4.14 POLIOMYELITIS

4.14.1 Virology

Polioviruses are classified as enteroviruses in the family Picornaviridae.[1] They have an RNA genome, and can inhabit the gastrointestinal tract transiently. There are three poliovirus serotypes, referred to as either type 1, type 2 or type 3. The virus enters through the mouth, multiplies in the pharynx and gut and is excreted in the stools for several weeks. The virus invades local lymphoid tissue, enters the bloodstream and may then infect and replicate in cells of the central nervous system.[2]

4.14.2 Clinical features

Poliomyelitis is an acute illness following gastrointestinal infection by one of the three 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 and 15 to 30% in adults. The case-fatality rate in bulbar polio is up to 75%. The infection rate in households with susceptible young children can reach 100%. The ratio 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 persons 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 who are immunocompromised. Oral vaccine strains shed for many years may mutate into potentially neurovirulent strains.[4-9]

4.14.3 Epidemiology

The incidence of poliomyelitis has been dramatically reduced worldwide through an intensified Global Polio Eradication Initiative by the World Health Organization (WHO).[10] In 1994, the continents of North and South America were certified to be free of polio,[11] followed by the Western Pacific region (including Australia) in 2000,[12] the European region in 2002[13] and the Southeast Asia region in 2014.[14] There are a few countries remaining in Africa and Asia where poliovirus transmission is still occurring; however, the disease incidence is low. In these countries poliomyelitis cases are seen sporadically or as outbreaks among non-vaccinated persons. Further information on the international epidemiology of polio and polio-affected countries is available from the WHO Global Polio Eradication Initiative website (www.polioeradication.org).

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 most recent laboratory-confirmed case of wild poliomyelitis in Australia occurred in 2007 in an overseas-born student who acquired the disease during a visit to Pakistan.[15] The last case of wild poliomyelitis prior to this was in 1977, due to an importation from Turkey, but two vaccine-associated cases were notified in 1986 and 1995.[16,17] Because of the rapid progress in global polio eradication and the diminished risk of wild virus-associated disease, inactivated poliomyelitis vaccine (IPV) is now used for all doses of polio vaccine in Australia.[3,18] The advantage of using IPV is that it cannot cause vaccine-associated paralytic poliomyelitis (VAPP).[19] Emergence of highly evolved vaccine-derived polioviruses (VDPV) in persons with primary immunodeficiency (iVDPV) with long-term excretion, and polio outbreaks due to circulating VDPV (cVDPV), particularly in areas with low vaccine coverage, are associated with oral poliomyelitis vaccine (OPV) administration.[20,21]

4.14.4 Vaccines

Inactivated poliomyelitis vaccine

- ***IPOL*** – Sanofi-Aventis Australia Pty Ltd (IPV; inactivated poliovirus). Each 0.5 mL pre-filled syringe contains 40 D-antigen units inactivated poliovirus type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett); 2–3 µL phenoxyethanol; 2–20 µg formaldehyde; polysorbate 80; traces of neomycin, streptomycin, polymyxin B and bovine serum albumin.

Combination vaccines that contain IPV

Formulations for children aged <10 years

- ***Hexaxim*** – Sanofi-Aventis Australia Pty Ltd (DTPa-hepB-IPV-Hib; diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-*Haemophilus influenzae* type b). Each 0.5 mL pre-filled syringe contains ≥20 IU diphtheria toxoid, ≥40 IU tetanus toxoid, 25 µg pertussis toxoid (PT), 25 µg filamentous haemagglutinin (FHA), 10 µg recombinant HBsAg, 40 D-antigen units inactivated poliovirus type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1), 32 D-antigen units type 3 (Saukett) and 12 µg purified Hib capsular polysaccharide (PRP) conjugated to 22–36 µg tetanus toxoid, adsorbed onto 0.6 mg aluminium as aluminium hydroxide. May contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin and polymyxin B.
- ***Infanrix hexa*** – GlaxoSmithKline Australia Pty Ltd (DTPa-hepB-IPV-Hib; diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-*Haemophilus influenzae* type b). The vaccine consists of *both* a 0.5 mL pre-filled syringe containing ≥30 IU diphtheria toxoid, ≥40 IU tetanus toxoid, 25 µg PT, 25 µg FHA, 8 µg pertactin (PRN), 10 µg recombinant HBsAg, 40 D-antigen units inactivated poliovirus 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, polysorbate 80, polysorbate 20, 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. May contain yeast proteins.
- ***Infanrix IPV*** – GlaxoSmithKline Australia Pty Ltd (DTPa-IPV; diphtheria-tetanus-acellular pertussis-inactivated poliovirus). 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 poliovirus type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett), adsorbed onto aluminium hydroxide; traces of formaldehyde, polysorbate 80, polymyxin and neomycin.
- ***Quadracel*** – Sanofi-Aventis Australia Pty Ltd (DTPa-IPV; diphtheria-tetanus-acellular pertussis-inactivated poliovirus). Each 0.5 mL monodose vial contains ≥30 IU diphtheria toxoid, ≥40 IU tetanus toxoid, 20 µg PT, 20 µg FHA, 3 µg PRN, 5 µg FIM 2+3, 40 D-antigen units inactivated poliovirus type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett); 1.5 mg aluminium phosphate; ≤50 ng bovine serum albumin; phenoxyethanol as preservative; traces of formaldehyde, glutaraldehyde, polysorbate 80, polymyxin and neomycin.

Reduced antigen formulations for adults, adolescents and children aged ≥10 years

- ***Adacel Polio*** – Sanofi-Aventis Australia Pty Ltd (dTpa-IPV; diphtheria-tetanus-acellular pertussis-inactivated poliovirus). Each 0.5 mL monodose vial or pre-filled syringe contains ≥2 IU diphtheria toxoid, ≥20 IU tetanus toxoid, 2.5 µg PT, 5 µg FHA, 3 µg PRN, 5 µg FIM 2+3, 40 D-antigen units inactivated poliovirus type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett); 0.33 mg aluminium as aluminium phosphate; phenoxyethanol; traces of formaldehyde, glutaraldehyde, polysorbate 80, polymyxin, neomycin and streptomycin.
- ***Boostrix-IPV*** – GlaxoSmithKline Australia Pty Ltd (dTpa-IPV; diphtheria-tetanus-acellular pertussis-inactivated poliovirus). 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 poliovirus type 1 (Mahoney), 8 D-antigen units type 2 (MEF-1) and 32 D-antigen units type 3 (Saukett), adsorbed onto 0.5 mg aluminium as aluminium hydroxide/phosphate; traces of formaldehyde, polysorbate 80, 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 doses with an interval of 2 months between each dose produces long-lasting immunity (both mucosal and humoral) to all three poliovirus types. IPV produces considerably lower levels of intestinal immunity than OPV.

4.14.5 Transport, storage and handling

Transport according to *National vaccine storage guidelines: Strive for 5*.[22] Store at +2°C to +8°C. Do not freeze. Protect from light.

Infanrix hexa *must be reconstituted* by adding the entire contents of the syringe to the vial and shaking until the pellet is completely dissolved. Reconstituted vaccine should be used as soon as practicable. If storage is necessary, hold at room temperature for not more than 8 hours.

4.14.6 Dosage and administration

The dose of IPV (IPOL) is 0.5 mL, to be given by SC injection. If IPV (IPOL) is inadvertently given intramuscularly, there is no need to repeat the dose.

The dose of the IPV-containing combination vaccines is 0.5 mL, to be given by IM injection.

The primary course consists of 3 doses of vaccine. An interval of 2 months between doses is recommended, but the minimum interval can be as short as 1 month for catch-up in children or adults.

Interchangeability of oral and inactivated 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.[23]

4.14.7 Recommendations

Primary vaccination of infants and children

IPV (IPOL) or IPV-containing vaccines are recommended for infants at 2, 4 and 6 months of age. The 1st dose of an IPV-containing vaccine can be given as early as 6 weeks of age. If the 1st dose is given at 6 weeks of age, the next scheduled doses should still be given at 4 months and 6 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 poliovirus types 1, 2 and 3.[24] Extra doses of IPV (IPOL) or IPV-containing vaccines are not needed for babies born prematurely.

Where only IPV vaccination is required, IPOL can be used for catch-up in children. If other antigens including poliomyelitis are required, Infanrix IPV or Infanrix hexa can be used for catch-up in children aged <10 years (refer to 2.1.5 *Catch-up*).

Booster doses for children

A booster dose of IPV (IPOL) or IPV-containing vaccine is recommended at 4 years of age. This is commonly provided as DTPa-IPV, which can be given as early as 3.5 years (refer also to 4.12 *Pertussis* and 4.19 *Tetanus*).

A completed poliomyelitis vaccination schedule for children is 3 primary doses and 1 booster dose of IPV (IPOL) or an IPV-containing vaccine.

Where a child received their 3rd primary dose of IPV or an IPV-containing vaccine after the age of 3.5 years, a booster dose is *not* required.

Primary vaccination of adults

A course of 3 doses of IPV (IPOL) or IPV-containing vaccines is recommended for the primary vaccination of adults. No adult should remain unvaccinated against poliomyelitis. For more information refer to 2.1.5 *Catch-up.*

Booster doses for adults

Booster doses for adults are not necessary unless an individual is at special risk, such as:

- travellers to areas or countries where poliomyelitis is epidemic or endemic;[23] refer also to WHO recommendations on vaccinations for travellers (www.who.int/ith/en)[25] and 3.2 *Vaccination for international travel*
- healthcare workers, including laboratory workers, in possible contact with poliomyelitis cases or poliomyelitis virus.

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.

International travel requirements

Documented evidence of polio vaccination is not routinely required for travellers under International Health Regulations but may be temporarily recommended in accordance with WHO recommendations in response to new evidence of the spread of wild poliovirus (refer to 3.2 *Vaccination for international travel*).

4.14.8 Pregnancy and breastfeeding

IPV (IPOL) or IPV-containing vaccines are not routinely recommended for pregnant or breastfeeding women, but can be given where vaccination is considered necessary (refer to 4.14.7 *Recommendations* above).

Refer to 3.3 Groups with special vaccination requirements, Table 3.3.1 Recommendations for vaccination in pregnancy for more information.

4.14.9 Contraindications

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

- anaphylaxis following a previous dose any IPV-containing vaccine
- anaphylaxis following any vaccine component.

4.14.10 Adverse events

IPV (IPOL) or IPV-containing vaccines cause erythema (in 33% of vaccine recipients), pain (in 13%), and induration (in 1%) at the injection site. Other symptoms reported in young babies are fever, crying and decreased appetite (in 5 to 10%).

Repeat doses of IPV or IPV-containing vaccines have not been associated with increased adverse events and, where extra doses are required, are safe.

4.14.11 Public health management of poliomyelitis

Poliomyelitis is a notifiable disease in all states and territories in Australia.

Further instructions about the public health management of poliomyelitis, including management of cases of poliomyelitis and their contacts, should be obtained from state/territory public health authorities (refer to Appendix 1 *Contact details for Australian, state and territory government health authorities and communicable disease control*).

4.14.12 Variations from product information

The product information for Infanrix hexa states that this vaccine is indicated for primary immunisation of infants from the age of 6 weeks and as a booster dose for children 18 months of age if boosting is required for all antigens. The ATAGI recommends that this vaccine may also be used for catch-up of the primary schedule in children <10 years of age.

The product information for Infanrix IPV states that this vaccine is indicated for use in a 3-dose primary schedule for immunisation of infants from the age of 6 weeks and as a single booster dose for children ≤6 years of age who have previously been vaccinated against diphtheria, tetanus, pertussis and poliomyelitis. In addition, the ATAGI recommends that this product may also be used for catch-up of the primary schedule or as a booster in children <10 years of age.

The product information for Quadracel states that this vaccine is indicated for use in a 3-dose primary schedule from the age of 2 months to 12 months and may also be used as a booster dose for children from 15 months to 6 years of age who have previously been vaccinated against diphtheria, tetanus, pertussis and poliomyelitis. The ATAGI recommends that, when appropriate, this product may also be used for either catch-up of the primary schedule or as a booster dose in children aged <10 years. The ATAGI also recommends that the primary schedule may be commenced at 6 weeks of age, if required.

The product information for Boostrix-IPV states that dTpa-containing vaccine should not be given within 5 years of a tetanus toxoid-containing vaccine. The product information for Adacel Polio states that dTpa-containing vaccine should not be given within 3 years of a tetanus toxoid-containing vaccine. The ATAGI recommends instead that, if protection against pertussis is required, dTpa-containing vaccines can be administered at any time following receipt of a dT-containing vaccine.

The product information for Adacel Polio, Boostrix-IPV, Infanrix hexa, Infanrix IPV and Quadracel states that these vaccines are contraindicated in children with encephalopathy of unknown aetiology or with neurologic complications occurring within 7 days following a vaccine dose. The ATAGI recommends instead that the only contraindication is a history of anaphylaxis to a previous dose or to any of the vaccine components.

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A full reference list is available on the electronic *Handbook* or website www.immunise.health.gov.au.

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