



STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
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March 12, 2008

TO: Washington State Board of Health Members

FROM: Dr. Diana Yu, SBOH Member

SUBJECT: DISCUSSION OF RESPONSE TO SHORTAGES OF VACCINES REQUIRED FOR CHILD CARE AND SCHOOL ENTRY, WAC 246-100-166

Background and Summary

On February 21, the State Board of Health held a special meeting to respond to a shortage of the vaccine for *Haemophilus influenzae* type b (Hib). To prevent the unwanted circumstance of children claiming exemptions or being excluded from childcare because they had not received a Hib booster, the Board reviewed and approved a Department of Health (DOH) implementation plan for the duration of the shortage. This was the first use of provisions in the Board's school and child care immunization rule, WAC 246-100-166, that allow DOH to develop implementation plans that differ from Board rules in order to respond to shortages. During the special meeting, I proposed that at our March meeting, we discuss how this process worked and options for how the Board might best respond to vaccine shortages in the future.

There were also questions from Board members about prior shortages, the reasons for the current shortage, and whether the Board might want to advocate for changes to the vaccine production and distribution system that would make future shortages less likely. Board staff recommended the Board discuss these issues at today's meeting.

I have asked Janna Bardi, DOH Manager of the Immunization Program and CHILD Profile, to participate in today's discussion.

Recommended Board Action

No specific action recommended.

Discussion

The last vaccine shortage affecting WAC 246-100-166 occurred in 2002. The vaccine in short supply then was DTaP, a combination vaccine for diphtheria, tetanus, and pertussis. The shortage resulted in the deferral of the last one to two doses of DTaP. At that time, the rule did not have a provision for responding to a shortage. To prevent children without the complete DTaP series from being kept out of school or forcing parents to claim a personal exemption, the Board passed an emergency rule that delegated authority to the state health officer to declare a shortage for up to 120 days. This allowed children to enter school and to catch up with the series once the shortage ended. The Board also wrote a letter to national leaders expressing concern over the shortage (attached).

In July 2005, the Board revised WAC 246-100-166. Changes included a new subsection (8)(b) that contains guidelines for how a DOH implementation plan might temporarily waive or modify immunization requirements during a shortage. Modifications must reflect best available medical research as indicated by the Advisory Committee on Immunization Practices (ACIP) or a state health officer recommendation; identify a specific vaccine-preventable disease or immunizing agent; identify a specific cohort of children by age or grade level; be limited in duration; and be approved by the Board.

On December 13, 2007, the pharmaceutical Merck issued a voluntary recall and suspension of production of two Hib vaccines, PedvaxHIB® and Comvax®. Merck does not expect to resume distribution until the fourth quarter of 2008. Merck issued the recall as a precaution because it cannot assure the sterility of equipment used to manufacture the recalled lots. Vaccine potency was not affected, and Merck reports no contamination. Children who received Hib conjugate vaccine from the recalled lots, therefore, do not need revaccination or any special follow-up.

Two other Hib vaccines manufactured by Sanofi Pasteur and licensed for use in the United States, ActHIB® and TriHIBit®, were unaffected by the recall. However, Sanofi Pasteur was not able to provide adequate vaccine to fully vaccinate all children. On December 19, 2007, the Centers for Disease Control and Prevention (CDC), in consultation with ACIP, recommended a temporary reduction of Hib vaccination.

On December 19, 2007 the Department sent an update on the Hib vaccine shortage and interim recommendations to health officers, nursing directors, immunization coordinators, and other immunization partners that explained the interim ACIP recommendations and provided information on vaccine supply and distribution in Washington. DOH requested that the update be shared broadly with providers to ensure equitable availability of Hib vaccine during the shortage, and appropriate vaccination of populations considered to be at high risk for Hib disease.

In January 2008, the CDC decreased its allocation of Hib vaccine to each state. Temporary ACIP recommendations defer the Hib booster dose that is routinely recommended to be given between ages 12 through 15 months, and also allow some exceptions for specific groups of high-risk children.