



Bulletin No. 21

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New Hepatitis A Vaccine Requires Fewer Doses

On January 1, 1996, the Section of Epidemiology began supplying hepatitis A vaccine for use in children 2-14 years of age (*Epidemiology Bulletin* #32, December 14, 1995). This program was developed in response to Alaska's history of periodic outbreaks of hepatitis A which have resulted in thousands of cases and at least eight deaths over the past 20 years.

Havrix, a SmithKline Beecham Company product, is the vaccine which has been distributed for the past 6 months. The initial pediatric formulation of this vaccine was **360 ELISA units (EL.U.)** per dose; *three* doses were required to complete the series. In April of this year, SmithKline Beecham received approval from the U.S. Food and Drug Administration for licensure of a second formulation of pediatric *Havrix*. The new formulation, which consists of **720 EL.U.** per dose, requires only *two* doses to complete the vaccine series. **Beginning July 1, 1996, the Alaska Immunization Program will begin supplying the new *Havrix* formulation.** This *Bulletin* answers questions anticipated to be raised during the transition period from use of the three dose to the two dose hepatitis A vaccine.

1. What are the major differences between the "old" and the "new" vaccine?

	Havrix 360 EL.U. "old"	Havrix 720 EL.U. "new"
No. doses required	3	2
Dates vaccine supplied by State	1/1/96 thru 6/30/96	beginning 7/1/96
Interval between doses	1→2 1 mo 2→3 6-12 mo	1→2 6-12 mo
Ages for use in AK	2-14 yrs	2-14 yrs
How supplied	single dose vial	single dose vial
Distinguishing package characteristics	box-kelly green band at top vial-"sea green" cap	box-brick red band at top vial-teal cap

2. What should I do with the 360 EL.U. vaccine I currently have?

Unless you receive specific instructions to the contrary from the Alaska Immunization Program, you should **utilize your remaining supply of hepatitis A vaccine before beginning to use the new vaccine.** As you change from one vaccine to the other, some children in your practice may already have received 1 or 2 doses of the 360 EL.U. vaccine, which will no longer be available. These children should be immunized as shown on the following chart.

Children who have received this many doses of the 360 EL.U. ("old") vaccine...	...should complete the series with this many doses of the 720 EL.U. ("new") vaccine...	...allowing these intervals between doses.
0	2	#1 (new) → #2 (new) 6-12 months
1	2	#1 (old) → #2 (new) <i>no minimum interval*</i> #2 (new) → #3 (new) 6-12 months
2	1	#1 (old) → #2 (old) 1 month #2 (old) → #3 (new) 6-12 months
3	0	series is complete
<p>* This schedule effectively disregards the initial 360 EL.U. dose and follows the standard recommendation for the 2-dose 720 EL.U. schedule. Therefore, no minimum interval is required between dose 1 and 2. However, if a provider feels the patient is compliant, he/she might choose to wait 1 month between dose #1 (360 EL.U.) and dose #2 (720 EL.U.) <i>Theoretically</i>, this could provide some children with earlier protection due to a potential "boosting" effect provided by the second dose. However, in the absence of firm immunogenicity data, absolute protection cannot be assured. Therefore, the additional dose (#3) of the 720 EL.U. vaccine should be given 6-12 months later.</p>		

3. If a child's record designates only that "hepatitis A" was given, how can I determine whether the 360 EL.U. or the 720 EL.U. formulation was used?

By Date: For providers who have received vaccine via the state program, only 360 EL.U. vaccine was distributed from January 1 through June 30, 1996. Beginning July 1, 1996, only 720 EL.U. vaccine will be distributed.

By Lot Number: An examination of the log sheet could provide additional assistance in determining the type of vaccine used. The only two lot numbers of 360 EL.U. vaccine which were distributed *through the state* were:

Lot VHA164A2 Exp. 01/03/97
Lot VHA178A2 Exp. 06/29/97

If neither of these methods provides sufficient information to determine which vaccine formulation was used, proceed as if the 360 EL.U. vaccine were used and vaccinate according to the chart above.

4. How should the vaccine series be completed for children who received one dose of the pre-licensure 720 EL.U. vaccine during the hepatitis A outbreak control efforts conducted in villages in 1993-94?

Children who received only *one* dose as part of the pre-licensure vaccination program can complete their series with one more dose of the 720 EL.U. vaccine. If *two* doses were given, the series is complete.

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