capsular polysaccharide (PRP) conjugated to 20–40 µg tetanus toxoid. The vaccine *must be reconstituted* by adding the entire contents of the syringe to the vial and shaking until the pellet is completely dissolved. May also contain yeast proteins.
- **Infanrix-IPV** – GlaxoSmithKline (DTPa-IPV; diphtheria-tetanus-acellular pertussis-inactivated poliomyelitis vaccine). Each 0.5 mL pre-filled syringe contains 30 IU diphtheria toxoid, 40 IU tetanus toxoid, 25 µg PT, 25 µg FHA, 8 µg PRN, 40 D-antigen units inactivated polioviruses type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett) adsorbed onto aluminium hydroxide; phenoxyethanol as preservative; traces of formaldehyde, polymyxin and neomycin.
- **Infanrix Penta** – GlaxoSmithKline (DTPa-hepB-IPV; diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliomyelitis vaccine). Each 0.5 mL pre-filled syringe contains 30 IU diphtheria toxoid, 40 IU tetanus toxoid, 25 µg PT, 25 µg FHA, 8 µg PRN, 10 µg recombinant HBsAg, 40 D-antigen units inactivated polioviruses type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett) adsorbed onto aluminium hydroxide/phosphate; phenoxyethanol as preservative; traces of formaldehyde, polymyxin and neomycin. May also contain yeast proteins.

Formulations for people aged ≥8 years

- **Adacel Polio** – Sanofi Pasteur Pty Ltd (dTpa; diphtheria-tetanus-acellular pertussis- inactivated poliomyelitis vaccine). Each 0.5 mL monodose vial contains ≥2 IU diphtheria toxoid, ≥20 IU tetanus toxoid, 2.5 µg PT, 5 µg FHA, 3 µg PRN, 5 µg pertussis fimbriae (FIM) 2+3; 40 D-antigen units inactivated polioviruses type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett); 1.5 mg aluminium phosphate; phenoxyethanol as preservative; traces of formaldehyde, polymyxin, neomycin and streptomycin.
- **Boostrix-IPV** – GlaxoSmithKline (dTpa-IPV; diphtheria-tetanus-acellular pertussis-inactivated poliomyelitis vaccine). Each 0.5 mL pre-filled syringe contains ≥2 IU diphtheria toxoid, ≥20 IU tetanus toxoid, 8 µg PT, 8 µg FHA, 2.5 µg PRN, 40 D-antigen units inactivated polioviruses type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett) adsorbed onto aluminium hydroxide/phosphate; traces of formaldehyde, polymyxin and neomycin.

IPV (IPOL) and IPV-containing combination vaccines contain polioviruses of types 1, 2 and 3 inactivated by formaldehyde. A course of 3 injections with an interval of 2 months between each dose produces long-lasting immunity (both mucosal and humoral) to all 3 poliovirus types. IPV produces considerably lower levels of intestinal immunity than OPV.

Transport, storage and handling

Transport according to *National Vaccine Storage Guidelines: Strive for 5*.²³ Store at +2°C to +8°C. Do not freeze. Protect from light.

Dosage and administration

The dose of IPV (IPOL) and of the IPV-containing combination vaccines is 0.5 mL. IPV is given by SC injection, whereas the IPV-containing vaccines are administered by IM injection. If IPV (IPOL) is inadvertently given intramuscularly, there is no need to repeat the dose.

Recommendations

Primary vaccination of infants and children

(i) IPV (IPOL) or IPV-containing vaccines are recommended for infants from 2 months of age. An open, randomised, multi-centre trial comparing the hexavalent and pentavalent IPV-containing vaccines found that infants receiving either vaccine at 2, 4 and 6 months of age had seroprotective levels of antibody to polio virus types 1, 2 and 3.²⁴

Extra doses of IPV (IPOL) or IPV-containing vaccines are not needed for babies born prematurely.

(ii) The primary course consists of 3 separate doses of vaccine. An interval of 2 months between each dose is recommended, but the minimum interval can be as short as 1 month for catch-up.

(iii) **Interchangeability of OPV and IPV:** Oral poliomyelitis vaccine (OPV) is no longer in use in Australia. OPV and IPV are interchangeable. Children commenced on OPV should complete their polio vaccination schedule using IPV (IPOL) or IPV-containing vaccines.

Primary vaccination of adults

A course of 3 doses of IPV (IPOL) or IPV-containing vaccines at intervals of 1 to 2 months is recommended for the primary vaccination of adults. No adult should remain unvaccinated against poliomyelitis.

Booster doses

Children

A booster dose of IPV (IPOL) or IPV-containing vaccine should be given at 4 years of age. A fifth dose of IPV is no longer recommended as Australia has been declared polio free since 2000¹⁴ and, as in the US, a completed poliomyelitis vaccination schedule for children is 3 primary doses and 1 booster dose of IPV (IPOL) or an IPV-containing vaccine.²⁵

Adults

Booster doses for adults are not necessary unless they are at special risk, such as:

- travellers to areas or countries where poliomyelitis is epidemic or endemic (see <http://www.polioeradication.org> for more information on affected countries), or
- healthcare workers, including laboratory workers, in possible contact with poliomyelitis cases.

For those exposed to a continuing risk of infection, booster doses are desirable every 10 years. dTpa-IPV combination vaccines can be used where otherwise indicated.

Contraindications

The only absolute contraindications to IPV (IPOL) or IPV-containing vaccines are:

- anaphylaxis following a previous dose of the vaccine, or
- anaphylaxis following any component of the vaccine.

Adverse events

IPV-containing vaccines cause erythema (33%, very common), pain (13%, very common), and induration (1%, uncommon) at the injection site. Other symptoms reported in young babies are: fever, crying and decreased appetite (5–10%, common).

Use in pregnancy

Refer to Chapter 2.3, *Groups with special vaccination requirements*, Table 2.3.1 *Vaccinations in pregnancy*.

Variations from product information

The product information for IPV suggests that the fourth dose be given 12 months after the third dose for both adults and children, followed by a fifth dose for children at 4 years of age. NHMRC recommends the fourth dose for children at 4 years of age and no fourth dose for adults unless they are at special risk.

The product information suggests that any sensitivity to vaccine components is a contraindication, whereas NHMRC recommends that the only contraindication is a history of anaphylaxis to a previous dose or to any of the vaccine components.

The product information for both Infanrix hexa and Infanrix Penta states that these vaccines may be given as a booster dose at 18 months of age. NHMRC recommends that a booster dose of DTPa (or DTPa-containing vaccines) is not necessary at 18 months of age. However, DTPa-containing vaccine may be used for catch-up of the primary schedule in children <8 years of age.

The product information for Infanrix-IPV states that this vaccine may be used as a booster dose for children ≤6 years of age who have previously been vaccinated against diphtheria, tetanus, pertussis and poliomyelitis. NHMRC recommends that booster doses of DTPa and IPV be given at 4 years of age; however, this product may be used for catch-up of the primary schedule or as a booster in children <8 years of age.

References

Full reference list available on the electronic *Handbook* or website <http://immunise.health.gov.au>.