Meeting Notes

Massachusetts Department of Public Health

Massachusetts Vaccine Purchasing Advisory Council (MVPAC) Meeting

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

MVPAC Attendees:

Ron Adler, MD, FAAFP
Kevin Cranston, MDiv.
Marie DeSisto, RN, MSN
Tony Dodek, MD
Thomas Hines, MD
Benjamin Kruskal, MD, PhD, FAAP, FIDSA
Susan Lett, MD, MPH
H. Cody Meissner, MD, FAAP
Richard Moriarty, MD, FAAP
David Norton, MD, FAAP
Sean Palfrey, MD, FAAP
Marissa Woltmann (by telephone)

Additional Attendees:

Heather Aspras, MBA
Judy Butler
Joe Costello
Michael Decker, MD, MPH
Leonard Demers
Brill Edwards, MD
Beth English, MPH
Michael Garvey
Michael Goldstein
Deb Gonyar
Rick Haupt, MD, MPH
Richard Keenan
Clem Lewin
John Paul Livingstone
Cynthia McReynolds, MBA
Robert Morrison
Patricia Novy
Corey Robertson, MD, MPH
Sherry Schilb
Stephen Smith
Reno Soucy
Pejman Talebian, MA, MPH

Opening Remarks

Mr. Cranston welcomed meeting participants.

The participants introduced themselves.

Mr. Cranston noted a quorum of Council members was not established at the start of the meeting. He added that a quorum would be confirmed if enough additional participants arrived and prior to any formal deliberations.

MDPH Updates

Legislative Update

Mr. Cranston noted that Chapter 28 of the Acts of 2014, "An Act Establishing the Massachusetts Childhood Immunization Program," is now law, providing a permanent mechanism for funding childhood vaccines and the immunization registry. He added that while it took seven years for the bill to pass, its passage was essential to the success of the immunization program. He offered thanks to everyone who had worked so diligently to ensure passage of the bill.

He added that with the passage of the Immunization Trust Fund Law, which includes explicit provisions regarding the Massachusetts Vaccine Purchase Advisory Council, this meeting would be the last Council meeting under the current construction. While the core concepts of the Council remain the same the law specifies the membership of the Council; these provisions take effect July 1. Participants were directed to the meeting handout, "Comparison of Chapter 28 and Current MVPAC Committee Structure."

In summary, the MVPAC Committee Structures which are needed by July 1, 2014, include:

- Addition of a Medicaid managed care representative;
- Addition of a representative of an employer who self-insures;
- Removal of the RN representative;
- Removal of two MD representatives (with maintenance of at least one representative each of MMS, AAP, and AAFP).

The Commissioner will make final decisions around Council appointments. Final decisions will be made before the Council meeting in July.

Mr. Cranston thanked Council members for their participation and noted that individuals who will no longer be Council members are welcome to participate as non-voting individuals. He added that all Council meetings are open by law.

Massachusetts Immunization Information System (MIIS) Update

Ms. English noted that 365 sites are reporting data regularly to the MIIS. 315 of those sites are reporting data through direct data exchange. 50 sites are reporting immunization data into the MIIS. 60% of sites are submitting vaccine orders directly online.

Budget Update

Mr. Talebian reported that the recently-filed House Ways and Means budget amendment did preserve the remaining resources in the historic immunization line. Even though Chapter 28 will generate resources for child immunizations and the immunization registry, the immunization program still has programmatic and administrative needs that must be met. There is $2.183M in the remaining line item. Hopefully this will be preserved in the Senate and maintained in the Governor's program.

Review of Meningococcal-Containing Vaccines

Dr. Meissner provided an overview of meningococcal disease and meningococcal vaccines.

He noted that meningococcal disease is a dreaded bacterial infection, which strikes otherwise healthy individuals in the prime of life, with a 10-15% mortality depending on host strain. He reviewed the epidemiology of meningococcal disease incidence in the US over the past forty (40 years.

There is a peak of disease in the first few years of life, and then another peak in college students.

Dr. Meissner provided a breakdown by serogroup and vaccine coverage. Before the introduction of conjugate vaccine, there was a disease decline in all serogroups. There has been an uptake of 70-75% since introduction of conjugate vaccines. It is unknown whether the continued decline in disease is because of the increased vaccine uptake or due to natural disease history.

It is important to understand the five principal serogroups. In the US, serogroup B accounts for about 35% of disease, serogroup C accounts for about 40%, serogroup Y accounts for about 25%, and serogroup W-135 accounts for a small percentage, and X is rarely encountered. Serogroup A has not been seen in the US since World War II, but has been a leading cause of meningococcal disease on a worldwide basis.

Available vaccines and the serogroups covered by these vaccines were reviewed. Serogroup B is not included in any licensed vaccines in the US.

If possible, the same vaccine should be used for administration of the series.

Dr. Meissner commented that to the infant meningococcal vaccines are not recommended for routine use because of the low burden of disease in this age group. The epidemiology of meningococcal disease in the US is carefully monitored and recommendations may change over time.

Laboratory workers routinely exposed to *Neisseria meningitidis* strains contained in the vaccine should be fully vaccinated.

Efforts are underway to develop a 5-valent vaccine, which includes the serogroups A, B, C, W, Y.

Manufacturer Presentations

Note: At this time, a Council quorum was not present. After discussion there was consensus that presentations would proceed in hopes that Dr. Palfrey (who was listening by telephone) would arrive in person before Council deliberations began.

Menhibrix Vaccine – GlaxoSmithKline

Ms. Asparas reviewed MenHibrix.

MenHibrix package insert information was distributed to meeting participants.

She reviewed the indications for administration of MenHibrix vaccine in children 6 weeks through 18 months of age and the dosing schedule.

She also reviewed vaccine safety information and common adverse reactions.

She detailed clinical trial results.

She noted that MenHibrix is a reconstituted vaccine and reviewed vaccine vial storage recommendations. The vaccine must be administered immediately after reconstitution and cannot be frozen.

The Vaccines for Children (VFC) price for MenHibrix is $8.60.

Menactra Vaccine – Sanofi Pasteur

Dr. Robertson reviewed Menactra, noting ACIP recommendations for Menactra based on epidemiology.

He added that safety has been established.

Safety and immunogenicity also has been established in more than 30 clinical trials. Menactra's effectiveness has been documented by CDC.

Though statistically different immune responses (that vary by age and serogroup) have been demonstrated between Menactra and Menveo, there is no known clinical relevance of these differences.

In 2014, the booster indication is under review by FDA, to bring the Menactra label in line with ACIP recommendations.

A Council member asked whether there are efforts to move the indication for Menactra to a lower age. Dr. Robertson noted that not at this time with the current vaccine, but he added that a new meningococcal vaccine with a lower age indication is in development.

Menveo Vaccine – Novartis Vaccines

Dr. Novy reviewed Menveo.

She reviewed product presentation and indications for its use, noting that it must be reconstituted.

She summarized key clinical trials, noting the vaccine's demonstrated safety profile.

She detailed important safety information.

Council Deliberations and Voting

[Note: At this time, Dr. Palfrey had arrived and a quorum was established.]

Mr. Talebian noted that the Council would include discussion of three vaccines in its deliberations (Menactra, Menveo, MenHibrix). He added that MDPH currently supplies Menactra and Menveo , and there is price parity between the two vaccines. MDPH currently does not supply MenHibrix.

1. ***Should MDPH continue to supply both Menactra and Menveo, allowing provider choice for vaccine selection, or should MDPH supply only one of these vaccines?***

A clarification was made that ACIP considers Menactra and Menveo equivalent and interchangeable for administration in adolescents.

A comment was made that one manufacturer has been claiming its vaccine is superior to the other vaccine, and that it is important for manufacturers to provide clinicians with accurate information. Mr. Talebian noted that providers should contact MDPH if they encounter problems with manufacturer presentation of accurate information to them. MDPH will track reports of such problems for the Council. The Council can discuss this further if there is evidence that this is a problem.

A comment was made that since reconstitution is required for Menveo, there can be administration errors, adding that administration errors often are underreported.

Representatives from Novartis noted that Novartis tracks reports to VAERS of incomplete administration of Menveo, and reports have not been significant. They added that they would bring Council feedback to Novartis.

After discussion, there was Council consensus that MDPH continue to offer provider choice for Menactra and Menveo.

2. ***Should MDPH begin to offer Menhibrix as part of its formulary, for routine administration of Hib vaccine?***

After a brief discussion, there was Council consensus that deliberation on MenHibrix should be tabled until the Council takes up discussion of all Hib vaccines.

3. ***Council to provide a recommendation to MDPH around MCV4 vaccine for high-risk children. If provider choice is maintained (see 1 above), should polypharmacy be allowed? (Providers would be able to stock both Menactra and Menveo).***

Currently, there are different indications for Menactra and Menveo for high-risk children. Menveo is recommended.

It was noted that a recommendation to allow providers to stock both Menactra and Menveo would mean an exception to the Council's polypharmacy guideline.

After discussion, there was Council consensus that polypharmacy be allowed for meningococcal vaccines.

There also was consensus that MDPH write an advisory clarifying polypharmacy for this vaccine and provide guidance around administration of these vaccines.

Final Comments

Mr. Cranston thanked Dr. Palfrey for his efforts throughout the past seven years in ensuring that the Vaccine Trust Fund legislation was passed.

He also thanked Council members for their service whether they would be continuing on the Council or not after July.

The meeting was adjourned.

Future Council Meeting Dates:

July 17, 2014
October 16, 2014
January 15, 2015
April 16, 2015
July 16, 2015
October 15, 2015

MVPAC webpage:
http://www.mass.gov/eohhs/gov/departments/dph/programs/id/immunization/mvpac.html