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Bulletin No. 34 December 5, 2003

## Pediarix™ Vaccine Reduces Number of Required Injections

Beginning January 1, 2004, the Alaska Section of Epidemiology will supply *Pediarix*™, a GlaxoSmithKline pediatric vaccine that combines protection against **diphtheria, tetanus, pertussis, polio, and hepatitis B** into one injection. In conjunction with this move:

- **Comvax**® [combination hepatitis B/ *Haemophilus influenzae* type b (Hib) vaccine] **will no longer be provided.**
- All vaccine components contained in either *Pediarix*™ or *Comvax*® (i.e., DTaP, polio, hepatitis B, and Hib) will continue to be available as individual antigens.

### WHAT ARE THE COMPONENTS OF PEDIARIX™?

*Pediarix*™ is a pentavalent vaccine that provides protection against diphtheria, tetanus, pertussis, polio, and hepatitis B. It contains the same DTaP and hepatitis B antigens used in existing vaccines (*Infanrix*® and *Engerix-B*®, respectively.) The IPV component is derived from a vaccine that has been used in other countries since 1996 and contains the same three poliovirus types, strains, and antigen content as currently licensed U.S. vaccine. *Pediarix*™ does not contain thimerosal as a preservative. Thimerosal is used during early production stages and subsequently removed, leaving only a clinically insignificant trace.

### WHY IS ALASKA USING PEDIARIX™?

As noted by the Advisory Committee on Immunization Practices (ACIP), "The use of licensed combination vaccines is preferred over separate injection of their equivalent component vaccines."<sup>1</sup> As shown in *Table 1*, using effective combination vaccines reduces the number of injections required to protect Alaska's children against vaccine-preventable diseases.

**Table 1: Number of Injections in the Pediatric Schedule**

Vaccine Used	@ 2 mo visit	by 18 mos*	by 18 yrs*
Single antigens	5	21	27
w/ <i>Comvax</i> ®	4	19	25
w/ <i>Pediarix</i> ™	3	16	22

\* Includes 2 doses of influenza vaccine for children 9-23 mos of age, per 2004 ACIP recommendations

### WHAT ARE PEDIARIX™ INDICATIONS FOR USE?

*Pediarix*™ is approved for hepatitis B and the **first 3 doses** of the DTaP and IPV series, which usually are given at about 2, 4, and 6 months of age. However, *Pediarix*™ is approved for use from 6 weeks through 6 years of age, the same as the DTaP component. Therefore, a child who is behind schedule can still receive *Pediarix*™ as long as:

- it is given for doses 1, 2, or 3 of the basic series *and*
- the child is less than 7 years of age.

Following completion of the primary series with *Pediarix*™, the 4<sup>th</sup> and 5<sup>th</sup> doses of DTaP and the 4<sup>th</sup> dose of IPV should be administered at appropriate ages with individual antigens.

### HOW DOES PEDIARIX™ FIT WITH THE HEP B SCHEDULE?

- (1) The ACIP and the Alaska Section of Epidemiology *strongly* recommend *all* children receive a birth dose of monovalent

monovalent hepatitis B vaccine.<sup>2</sup> A child who receives this birth dose may still receive a 3-dose series of *Pediarix*™ at the 2, 4, and 6 month visits, even though this will mean getting an "extra" dose of hepatitis B. The ACIP has approved *Pediarix*™ use among infants whose mothers are HBsAg+ or whose HBsAg status is unknown.

- (2) The minimum interval between hepatitis B doses 2 and 3 is 8 weeks. If a birth dose is given, this minimum interval may be met by assuring at least 8 weeks have elapsed between the second and final (4<sup>th</sup>) doses of *Pediarix*™.
- (3) The final dose of hepatitis B vaccine must be given no earlier than 24 weeks of age.

### HOW DO IMMUNOGENICITY AND ADVERSE EVENTS COMPARE BETWEEN PEDIARIX™ & INDIVIDUAL COMPONENT VACCINES?

**Immunogenicity** – Clinical studies have shown the immune response to *Pediarix*™ is comparable to that of the individual component vaccines.<sup>3</sup>

**Adverse Events** – Prelicensure trials comparing rates of adverse events in children who received *Pediarix*™ and those who received the component vaccines individually indicated no significant difference in local reactions between the two groups. However, a larger proportion of *Pediarix*™ recipients reported a fever (100.4°F – 101.3°F) within 4 days of administration (28% of *Pediarix*™ recipients vs 20% of individual component recipients). There was no difference in other systemic reactions such as crying, restlessness, or loss of appetite.<sup>3</sup>

### HOW SHOULD PROVIDERS TRANSITION TO PEDIARIX™?

For children beginning their vaccine series, simply give *Pediarix*™ at the 2, 4, and 6 month visits as shown on the recommended schedule.<sup>4</sup> If a child already has received *Comvax*® or individual antigens, examine his/her immunization history *antigen by antigen* and follow the steps in the *Decision Tree* below. ***Pediarix*™ may be used when at least 2 of the 3 component vaccines (i.e., DTaP, IPV, hep B) are indicated.**

Providers should deplete supplies of *Comvax*® prior to implementing *Pediarix*™. As an option, remaining supplies of *Comvax*® may be used for children in the midst of their vaccine series, while *Pediarix*™ is used for children beginning their immunizations. The appropriate regimen should be chosen based upon the ability to assure all *Comvax*® supplies are used prior to expiration. **Note:** Children who received *Comvax*® at their 2 and/or 4 month visits will need an additional dose of hepatitis B to complete their series.

For additional information, see *FAQs on Pediarix Vaccine* at: <http://www.cdc.gov/nip/vaccine/pediarix/pediarix-faqs-hep.htm>.

<sup>1</sup> MMWR, 1999; 48 (RR-5):1-15 *Combination Vaccines for Childhood Immunization*, <http://www.cdc.gov/mmwr/PDF/rr/tr4805.pdf>

<sup>2</sup> *Epidemiology Bulletin* No. 14, June 18, 2002, *Importance of Birth Dose of Hep B Vaccine Reaffirmed*, [http://www.epi.hss.state.ak.us/bulletins/docs/b2002\\_14.htm](http://www.epi.hss.state.ak.us/bulletins/docs/b2002_14.htm)

<sup>3</sup> Final Script from "Immunization Update 2003" Satellite Broadcast, August 21, 2003, <http://www.cdc.gov/nip/ed/ImUpdate2003/update03pediarix.pdf>

<sup>4</sup> *Epidemiology Bulletin* No. 33, December 4, 2003, *Pediarix Vaccine Reduces Number of Required Injections* [http://www.epi.hss.state.ak.us/bulletins/docs/b2003\\_33.htm](http://www.epi.hss.state.ak.us/bulletins/docs/b2003_33.htm)

### Decision Tree for Use of Pediarix™

