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DATE: October 14, 2008

TO: Vaccine Providers
Vaccine Manager

FROM: Marcella Bobinsky, Program Manager
Immunization Program

SUBJECT: Hib/Pentacel Update

Please pass the attached material to all Vaccine Providers.

PLEASE FORWARD
ALL APPROPRIATE PERSONNEL AS SOON AS POSSIBLE

NOTICE:

You have received this message based upon the information contained within the Swift Information System (SIS) notification database. If you have a different fax address that you would like us to use please notify us as soon as possible by e-mail at LJOHNSON@DHHS.STATE.NH.US

To: Vaccine Providers
From: Marcella J. Bobinsky, Program Manager
New Hampshire Immunization Program
Re: Hib containing vaccines

We need your cooperation to ensure that children receive their primary Hib series. If you haven't already, I urge you to incorporate Pentacel into your practice as soon as possible.

The Centers for Disease Control and Prevention (CDC) announced that the Hib vaccine shortage would continue through December 2008. The CDC said that the number of ActHIB doses will decrease as the number of Pentacel doses available to the New Hampshire Immunization Program (NHIP) is expected to increase.

Deferral of the fourth ActHIB dose will remain in effect until 2009. Furthermore, the NHIP will not receive enough ActHIB vaccine to provide the second and third dose in the series. Our only alternative to ensure that children receive all three doses of the primary series is to ask our providers to begin using Pentacel vaccine whenever a HIB-containing vaccine is required. Based on the attached letter and the fact that "The Pink Book, Edition 10" states, "Pediarix may be used interchangeably with other pertussis-containing vaccine if necessary" (P. 94), we encourage you to use the Pentacel that is available to New Hampshire providers.

In a related note, the NHIP has learned that each Pentacel dose has two lot numbers that must be recorded in the patient's medical record. According to the October 3, 2008 MMWR:

"Different lot numbers for the different components of DTAP-IPV/Hib are included on the DTaP-IPV vial and on the Hib powdered vial. Providers should record lot numbers separately for the DTaP-IPV and Hib components."

This may pose a problem for those using electronic medical records. One New Hampshire provider has found that they can record both lot numbers on one line as: "lot # & lot#". For example, if the lot number of the DTaP-IPV vial is 1234 and the Hib vial is 5678, they entered the lot numbers as: "1234&5678". They were able to retrieve accurate data using this method.

Vaccine shortages mean that we must be diligent when providing alternative vaccine choices to our children. Providers must double check immunization records to determine which vaccines are required at each visit and make the right vaccine selection. The CDC website below provides guidance on the use of Pentacel and Pediarix.

www.cdc.gov/vaccines/Pubs/downloads/pentacel-guidance.pdf

The NHIP staff is also available to provide technical assistance. Please contact us at: 603.271.4482.

The following is a letter that was sent from the CDC and Nancy Messonnier, Chief of the Meningitis and Vaccine Preventable Diseases Branch. The message reinforces the need to make Pentacel available to your families.

We are writing to stress the critical importance of providing the full, three-dose primary series of Hib-containing vaccine to infants who are served by your immunization providers. The only exception is for American Indian and Alaska Native children who receive the VFC stockpile's Merck Hib vaccine, which is a two-dose primary series that must be followed by a booster dose during the second year of life.

So far, you are doing a great job by any measure. Most importantly, the Hib experts at CDC have not seen any increase in invasive Hib disease. This is great news that we hope to be able to say at the end of the Hib shortage as well. Also important is that you are successfully allocating to your immunization providers the doses you are rationed by CDC.

We believe that we are in the final stretch of the Hib vaccine shortage. We still expect Merck to come back to the market by the end of this calendar year; we know that the company is making Hib vaccine, but we do not have a release schedule from them, yet.

The current challenge is that we are receiving shrinking supplies of monovalent Hib vaccine and increasing supplies of the combination vaccine Pentacel. To maximize the number of children protected from Hib, some practices will need to use Pentacel, even if they are not enthusiastic about use of this combination vaccine. However, we have no alternative, and so choice of Hib vaccine product is not an option for many immunization programs and many of your providers. A further challenge is that Pentacel is more expensive than the sum of its three component vaccines, which poses a financial burden on states with generous vaccine purchase policies for underinsured and fully insured children.

We have been hearing from some states and providers that some immunization programs would like to vaccinate with a 2-dose primary series of ActiHIB rather than incorporate Pentacel into their program or into provider practices. This is a practice that CDC cannot support for two reasons. First, VFC is an entitlement to certain children, and all of us have a shared responsibility to protect VFC-entitled children with the full recommendations of the ACIP and CDC.

The second reason for not supporting programs to vaccinate with only 2 of the 3 doses required for priming with ActHIB is relevant to more than the VFC population. The full primary series is absolutely essential to successfully immunize infants. Experience with Hib vaccine clinical trials has shown that a reduced primary series will not accomplish basic protection through the at-risk period. This is especially critical in our current, precarious situation of having 10-months of no booster dose for healthy children. The booster dose is needed to reduce carriage of the bacterium, and the accumulation of toddlers without this protection from carriage means that Hib is or will soon creep back into the population and be able to infect an incompletely protected infant – one that did not receive the full primary series.

The United Kingdom recently published a review of their experience that showed the importance of the booster dose in reducing carriage. Reduction of carriage provides direct and indirect protection from invasive Hib disease. Since the start of their program, the UK has vaccinated with only a primary series. Unlike the U.S., they had continued transmission of Hib which prompted them to institute a booster dose, after which their rates of invasive Hib disease declined. Because we do not have enough vaccine for a booster dose for routine use, we have to

directly protect the infants. This means that for many, if not most or all of your providers will need to use Pentacel as a part of this early protection.

We know that incorporating Pentacel may be a challenge, but we have constraints that make it an essential part of protection until Merck brings their monovalent Hib vaccine back to the market and to the program. Until Merck comes back to the market, grantees must use Pentacel to supplement their shrinking supplies of monovalent sanofi Hib vaccine. If you feel that you do not have sufficient Pentacel, more is available.

We all hope to continue to keep invasive Hib disease away from U.S. children. So far, so good. We are almost to the end of the shortage, but until the shortage ends, we have to work even harder to maintain that primary series.

Thanks.