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

Date: Thursday, April 25, 2013
Time: 4-6 PM
Location: Massachusetts Medical Society, 860 Winter Street, Waltham, MA 02451
Middlesex North Conference Room

Agenda

1. DPH/Legislative Update
2. Review and Final Approval of Guiding Principles for Council Deliberations
3. Informational review of flu vaccine formulations for 2013-2014 season
4. Review of DTaP and Tdap vaccines
    - Overview of products to be considered
    - Manufacturer presentations
    - Deliberation and voting

Meeting Attendees:

MVPAC Council Members

Ronald Adler, MD
David Brumley, MD, MBA
Michael Chin, MD
Benjamin Kruskal, MD, PhD (by telephone)
Thomas Hines, MD
Susan Lett, MD, MPH, MDPH
Pejman Talebian, MA, MPH, MDPH
Cody Meissner, MD
Richard Moriarty, MD
David Norton, MD
Sean Palfrey, MD
Ronald Samuels, MD, MPH
Kate Wallis, RN, BSN

Additional Attendees

Beth English, MPH, MDPH
Cynthia McReynolds, MBA, MCAAP
Bob Morrison, MDPH
Elizabeth Brewer, Sanofi Pasteur
Judy Butler, Merck
Joe Costello, Novartis
Lenny Demers, MedImmune
Michael Decker, MD, Sanofi Pasteur
Leonard Friedland, GlaxoSmithKline (GSK)
Michael Goldstein, Merck
Deb Gonyar, GSK
Kim Haupt, GSK
Misha Honaker, GSK
Richard Hughes, Merck
Richard Keenan, GSK
Clem Lewin, Novartis
Katrina Murphy, Merck
Patricia Novy, Novartis
Sherry Schilb, Sanofi Pasteur
Stephen Smith, Sanofi Pasteur
Reno Soucy, GSK

Welcome/Introductions

Pejman Talebian chaired the meeting on behalf of the Commissioner as Kevin Cranston was unable to attend.

The meeting started without a Council quorum. [Note: a quorum was reached prior to Council deliberations.

Meeting attendees introduced themselves. Additional attendees introduced themselves as they arrived.

DPH/Legislative Update

Mr. Talebian noted that Dr. Lauren Smith, Interim Commissioner, would be leaving on May 10th. There was no news about her replacement or appointment of an interim Commissioner.

Sean Palfrey provided a brief legislative update. He had spoken with Ed Brennan, the MCAAP's legal counsel about the next steps for the Vaccine Trust Fund Bill. While hearings are being scheduled, it is unknown when the Vaccine Trust Fund Bill will come up for discussion. With momentum, it is believed that the bill will be passed. The bill includes funding for the MIIS (immunization registry). Without designated funding for the registry, full state-wide roll out, as well as system enhancements will be compromised.

Mr. Talebian noted that the passage of the Vaccine Trust Fund Bill could slightly affect the Council. The bill will formalize the Council and could slightly change its composition, or its operating procedures.

Meeting Materials

Included in the distributed folders were minutes from the last Council meeting, along with operating procedures which had been updated as a result of the discussions at the last Council meeting. Also included were materials for use in Council discussions during this meeting.

MIIS Update

Mr. Talebian provided a brief registry update. The MIIS roll-out is ongoing. There are currently 235 sites actively entering immunization data into the MIIS primarily through a HL7 data exchange. Atrius and Walgreens are among those sites sending data. There are more than 1 million patient records and more than 4 million immunization records in the registry.

There will be another version release of the system in late June, which will include the new online vaccine ordering system. Training for the new system will be available throughout the summer.

Overview of 2013-2014 Influenza Vaccines

Susan Lett provided an overview of the 2013-2014 influenza vaccines and formulations.

Quadrivalent influenza vaccine will be available for the 2013-2014 influenza season.
The 2013-2014 trivalent influenza vaccine will be made from the following three viruses:

- an A/California/7/2009 (H1N1)pdm09-like virus;
- an A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011; (NEW)
- a B/Massachusetts/2/2012-like virus. (NEW)

It is recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Brisbane/60/2008-like virus.(NEW). Dr. Lett reviewed the rationale for the additional B strain.

Dr. Lett thanked those who had provided influenza testing information to the DPH. DPH forwarded this information CDC. The new Massachusetts B strain was chosen based on this data.

A question was raised as to whether the Massachusetts strain is new. Dr. Lett noted that it is a drifted strain.

Dr. Lett detailed the new acronyms that will be used to reflect the new vaccine formulations.

CDC has released interim recommendations for the prevention and control of influenza. Because of the new strains, CDC has issued guidance prior to the ACIP release of formulations (August). The guidance lists the influenza vaccines for the 2013-2014 season, by manufacturer. Final guidance about the new products will be forthcoming.

CDC is expecting that most of the national supply next year will be trivalent. Currently, CDC has no recommended preference. There will be a greater quadrivalent supply as time goes on. ACIP will decide in June and vote on the specific influenza vaccine recommendations for the 2013-2014 season.

A question was raised as to whether more than one dose will be needed because new strains are being introduced. Dr. Lett noted that this is not anticipated.

Mr. Talebian provided a brief update on DPH plans for influenza vaccine for the 2013-2014 influenza season. He noted that in the future, the Council might be asked to provide guidance about formulations. Timing for the 2013-2014 season required DPH to make a decision about the vaccines that it will order. 835,000 doses are planned (800,000 were purchased for the 2012-2013 influenza season). Despite the anticipated national supply of quadrivalent influenza vaccine, DPH is anticipating that 40% of its supply will be quadrivalent influenza vaccine.

Review and Final Approval of Guiding Principles for Council Deliberations

Mr. Talebian noted that one of the goals of this meeting was to review and approve the Council's Guiding Principles. The updated document was the result of discussions at the January Council meeting. He noted that the Guiding Principles are intended to provide guidance for Council discussions. They are not a formal point rating system.

The beginning of the document reiterates the guiding principles. The overarching themes are listed and categories are detailed as follow:
Category 1: Safety and efficacy
Category 2: Cost and supply issues
Category 3: Provider and patient issues
Category 4: Market share
Category 5: Conservatism

The primary principles are defined in Category 1 as Safety and Efficacy.

There was Council consensus about safety and efficacy being primary guiding principles.

A question was raised as to whether the Council would only consider ACIP-recommended vaccines in its deliberations. The guiding principles state that ACIP recommendations will generally be followed.

After discussion, the consensus of the group was that ACIP recommendations would serve as a guide for Council deliberations.

After discussion, there was Council consensus that with the exception of Category 1 (Safety and efficacy) the other categories (Categories 2-5) should not be listed in rank order. These categories may be ranked differently based on the particular vaccine being discussed.
A motion was made to accept the guiding principles as amended. The motion was seconded and carried.

The final document will be circulated with minutes after the meeting.

Review of DTaP and Tdap vaccines

Overview of Products to be Considered

Mr. Talebian reminded Council members that all vaccine formulations will be reviewed on an annual basis by the Council.

He noted that at this meeting, pertussis-containing vaccines would be reviewed.

Dr. Lett discussed the current supply of diphtheria, tetanus and pertussis combination vaccines. She referred to the materials for the diphtheria, tetanus and pertussis containing vaccine group that had been distributed.

A table detailing diphtheria, tetanus and pertussis-containing vaccines was reviewed. The table was based on one that is in the Red Book. CDC reviewed the table and considered it to be an accurate presentation of the vaccines that would be discussed. The table included the vaccine, its manufacturer, whether it is provided by DPH, number of antigens, its recommended use and cost per dose/premium.

Binders with the packaging inserts and a document listing the packaging insert links also were available if needed for Council deliberations.

The considerations for Council discussion included:

1. Pentacel and Pediarix are currently supplied by DPH. Council to recommend whether DPH should continue to supply both of these combination vaccines or only one of them.
2. Review of DTaP vaccine - DPH currently supplies Daptacel, but not Infanrix. Council to recommend whether DPH should continue only supplying Daptacel, switch to only Infanrix or allow provider choice of both.
3. Kinrix, a combination vaccine, is not currently supplied by DPH. Council to recommend whether DPH start supplying this vaccine.
4. Review of Tdap vaccines - DPH currently supplies Adacel, but not Boostrix. Council to recommend whether DPH should continue to supply Adacel, switch to Boostrix, or allow provider choice.

A question was raised about the definition of market share – whether it was determined per vaccine, vaccine formulations, is state-supplied. A clarification was made that the Council would not consider market share by antigen, but by the overall dollars spent. The premium costs would be pro-rated across all vaccines. Market share being the market share of Massachusetts-purchased vaccines also was clarified.

Manufacturer Presentations

GlaxoSmithKline and Sanofi Pasteur provided fifteen-minute presentations.

Sanofi Pasteur

Michael Decker, MD, presented information about Pentacel and Adacel.

He reviewed the components, licensure, dosage, indications and contraindications for use, and adverse reactions and events.

Pentacel was licensed in 2008. It is a four-dose combination vaccine, approved for use in children 6 weeks to 4 years of age (up to 5 years of age).

Use of Pentacel as a combination vaccine benefits shots reduction and optimizes immunization.

Adacel is approved for use as a single dose booster immunization in persons 11 through 64 years of age. Adacel has the same component antigens as Daptacel.

Dr. Decker provided a review across clinical trials.

With regard to Adacel versus Td, all non-inferiority criteria were met. Adding pertussis doesn't change the efficacy of the Td vaccine.

Adacel is well-tolerated among adolescents and adults.

He noted the ACIP off-label pregnancy recommendation.

Dr. Decker noted that Sanofi Pasteur has partnered Americares to create the Give Immunity, Fight Transmission (GIFT) Program. Sanofi Pasteur also is working with the March of Dimes on the Sounds of Pertussis campaign. Sanofi has encouraged multi-channel efforts to help motivate adults to request Tdap.

Dr. Palfrey inquired how to apply to the GIFT Program. Ms. Schilb noted that there is a website where people can apply for the GIFT Program. In Massachusetts the program has been targeted to Boards of Health and to Community Health Centers, for those who don't have insurance for the vaccine, or don't have access to the vaccine.

A question was raised about current Pentacel production.

Dr. Decker noted that there was a glitch in the application to release product submitted to FDA. This has resulted in a two-month delay in release of product (manufacturing is continuing throughout). The plan is that product distribution will resume in June, but Pentacel will remain on allocation until the vaccine safety stock can be re-built. He added that relying on a single supplier can result in problems. Allowing provider choice would permit access to vaccines at all times. He emphasized that Sanofi Pasteur has always supported practitioners to choose from the full array of licensed vaccines.

<u>GlaxoSmithKline (GSK)</u>

Handouts with supporting materials, prescribing and safety information were distributed.

Dr. Friedland noted that GSK supports provider choice.

Ms. Honaker presented information about Pediarix, Kinrix ,Infanrix, and Boostrix.

GSK offers three DTaP-containing vaccines – Pediarix, Infanrix and Kinrix. Each contains an identical DTaP component. The DTaP series can be fulfilled with these vaccines.

Pediarix was licensed in 2002 and was the first combination vaccine to provide five vaccines in one shot. It is a three dose series (0.5 mL each), given at two, four and six months of age. It can be given beginning at six weeks through six years of age (until the seventh birthday).

One benefit to giving a dose at 4 to 6 years of age is related to school entry. Pediarix does allow catch-up with a combination vaccine, which can eliminate shots.

Pediarix is available in a ready-to-administer pre-filled syringe. It has a peel-off label with color banding. Another benefit to Pediarix is that it does not need to be re-constituted.

Kinrix is a combination DTaP/IPV vaccine. A single dose is indicated as the 4th dose of IPV and the 5th dose of DTaP in children four to six years of age whose previous DTaP doses have been with Infanrix and/or Pediarix for the first three doses and Infanrix for the fourth dose. Kinrix is available in ready-to-administer pre-filled syringe or in a single dose vial.

The 4th dose of IPV should be given after the 4th birthday. Kinrix ensures that kids are receiving appropriate vaccines for school entry and following ACIP recommendations.

Contraindications and common adverse events are detailed in the packaging insert included in handout materials.

Boostrix is approved for use as single dose in individuals ten years of age and older. It has the broadest age indication of Tdap vaccines. It is approved for use in individuals 65 years and older as well. It has an established immunogenicity and safety profile.

Contraindications and common adverse events are detailed in the packaging insert included in handout materials.

In summary, use of the combination vaccines makes it easier for children to receive all school-entry vaccines. Use of the three GSK products allows consistent DTaP throughout the series. The availability of these vaccines provides better management of supply challenges.

A question was raised about the current GSK supply of Pediarix.

Ms. Haupt, GSK leader for CDC engagement, noted that Pediarix production had been increased to meet increased demand; however, the supply of and demand for Pediarix continues to be a challenge. GSK met with CDC and together they decided that Pediarix should go on allocation until doses are stable. CDC has contacted state immunization programs. The CDC issued a communication that stated that These programs will receive approximately 50% of doses based on historical use.. By September 2013, GSK expects to come off allocation.

Although there is a gap, both GSK and Sanofi Pasteur believe that there isn't a current public health risk. They expect to have enough of the component vaccines to fill any gap due to the shortage of Pentacel and Pediarix.

Dr. Friedland noted that GSK is working with FDA to see how manufacturing and release controls can be tightened so that processes are more streamlined.

Dr. Decker also noted that Sanofi is staying tightly engaged with CDC to make processes more robust.

Dr. Norton noted that changing immunization schedules is a bigchallenge. Dr. Samuels noted that mistakes are more likely to be made when schedules are changed.

Dr. Meissner asked whether the companies could comment about the antigen differences in the two vaccines (Pediarix and Pentacel) in light of recent discussions about pertactin.

Dr. Decker noted that even for organisms that don't express pertactin, there still are two or three effective antigens in these vaccines in addition to the pertactin. At this time, he noted there is no good evidence that it matters with respect to clinical protection. He added that in Europe, there are circulating strains that are different from the antigens in these vaccines. Endpoint clinical trials are needed; comparative clinical trials can't be done because all the vaccines are good.

Dr. Friedland added that all of the US-licensed DTaP and Tdap vaccines are excellent products and work as they are designed. Even with the growing problems with pertussis, these vaccines provide outstanding protection in the first five years of life. GSK is committed to moving forward and developing new vaccines in the future.

Dr. Lett noted that at the current time ,the pertussis team at CDC thinks that the vaccines are equivalent. It is unclear what would be the optimal combination of antigens. Some data may become available regarding relative performance of Tdap products in the California and Washington outbreaks. At this time it is unclear what the significance is of the isolation of pertussis bacteria (11 cases) that do not express pertactin protein.

Dr. Meissner added that from the COID meeting, there are different immune responses to the two vaccines, but impact of these differences are not known at this time.

<u>Deliberation and Voting</u>

Council deliberation: Should the Council recommend that DPH continue to supply both Pediarix and Pentacel?

There is a cost premium to supplying these vaccines, but the premium is included in the state budget.

After discussion, the Council recommended that DPH continue to supply Pediarix and Pentacel. There was consensus that having two suppliers and two formulations available is better for stable supply. The Council also recommended that DPH should supply one or the other to a practice to avoid polypharmacy and administration errors.

In a normal situation, where supply is stable, DPH requires practices to choose either Pediarix or Pentacel. This will happen again once the Pediarix and Pentacel supplies are stabilized.

While there was general discussion about provider choice, the Council was directed to focus on the diphtheria, tetanus and pertussis-containing vaccines.

Council deliberation: (1) Should the Council recommend that DPH continue to supply Daptacel only (2) Supply Infanrix only, or (3) Supply both Daptacel and Infanrix?

DPH would suggest that it start to supply Infanrix to those practices that use Pediarix once the shortage is over.

There is a cost difference between the two vaccines. The pricing is based on the CDC contract prices as of 4/1/13; however, it was noted that in general, similar products' pricing becomes comparable after a couple months since manufacturers are able to lower their price which they usually do to match their competition.

A question was raised as to whether there are logistical challenges to adding a formulation. Centralized distribution and online ordering make it easier; the change can be made without a lot of additional resources.

After discussion, there was Council consensus that for DTaP vaccines DPH implement a form of provider choice that will be instituted after the shortage is over and may be linked to the type of DTaP combination vaccine that the practice chooses to use.

Council deliberation: Should the Council recommend that DPH supply Kinrix (not currently supplied)?

A combination vaccine would fit in with the Pediarix schedule. Kinrix is not currently included in the DPH budget. The impact on the budget would be $300,000.

After discussion, there was Council consensus that DPH should consider supplying Kinrix, if the budget for it is affordable.

Council deliberation: Should the Council recommend that DPH (1) Continue to supply only Adacel, (2) switch to supplying only Boostrix, or (3) supply both vaccines and consider provider choice for this vaccine. If both vaccines are supplied, providers would have to choose one vaccine or the other.

DPH was asked about the logistics involved in switching or adding vaccines. Bob Morrison noted that a concern would be if vaccines were being wasted when providers switched to another vaccine. Providers would need to use up their supply of Adacel before switching to Boostrix. Otherwise, it shouldn't be difficult to offer both vaccines.

There was Council consensus that DPH supply both Adacel and Boostrix and provide choice for these vaccines.

Council members raised a concern about the issues involved with practices being inundated with vaccine manufacturer's representatives if provider choice is allowed.

Mr. Talebian noted that the results of Council deliberations are communicated as recommendations to the DPH. DPH will take the Council minutes to the Bureau Director and Commissioner. DPH will ultimately decide which formulations to offer and the timing of such decisions.

He added that DPH will communicate the results of its deliberations to the Council at future Council meetings. DPH also will provide feedback on how things are going on its end.

The next Council meeting will be Thursday, July 18, at 4:00 p.m.

Council members with agenda items for the next meeting should send them to Mr. Talebian. Council members also should suggest which family of vaccines should be reviewed at the next Council meeting.

The meeting was adjourned.