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

Date: Thursday, July 17, 2014
Time: 4-6 PM
Location: Massachusetts Medical Society, 860 Winter Street, Waltham, MA 02451

MVPAC Attendees:

David Brumley, MD, MBA
Kevin Cranston, MDiv
Benjamin Kruskal, MD, PhD, FAAP, FIDSA
Susan Lett, MD, MPH
H. Cody Meissner, MD, FAAP
David Norton, MD, FAAP
Michael Norton (attended by telephone)
Sean Palfrey, MD, FAAP

Additional Attendees:

Heather Aspras
Liz Brewer
Patrick Brill-Edwards, MD
Judy Butler
Krista Cormier
Joe Costello
Deborah Elliot
Beth English, MPH
Michael Goldstein
Deborah Gonyar
David Greenberg, MD
Barbara Homeier, MD
JP Livingston
Larry Madoff, MD
Cynthia McReynolds
Sherry Schilb
Reno Soucy
Larry Bressler
Pejman Talebian, MA, MPH

DPH Updates

Mr. Cranston convened the meeting and welcomed attendees. Meeting attendees introduced themselves.

Mr. Cranston noted that due to the passage of Chapter 28 of Acts of 2014, there were some changes to the MVPAC, including MVPAC membership, effective July 1, 2014. With the change in membership stipulated by the statute, Drs. Adler and Moriarty and Ms. DeSisto no longer were Council members. He thanked them for their participation and noted that while they would be unable to participate in future formal deliberations, they were welcome to attend MVPAC meetings and participate in MVPAC open discussions.

The meeting agenda was reviewed.

Governor Patrick has signed the FY15 budget. Although the immunization program is less dependent overall on the annual budget cycle with the passage of the immunization bill, the program must still be

run and adult vaccines must still be purchased. The immunization program was level funded for the non-childhood vaccine portion of the budget.
Dr. Palfrey noted that MVPAC should continue to advocate for the pediatric budget to be increased until all vaccines are covered. Mr. Cranston noted that DPH shares the goal for Massachusetts to reach universality, but noted it might be premature to discuss what will be possible in the upcoming fiscal year, because the basis for the assessment calculation is the prior fiscal year and at this time the final calculation is not known. He added that if growth exceeded the legislation benchmark a special report to the legislature would be needed, but also added that it was not known currently if this would be the case. Discussion of funding can be included as a future meeting agenda item.

Ms. English provided an immunization registry update. Four hundred sites are regularly reporting data to the MIIS and it is anticipated that more than one hundred sites will be added by the end of the year. More than ten million shots have been entered in the registry. Partners-affiliated sites are coming on board.

Mr. Cranston noted that the Immunization Program's Vaccine Unit and MIIS team received a performance recognition citation from Governor Patrick for their excellent work.

Updated MVPAC Operating Procedures

MVPAC Operating Procedure changes resulting from the statute were reviewed.

Going forward, the Massachusetts Vaccine Purchasing Advisory Council will be referred to as MVPAC and not "the Council."

Changes to MVPAC membership were detailed in Article III, Section 1. Representation from the Massachusetts Academy of Family Physicians (MAFP) was reduced from two to one member. Representation from the Massachusetts Chapter of the American Academy of Pediatrics (MCAAP) was reduced from three to one member. Representation from two nurses or other clinicians was removed.

As of this meeting date, MVPAC was still lacking two designated positions: (1) a representative from a managed care organization contracting with MassHealth; (2) one health insurance company representative appointed by the Commissioner of Insurance. These appointments are still in process.

Lacking clear guidance about conducting deliberations with two positions currently not seated, for the purposes of this meeting DPH interpreted the written procedure to mean that 50% of the "seated" members must be present, or seven individuals. **(NOTE: Subsequent to the meeting DPH legal council clarified that quorum must be based on the total membership as defined by the statute not based on seated members. Therefore, an official quorum was not met at this meeting)**

Regarding Conflict of Interest (Article III, Section 4), MVPAC members must complete a "Voluntary Disclosure Statement" Form. Members must determine their own conflict of interest. It is the member's responsibility to consult with the State Ethics Commission if they feel they may have a potential conflict of interest. Additionally, if an additional or undisclosed conflict arises or becomes apparent to a committee member, the member shall act promptly by making oral and written disclosures of the conflict of interest and abstaining from participation as appropriate.

Mr. Talebian noted that the number of annual MVPAC meetings in Article IV, Section 2 (Attendance) has been changed from four to "at least two" meetings per year to allow for flexibility in scheduling.

Clarifications to the Operating Procedures were discussed.

The overall MVPAC charge was preserved in the Statute, to make vaccine purchasing recommendations to the Commissioner, based upon safety, efficacy and issues of administration.

Mr. Norton noted that in Article III, Section 1 (Council Members), the wording should be "Director, Office of Medicaid," not "Commissioner."

Also noted in Article III, Section 2 (Term of Office), the first sentence of the final paragraph should read "The self-insured employer representative," not "self-employed employer representative."

After discussion there was a move to accept the Operating Procedures as amended, followed by MVPAC consensus. The revised Operating Procedures are immediately in effect. **(This decision will need to be revisited at an upcoming meeting due to the absence of a quorum.)**

Review of Haemophilus Influenzae type B (Hib)-Containing Vaccines

Dr. Lett noted the process for reviewing Hib-containing vaccines.

Dr. Meissner presented an overview of Hib disease and Hib-containing vaccines. He noted no conflict of interest and that his review followed guidance by the ACIP, AAP and AAFP. He added that Hib-containing vaccine indications are in the package inserts.

He reviewed the incidence in children less than 5 from 1980 to 2011, and the remarkable success of the Hib-containing vaccines after their introduction in 1985 (polysaccharide) and 1990 (conjugate). Since 2011, disease incidence has been better than (below) the Health People 2020 goal. For the last five years, there have been fewer than 35 cases in the United States (prior to vaccine introduction there were 20,000 cases per year, two-thirds of which involved meningitis). There have been no cases in Massachusetts.

Current monovalent (ActHib, PedvaxHib), and combination (MenHibRix, Pentacel) Hib vaccines, along with guidance for routine use and use in special populations were reviewed.

Manufacturer presentations

Merck Vaccines - PedvaxHib

Dr. Homeier reviewed PedvaxHib, Merck's Hib-containing vaccine.

She noted the burden of disease and the remarkable ability of vaccines to decrease Hib disease.

She reviewed Merck clinical trials, vaccine efficacy and safety information.

She also reviewed the dosing schedule and contraindication for use, noting that a latex stopper is utilized and caution should be used in those who have latex sensitivity.

She confirmed that the vaccine is used in liquid form at this time.

GlaxoSmith Kline (GSK) Vaccines - MenHibRix

Dr. Brill-Edwards presented MenHibRix, GlaxoSmithKline's Hib-containing vaccine.

The indications for use, dosage and administration were reviewed.

He confirmed no evidence of immune interference and an acceptable safety profile.

Dr. Brill-Edwards noted that while MenHibRix is FDA-approved in the US, because high risk patients were not studies, GSK cannot promote the ACIP meningococcal recommendation

GSK has adequate MenHibRix supply available.

Sanofi-Pasteur – ActHIB, Pentacel

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Dr. Greenberg reviewed Sanofi Pasteur's Hib-containing vaccines, ActHIB and Pentacel.

He reviewed the history of Hib disease and noted the consideration for efficacy - individual protection and herd immunity.

There is a variance among Hib conjugate vaccines based upon the kinetics of antibody response. Dr. Greenberg reviewed the comparative immunogenicity data and noted antibody persistence following the primary series and booster of ActHIB vaccine.

He reviewed efficacy trials and noted that rates were well over 90%.

Pentacel vaccine was licensed in 2008. Dr. Greenberg reviewed the dosing schedule and noted that Pentacel is licensed and approved to use for a fourth dose. He concluded by noting that ActHIB and Pentacel have enjoyed a large percentage of the Hib vaccine market share and that invasive Hib disease has been well controlled during this time.

MVPAC Deliberations (NOTE: QUORUM WAS NOT ACHIEVED SO MEETING DELIBERATIONS WERE FOR INFORMATIONAL PURPOSES ONLY AND WILL BE REVISITED AT AN UPCOMINGMEETING)

Mr. Talebian directed members to the Hib-containing vaccine table included in meeting handouts.

He noted that there would be no deliberation on Pentacel at this meeting, as it had been reviewed at a prior MVPAC meeting.

The following options for MVPAC deliberation were summarized:

1. Continue to recommend that MDPH only supply ActHib;
2. Recommend that MDPH supply PedvaxHib exclusively;

3. Recommend that MDPH supply MenHibRix exclusively;
4. Recommend that MDPH allow provider choice for all Hib-containing vaccines;
5. Recommend that MDPH allow provider choice for two Hib-containing vaccines.

Deliberations

Historically, before the supply shortage, 95% of practices were using Pentacel.
At this time, Pediarix also is being used. Although it is hard to estimate the current usage, it is anticipated that close to usage levels will be reached over time.

A comment was made that each of the three on-Pentacel vaccines has specific advantages: PedvaxHib is two-doses and doesn't need reconstitution; ActHIB is the cheapest; MenHibRix offers meningococcal coverage. There is an argument for all three because of the varying advantages.

There can be confusion about switching vaccines between dose 2 and 3 with a monovalent vaccine.

For people moving around, if dose 1 and dose 2 are monovalent and mixed, three primary doses and perhaps a fourth dose will be needed.

Dr. Lett voiced concern about adding MenHibRix to the formulary at this time, with the upcoming change in MDPH policy to allow both Menactra and Menveo in a provider office as recommended at the last MVPAC meeting. If practices choose to carry products, the introduction of another product could be very confusing. Formulary changes and the resulting communication and rollout schedule need to be carefully considered to avoid confusion and error. Guidance to clinicians should be clear.

Additionally, CDC is treating MenHibRix like a special vaccine with a special allocation as if it is only for a high risk population despite the ACIP recommendation to treat it like a routine Hib vaccine.

Question was raised about the MIIS's forecasting capabilities. The system will correctly show what is due and based on which formulation has been received.

It was noted that it is would easier to add a vaccine to the formulary later rather than to than take it away.

The MDPH can decide the timing for the rollout of additional vaccines.

Having a single vaccine in the formulary is attractive, keeping things as simple as possible; however, multiple vaccines are good when vaccine shortages occur.

After discussion there was consensus that MVPAC recommend that MDPH continue to supply one monovalent vaccine (ActHIB). This decision will be revisited at the next MVPAC meeting and in the future as additional information is available for Pediarix and Pentacel usage in MA.

Mr. Talebian will provide an update at the next few MVPAC meetings, at which time MVPAC can review its recommendation if needed. Since the vaccine manufacturer presentations at today's meeting are on record, repeat presentations will not be needed.

Upcoming MVPAC Meetings

A change to the annual four-meeting schedule was proposed.

The current schedule called for a meeting on the third Thursday of the first month of the quarter.

Discussion ensued about how to structure the meeting schedule.

A proposal was made to meet October 16th, as previously planned, and then meet in March, June and October 2015. Meetings will continue to be scheduled on Thursdays, from 4:00-6:00 p.m.

A request was made for meetings to be scheduled with as much lead time as possible. Mr. Talebian will circulate the 2015 dates, once confirmed.

The meeting was adjourned.