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

Date: Thursday, January 16, 2014
Time: 4-6 PM
Location: Massachusetts Medical Society, 860 Winter Street, Waltham, MA 02451

Council Members:
Ronald Adler, MD
David Brumley, MD, MPH
Kevin Cranston, MDiv
Marie DeSisto, RN, MSN
Tony Dodek, MD
Thomas Hines, MD
Susan Lett, MD, MPH
Cody Meissner, MD
David Norton, MD
Ronald Samuels, MD, MPH
Kate Wallis, RN, BSN
Catherine West
Marissa Woltmann, MD
(by telephone)

Additional Attendees:
Elizabeth Brewer, MS, MPH
Leonard Demers
Beth English, MPH
Leonard Friedland, MD
Michael Garvey
Michael Goldstein
Deb Gonyar
Dominic Hein, MD, MPH
Barb Homeier, MD
Richard Keenan
Clem Lewin
John Paul Livingstone
Cynthia McReynolds
Robert Morrison
Patricia Novy
Sherry Schilb
Stephen Smith
Reno Soucy
Pejman Talebian, MA, MPH
Anthony Urciuoli

Agenda

1. DPH/Legislative Update
2. Review and Final Approval of Operating Procedures
3. Discussion of Guiding Principles for Council Deliberations
4. Confirmation of future meetings (thru 2014)

DPH Updates

Mr. Cranston opened the meeting.

Meeting attendees introduced themselves.

Mr. Cranston began DPH Updates, noting that the Council was awaiting a quorum.

(Meeting note: the Council did not have a quorum at the meeting start; however, it did have a quorum at the beginning of its deliberations and throughout the consensus process.)

Mr. Cranston noted that DPH was awaiting the release of the Governor's House 2 Budget on January 22nd. DPH does not anticipate that the House 2 Budget will be different from previous years at it relates to immunization.

On the legislative front, Mr. Cranston noted that the proposed Vaccine Trust Fund legislation, S.534, was redrafted as S.1971, and passed out of the Senate Ways & Means Committee with a favorable recommendation. The legislation previous passed the Senate unanimously in informal session.

The redrafted legislation includes minor changes to the assessment component and caps on annual increases.

There are language changes in the redrafted bill that have some relevance to the construction and deliberations of the Council; however, these are minor changes.

The redrafted bill is before the House Ways & Means Committee. DPH has urged prompt action on this bill and has communicated its need to have the legislation passed by the end of January, 2014 to fill a budget gap on the MIIS. While DPH has authorization to expend previously accessed resources from the current line item, there is a shortfall for maintenance and rollout costs. DPH is only able to support the MIIS through the end of January, 2014.

A Council member asked whether the registry was part of the MA health information 'HIway'. Ms. English confirmed that the HIway is a transport mechanism to the MIIS. Providers can utilize the HIway to transmit immunization data electronically from electronic health record (EHR) systems. This will assist providers in getting information to the MIIS withough having to do data entry into both their EHR and the MIIS.

Mr. Talebian reviewed the meeting handout materials: meeting agenda, minutes from the previous Council meeting (October 2013), and updated membership list. He noted that these materials are available online as well. Also included in the handout materials: a DPH advisory related to Pentacel vaccine supply and an updated DPH Childhood Vaccine Availability Table

(January 1, 2014). Mr. Talebian added that the two significant changes/additions to the Table (Kinrix, MCV4 vaccine) reflect Council recommendations.

Recent arrivals introduced themselves. A Council quorum was established.

Dr. Lett discussed the DPH's HPV initiative to increase Massachusetts HPV immunization rates. She noted that Massachusetts is one of eleven states funded by CDC.

The main components of the initiative include: the creation of a HPV task force to plan and execute activities to improve HPV knowledge; the undertaking of a public HPV awareness campaign; the implementation of coverage reports and promotion of the MIIS for reminder/recall, and the development of educational activities and communication of educational resources for providers.

Dr. Lett reviewed some of the available resources, including CDC materials (handouts and speaker slides), DPH Twitter feed, and a recent MCAAP newsletter article written by Rebecca Perkins, MD, MSc. She also noted that there will be four provider webinars during 2014 dedicated to raising HPV vaccination awareness, and an educational summit is planned for November 2014.

Mr. Cranston noted that while Donna Lazorik had retired from the DPH in December 2013, one of her last efforts was applying for and receiving the HPV grant from CDC.

Dr. Lett added that people who are interested in participating on the HPV task force, or have questions can contact her (susan.lett@state.ma.us), Allison Hackbarth (Project Manager; ahackbarth@jsi.com) or Cynthia McReynolds at the Immunization Initiative (cmcreynolds@mms.org).

Dr. Hines joined the meeting.

Review of Human Papillomavirus (HPV) Vaccines

Dr. Meissner provided Council members with a HPV vaccine update (current and future).

He noted that he had no financial relationships to disclose, but that he would discuss off-label uses of HPV vaccines, in accordance with CDC recommendations.

Most people become infected by at least one type of HPV during their life. There are six million cases of common HPV infection per year in the United States. Most people are not aware that they are infected and have no symptoms. The virus usually resolves spontaneously.

Most HPV infections begin in the second decade of life, with an uptake in prevalence in late teens/early twenties. The progression of infection to pre-cancerous and cancerous lesions can take decades.

13,000 HPV-related cancers in females and 7,000 HPV-related cancers in males are caused annually in the United States by HPV 16/18. HPV 16 and 18 cause 70% of cervical cancers and a majority of other HPV cancers.

Dr. Norton commented that the CDC-VIS for HPV details the prevention of warts, but not the prevention of cancer in males.

Dr. Meissner reviewed the currently available HPV vaccines, Gardasil (quadrivalent HPV4) and Cervarix (bivalent HPV2).

He noted that the recommendation to vaccinate at 11 or 12 years is because the vaccination is intended to prevent HPV infection not to treat it. The vaccine should be administered before the risk of HPV exposure. Additionally, the immune response is better in younger children.

Dr. Meissner concluded by noting that progress among vaccinating US adolescent girls has stalled. Vaccination coverage among boys is increasing. The main reason parents give for not vaccinating daughters indicate a lack of awareness and gap in understanding a need for vaccination.

Primary care providers are the key to increasing vaccine coverage by providing strong recommendations, not delaying vaccination, implementing evidence-based strategies to improve vaccine delivery, and working to prevent missed vaccination opportunities.

Manufacturer Presentations

Cervarix
Dominic Hein, MD, MBA, GlaxoSmithKline

Cervarix is designed to prevent infection from HPV types 16 and 18, as well as the malignant and pre-malignant cervical lesions caused by HPV 16 and 18. As noted previously, HPV types 16 and 18 cause approximately 70% of cervical cancers. Cervarix is indicated for use in females aged 9-25 years of age.

Dr. Hein reviewed safety and efficacy data, noting phase 2 and 3 clinical studies that enrolled 19,778 females 15 through 25 years of age and additional studies enrolling 1275 females 9-14 years of age . He noted that package inserts detail clinical studies.

He noted local adverse reactions; the safety points are prominent in the vaccine labeling.

He concluded by noting schedule and administration.

Gardasil
Barbara Homeier, MD, Merck

Dr. Homeier noted that HPV disease is widespread and infection can lead to clinically significant disease. She reiterated the estimated annual burden of HPV-related diagnoses in the United States.

She reviewed the ACIP recommendations for Gardasil, noting that it is recommended for females and males 11 or 12 years of age. It may be given starting at age 9.

She reviewed efficacy and safety data.

She reviewed indications and contraindications, and noted that Gardasil is not recommended for use in pregnant women.

She concluded by noting dosage and administration.

Council Deliberations

(Meeting note: there was a Council quorum for deliberations.)

Council members were referred to a table in the meeting handouts that highlighted the differences between the two vaccines.

The following options were discussed:

1. DPH should continue to supply Gardasil only;
2. DPH should offer provider choice and supply both Gardasil and Cervarix.

Normally, a third option would be to only supply Cervarix; however, since it is only licensed for use in females, this would not be practical.

It was noted that the general policy is for practices to provide only one vaccine when offered choice. This vaccine is different, as providers choosing Cervarix, would also need to provide Gardasil.

The following points were discussed:

While the quadrivalent vaccine has some advantages, it is good to have two vaccines in the market to control prices.

Are efforts being made to have Cervarix licensed for boys? (Mr. Friedland, GSK, noted that GSK is not pursuing this option at this time.)

There could be a struggle in practices which stock both vaccines. There could be confusion leading to incorrect use of Cervarix for boys

If Cervarix were chosen, practices would need to stock Gardasil as well.

If a practice used Gardasil, could it switch to Cervarix if supply were an issue? DPH said yes but not for boys.

DPH would need to create and communicate a policy clarifying use of both vaccines and note that it is an exception from their routine practice to not allow multiple formulations of the same vaccine in a provider office. DPH would also have to make it very clear to providers that the vaccines are not interchangeable and Cervarix can not be used for boys.

There could be a niche marketing opportunity for Cervarix for ob/gyns with many adolescent patients or in the case of Gardasil shortage, Cervarix could be used as a back-up for females.

There was discussion that there could be a very small number of Cervarix only sites for practices that only see females (i.e.: OB/GYNs) but the numbers of such sites receiving state-supplied vaccines is very small.

Regarding cost differential, HPV is the one vaccine that DHP currently supplies only for VFC-eligible children. The vaccine cost is incurred at the national level.

The downside to offering both vaccines is sending a mixed message to practices about offering practices the ability to stock two vaccines of the same formulation.

After discussion, a proposal was made to recommend that DPH purchase and offer provider choice for both Gardasil and Cervarix. There was Council consensus.

There was also consensus the DPH should create and communicate a policy clarifying the use of both vaccines. Practices would need to know that the vaccines are not interchangeable.

Upcoming meeting dates were noted (see below). A request was made for Council members to notify DPH if they would be unable to attend a meeting.

The meeting was adjourned.

Future Meeting Dates:

April 17, 2014

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