

**OREGON PUBLIC HEALTH DIVISION, DHS
IMMUNIZATION PROGRAM**

**ENHANCED-POTENCY INACTIVATED
POLIOVIRUS-CONTAINING VACCINE [IPV] AND
COMBINATION VACCINES
PEDIARIX®
PENTACEL®
KINRIX™**

Revisions as of 10/24/08

- New combination vaccines Kinrix™ and Pentacel® added to licensed vaccines (Section II) and to the vaccine schedules (Section III) p.5 & 6. Review the footnotes in the Pentacel® and Kinrix™ schedules carefully to understand what constitutes a valid IPV dose when using these combination vaccines.
- Vaccine schedule for Pediarix™ in Section III p.4
- A new adult vaccine schedule added to Section III p.3

I. ORDER:

1. Screen for contraindications.
2. Provide the current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Give polio-containing vaccine as recommended:
 - Single antigen IPV is 0.5 ml given IM or SQ.
 - IPV-containing Pediarix™ vaccine is 0.5 ml given IM.
 - IPV-containing Pentacel® vaccine is 0.5 ml given IM.
 - IPV-containing Kinrix™ vaccine is 0.5 ml given IM
5. Simultaneous vaccination: may be given with all routine childhood vaccines.

Signature

Health Officer or Medical Provider

Date

October 2008

| II. LICENSED POLIO-CONTAINING VACCINES | | | |
|--|---|-----------------------------|-------------------|
| Product Name | Vaccine components | Acceptable Age Range | Thimerosal |
| IPOL® ¹ | Inactivated polio virus (IPV) serotypes 1,2 and 3 | ≥6 weeks | None |
| Pediarix™ ² | DTaP, IPV, Hepatitis B | 6 weeks – 6 years | None |
| Pentacel® ³ | DTaP, IPV, HIB | 6 weeks – 4 years | None |
| Kinrix™ ⁴ | DTaP and IPV | 4–6 years | None |
| <p>¹ Less than 5 ng of neomycin, 200 ng of streptomycin, and 25 ng of polymyxin B per dose are present in vaccine.</p> <p>² Pediarix™ is licensed for the first three doses of the Polio series only. It is not approved for the 4th polio dose and should not be administered to infants <6 weeks of age or to children ≥7 years of age.</p> <p>³ Pentacel® is licensed for 3 or 4 doses in the polio series at 2 months, 4 months, 6 months and through 4 years of age.</p> <p>⁴ Kinrix™ is licensed for the 4th dose of IPV at 4–6 years of age.</p> | | | |

III. IPV-CONTAINING VACCINE SCHEDULES

| A. Inactivated Poliovirus Vaccine (IPV) Schedule for persons <18 years of age¹ | | | |
|---|--------------------------------------|------------------------------------|--------------------------|
| DOSE 0.5 ml | MINIMUM AGE^{2,3} | MINIMUM SPACING² | RECOMMENDED AGE |
| 1 | 6 weeks | ----- | 2 months |
| 2 | 10 weeks | 4 weeks | 4 months |
| 3 | 14 weeks ⁵ | 4 weeks ³ | 6–18 months ⁴ |
| 4 ⁵ | 18 weeks ⁶ | 4 weeks | 4–6 years |

¹ The use of an IPV-containing combined vaccine is acceptable as long as the other antigen(s) are not contraindicated.

² For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as appropriate for age.

³ The preferred interval between the 2nd and 3rd doses of IPV is 2–8 months. However, if accelerated protection is needed, the minimum interval between all doses of IPV is 4 weeks.

⁴ The administration of IPV3 at 6 months of age is encouraged to minimize the number of injections needed at the 12-month visit.

⁵ If the 3rd dose of an all-IPV or all-OPV series is given on or after the fourth birthday, the series is complete. If the series is combined IPV/OPV, a 4th dose is required. If the immunization history is unclear, give a 4th dose of IPV to ensure completion of the series.

⁶ The fourth dose of polio vaccine will not be forecast until age 4 years, but for retrospective analysis, any combination of 4 doses of IPV and OPV by 4–6 years of age constitutes a complete series as long as the doses meet minimum spacing.

| B. Inactivated Polio Vaccine (IPV) Adult Schedule for Persons ≥18 Years of Age¹ | | |
|---|---------------------------------------|---|
| DOSE 0.5 ml | PRIMARY SCHEDULE^{2,3} | ACCELERATED SCHEDULE for HIGH-RISK PERSONS^{4,5} |
| 1 | | |
| 2 | 1–2 months from dose 1 to 2 | 4 weeks from dose 1 to 2 |
| 3 | 6–12 months from dose 2 to 3 | 4 weeks from dose 2 to 3 |

¹ Routine polio vaccination of persons ≥18 years of age who reside in the U.S. is not necessary due to childhood immunity and minimal exposure risks. However, IPV is recommended for certain adults at an **INCREASED RISK OF EXPOSURE TO POLIO** (e.g., **international travelers, laboratory workers, healthcare personnel caring for polio cases, and contacts of cases during an outbreak**)

² The primary IPV series recommended for high-risk unvaccinated adults (with or without written record) is 2 doses separated by 1–2 months, and a 3rd dose 6–12 months after 2nd dose.

³ If previously completed a primary series of ≥3 doses, 1 more IPV dose can be given if high-risk.

⁴ If 8 weeks are available before protection is needed, 3 doses 4 weeks apart are recommended. If 4–8 weeks are available before protection is needed, 2 doses should be given 4 weeks apart.

⁵ If <4 weeks are available before protection needed, one dose of IPV is recommended. In all cases, the remaining doses should be given later at recommended intervals.

| C. COMBINATION PEDIARIX® VACCINE SCHEDULE^{1,2,3,4,5} (DTaP, IPV, and HepB) | | | |
|---|----------------------------|--------------------|---|
| DOSE 0.5 ml | RECOMMENDED AGE | MINIMUM AGE | MINIMUM SPACING |
| 1 | 2 months | 6 weeks | |
| 2 | 4 months | 10 weeks | 4 weeks dose 1 to 2 |
| 3 | 6–18 months | 6 months | 8 weeks dose 2 to 3 16 weeks dose 1 to 3 |

¹Pediarix® is licensed for the first three doses of the IPV series. It is not approved for the 4th dose of the IPV series. However, if this combination vaccine is misadministered as the 4th or 5th dose of the DTaP or IPV series, ACIP suggests that the dose does not need to be repeated and can be counted as valid.

²Pediarix® can be used interchangeably before or after any individual DTaP, HepB, or IPV dose in the primary series.

³The use of a IPV-containing combined vaccine is acceptable as long as one antigen is indicated and the other antigens are not contraindicated

⁴For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as appropriate for age.

⁵Pediarix® should not be administered to children ≥ 7 years of age.

D. COMBINATION PENTACEL® VACCINE SCHEDULE^{1,2,3}

(DTaP, IPV, and Hib)

| DOSE 0.5 ml | RECOMMENDED AGE | MINIMUM AGE⁴ | MINIMUM SPACING⁴ |
|------------------------|----------------------------|--------------------------------|------------------------------------|
| 1 | 2 months | 6 weeks | |
| 2 | 4 months | 10 weeks | 4 weeks dose 1 to 2 |
| 3 | 6 months | 14 weeks | 4 weeks dose 2 to 3 |
| 4 | 15–18 months | 12 months ⁵ | 6 months dose 3 to 4 ⁶ |

¹Pentacel® can be administered to any child 6 weeks–4 years of age who has no contraindication to any component, and for whom DTaP, IPV, and Hib vaccines are indicated. While Pentacel® is approved for the primary DTaP series and the first booster dose (doses 1–4), it is not licensed for children ≥5 years of age. However, if Pentacel® is inadvertently administered to children ≥5 years of age, the DTaP, IPV and Hib doses should be counted as valid doses (CDC. MMWR 2008; 57[39]: 1079).

²Pentacel® may be used to complete the vaccination series in children previously vaccinated with one or more doses of any single or combination Hib vaccine when other antigens of Pentacel® are also needed.

³Pentacel's® lyophilized ActHIB® component needs to be reconstituted with the DTaP-IPV component to prepare for vaccine administration. Shake the reconstituted vial thoroughly until a cloudy, uniform suspension results, then vaccinate immediately.

⁴For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as appropriate for age.

⁵This minimum age is determined by the DTaP and Hib components of Pentacel®.

⁶This minimum interval is determined by the DTaP component of Pentacel®.

| E. COMBINATION KINRIX™ VACCINE SCHEDULE (5 TH DTaP and 4 TH IPV) ^{1,2,3,4,5} | | |
|---|------------------------|--------------------------------|
| DOSE² 0.5 ml | RECOMMENDED AGE | MINIMUM AGE⁷ |
| 1 ^{4,5,6} | 4–6 years | 4 years |
| <p>¹ This combined DTaP-IPV vaccine is approved for the booster dose of DTaP and IPV (5th dose of DTaP and 4th dose of IPV) at 4–6 years of age. However, if Kinrix™ is inadvertently administered for an earlier dose of the DTaP or IPV series, the dose should be counted as valid and does not need to be repeated provided minimum interval requirements have been met.</p> <p>² This combination booster dose can be administered whenever one of the antigens is recommended and the other is not contraindicated.</p> <p>³ Can be given simultaneously with MMR and varicella-containing vaccines.</p> <p>⁴ The 5th dose of the DTaP series is not required if the 4th dose was given on or after the 4th birthday. Although Kinrix™ is licensed for the 5th dose of the DTaP series, it can be administered for the 4th (and final) dose of the DTaP series and the 3rd (and final dose) of the IPV series, if the child is ≥4 years of age (approved by the Oregon Immunization Program Medical Director and ACIP).</p> <p>⁵ While ACIP recommends that the DTaP series be completed with the same brand of DTaP vaccine previously given, Kinrix™ can be given to complete the DTaP series following the 3rd or 4th dose of any DTaP vaccine or any DTaP-containing combination vaccine previously administered.</p> <p>⁶ Must be given at <7 years of age.</p> <p>⁷ For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as appropriate for age.</p> | | |

| IV. CONTRAINDICATIONS | V. PRECAUTIONS |
|---|---|
| <p>A. Serious allergic or anaphylactic reaction (hives, swelling of the mouth and throat, difficulty breathing, hypotension, and shock) to a previous dose of IPV-containing vaccine. For example:</p> <ul style="list-style-type: none"> -neomycin or polymyxin B in Pentacel® -neomycin, polymyxin B, and latex rubber in syringe plunger of Kinrix™ -latex rubber in syringe of Pediarix® | <p>A. Vaccination with an IPV-containing vaccine should be deferred during a moderate or severe illness (with or without fever) until symptoms have resolved.</p> <p>B. Pregnancy: If immediate protection against poliomyelitis is needed, IPV may be administered. Otherwise, vaccination of pregnant women should be avoided.</p> <p>Immunodeficient persons may receive IPV vaccine, though due to their immune status, only partial protection may be conferred.</p> |

VI. SIDE EFFECTS AND ADVERSE REACTIONS

- A. Minor local reactions (pain, redness) may occur following IPV.
- B. No serious side effects have been documented with IPV.

VII. OTHER CONSIDERATIONS

A. Post-Polio Syndrome

After an interval of 30–40 years, 25%–40% of persons who contract paralytic poliomyelitis in childhood may experience muscle pain and exacerbation of existing weakness or develop new weakness or paralysis. This disease entity, referred to as post-polio syndrome, has been reported only in persons infected during the era of wild poliovirus circulation. This is not an infectious process. For further information contact:

- International Polio Network; 4207 Lindell Blvd, Ste 110 St. Louis MO 63108-2915; 314-534-0475.
- March of Dimes; Birth Defects Foundation; Community Services Department; 1275 Mamaroneck Ave.; White Plains, NY 10605; 914-428-7100.

B. Vaccination of Internationally Adopted Children

- The recommended approach is to revaccinate adopted children with IPV according to the US schedule.
- Alternative approaches are to order serologic testing for neutralizing antibody to poliovirus types 1,2 and 3; or to administer a single dose of IPV, followed by serologic testing,
- Children with protective titers *against all three types* do not need revaccination.

- C. For someone with a history of fainting with injections, a 15-minute post-immunization observational period is recommended.

VIII. ADVERSE EVENT REPORTING

Adverse events following immunization should be reported by public providers to the Immunization Program, Health Services, using a Vaccine Adverse Events Reporting System form (VAERS), according to state guidelines. Private providers report all adverse events directly to VAERS.

VAERS phone number: 800-822-7967, and the website address is <http://vaers.hhs.gov>

Table 1. Adverse Events To Be Reported To VAERS

| Vaccine | Event | Time Period |
|---------|---|--------------------|
| OPV | Paralytic polio in a vaccine-associated community case | No limit |
| | Vaccine-strain polioviral infection in a vaccine-associated community case | No limit |
| IPV | Anaphylaxis or anaphylactic shock | 4 hours |
| | Any sequela, including death, of the above events | No limit |
| | Events described in the manufacturer's package insert as contraindications to additional doses of vaccine | See package insert |

POLIO CASE INVESTIGATION: Notify ODPE immediately, day or night.

IX. REFERENCES

1. CDC. Licensure of a diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, and *Haemophilus b* conjugate vaccine and guidance for use in infants and children. MMWR 2008; 57 (39): 1079–80. Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a5.htm.
2. CDC. Licensure of a diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine and guidance for use as a booster dose. MMWR 2008; 57 (39):1078–9. Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a4.htm.
3. Poliomyelitis. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* (“Pink Book”). Atkinson W, Hamborsky J, Wolfe S, eds. 10th ed. Washington, DC: Public Health Foundation, 2008:101–13.

4. CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006; 55 (RR-15). Available at www.cdc.gov/mmwr/PDF/rr/rr5515.pdf.
5. CDC. Poliomyelitis prevention in the United States: updated recommendations of the Advisory Committee of Immunization Practices (ACIP). MMWR 2000; 49 (RR-5). Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4905a1.htm>.
6. Pediarix™ 2007 package insert. Available at http://us.gsk.com/products/assets/us_pediarix.pdf.
7. Pentacel® 2008 package insert. Available at <http://www.fda.gov/CbER/label/pentacelLB.pdf>.
8. Kinrix™ 2008 package insert. Available at <http://www.fda.gov/cber/label/kinrixLB.pdf>.

For more information or to clarify any part of the above order, consult with your Health Officer or call the Oregon Public Health Division Immunization Program at 971-673-0300.

**To download a copy visit our website at
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