

NURSING CARE AND POLIOVIRUS VACCINATION PROTOCOL

By

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Abstract

Polio or poliomyelitis was around since the ancient Egyptian times as a disabling and life-threatening disease caused by the poliovirus, which is very contagious and spreads from person-to-person contact. About 25% with poliovirus infection will have flu-like symptoms including sore throat, fever, tiredness, nausea, headache, and stomach pain, usually last 2 to 5 days that went away on their own. The non-polio enteroviruses that cause meningitis are transmitted fecal-orally, which live in human gastro-intestinal tract, and are shed in the feces as very stable in the environment and can live outside human body for days. There is no cure for polio. Paralysis is the most severe symptom associated with poliovirus because it can lead to permanent disability and death. Polio vaccine is the best way to protect against polio.

Keywords: Poliomyelitis, complications, vaccination

Introduction

Immunization against poliovirus infection represents one of the world's great medical achievements. Last cases of naturally occurring wild type paralytic poliomyelitis in the United States occurred during a small outbreak due to type 1 poliovirus in an unvaccinated religious community in 1978 to 1979 (Francis *et al*, 1955). All nations in the Western Hemisphere, Europe, Southeast Asia, and Pacific Region are now poliomyelitis free. As of February 2017, wild type 1 poliovirus remains endemic in Nigeria, Pakistan, and Afghanistan (Kim-Farley *et al*, 1984).

Review and Discussion

Poliovirus vaccines: Both inactivated poliovirus vaccine (IPV) and live attenuated oral poliovirus vaccine (OPV) were developed in the 1950s and have since been used worldwide (Salk, 1953): 1- IPV is the only vaccine available for routine infant and childhood immunization in the United States and is the preferred vaccine in most middle- and upper-income countries because it does not cause vaccine-associated paralytic poliomyelitis (VAPP), & 2-A combination of type 1 and 3 bivalent OPV (bOPV) vaccine and IPV is now recommended by the WHO Expanded Program on Immunization (EPI) for routine infant immunization in low-income countries; both OPV and IPV conti-

nue to be administered through supplementary immunization activities in countries at increased risk of poliovirus transmission. Advantages of OPV include low cost, ease of administration, induction of mucosal immunity, and transmission of vaccine virus to unimmunized contacts; the major disadvantage is that OPV can cause VAPP in rare cases (Parker *et al*, 2015). Worldwide polio immunization practice has begun a phased transition from OPV to IPV in anticipation of global polio eradication before 2018, beginning with cessation of type 2 OPV use in April 2016 and the recent addition of one or more IPV doses to the EPI schedule (WHO, 2021).

Inactivated poliovirus vaccine: IPV is prepared by inactivation of wild type or Sabin (OPV) strain polioviruses treated with dilute formalin (Liao *et al*, 2012). IPV is combined with diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B vaccine, and *Haemophilus influenzae* type B vaccine for intramuscular administration in most upper- and middle-income countries, as well as in standalone formulations for countries that have continued whole cell pertussis (DTPw) vaccination. Thimerosal used in the production of DTPw reduces the potency of IPV, creating a challenge for manufacturers of these vaccine combinations (Shimizu, 2016).

Immune response and efficacy: IPV seroconversion rates and antibody titers depend on the number of doses, the interval between doses, age at the first dose, and maternal antibody levels. In general, three doses given at 2, 4, & 6 to 18 months of age were expected to induce seroconversion in >95% of infants (McBean *et al*, 1988). The 6-, 10-, & 14-week schedule followed in many low- and middle-income countries in order to maximize immunization coverage results in lower, but acceptable seroconversion rates (Estívariz *et al*, 2013).

Detectable antibody persists at protective levels for at least five years, although geometric mean titers decline. In some cases, the level of antibody may fall below detectable levels over time, but persons who have previously seroconverted were likely protected by immune memory (Estívariz *et al*, 2012). Fractional doses were studied to mitigate the high cost of IPV for low-income countries and to expand supplies in response to a current IPV shortage. Dose per dose, fractional doses equal to 0.2 times a full dose delivered by intradermal injection result in lower seroconversion rates than full doses but effectively boost preexisting antibody titers (Resik *et al*, 2013). The influence of primary IPV immunization on mucosal immunity was quite limited compared to OPV. However, IPV boosts both humoral and intestinal immunity in children who have previously received OPV. In an open-label trial in India, 450 children one to four years of age who had previously received OPV were randomly assigned to receive IPV or no vaccine (John *et al*, 2014). Seven days after a bOPV challenge dose, children in the IPV group were significantly less likely to shed poliovirus than the children in the no vaccine group, but the absolute differences were small (12 versus 19% for serotype 1 poliovirus, risk ratio [RR] 0.62, 95 CI 0.40-0.97; 8 versus 26 percent for serotype 3 poliovirus, RR 0.30, 95% CI 0.18-0.49). There have been few opportunities to assess the efficacy of current IPV vaccine formula-

tions under conditions of natural exposure to wild type or circulating vaccine-derived polioviruses (cVDPV). A case-control study conducted following a type 1 poliomyelitis outbreak in Senegal in 1986 to 1987 found that one and two IPV doses administered to children in 1980 provided 36 percent (CI 0 to 67%) and 89% CI 62 to 97%) efficacy, respectively, against paralytic disease, albeit with wide confidence intervals (Robertson *et al*, 1988). These efficacy estimated track observed seroconversion rates for one and two IPV doses, respectively (Grassly, 2014). Previously, a study in Tamil Nadu, India, found that three IPV doses had an efficacy of 92% (Kurstak, 1993).

Adverse effects: Transient local reactions (erythema, pain, and induration) were comparable with reactions following a placebo injection (Hervé *et al*, 2019). With the exception of a single incident in which inadequately inactivated IPV from one manufacturer caused a serious outbreak of polio shortly after initial licensure in the 1950s, without proven serious adverse events associated with IPV (Nathanson and Langmuir, 1963).

Live attenuated oral poliovirus vaccine: OPVs were developed by repeated passage of wild type polioviruses in primates and in cell culture (Sabin, 1985). OPV remains an important tool for control of poliovirus transmission in the developing world due to low cost, ease of administration, induction of mucosal immunity, and transmission of OPV viruses from OPV-vaccinated children to their non-immune contacts (Sabin, 1957). A trivalent OPV formulation (tOPV) containing Sabin 1, 2, and 3 vaccine viruses was used worldwide until April 2016 when it was replaced with bivalent type 1 and type 3 OPV during a global synchronized switch (Patriarca *et al*, 1991). Withdrawal of type 2 OPV was required as type 2 wild polioviruses no longer circulate, and continued use of Sabin 2 viruses has been responsible for a disproportionate VAPP number and cVDPV cases (Garon *et al*, 2016). Assuming success of the global polio eradication program,

all OPV vaccination will cease by 2021 in order to prevent ongoing generation of VDPV viruses. OPV vaccines are no longer licensed in the United States. An optimal immune response to OPV required multiple doses. In developed countries, three tOPV doses given at least two months apart induced $\geq 96\%$ seroconversion to all three types after the third dose, and detectable serum antibody to all three types persists in 84 to 98% of vaccines five years after primary immunization (Krugman *et al*, 1977). However, in low-income countries as Gaza, a series of tOPV doses at birth and at 6, 10, and 14 weeks of age induced lower seroconversion rates (Lasch *et al*, 1984), averaging 73, 90, & 70% for types 1, 2, & 3, respectively. Diarrheal disease at the time of immunization is a major factor. One study conducted in Brazil and Gambia (WHO, 1992). Also, a study in Bangladesh showed that diarrhea reduced seroconversion rates to types 2 and 3 OPV, while the response to type 1 was not affected (Myaux *et al*, 1996). The impact of diarrhea on seroconversion persists despite the administration of three or four trivalent OPV doses.

Bivalent type 1 & type 3 OPV: Bivalent type 1 & type 3 OPV vaccine are now the only OPV routinely used worldwide. Interference absence from type 2 poliovirus in the trivalent formulation led to superior bOPV immunogenicity for types 1 and 3 compared with tOPV (Sutter *et al*, 2010).

Trials in Latin America and Bangladesh have demonstrated seroconversion rates of >94 percent to both type 1 and type 3 OPV among infants vaccinated with three bivalent OPV doses at 6, 10, and 14 weeks of age (O’Ryan *et al*, 2015)

The efficacy of trivalent OPV was never tested under conditions of exposure to natural polioviruses in the United States; but, nearly four decades of use from 1961 to 2000 provided overwhelming evidence of OPV effectiveness (Minor *et al*, 2005). OPV efficacy was directly evaluated during a type 1 poliovirus outbreak in Taiwan in the early

1980s when vaccine efficacy was estimated to be 82, 96, & 98% for one, two, and three or more doses, respectively (Kim-Farley *et al*, 1984)

Adverse effects: OPV viruses are shed from the oropharynx for up to 7 to 14 days after administration and in stool for as long as 6 to 8 weeks in normal infants (Alexander *et al*, 1997). Stool shedding was associated with rapid loss of attenuating mutations in each of the three serotypes and an increase in the phenotypic neurovirulence markers (Macadam *et al*, 1994)

VAPP is a rare but important consequence of reversion to neurovirulence, which was reported in an average of nine persons per year in the United States between 1961 and 1997 (DeVries *et al*, 2011) and is estimated to occur in 3.8 persons per million births or 399 cases (range 306 to 490) in current OPV-using countries (Platt *et al*, 2014). VAPP occurs in OPV recipients (mostly infants) and among direct contacts of OPV recipients (mostly adult caretakers with inadequate immunity). The overall risk is about 1 case per 900,000 first-dose OPV recipients (Alexander *et al*, 2004). Thus, doses were less likely to be associated with VAPP in the United States but carry a higher risk in resource-poor countries, where OPV viruses may be less likely to replicate in the gastrointestinal tract following the first OPV dose (Sutter and Prevots, 1994). Individuals with B cell immunodeficiency carry the highest risk, with an estimated VAPP rate of 2/1000 vaccines (Wyatt, 1975). For this reason, OPV was contra-indicated for immunodeficient individuals.

In settings with inadequate vaccine coverage, OPV viruses can spread into the community as cVDPV that accumulate neurovirulent traits similar to wild type polioviruses through loss of the attenuating mutations associated with OPV (Kew *et al*, 2005). The cVDPV emergence was influenced plans for the eventual cessation of poliovirus immunization following eradication of poliomyelitis, which would include a strategy to the

discontinue OPV use, introduce IPV for risk mitigation, develop monovalent OPV vaccine stockpiles to deploy in the event of unanticipated polio outbreaks, and plan for containment of laboratory stocks of naturally occurring and attenuated polioviruses (WHO, 2011). Other than vaccine-associated paralytic poliomyelitis, there are no adverse reactions attributed to OPV. The available data suggest that OPV didn't increase risk of fetal malformation or other adverse pregnancy outcomes (Harjulehto *et al*, 1989) OPV is contraindicated for immunodeficient individuals. OPV vaccines are no longer licensed in the United States.

WHO Recommended that most countries that adopt the World Health Organization Expanded Program for Immunization (EPI) schedule for routine infant immunization administer bivalent oral poliovirus vaccine (bOPV) at birth and at 6, 10, and 14 weeks of age (WHO, 2016). The WHO Strategic Advisory Group of Experts (SAGE) also recommends addition of at least one dose of inactivated poliovirus vaccine (IPV) at ≥ 14 weeks of age to boost immunity to poliovirus types 1 and 3 and to provide protection against type 2 now that trivalent OPV is no longer given.

For countries that employ IPV alone, the WHO recommends three doses for countries that use a 2, 4, & 6 month schedule for routine infant immunization and four doses for countries that use a 6, 10, 14 week schedule; the fourth dose should be administered ≥ 6 months after the third dose. For countries that have introduced sequential IPV-OPV schedules, one or two IPV doses followed by a minimum of two OPV doses were recommended.

CDC reported that inactivated poliovirus vaccine (IPV) is the only vaccine recommended by the United States CDC Advisory Committee on Immunization Practices (ACIP) and the American Academy of the Pediatrics (AAP) for routine immunization in the United States (CDC, 2009). Oral poliovirus vaccine (OPV) is no longer lic-

ensed in the United States. Licensed vaccines containing IPV were given (Table 1).

Infants and children: The recommended polio vaccination series in the United States consists of four doses of IPV administered subcutaneously or intramuscularly. The first and second doses are administered at 2 and 4 months of age, respectively. The third dose may be given at 6 to 18 months of age, and a fourth dose was given at 4 to 6 years of age before school entry (CDC, 2022). The minimum interval between doses 1 and 2 and between doses 2 and 3 is four weeks, and the minimum interval between doses 3 and 4 is six months. The minimum age for dose 1 is six weeks. Minimum age and intervals should be applied when there was imminent threat of exposure, such as travel to an area in which polio is endemic or epidemic.

Children who are inadequately vaccinated should complete the vaccination series. The fourth dose is not required if the third dose of IPV was delayed until after the child's fourth birthday.

Adults: Routine poliovirus vaccination is not necessary in the adults residing in the United States (Muhoza *et al*, 2021). Such individuals are at minimal risk for exposure and most are adequately protected because of vaccination during childhood. However, vaccination is recommended for individuals at increased risk for exposure (CDC, 2023). This includes: 1- Travelers to areas or countries when polio is endemic or epidemic, 2- Members of communities or population groups with disease caused by the wild polioviruses, 3- Unvaccinated adults whose children must receive OPV, & 4- Healthcare workers who have close contact with patients who might be excreting wild poliovirus or laboratory workers who handle specimens that may contain polioviruses

Adults at increased risk who have had a primary vaccination series with IPV or OPV should receive a single booster dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose of IPV. An exception are adults who will be in

a polio-exporting or polio-infected country for >4 weeks and received a booster dose >12 months earlier; they should receive an additional dose of IPV or OPV before exiting that country (Wallace *et al*, 2014). These adults at increased risk who were unvaccinated or whose vaccination status is not documented should receive a primary vaccination series with IPV. This consists of two doses of IPV at 4- to 8-week intervals and a third dose 6 to 12 months after the second dose. If this regimen cannot be completed within the recommended intervals before protection is needed, the following alternatives are recommended: 1- If there are more than eight weeks before protection is needed, three doses of IPV should be given at least four weeks apart, 2- If there are only four to eight weeks before protection is needed, two doses of IPV must be given at least four weeks apart, & 3- If there are less than four weeks before protection is needed, a single dose of IPV must be given. For the second and third options, the remaining doses must be given later at the recommended intervals if the person remains at risk for exposure to poliovirus.

Pregnant women: Although the adverse effects of IPV have not been documented in either the mother or the fetus, vaccination is not recommended during pregnancy on theoretical grounds (Prevots *et al*, 2000). If, however, a pregnant woman is at increased risk for infection and requires immediate protection, IPV should be given according to the above schedule in adults.

Immunocompromised patients: IPV is the only vaccine recommended for immunodeficient individuals and their household contacts (Ehrenfeld and Chumakov, 2008). However, a protective immune response cannot be assured in patients who are immunodeficient at the time of vaccination. The response in hematopoietic cell transplant recipients is optimized when more than one dose is administered at least one year after transplantation (Kew *et al*, 2004).

Egypt's last confirmed case of wild poli-

ovirus (WPV) was reported in 2004, and the country was declared polio-free in 2006. The earliest evidence of poliovirus comes from pharaonic illustrations in Egyptian artifacts from 3000 years ago, and since then the disease has paralyzed millions of the Egyptian children. WHO (2022) reported that in December 2021, Egypt was the first Eastern Mediterranean Region country to use novel oral polio vaccine type 2 (nOPV2), a next-generation version of the existing type 2 monovalent OPV (mOPV2). Routine children immunization (shown in the vaccination schedule) through 7 doses, the first at birth, the second month, the fourth month, the sixth month, the ninth month, one year, and one & half year. The vaccine scheduler table summarized the current vaccination schedule for young children, adolescents, and adults in Egypt. These data are updated regularly with the most recent official country reporting collected through the WHO/UNICEF joint reporting process.

Recommendations for travelers: The CDC (2014) recommended that the travelers to poliovirus-affected areas must be fully vaccinated against poliovirus with the age-appropriate vaccine series; adults must also receive a one-time booster dose of a poliovirus vaccine.

The international spread of wild poliovirus was declared by the World Health Organization to be a Public Health Emergency of International Concern (PHEIC). Temporary recommendations to reduce the international spread of wild poliovirus were issued, and the situation was been reassessed at 3 months intervals thereafter. In February 2017, after temporary recommendations were issued (WHO, 2014): 1- All residents and long-term visitors (>4 weeks) traveling from Pakistan should receive a booster dose of OPV or IPV between 4 weeks and 12 months prior to international travel and should have the dose documented. Those undertaking urgent travel (i.e., within 4 weeks) who didn't receive a dose of poliovirus vaccine in the previous 4 weeks to 12 months should receive a

dose of OPV or IPV at least by the time of departure, 2- All residents and long-term visitors (>4 weeks) traveling from Nigeria, Pakistan, Afghanistan, and Lao People's Democratic Republic must be encouraged to receive a booster dose of OPV or IPV 4 weeks to 12 months prior to international travel; those undertaking urgent travel (i.e., within 4 weeks) should be encouraged to receive a dose at least by the time of departure, and 3- Travelers who are vaccinated must be provided with an International Certificate of Vaccination or Prophylaxis to serve as proof of vaccination.

The burden for implementation and enforcement of these recommendations lies with the poliovirus-affected countries. For countries implementing this recommendation, previous vaccination history is to be disregarded, and the required dose must have been given within the previous one year. Travel health practitioners must be aware of these individual country exit requirements in order to discuss whether vaccination prior to travel to the listed countries might be advisable.

Conclusion

Inactivated poliovirus vaccine (IPV) is the preferred vaccine for developed countries because it does not cause vaccine-associated paralytic poliomyelitis (VAPP) and can be combined with other routine childhood vaccines. Polio vaccination series in the United States consists of four doses of IPV administered at 2 months, 4 months, 6 to 18 months, and 4 to 6 years of age. The WHO recommended the addition of one or more IPV doses beginning at 14 weeks of age to supplement bivalent oral poliovirus vaccination.

Oral poliovirus vaccine (OPV) is preferred vaccine for developing countries. Its advantages include cost, ease of administration, and transmission of vaccine virus to unimmunized contacts. The WHO recommended a bivalent OPV dose at birth, followed by a primary series of three OPV doses (at 6, 10, and 14 weeks) as well as at least one IPV dose (at ≥ 14 weeks of age).

VAPP occurs as a result of reversion of an

attenuated viral strain to a neurovirulent strain. OPV is associated with rare VAPP cases in vaccine recipients and their contacts.

Vaccine-derived polioviruses (VDPV) are Sabin (OPV) virus derivatives that circulate in settings of low population immunity (e.g., with low immunization rates), and revert to neurovirulence with the ongoing transmission. The VDPV emergence requires that use of all OPV vaccines must cease to achieve the goal of global poliomyelitis eradication.

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Table 1: Licensed vaccines containing inactivated poliovirus vaccine (IPV) - United States

Vaccine composition	Trade name	Manufacturer	ACIP routine schedule*	Approval
IPV	Ipol (Poliovax ^Δ)	Sanofi Pasteur	2, 4, 6 to 18 months, & 4 to 6 years [¶]	infants, children, and adults [◊]
DTaP-HepB-IPV [§]	Pediarix	GlaxoSmithKline	2, 4, & 6 months	first 3 doses of IPV through age 6 years [‡]
DTaP-IPV/Hib [‡]	Pentacel	Sanofi Pasteur	2, 4, 6, & 15 to 18 months [†]	4 doses of IPV through age 4 years**
DTaP-IPV [¶]	Kinrix	GlaxoSmithKline	4 to 6 years	booster dose at age 4 to 6 years ^{ΔΔ}

* Advisory Committee on Immunization Practices; at www.cdc.gov/mmwr/preview/mmwrhtml/mm571a5.htm.

¶ In the IPV series, the minimum age for dose 1 is six weeks. Minimum interval is four weeks between dose 1 and 2 and between dose 2 & 3. Minimum interval between dose 3 & 4 is six months. Dose 4 should be administered at age ≥4 years regardless of the number of previous doses. Shorter intervals and earlier start dates lead to lower seroconversion rates; thus, minimum age and minimum intervals in the first six months of life are recommended only if the recipient is at risk for imminent exposure to circulating poliovirus (e.g., during an outbreak or because of travel to an endemic region).

Δ Not currently distributed in the United States.

◊ Package insert available at www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm133479.pdf.

§ Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B (recombinant), and inactivated poliovirus vaccine combined.

‡ Package insert available at <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm136517.htm>.

‡ Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, and *Haemophilus influenzae* b conjugate (tetanus toxoid conjugate) vaccine.

† When Pentacel is used to provide four doses at ages 2, 4, 6 and 15 to 18 months, an additional booster dose of age-appropriate IPV-containing vaccine (Ipol or Kinrix) should be administered at age 4 to 6 years. This results in a five-dose IPV series; Pentacel is not indicated for booster dose at age 4 to 6 years. Minimum interval between dose 4 and dose 5 should be at least six months to optimize booster response.

** Package insert available at www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109810.pdf.

¶¶ Diphtheria and tetanus toxoids and acellular pertussis adsorbed, and inactivated poliovirus vaccine.

ΔΔ Package insert available at <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094027.htm>: Updated Recommendations of Advisory Committee on Immunization Practices (ACIP) Regarding Routine Poliovirus Vaccination. *MMWR Morb Mortal Wkly Rep* 2009; 58:829