The Immunisation Advisory Centre

Review of evidence to inform the New Zealand National Immunisation Schedule, 2019: Poliovirus

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Abbreviations

cVDPV	Circulating vaccine-derived poliovirus
DTaP-IPV	Combined diphtheria, tetanus, acellular pertussis, inactivated poliovirus
ESR	Institute for Environmental and Scientific Research
fIPV	Fractional doses of inactivated poliovirus vaccine.
GPEI	Global Polio Eradication Initiative
GSK	GlaxoSmithKline Ltd
IPV	Inactivated poliovirus vaccine
NZ	New Zealand
OPV	Oral poliovirus vaccine
RCT	Randomised clinical trial
Td / Tdap	Tetanus, reduced diphtheria / and acellular pertussis vaccine
UK	United Kingdom
US	United States of America
VAPP	Vaccine associated paralytic poliomyelitis
WHO	World Health Organization
WPV	Wild poliovirus

1 Overview summary

The numbers of wild poliovirus (WPV) cases increased dramatically in 2019 to 73 in September 2019 from 15 over the same time period in 2018, primarily due to increasing numbers of outbreaks in Pakistan and accompanied by evidence of spread to Afghanistan and Iran.[1] The main driver is continuing disruption of immunisation programmes. Although the African Region is close to declaring WPV1 eliminated, there are insecure, inaccessible regions in which trapped children cannot be monitored or immunised.[1]

In the Western Pacific Region, the key development has been environmental detection of circulating vaccine-derived poliovirus type 2 (cVDPV2) in China and the Philippines during 2019 and cases of cVDPV1 acute flaccid paralysis were reported in Papua New Guinea in November 2018 associated with exportation from the Western Papua region of Indonesia.[1]

1.1 World Health Organization recommendations

International travel, particularly air travel, remains a critical control point to prevent international spread. Most notable is the risk of spread of WPV1 beyond Pakistan and Afghanistan. Adequate border control monitoring and travel vaccination are essential, although possible fatigue and underfunding in implementing controls are increasing the risk of international spread.[1]

All countries can help protect themselves from poliovirus by:

- Maintaining high immunisation coverage in the infant schedule and booster ages to maintain community immunity.
- Vaccination of non-immune adults,
    - Providing good travel advice and booster vaccination for those travelling to the polio-endemic or high-risk countries
    - Those who have received three or more doses of IPV or OPV should receive a booster dose of IPV at least four weeks prior to travel to a high-risk country or prior to international departure for residents or long-term visitors from these countries.
    - If urgent travel is required (within four weeks), those who have not received a dose of IPV or bOPV within four weeks to 12 months, should receive a dose of polio vaccine at least prior to the time of departure to provide some benefit.
    - All travellers are advised to carry their written vaccination record or an International Certificate of Vaccination or Prophylaxis to provide evidence of polio vaccination. This is required for entry to or departure from certain countries, irrespective of the means of transport (e.g. by road, air, sea).
- Continued acute flaccid paralysis screening to maintain surveillance for the possible re-introduction of polio viruses to countries, including New Zealand, who have eradicated polioviruses.

1.2 Immunity and duration of protection

Inactivate poliovirus vaccines (IPV) induce good systemic immune responses to protect against paralytic polio but do not induce adequate intestinal neutralising antibody to prevent infection and transmission in regions with circulating poliovirus.

In countries in which poliovirus continues to spread, children require direct protection within the gut mucosa with oral polio vaccines (OPV) to stop transmission. A dose of inactivated poliovirus vaccine (IPV) is given subsequently to ensure protection against paralytic disease, particularly caused by cVDPV2 disease. In countries that have eradicated polio infection or ceased transmission, IPV vaccine alone is required to provide systemic protection against the risk of paralytic disease.

Vaccination provides life-long protection against poliovirus. Protection is further enhanced by good hygiene and sanitation. However, booster doses are recommended at least 4 weeks prior to travel to high-risk regions to induce antibody protection against paralytic poliomyelitis.

Due to a shortage of vaccine, fractional doses of IPV are being administered in some countries intradermally.[2] These have been shown to induce similar immune responses to full doses in both poliovirus-naïve infants and OPV-primed young adults. [3-5]

1.3 Recommended updates for the Immunisation Handbook

16.2 Clinical features – check slight differences with WHO description (e.g. post-polio syndrome)

16.3.1 Global burden of disease

- WPV type 2 and 3 eradication
- describe cVDPV
- update with description of Polio endgame strategy 2019-2023
- update latest global epidemiology – increase in cases of WPV1 and emergence of previously unreported transmission of cVDPV2 in China, Philippines and cVDPV1 in Indonesia.

16.4.2 Efficacy and effectiveness - include description of immune response and rationale for IPV vs OPV and duration of immunity

16.8 Public health measures - update reference for National Poliomyelitis Response Plan for New Zealand

1.4 Outstanding questions

Booster doses are recommended prior to travel to high-risk regions, but the interval between doses required for individuals making frequent visits to endemic areas is currently unclear. For personal safety and to prevent poliovirus carriage, good hygiene and safe food and water consumption habits need to be practiced by all travellers, including those visiting relatives and friends less aware of any risk to non-immune individuals.

2 Poliomyelitis and poliovirus vaccination

Poliomyelitis is highly transmissible disease caused by the spread of polioviruses through oral-oral and faecal-oral contact. Three serotypes of wild-type poliovirus (WPV) cause disease; WPV 2 and 3 have been eradicated globally.

In up to 95% of cases, poliovirus infection is asymptomatic, but virus is shed in the stool. Most other cases may exhibit fever, headache, malaise, muscle pain and gastrointestinal upset (non-paralytic polio). Acute flaccid paralysis occurs in less than 1% of infected children aged under 5 years and has a case-fatality rate of 5-10% in children and 15-30% in adults. Respiratory paralysis where the cranial nerves in the respiratory centre become affected (bulbar polio) has the highest case-fatality rate.[6, 7] Infection in children tends to be biphasic – as they appear to recover from initial viral illness-like symptoms that last for 1-3 days, viral meningitis and paralysis can occur abruptly. In adults and adolescents, gradual paralysis and pain present without early symptoms. Post-polio syndrome, characterised by exacerbated muscle weakness and pain, can strike 15-30 years after the initial acute infection in 25-50% of cases.[6]

Immunisation against poliovirus began in 1956 in New Zealand (for further details see Appendix 5.2). Since 1962, six vaccine-associated paralytic polio (VAPP) cases have been reported and no wild-type disease. The last case was in 1999 and this led to a switch from OPV to IPV in 2002.[8] The last case of imported WPV polio was in 1976 in a child from Tonga.[9] A case of paralytic polio was seen in Australia in 2007 in an Australian citizen who had returned from visiting family in Pakistan.[10]

These imported cases highlight the continued risk of importation of either wild-type poliovirus or circulating vaccine-derived poliovirus. Maintaining immunisation is essential, globally and within NZ, to prevent re-emergence of this highly contagious and potentially devastating disease.

International travel, particularly air travel, remains a critical control point to prevent international spread. Most notable is spread of WPV1 beyond Pakistan and Afghanistan. Adequate border control monitoring and travel vaccination are essential, although possible fatigue and underfunding in implementing controls are increasing the risk of international spread.[1] WHO has recommended that countries no longer infected with WPV or cVDPV, but at risk of reinfection, should intensify their border control efforts to ensure mobile and cross-border populations are vaccinated.[1]

The National Poliomyelitis Response Plan for New Zealand was updated in 2019 to set out the response required to a case of probable and/or confirmed poliomyelitis (polio) caused by a wild-type or vaccine-derived poliovirus.[10]

Table 1: Summary of WHO position for poliovirus vaccine, 2016

Group	Recommendation or comment
Children	All children should be fully vaccinated against polio
Withdrawal of trivalent OPV	Only bivalent OPV is available from April 2016
OPV plus IPV	Countries using OPV recommended to include at least one dose of IPV on schedule to provide immunity against type 2.
Dose zero	In countries with circulating disease a dose of bOPV should be given at birth or soon after.
IPV-OPV schedule	Countries with high vaccination coverage and low importation risk can use IPV plus bOPV where VAPP is a concern.
IPV only schedule	In countries with sustained high vaccination coverage and low risk of WPV transmission or importation. Three dose primary series with a booster dose at least 6 months later if the primary series begins before 2 months of age (ie. 6 weeks)
Travellers and healthcare workers	All travellers residing in countries with active transmission of WPV or cVDPV should have completed a full course of polio vaccine within 4 weeks to 12 months before travel. A dose at any time prior to departure in the case of urgent travel needs can be protective.

3 Poliovirus epidemiology

The global incidence of polio has declined dramatically by more than 99% since 1988 when the annual burden was estimated to be over 350,000 cases and WPV was being transmitted in more than 125 countries. The Global Polio Eradication Initiative (GPEI) resolved to eliminate poliovirus by 2000 through sustained use of polio vaccines. However, this target has not yet been reached.[6]

On 5 May 2014, the WHO Director-General declared the international spread of poliovirus to be a Public Health Emergency of International Concern and issued temporary recommendations to reduce the spread.[11] The situation is reassessed every 3 months. Table 2 gives the status as of September 2019.[1, 11, 12]

States infected with wild type (WPV) or circulating vaccine-derived poliovirus (cVDPV), with potential of international spread	
• Afghanistan • Pakistan • Nigeria*	WPV1
• Somalia	cVDPV3
• Papua New Guinea • Indonesia (West Papua) • Myanmar	cVDPV1
States infected with cVDPV2, with potential international spread	
• Angola • Benin • Cameroon • Central African Republic • China • Democratic Republic of Congo	• Ethiopia • Ghana • Mozambique • Niger • Nigeria • Philippines • Somalia
States no longer infected by WPV1 or cVDPV but remain vulnerable to reinfection.	
• Chad† • Kenya • Syrian Arab Republic	

* Last detected September 2016, concerns of pockets of inaccessible children.
† Last case June 2012, infection status linked to Nigerian status.

Table 2: At a glance, WHO member states infected with poliovirus, declared Pubic Health Emergency of International Concern, as of 25 September 2019

An increasing number of wild-type poliovirus type 1 (WPV1) cases were reported in 2019, particularly in Pakistan. Attacks on vaccinators have resulted in disruption of the immunisation programme and refusal to accept vaccines due to mistrust has been increasing in certain communities. Poliovirus has also been reported in Afghanistan and detected in

sewerage in neighbouring Iran.[11] No WPV1 has been detected in Nigeria for 3 years and it is hoped that the Africa Region can be certified WPV free in 2020. However, there remain inaccessible regions with children trapped due to conflict that may still harbour the infection.[11]

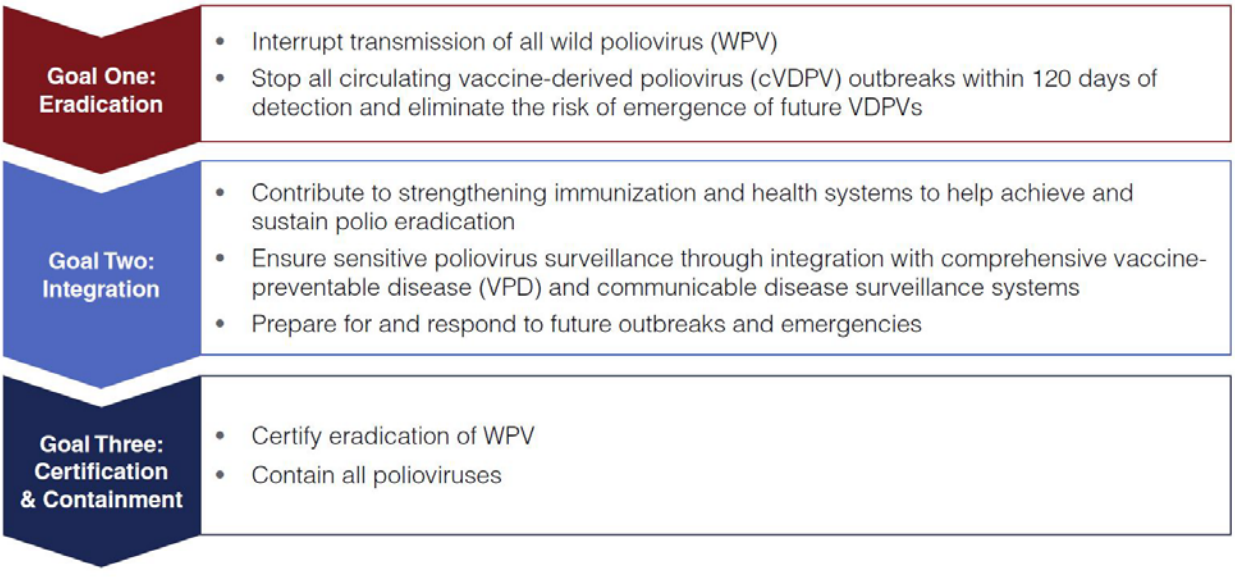
Although WPV2 has been eradicated globally, cVDPV2 has become a significant issue in multiple countries. Countries that routinely used monovalent OPV2 have been identified as the source of cVDPV2 emergence and resulting exportation.[11] In areas distant from mOPV2 use, this has been presumed to be due to the spread of Sabin-like viruses. Countries that still use oral poliovirus vaccines (OPV) have moved to using bivalent (bOPV) vaccine that does not contain type 2. Countries without circulating WPV have switched to trivalent inactivated poliovirus vaccines (IPV) to provide polio immunity without the risk of cVDPV. However, there are concerns that global immunity to type 2 disease is falling as the number of children immunised with OPV2 has declined and immunisation coverage with IPV is suboptimal, particularly in cVDPV2 infected countries. In many of these countries, sizeable populations have been unimmunised for prolonged periods due to poor routine immunisation coverage. Outbreaks of imported cVDPV can occur in any under-vaccinated community, for example, as occurred in Amish Community in the US.[11] Most recently, cVDPV2 has appeared in China and the Philippines with transmission going undetected for a year or even longer. An emergency stockpile of monovalent OPV2 is being retained in case of an outbreak of cVDPV2 or WPV2.[6]

Transmission of cVDPV1 in West Papua, Indonesia has been linked to exportation to Papua New Guinea in November 2018.[1, 11]

WPV3 was declared eradicated in September 2019 and enables a potential switch to monovalent OPV1 vaccines.[13]

In 2019, the GPEI set down a 'roadmap' designated the Polio Endgame Strategy 2019-2023 that describes specific steps to achieved polio eradication as presented in Table 3.[14]

Table 3: Goals of Polio Endgame Strategy 2019-2023 (Source WHO)



Source: WHO

4 Immunity and duration of protection

The role of OPV and IPV in polio immunisation depends on risk of exposure to the virus. IPV is less effective than OPV in inducing intestinal mucosal immunity in previously unvaccinated recipients. IPV can reduce the quantity and duration of viral shedding and help to reduce transmission, but WPV circulation may be sustained where hygiene and living conditions are poor.[6] In some countries, sequential use of IPV following OPV has reduced or prevented VAPP while conferring high levels of intestinal immunity with OPV. IPV has been suggested to boost intestinal immunity induced by OPV.

IPV-induced circulating antibody has been shown to persist for several decades or even life in high-income countries, although in some adults the antibody titres may become undetectable.[6] The immunogenicity of IPV in infants is dependent on age and number of priming doses due to potential interference from maternal antibodies, but even in the absence of seroconversion, individuals are primed to respond to subsequent booster doses.[6]

In New Zealand, the risk of poliovirus transmission is very low with good sanitation and clean drinking water. However, there is a chance that cVDPV and/or WPV could enter the country. Infection could be imported by unvaccinated individuals entering New Zealand as non-quota refugees, from areas with disrupted immunisation programmes, or travellers returning from areas with circulating poliovirus, particularly humanitarian workers and those visiting friends and relatives who do not understand the risk.

4.1 OPV and IPV combined schedules in children

A systematic review and meta-analysis concluded that the addition of one IPV dose for all birth cohorts should be prioritised to protect against paralysis caused by type 2 poliovirus. However, this vaccine will not prevent transmission or circulation of poliovirus in areas with poor sanitation and faecal-oral transmission.[15] Humoral immunity against type 2 poliovirus was increased following the addition of one IPV dose to a bOPV schedule, but there was no evidence of increased intestinal immunity against type 2. No differences in relative immunogenicity was observed for any IPV formulations (Salk IPV, intradermal fractional IPV or adjuvanted IPV).

4.2 Adults primed with IPV

Although highly effective at preventing paralytic polio, IPV has a limited capacity to confer intestinal immunity and therefore interrupt poliovirus transmission. The intestinal response to challenge with monovalent OPV1 was investigated in 12 Swedish adults aged 18-50 years who had received four doses of IPV in childhood.[16] In contrast to children who had been previously vaccinated with IPV, adults had only a modest intestinal OPV1 neutralisation response and no IgA was measurable in the stool. Prior to OPV1 challenge, there was no evidence of pre-existing intestinal neutralising antibody to any of the three polioviruses, but OPV1-specific serum neutralising activity increased significantly (p=0002). Following challenge, sustained viral shedding lasted for between 11-17 days in all participants.[16]

4.3 Adults primed with OPV

There are no concerns that adults who were immunised with OPV are at risk from paralytic polio. Protection is lifelong and there is no evidence that immunity wanes with time.

Antibody levels wane with time, but although seroconversion is a reliable correlate of protection against paralytic disease, there is no evidence that loss of detectable antibody increases the risk for paralytic disease in immunocompetent individuals.[6]

However, for those who have been primed since the switch to bOPV in 2016, additional IPV doses extend protection to type-2 paralytic polio not included in the bOPV.

4.4 Booster doses for travellers

WHO recommends that anyone who is travelling to countries with circulating poliovirus should receive a booster dose of IPV within 4 weeks to 12 months prior to departure if it has been 10 or more years since their last dose. Many polio-free countries require written evidence of polio immunisation for visa approval and entry.

If urgent travel to high-risk countries is required (within four weeks), those who have not received a dose of IPV or bOPV within four weeks to 12 months, should receive a dose of polio vaccine at least by the time of departure to provide some benefit. An International Certificate of Vaccination or Prophylaxis may be required.[1]

4.5 Dose-sparing fractional vaccines

A global shortage of IPV has led to the use of fractional doses IPV (fIPV) that are given intradermally (ID) using a fifth of a full dose. Two doses use only 40% of the antigen used in a full intramuscular (IM) dose. Two-dose intradermal fractional IPV schedules have been introduced in various countries, including in India, Bangladesh, Sri Lanka, Cuba and Ecuador.[17]

An open label non-inferiority randomised control trial was conducted in Bangladesh to compare intramuscular IPV and intradermal fIPV in OPV-naïve health infants immunised at 6 weeks, 14 weeks and booster at 22 weeks: IPV 14 plus IPV; IPV 14 plus fIPV; IPV 6 plus fIPV; fIPV 6/14 plus fIPV. At 22 weeks, two doses of fIPV induced a significantly higher vaccine response against all three polioviruses than one dose of IPV ($p<0.0001$) and at 26 weeks, fIPV booster was non-inferior to IPV. These data support the Strategic Advisory Group of Experts on Immunisation (SAGE) recommendations to introduce two doses of fIPV at 6 weeks and 14 weeks and to use fIPV booster in an outbreak situation for infants previously immunised with IPV or fIPV.[5]

Seroconversion non-inferiority was demonstrated for all three polioviruses when fIPV was given IM compared with ID. Two doses of fIPV (either 0.1 or 0.2ml as opposed to 0.5ml IPV) were administer to polio-naïve Cuban infants at 4 and 8 months of age.[3]

To boost population immunity in an outbreak situation, the findings of a randomised control trial in Cuba found that that fIPV given ID induced similar immune responses to IM IPV in young adults who had previously been vaccinated with OPV in Cuba.[4]

Conclusion

Fractional doses of IPV vaccine can be used to immunise polio-naïve infants and to provide booster doses during outbreaks for those previously vaccinated with IPV or OPV.

5 Appendix

5.1 Inactivated poliovirus-containing vaccines available in New Zealand

The contents of the currently licensed inactivated poliovirus-containing vaccines available in NZ are provided in Table 3.[18-22]

Table 4: Inactivated poliovirus-containing vaccines available in New Zealand, licensed by Medsafe

DTaP combinations
Infanrix-hexa®, GSK Combined diphtheria-tetanus-acellular pertussis, inactivated poliovirus types, hepatitis B and *Haemophilus influenzae* type B vaccine (DTaP-IPV-HepB/Hib), containing ≥30IU DT, ≥40IU TT, 25µg PT, 25µg FHA, 8µg PRN, as well as HepB surface antigen, IPV VERO cell propagated types 1 (Mahoney), 2 (MEF-1) and 3 (Saukette); Hib-PRP conjugated to TT.
Infanrix-IPV®, GSK Combined diphtheria-tetanus-acellular pertussis and inactivated poliovirus vaccine (DTaP-IPV), containing ≥30IU DT, ≥40IU TT, 25µg PT, 25µg FHA, 8µg PRN with IPV types 1, 2 and 3.
Tdap combinations
Boostrix®-IPV, GSK Combined tetanus, reduced antigen dose of diphtheria and three-component acellular pertussis vaccine (Tdap) containing ≥2IU DT, ≥20IU TT, 8µg PT, 8µg FHA and 2.5µg PRN adsorbed 0.5mg aluminium and suspended in isotonic sodium chloride plus IPV types 1, 2 and 3
Adacel®-Polio, Sanofi-Pasteur Combined five-component acellular pertussis vaccine combined with diphtheria and tetanus toxoids (Tdap) containing ≥20IU TT, ≥2IU DT, 2.5µg PT, 5µg FHA, 3µg PRN and 5µg FIM2/3 adsorbed with 0.5mg aluminium and IPV types 1, 2 and 3.
Poliovirus only vaccine
IPOL®, Sanofi-aventis Contains formaldehyde inactivated polioviruses: 40DAgU type 1 (Mahoney), 8 DAgU type 2 (MEF-1) and 32 DAgU type 3 (Saukette) cultured in VERO cells. Contains phenylalanine.
Abbreviations: DT – diphtheria toxoid; FHA – filamentous haemagglutinin; FIM2/3 -fimbriae types 2 and 3; GSK – GlaxoSmithKline; HepB – hepatitis B, Hib – *Haemophilus influenzae* type B; IPV - inactivated poliovirus; PRN – pertactin, PRP - polysaccharide polyribosylribitol phosphate; PT – pertussis toxin

5.2 History of poliovirus immunisation in New Zealand

NZ began immunisation against polio in 1956 with the Salk IPV vaccine. In 1960, coverage was around 80% in children. In 1961 OPV was introduced and then subsequently replaced with Salk-derived enhanced-potency IPV in 2002.[8]

Table 5: History of poliomyelitis immunisation in New Zealand.

Date	Vaccine	Age group
1956	IPV	Gradual introduction, starting with age 8-9y to 5-10 and then 11-15 y
1960	IPV	6 months – 21 years
1961	OPV	Under 12 months
1962	OPV	95% coverage in school children, offered to adolescent and adults.
1967	OPV	General practice offered with DTwP at 3, 4, 5, 18 months.
1971	OPV	4 months dose removed
1980	OPV	Preschool dose at 4 years given due to low immunity against type 1 and 3
2002	IPV replaced OPV	DTaP-IPV at 6 weeks, 3 and 5 months, 4 years. IPV at 11 years (for those not received 4th polio dose)
2008	Tdap-IPV replaced by Tdap	11-year-old IPV removed
2014	IPV	Revaccination following immunosuppression

Abbreviations: IPV – inactivated polio vaccine (Salk); OPV – oral polio vaccine (Sabin); DTwP – diphtheria, tetanus, whole-cell pertussis vaccine; DTaP – diphtheria, tetanus, acellular pertussis vaccine; Tdap – tetanus, reduced dose diphtheria and acellular pertussis vaccine.

5.3 International policy and practice

As part of the polio eradication programme, all high income countries include IPV vaccines on their National Immunisation Schedules.

Table 6: Summary of international immunisation recommendations for poliovirus vaccines, as of September 2019

Country	Age of vaccination	Number of doses in childhood	Special recommendations
USA	2, 4, 6-18m 4-6y	4	
Canada	2, 4, 6m, 18m 4-6y	6	Tdap-IPV at 4-6 years
Australia	6w/2, 4, 6m 4y	4	
NZ	6w, 3, 5m 4y	4	
Austria	2, 4 (11m) 6y, 12y 18-60y, ≥65y	4	11m if unvaccinated Tdap-IPV every 10 years until 60, then every 5 years from 65 years
Denmark	3, 5, 12m 5y	4	
Germany	2, 4, 11-13m 5-6y, 9-17y	5	Optional dose at 3m if monovalent used Adult formulation from 5 years
Ireland	2, 4, 6 4-5 y	4	
Portugal	2, 4, 6, 18 m 5 y	5	
UK	8, 12, 16 w 3y 4m 14 years	5	DTaP-IPV or TdaP-IPV at age 3y 4m Td-IPV at 14 years Tdap-IPV in pregnancy from week 16
Abbreviations: w – weeks; m – months; y – years; gw – gestation weeks; Tdap – tetanus-diphtheria-acellular pertussis vaccine; IPV – inactivated polio vaccine			

5.4 World Health Organization recommendations for travel

WHO recommends that before travelling to areas with active poliovirus transmission, travellers from polio-free countries should ensure that they have completed the age-appropriate polio vaccine series, according to their respective national immunization schedule.[1, 6] Adult travellers to polio- infected areas who have previously received three or more doses of OPV or IPV should also be given another one-time booster dose of polio vaccine. Travellers to polio-infected areas who have not received any polio vaccine previously should complete a primary schedule of polio vaccination before departure.

For states with WPV1, cVDPV1 or cVDPV3 transmission with potential risk of international spread:[11]

1. All residents and long-term visitors (>4 weeks) of all ages should receive bOPV or IPV between 4 weeks and 12 months prior to international travel.
2. International travellers undertaking urgent travel (within 4 weeks) can be protected with bOPV or IPV prior to the time of departure.
3. Travellers should receive an International Certificate of Vaccination or Prophylaxis to serve as proof of polio vaccination
4. Any resident lacking documentation should be restricted on point of departure, including international travellers from all points of departure (air, sea, road)

For states with cVDPV2 transmission with potential risk of international spread

1. All residents and long-term visitors (>4 weeks) of all ages should receive bOPV or IPV between 4 weeks and 12 months prior to international travel.
2. Travellers should have access to an appropriate document to record their polio vaccination status.

Some individual polio-free countries also require proof of polio vaccination for a visa or entry into their territory. Travellers should confirm individual country requirements by contacting the relevant consulate or embassy of the country they intend to visit.

5.5 Methodology for review

5.5.1 Literature search strategy

Medline search terms and strategy

Ovid

MeSH focus poliovirus vaccine, inactivated 1752

Limit English, humans 2016- current [07aug19] 160

Selected

Pubmed

Poliovirus Vaccine, Inactivated 3325

Limit humans English 01/01/2016 to 31/12/2019 251

Selected 13 (stopped searching at record 100)

Additional searches

Where questions arose, additional searches were undertaken to ensure there was no further available data. Where articles were missing, they were accessed and added to the library. All duplicates were removed from the final library.

Final Endnote Library 84 references, including 67 journal articles

Where systematic reviews and/or meta-analysis were available the preceding literature has been excluded from the review.

The studies included in this update are meta-analysis, systematic reviews, reviews, randomised controlled trials, case-control studies, case reports and observational studies using database matching.

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