

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

Date: Thursday, October 13, 2016

Time: 4-6 PM

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

Council Member Attendees:

Kevin Cranston, MDiv

Leanne DiMaio, MPH, MBA

Sansei Fowler, MD, MPH

Ben Kruskal, MD, PhD

Susan Lett, MD, MPH

Cody Meissner, MD

David Norton, MD

Sean Palfrey, MD

Ron Samuels, MD, MPH

Patricia Toro, MD, MPH

Marissa Woltman

Additional Attendees:

Richard Aceto

Adam Bloomfield, MD

Lenny Demers

Beth English, MPH

Chris Germaine

Michael Goldstein

Larry Madoff, MD

Cynthia McReynolds

Jim Palazzo, PharmD

Sherry Schilb

Pejman Talebian, MA, MPH

MDPH Updates

Mr. Cranston opened the meeting and welcomed attendees. He noted that there was a quorum for Council deliberations.

Attendees introduced themselves.

Mr. Talebian reported that the Immunization Program is a recipient of a Prevention and Public Health Fund (PPHF) grant from the CDC. The purpose of the grant is to actively promote human papillomavirus (HPV) vaccination using the Assessment, Feedback, Incentives and eXchange (AFIX) quality improvement program. The two-year grant is \$500,000. One of the grant activities will be physician to physician education utilizing American Academy of Pediatrics (AAP) faculty.

Ms. English provided a Massachusetts Immunization Information System (MIIS) roll-out update. She noted that the MIIS contains almost 40 million shot records and by the end of year more than 2,000 sites will be reporting to the MIIS.

Dr. Lett reviewed the 2015-2016 influenza season, noting that the season had been mild, with a late peak. Influenza A H1N1 strain predominated. The circulating strains appeared to be an excellent match for the vaccine. Influenza hospitalization rates appeared to be lower than for the previous year.

At its June 2016 meeting, the Advisory Committee for Immunization Practices (ACIP) discussed the live attenuated influenza vaccine (LAIV). After reviewing data for the past several influenza seasons, the ACIP made an interim recommendation that LAIV not be used for the 2016-2017 influenza season.

Researchers, CDC, FDA and the manufacturer are all committed to gaining insight into the issue and are continuing to review data as it becomes available.

Dr. Bloomfield (AstraZeneca) noted that the company is working to understand this issue and hopes to bring the vaccine back to market soon.

Dr. Lett also reviewed the ACIP recommendations for the 2016-2017 influenza season, noting the principal changes from the 2015-2016 influenza season:

- LAIV is not recommended for use during this season;
- Updated egg allergy recommendations;
- Newly-recommended vaccine licensures, including:
 - Flud
 - Flucelvax Quadrivalent
 - Afluria Quadrivalent

Dr. Lett reviewed the available formulations of influenza vaccine.

Adequate supplies of inactivated influenza vaccine (IIV) are expected. There are no known problems for private sector purchase of IIV

ACIP does not recommend a vaccine preference for those with egg allergy.

CDC and DPH flu resources were reviewed.

Dr. Lett also provided a 2016 mumps outbreak update. Since February 15, 2016, DPH has investigated more than 600 suspect cases. There have been 111 confirmed and 101 probable cases of mumps. 67 of the 111 confirmed cases were at Harvard University, with additional cases confirmed at seven other Boston-area universities and probable cases at two other universities. The majority of cases were in people vaccinated with two measles, mumps, and rubella (MMR) doses.

Deliberation regarding inclusion of Category B recommendation for Meningococcal B vaccine in DPH universal program

Dr. Meissner provided a review of data for meningococcal disease in the United States and the licensed meningococcal B (MenB) vaccines.

He noted that rates of meningococcal disease in the U.S. are declining.

The current ACIP and AAP recommendation for use of serogroup meningococcal B vaccines in adolescents and young adults is:

- MenB vaccination is recommended for people ≥ 10 years at increased risk of meningococcal B disease (complement deficiency, anatomic/functional asplenia, outbreak settings, and microbiologists.) (Category A recommendation.)
- MenB vaccine may be administered to adolescents and young adults 16 through 23 years of age to provide short term protection against most group B strains (Category B recommendation).
- The preferred age for MenB vaccination is 16 through 18 years of age.

There are currently two licensed meningococcal serogroup B vaccines for persons aged 10 through 25 years (Bexsero-GSK; Trumenba-Pfizer).

Data shows that college students have a lower/equal risk of MenB disease than non-college students.

A summary of different Men series cost-effectiveness strategies was reviewed.

There are unresolved issues regarding the MenB vaccines. These issues include:

- The duration of antibody persistence is unknown;
- The number of vaccine-preventable cases is not known;
- The impact on carriage is not known;
- Vaccine pressure on circulating strains is not known;
- Vaccine safety is uncertain;
 - Theoretical concerns about safety from animal models regarding autoimmune disease;
 - FDA aware of concerns at time of licensure.
- The quality-adjusted life year (QALY) saved is >20 times higher than for any other vaccine.

Discussion ensued about how public health policy is determined and whether there will ever be a vaccine that is too expensive to recommend (QALY threshold). QALY methodology is not infallible. It was noted that the emotional components of public health policy are not factored into QALY measurements.

Council Deliberation

Mr. Talebian noted that the Council first discussed MenB vaccines at its October 2015 meeting. At that time the Council recommended that a decision regarding inclusion of MenB vaccines in the DPH formulary be deferred, allowing time to consider the Category B recommendation.

DPH currently supplies MenB vaccines for high-risk children aged 10 through 18 years of age, and for VFC-eligible children aged 16 to 18 years of age.

A chart detailing the distribution of state-supplied MCV4 and MenB vaccines from July 2015-September 2016 was reviewed.

Mr. Talebian reviewed the following options for Council deliberation:

1. Recommend that DPH maintain its current policy of universally providing MenB vaccines for high risk children 10 through 18 years of age and for VFC-eligible children 16 to 18 years of age (Category B recommendation).
2. Recommend that DPH change its policy to include universally supply MenB vaccines for all Category A and Category B recommendations including healthy adolescents 16 to 18 years of age.
3. Defer a decision for future Council deliberation.

Council discussion ensued.

It is not currently known whether providers are recommending MenB vaccines. Anecdotally, it appears that some physicians are providing the vaccine if requested, some are recommending the vaccine and some are not offering or recommending it.

The cost to DPH to supply non-VFC MenB vaccines universally would be approximately \$6-7 million. The total DPH budget is close to \$160 million.

At its October meeting, the ACIP will be considering recommending a reduced HPV vaccine dosing schedule (from 3 doses to 2 doses). The savings from this reduction could potentially offset the cost to add MenB vaccines to the formulary.

Per the ACA, insurers are required to cover vaccines for which the ACIP has made a Category A or Category B recommendation. Self-insured groups which are grandfathered are not subject to these requirements.

A question was asked whether area colleges require MenB vaccine. (Note: At this time we only know of Providence College requiring the vaccine. Anecdotally we have heard of a few others nationally.)

If the MenB vaccine is not part of DPH's formulary, will there be inequity? If the vaccine is not provided by DPH, and not covered by insurance, parents may not want to pay for it. There are a small number of children who are not VFC-eligible and are enrolled in grandfathered programs. These children may not be covered, unless they are not seen at a federally-qualified health center (VFC program does cover under-insured children who are seen at a FQHC).

Providers may be confused when a state is "universal" but not all vaccines are included in the state's formulary. Providers do not want to misuse vaccine. Vaccine uptake may be affected.

After deliberation, there was consensus that the Council recommend that DPH not add MenB vaccines to its universal program. DPH will continue to provide both MenB vaccine formulations for all high risk children 10 through 18 years of age and VFC-eligible children 16 to 18 years of age.

The Council will continue to review new data as it becomes available.

Discussion regarding future topics for consideration

The next Council meeting will be on March 9, 2017. Council members should send agenda items for the March meeting to Mr. Talebian.

The meeting was adjourned.

Future Meeting Dates:

March 9, 2017

June 8, 2017

October 12, 2017

MVPAC webpage:

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