

Minutes
Massachusetts Department of Public Health
Massachusetts Vaccine Purchasing Advisory Council (MVPAC) Meeting

Date: Thursday, June 11, 2015

Time: 4-6 PM

Location: Massachusetts Medical Society, 860 Winter Street, Waltham, MA 02451

Attendees:

Council Members:

Kevin Cranston	Elizabeth Lindahl (for Marissa Woltman)
Sansei Fowler, MD, MPH (for Duke Dufresne, MD)	David Norton, MD, FAAP
Benjamin A. Kruskal, MD, PhD, FAAP, FIDSA	Sean Palfrey, MD, FAAP
Susan Lett, MD, MPH	Ronald Samuels, MD, MPH
	Kate Wallis, RN, BSN
	Jane Williams, MD, MPH

Additional Attendees:

Rich Aceto	Larry Madoff, MD
Eric Blum	Eric McCullough
Judy Butler	John McLaughlin, PhD, MSPH
Brandis Dohman	Cynthia McReynolds
Patrick Brill-Edwards, MD	Dorothy Miller
Debra Eliot	Robert Morrison
Beth English, MPH	Patricia Novy, PhD
Diane Frazier	Sherry Schilb
Michael Garvey	Pejman Talebian, MA, MPH

Welcome

Mr. Cranston convened the meeting and welcomed attendees.

Attendees introduced themselves.

DPH Updates

The FY16 budget is currently in conference committee. The pediatric vaccine budget will not be impacted by House and Senate budget deliberations.

As noted at the previous Council meeting, the Vaccine Trust Fund has enabled DPH to provide Hepatitis A, Tdap and Varicella vaccines for catch-up vaccination of children up through 18 years of age. In FY16, the program will be expanded to include universal supply of influenza vaccines for children up to 18 years of age.

A proposal to expand the program to include all pediatric vaccines is under review by the administration.

There are significant budget considerations that may impact the Department of Public Health as a whole; however, these considerations probably will not impact the immunization program.

Review of MCV4 distribution data

At the request of the Council, DPH reviewed distribution data for MCV4 doses from July 2011 through May 2015.

July 2011 represents the date when the pilot program for provider choice of MCV4 vaccine was began.

Distribution of MCV4 vaccine is seasonal, with higher levels of distribution in the summer around the beginning of school.

A slight increase in market share of Menveo® was noted; however, the total distribution of Menveo® has been low compared to Menactra®.

DPH will continue to provide distribution data to the Council as requested for any DPH-supplied vaccines.

Review of Meningococcal B vaccines

A handout detailing the Meningococcal Group B vaccines (Bexsero® and Trumenba®) was reviewed.

Both formulations are only licensed for use in those 10-25 years of age. However, the ACIP has made an off-label recommendation for use of meningococcal B vaccines in those 10 years of age and older at increased risk for serogroup B meningococcal disease.

Trumenba® is administered on a two-dose schedule and Bexsero® is administered on a three-dose schedule.

Neither vaccine requires reconstitution.

Based on the February 2015 deliberations at the ACIP meeting, meningococcal B vaccine is currently recommended only for certain high risk groups. ACIP will be further considering the recommendation for routine use at its June meeting. Mr. Cranston noted that it is unlikely that the Council will be reconvened before its next scheduled meeting because of the outcome of June ACIP deliberations regarding meningococcal B vaccines.

Presentations

Bexsero® (GlaxoSmithKline)

Dr. Novy presented information about Bexsero®.

MenB-4C consists of three recombinant proteins (Neisserial adhesin A [NadA], factor H binding protein [FHbp] fusion protein, and Neisserial Heparin Binding Antigen [NHBA] fusion protein), and outer membrane vesicles (OMVs) containing outer membrane protein PorA serosubtype P1.4. MenB-4C is licensed as a 2-dose series, with doses administered at least 1 month apart, although in some studies, MenB-4C doses were administered up to 6 months apart.

Clinical trial information was reviewed.

Information about safety and contraindications was reviewed.

There is additional pre-license safety experience data from vaccine administration at two US universities in response to an outbreak.

The tip cap contains natural rubber latex.

Bexsero® is licensed in 37 countries. It has been used the most in Quebec, where more than forty-five thousand people have been vaccinated to date.

Use in higher incidence countries is just beginning. Most countries administer the vaccine earlier than 10 years of age.

Sufficient data are not available on the safety and effectiveness of using Bexsero® and other meningococcal group B vaccines interchangeably to complete the vaccination series.

Data on co-administration of Bexsero® with other adolescent vaccines has not been tested.

Trumenba® (Pfizer)

Dr. John McLaughlin presented information about Trumenba®

He discussed the impetus behind the development of meningococcal serogroup B vaccines. In the United States, in the 17-22 year age group, serogroup B accounts for almost half of all invasive meningococcal disease. Until recently, there were no available vaccines for serogroup B meningococcal vaccine.

MenB-FHbp consists of two purified recombinant FHbp antigens. One antigen from each FHbp subfamily (A and B) is included in the vaccine. Previous studies have shown limited cross-protection across FHbp subfamilies, and only MenB-FHbp targets both subfamilies, A and B. MenB-FHbp is licensed as a 3-dose series, with the second and third doses administered 2 and 6 months after the first dose.

FDA approval of MenB-FHbp was based on demonstration of immune response as measured by serum bactericidal activity against four serogroup B strains representative of the prevalent strains in the U.S.

Safety data and contraindications were reviewed.

Sufficient data about mixing vaccines is not available. If vaccination is initiated with one vaccine it should be finished with it.

Deliberation

As noted previously, ACIP has voted only to recommend these vaccines for high-risk groups. The ACIP has not recommended a preference for one vaccine over the other.

Although these vaccines are covered by the Vaccines for Children (VFC) Program, DPH has not distributed them yet. DPH is awaiting the outcome of the ACIP's June deliberations. Today's Council deliberation represents the first deliberation on vaccines not currently in the DPH formulary.

The following options for Council deliberation included:

- Council to recommend that DPH supply Trumenba® exclusively;
- Council to recommend that DPH supply Bexsero® exclusively;
- Council to recommend that DPH supply both Trumenba® and Bexsero®, allowing for provider choice.

Discussion ensued as to whether the Council could make a provisional recommendation based on the expected outcome of the ACIP deliberations, with the possibility of changing the recommendation if the ACIP recommends a specific vaccine.

Choice would provide greater flexibility in the event of an outbreak or if there is a break in availability of either vaccine. Having an available vaccine is most important.

In the event of an outbreak, the differing administration schedules (two-dose versus three-dose) might present logistical problems. However, provider reporting of doses administered by formulation to the MIIS, and utilizing the MIIS forecasting algorithm would help to ameliorate some of these concerns.

After discussion, a proposal was made that the Council recommend that DPH supply both Trumenba® and Bexsero®. There was Council consensus that DPH supply both vaccines at this time.

The next Council meeting will be held on October 8, 2015.

The meeting was adjourned.

Future Meeting Dates:

October 8, 2015

March 10, 2016

June 9, 2016

October 13, 2016

MVPAC webpage:

<http://www.mass.gov/eohhs/gov/departments/dph/programs/id/immunization/mvpac.html>