INFORMATION PAPER

DHA-IHD
27 Mar 2023

SUBJECT: Poliomyelitis and Poliovirus Vaccine

1. Purpose. To describe poliomyelitis and the vaccine to prevent it.

2. Facts.

    a. Microbiology. Poliovirus is a member of the enterovirus subgroup, family Picornaviridae. Enteroviruses are transient inhabitants of the gastrointestinal tract and are stable at acid pH. Picornaviruses are small, ether-insensitive viruses with an RNA genome. There are three poliovirus serotypes (P1, P2, and P3); immunity to one serotype does not produce significant immunity to the other serotypes. The poliovirus is rapidly inactivated by heat, formaldehyde, chlorine, and ultraviolet light.

    b. Disease. Polio is a highly infectious disease caused by a virus that infects the throat and intestinal tract, and occasionally, the central nervous system. Person-to-person spread of poliovirus via the fecal-oral route is the most frequent means of transmission, although the oral-oral route may account for some cases. Most people infected with poliovirus have no symptoms or very mild symptoms. When symptoms are present, clinical presentation may be characterized by: influenza-like illness, upper respiratory tract infection, and/or gastrointestinal disturbances. Persons infected with poliovirus are most infectious from 7 to10 days before and after the onset of symptoms, but poliovirus may be present in the stool for 3 to 6 weeks after acute infection. In a small number of patients, symptoms will develop for 2-3 days and progress to asymmetrical paralysis with diminished deep tendon reflexes. Many persons with paralytic poliomyelitis will recover completely and, in most, muscle function returns to some degree; however, for the less than 1% who develops paralysis, it may result in permanent disability and even death. Weakness or paralysis still present 12 months after onset is usually permanent.

    c. Epidemiology. Humans are the only known reservoir of poliovirus, which is transmitted most frequently by persons with unapparent infections. Poliovirus is highly infectious, with seroconversion rates among susceptible household contacts of children nearly 100%, and greater than 90% among susceptible household contacts of adults. In the pre-vaccine era, infection with poliovirus was common worldwide, with seasonal peaks and epidemics in the summer and fall in temperate areas. In the United States, the incidence of poliomyelitis declined rapidly after the introduction

of polio vaccine in 1955 and the last case of indigenously acquired polio in the U.S. was in 1979. The Global Polio Eradication Initiative has made great progress in eradicating wild polio virus, reducing the number of reported polio cases worldwide by more than 99% since the mid-1980s. Of the 3 strains of wild poliovirus (type 1, type 2, and type 3), wild poliovirus type 2 was eradicated in 2015 and no case of wild poliovirus type 3 has been detected since the last reported case in Nigeria in November 2012. In 2020, wild poliovirus type 1 continues to circulate in Afghanistan and Pakistan. In spite of progress made in eradicating wild polioviruses globally, some countries are still at risk for local transmission or imported cases, as well as cases of circulating vaccine derived polioviruses (cVDPV). In May 2014, the World Health Organization declared wild polio virus to be a Public Health Emergency of International Concern, with extra immunization requirements for entering and exiting the most affected countries. In June 2022, temporary recommendations were extended.

d. Vaccine(s). The inactivated poliovirus vaccine (IPV) is the only polio vaccine currently available in the United States. The use of the oral poliovirus vaccine (OPV) was discontinued in 2000 in the United States, but OPV is still used as the preferred vaccine in many parts of the world. To remove the risk for infection with circulating type 2 vaccine-derived polioviruses (cVDPV) which can lead to paralysis, in April 2016 all countries using OPV simultaneously switched from trivalent (tOPV) to bivalent OPV (bOPV) which contains types 1 and 3 polioviruses.

(1) IPOL® (IPV), produced by Sanofi Pasteur, is a sterile suspension of all three poliovirus serotypes. IPV is indicated for active immunization of infants as young as 6 weeks of age, children, and adults for the prevention of poliomyelitis caused by poliovirus Types 1, 2, and 3. A primary series of IPV consists of three doses, with a minimum interval of 4 weeks apart. A booster dose of IPV should be received after age 4 years, with 6-month minimum interval between dose #3 and booster dose. Administer each 0.5-mL dose intramuscularly or subcutaneously in the deltoid for adults or the mid-lateral aspect of the thigh for infants and small children. There is no latex in any component of the vial or syringe.

(2) There are five combination pediatric vaccines that contain inactivated polio vaccine:

(a) Pediarix® (DTaP-HepB-IPV) is produced by GlaxoSmithKline and contains DTaP, hepatitis B and IPV vaccines. Administer each 0.5-mL dose intramuscularly. Three doses of Pediarix® constitute a primary immunization series for IPV among children 6 weeks through 6 years of

age. Pediarix® is not approved for the polio booster dose. The tip caps of the prefilled syringes may contain latex.

(b) Kinrix® (DTaP-IPV) is produced by GlaxoSmithKline and contains DTaP and IPV. Administer each 0.5-mL dose intramuscularly. Kinrix® is licensed only for the booster dose of IPV among children 4 through 6 years of age. The tip caps of the prefilled syringes may contain latex.

(c) Pentacel® (DTaP-IPV/Hib) is produced by Sanofi Pasteur and contains DTaP, IPV, and Hib. Administer each 0.5-mL dose intramuscularly. Pentacel® is licensed for the first four doses of the component vaccines among children 6 weeks through 4 years of age (not licensed for children past 5 years); an additional booster dose of age-appropriate IPV-containing vaccine (IPV or DTaP-IPV [Kinrix®]) should be administered at age 4-6 years. This will result in a 5-dose IPV vaccine series, which is considered acceptable by ACIP.

(d) Quadracel® (DTaP-IPV) is produced by Sanofi Pasteur and contains DTaP and IPV. Administer single dose of 0.5-mL intramuscularly. A single dose of Quadracel® is approved for use in children 4 through 6 years of age as a fifth dose in the diphtheria, tetanus, pertussis vaccination (DTaP) series, and as a fourth or fifth dose in the inactivated poliovirus vaccination (IPV) series, in children who have received 4 doses of Pentacel® and/or DAPTACEL® vaccine.

(e) Vaxelis™ (DTaP-IPV/Hib/Hep B) is produced by MSP Vaccine Company and contains DTaP-IPV/Hib and Hep B. It is a three dose primary series dose for infants at ages 2, 4 and 6 months and catch-up vaccination for children age 6 weeks through 4 years of age (prior to 5th birthday). Vaxelis™ is not recommended as a 4th dose for IPV. A different IPV vaccine should be used for dose 4.

e. Immunization. The childhood IPV series should be administered at ages 2 months, 4 months, and 6-18 months, with a booster dose at age 4--6 years. The minimum age for dose #1 is age 6 weeks. The minimum interval from dose #1 to dose #2, and from dose #2 to dose #3, is 4 weeks; the minimum interval from dose #3 to the booster dose is 6 months. Use of the minimum age and minimum intervals for vaccine administration in the first 6 months of life are recommended only if the vaccine recipient is at risk for imminent exposure to circulating poliovirus (e.g., during an outbreak or because of travel to a polio-endemic region). The final dose in the IPV series should be administered at age ≥4 years

regardless of the number of previous doses. ACIP recommends that, when more than 3 doses are given before age 4, the minimum interval between the last dose and the booster dose should be at least 6 months to provide an optimum booster response. A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose. Adults who have previously completed a primary series of 3 or more doses, and who are at increased risk of exposure to poliomyelitis, should be given one dose of IPV. An exception to this would be additional IPV dose based on WHO guidance in response to public health emergency of international concern. Adults who have previously received less than a full primary series of OPV or IPV, regardless of the interval since the last dose, should receive the remaining doses of IPV (i.e., a total of 3 doses with at least 4 weeks between dose 1 and 2, and at least 6 months between dose 2 and 3). Polio vaccine may be given at the same time as other vaccines.

f. Contraindications and Precautions. IPV is contraindicated in persons with a history of hypersensitivity to a previous polio vaccine or any component of the vaccine including 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, and polymyxin B. Defer vaccination of people with a moderate to severe acute illness until after recovery.

g. Adverse Events. The most common adverse reactions after IPV are injection-site complaints, such as pain, swelling and redness. Because IPV contains trace amounts of streptomycin, polymyxin B, and neomycin, a spectrum of allergic reactions may occur among people sensitive to these antibiotics, including a severe allergic reaction. Vasovagal syncope can occur with vaccination. Shoulder injury related to vaccine administration (SIRVA) may occur following intramuscular vaccination administered high in the deltoid.

h. DoD Policy. All military accessions and officer candidates receive a single dose of IPV. If there is no documentation of at least one dose of polio vaccine as an adult, then service members must receive one dose of polio vaccine prior to traveling to endemic countries. Personnel who have not received the primary IPV series must complete the series using IPV. Unless there is reason to suspect otherwise (for example, childhood spent in a developing country, childhood immunizations not administered), receipt of the primary series of IPV may be assumed. For other adults and children, DoD follows guidelines of the CDC/ACIP. More stringent vaccination requirements may be recommended IAW World Health Organization (WHO) or ACIP disease outbreak guidance; since the situation is dynamic, refer to current COCOM Force Health Protection/Deployment guidance for military deployment/travel.

i. Special Considerations: In May 2014, WHO issued temporary polio

vaccine exit recommendations under the authority of the International Health Regulations (IHR) for long term travelers (staying > 4weeks) and residents departing from countries with wild poliovirus (WPV) transmission. Recommendations have since been updated to include countries with cases of circulating vaccine-derived poliovirus (cVDPV). The polio vaccine must be given between 4 weeks and 12 months of departure from an affected country and recorded in the International Certificate of Vaccination or Prophylaxis (ICVP). Some polio-free countries may have non-IHR requirements for polio vaccination for travelers residing in or arriving for polio-endemic or polio-infected countries. The purpose of this requirement is to prevent viral shedding and spread in non-endemic countries. Official updates to country-specific vaccine requirements are found on CDC, WHO, and DoD resources:

- https://wwwnc.cdc.gov/travel/
- https://www.who.int/news/item/24-06-2022-statement-of-the-thirty-second-polio-ihr-emergency-committee
- http://polioeradication.org/polio-today/polio-now/this-week/
- https://health.mil/Polio

3. References.

a. Centers for Disease Control and Prevention. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) Regarding Routine Poliovirus vaccination. MMWR 2009;58(30):829-30. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5830a3.htm

b. Centers for Disease Control and Prevention. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP), Licensure of a Diphtheria and Tetanus Toxoid and Acellular Pertussis, Inactivated Poliovirus, *Haemophilus influenza* Type b Conjugate, and Hepatitis B Vaccine and Guidance for use in Infants. https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6905a5-H.pdf

c. Centers for Disease Control and Prevention. Poliomyelitis. In: Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition, 2015. http://www.cdc.gov/vaccines/pubs/pinkbook/polio.html

d. Centers for Disease Control and Prevention. Poliomyelitis. In: Health Information for International Travel 2020. https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/poliomyelitis

e. Centers for Disease Control and Prevention. Interim CDC Guidance for Polio Vaccination for Travel to and from Countries Affected by Wild Poliovirus. MMWR 2014;63(27):591-4. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6327a4.htm?s_cid=mm6

327a4_w and related guidance: https://wwwnc.cdc.gov/travel/

f. Multiple resources (e.g., package insert, Vaccine Information Statements) assembled by DHA-IHD: https://health.mil/Polio

Pacific Region Vaccine Safety Hub
Approved: Deputy Chief, Immunization Healthcare Division
877-438-8222 (DSN 761-4245), Option 1