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

Date: Thursday, January 4, 2024

Time: 4-6 PM

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

Attendees

***Council Members**:*
In-Person
Lloyd Fisher, MD, FAAP
Angela Fowler, MD, MPH
Robbie Goldstein, MD, PhD
Benjamin Kruskal, MD, PhD, FAAP, FIDSA
Everett Lamm, MD, FAAP
David Norton, MD, FAAP
Desiree Otenti, ANP, MPH
Virtual
Aditya Chandrasekhar, MD
Jennie Chiang, MD, MS, FAAFP
Vandana Laxmi Madhaven, MD, MPH, FAAP
Additional Attendees:
In-person
Rich Aceto
Susanna Bächle
Rattana Bip
John Crowley
Luke Cunniff
Kim Daly
Bob Fontenelli
Katie Kelley
Ali Lydon
Larry Madoff
Cynthia McReynolds
Andrew Rennekamp
Rajeev Shah
Pejman Talebian
Tim Temple
Virtual
Bryan Baxter
Jeffrey Benton
Brooke Cardoso
Laura Efros
Kathleen Talbot
Trent Wilson

Welcome and Introductions

Mr. Talebian welcomed attendees and thanked them for meeting in January.

Mr. Talebian introduced Commissioner Goldstein. Commissioner Goldstein talked about his background and his support for immunization.

New Massachusetts Vaccine Purchasing Advisory Council (Council) members were introduced.

Meeting attendees (in-person and virtual) introduced themselves.

DPH updates

There is an ongoing nirsevimab (RSV mab) shortage. There are no other state-supplied pediatric vaccine supply issues.

MDPH has launched a respiratory illness dashboard. The dashboard has been recently enhanced to include information about vaccine preventable diseases.

On January 18, the MCAAP Immunization Initiative will host a 2024 Human Papillomavirus (HPV) Update webinar. A webinar registration link will be posted in the chat.

Dr. Fisher inquired whether there has been an increase in the number of birthing hospitals enrolling in the Vaccines for Children (VFC) Program. Mr. Talebian confirmed that there has been an increase thanks to the push in the early fall by DPH and MHA in advance of nirsevimab roll-out. Approximately 75% of birthing hospitals are now enrolled in the VFC Program.

Background for Council Deliberation

Mr. Talebian noted that three vaccines were added to the VFC Program in October by the federal Advisory Committee on Immunization Practices (ACIP). Whenever new vaccines are added by ACIP it triggers the Council to deliberate about adding these vaccines to Massachusetts' universal (state-supplied) pediatric vaccine program.

Further to deliberation the Council will make a consensus recommendation. A formal vote is not required. If consensus cannot be reached, a formal vote may be taken.

Deliberation regarding inclusion of RSV vaccine for pregnant persons 18 and under in the universal pediatric vaccine program

Dr. Kathleen Talbot, Field Medical Director at Pfizer, presented information about Pfizer's bivalent RSVpreF vaccine (Abrysvo™).

Dr. Talbot reviewed the burden of RSV disease in children. As a strategy to protect infants from RSV disease, the ACIP recommended the RSVpreF vaccine (one dose) for pregnant persons during 32–36 weeks' gestation, using seasonal administration, to prevent RSV-associated lower respiratory tract infection (LRTI) in infants.

To prevent severe RSV disease in infants, either maternal RSV vaccination or infant immunization with RSV monoclonal antibody is recommended. Most infants will not need both.

The RSVpreF vaccine consists of a recombinant RSV F protein antigen (based on both the RSV-A and RSV-B subtypes), stabilized in the prefusion conformation (preF). The vaccine is supplied as a single-dose vial to be reconstituted with a diluent component.

The RSVpreF vaccine can be administered at the same time as other vaccines.

The American College of Obstetrics and Gynecology (ACOG) and other groups have endorsed use of the maternal RSV vaccine.

In September 2023, the CDC updated its child/adolescent and adult immunization schedule to include the maternal RSV vaccine.

In October, the ACIP recommendations with clinical guidance details were published in *Morbidity and Mortality Weekly Report (MMWR*).

Dr. Talbot reviewed clinical trial data.

Data from the clinical trial demonstrated that the maternal RSV vaccine is safe and efficacious for use in pregnant people to prevent severe RSV disease in infants from birth through 6 months of age.

Side effects included pain, headache, myalgia, and nausea. Side effects were mild to moderate and resolved within 1- 3days.

The maternal RSV vaccine reduced the risk of severe RSV disease by 82% within 3 months and by 69% within 6 months after birth.

Participants in the clinical trials who received the maternal RSV vaccine received it during weeks 24 through 36 of pregnancy. More preterm births were observed among maternal RSV vaccine recipients than among placebo recipients. However, this difference was not statistically different.

Among pregnant people in the clinical trial who received either the maternal RSV vaccine or a placebo during weeks 32 through 36 of pregnancy, preterm birth occurred in 4.2% of pregnant people who received the RSV vaccine compared to 3.7% of pregnant people who received a placebo.

Available data are insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF (Abrysvo). To reduce the potential risk of preterm birth when administering maternal RSV vaccine, FDA approved the vaccine for use during weeks 32 through 36 of pregnancy.

Dr. Talbot noted the following resources:

- Standing Orders: Administering Pfizer Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo) During Pregnancy, Immunize.org.
- Pfizer Maternal Vaccination Card (to enhance communication between providers)
- Pfizer Preparation and Storage Kit

Discussion

Dr. Goldstein asked whether it is known how many pregnant persons under 18 were enrolled in the clinical trial. Dr. Talbot noted that while the age range of people enrolled in the trial was 14-47, and the average age was 29, it is not known how many people under 18 were enrolled in the trial.

Ms. Otenti asked whether there were concerns about infants receiving nirsevimab if there is a lack of communication between the birthing hospital and the pediatrician. Dr. Talbot noted that the ACIP provided additional clinical guidance in the *Morbidity and Mortality Weekly Report (MMWR)* recommendation. She added that if the mother is vaccinated and the delivery occurred less than 14 days later, the infant should receive nirsevimab. There also is a subset of infants who should receive nirsevimab even if the mother has received the bivalent RSVpreF vaccine.

Dr. Fisher noted that it is not an issue in terms of safety to give both the maternal RSV vaccine to the mother and nirsevimab to the infant.

Dr. Fowler inquired whether Pfizer has done any studies looking at whether efficacy is modified by whether the mother is breastfeeding. Dr. Talbot noted that data was collected about whether the mother was breastfeeding, but the effect of breastfeeding on antibodies was not analyzed. She added that more data may be available in the future.

Mr. Talebian noted that since the maternal RSV vaccine has been added to the VFC Program, MDPH must supply it for VFC-enrolled providers to administer to pregnant patients under 19.

Council deliberation should focus on recommending that the maternal RSV vaccine be supplied universally to those 18 and under.

Dr. Fisher noted that he supports adding the maternal RSV vaccine to the universal program, but had a logistics question. If the number of people under 19 who meet the criteria to receive the maternal RSV vaccine is fairly small, and since most obstetrical (OB) practices are not enrolled in the VFC Program, if the vaccine is added to DPH's formulary, will payers reimburse OB practices? If not, would OB practices enroll in the VFC Program, or refer the patient to their PCP/pediatrician?

Mr. Talebian noted that the COVID pandemic resulted in an improved connection with OB providers. Many OB providers are enrolled in the Massachusetts Immunization Information System (MIIS). Enrollment is not an issue. The issue for OB providers is having the infrastructure to vaccinate. OB practices which are part of larger medical groups or CHCs are enrolled and have the proper vaccine infrastructure while some smaller independent practices may be in a bind.

Dr. Goldstein noted that as the RSV season is hopefully nearing its end, there is time to get organized for the next RSV season.

Ms. Otenti inquired whether the cost to supply the maternal RSV vaccine is part of the Council's deliberation. Mr. Talebian noted that cost for one vaccine generally is not an issue. Half of the state's budget is covered by the VFC Program.

Ms. Otenti inquired whether the Council's primary deliberation should be related to vaccine safety and efficacy. Mr. Talebian confirmed that the deliberation should include safety and efficacy, as well as the logistics of implementation if there is more than product.

Dr. Norton inquired whether MDPH was expecting that pediatric practices would be giving the maternal RSV vaccine. He added that practices would be stocking a small amount of vaccine. The minimum dose order and minimizing wastage would need to be considered.

Mr. Temple (Pfizer), noted that the AbryvsoTM is a single dose and comes in a 5-dose pack.

Ms. Bip confirmed that the minimum CDC order is 10 doses.

Mr. Fontenelli (Pfizer) noted that Pfizer is studying ways to avoid over vaccination (mother is vaccinated with the maternal RSV vaccine and infant is vaccinated with nirsevimab).

Dr. Fisher noted that to avoid this the Massachusetts Chapter, American Academy of Pediatrics (MCAAP) has been advocating for birthing hospitals to document RSV vaccination status of both the mother and the infant in the discharge summary.

Dr. Madoff noted that he is concerned about the opposite – that the mother believes incorrectly that received the maternal RSV vaccine and the infant does not get nirsevimab.

Dr. Lamm inquired about the cost of the vaccine from a wastage perspective. The CDC contact price is $227.50, compared to private purchase cost of $295.00. This is comparable to other vaccines.

Dr. Fisher asked whether there are ongoing studies to determine if the maternal RSV vaccine should be given with every pregnancy. Dr. Talbot noted that studies are ongoing.

Deliberation

Dr. Fisher made a motion to recommend that Pfizer's bivalent RSVpreF vaccine (AbrysvoTM) be added to MDPH's universal pediatric immunization program. There was Council consensus that the motion be approved.

Deliberation regarding inclusion of pentavalent meningococcal vaccine (MenABCWY) in the universal pediatric vaccine program

Dr. Susanna Bächle, Field Medical Director-Vaccines, presented information about Pfizer's pentavalent meningococcal (MenABCWY) vaccine (PENBRAYA™).

While meningococcal disease is uncommon, it can cause serious disease and death.

Between 2011 and 2019 there were 14 outbreaks in college settings caused by meningococcal serogroup B.

The MenACWY vaccine is recommended for 11–12-year-olds, with a booster dose at 16 years old. The MenB vaccine is recommended (shared clinical decision-making) at 16-23 years.

PenBraya™ is a pentavalent meningococcal vaccine (MenABCWY). It is a combination of two previously licensed vaccines, Nimenrix™ (Men A, C, W-135, Y) and Trumenba™ (Men B).

In October 2023, the ACIP voted to recommend the pentavalent meningococcal vaccine as an option for adolescents and young adults (10 through 25 years of age) in limited circumstances. The ACIP recommendation has not been published yet in *MMWR* but should be published soon.

The administration schedule was reviewed.

Clinical study data was reviewed. The safety profile and immunogenicity were non-inferior to the MenACWY vaccine.

Local reactions were similar between MenACWY (Nimenrix), MenB-FHbp (Trumenba™) and MenABCWY (PenBraya™).

The two Men B vaccines (Bexsero™ and Trumenba™) are not interchangeable.

The vaccine is supplied as a needle-free reconstitution kit.

Discussion

Dr. Fisher inquired whether there are any longer-term immunogenicity studies. He noted concern about waning protection for college-aged populations if the vaccine is given at 16. Dr. Bächle noted that there are ongoing studies looking at persistence, but these studies are not part of the label.

Dr. Fisher also noted that the number needed to treat meningococcal disease is extremely high (Cost/benefit for rare incidence).

Ms. Otenti noted that uptake/adherence might be improved with two vaccine doses instead of three or four.

Dr. Goldstein inquired whether there are risks associated with the recommendations for the different meningococcal vaccines that could lead to vaccine errors.

Could the pentavalent vaccine be administered in error off-schedule? The current ACIP recommendation for the MenABCWY vaccine is limited.

Dr. Fowler noted that the ACIP is planning to revisit its meningococcal vaccine recommendations in the next year. It may vote on an updated recommendation by February 2025.

Mr. Talebian noted that MDPH universally supplies MenACWY vaccine. MDPH supplies Men B vaccine only for VFC-eligible people. He added that while the pentavalent meningococcal vaccine has been added to the VFC Program, CDC has noted that if all the meningococcal antigens are available, MDPH will not be required to supply MenABCWY as part of its VFC program.

Dr. Fisher made a motion to defer Council deliberation for adding the pentavalent meningococcal vaccine to MDPH's universal pediatric vaccine program until ACIP clarifies the meningococcal immunization schedule.

Dr. Norton noted that the hope in the future is that there will be enough data to recommend that the vaccine be given at 16/before 11th grade and protection will last through college.

Dr. Fisher added that there is a benefit to two total shots. In the long run, the benefits of the pentavalent product make more sense.

If the ACIP recommendation is changed, MDPH also will need to re-visit the meningococcal vaccine school requirement.

Deliberation

After discussion, there was Council consensus that deliberation about adding the pentavalent meningococcal vaccine to MDPH's universal pediatric vaccine program will be delayed until ACIP clarifies its meningococcal vaccine recommendations.

Deliberation regarding inclusion of Mpox vaccine in the universal pediatric vaccine program

It is anticipated that the smallpox/Mpox vaccine (JYNNEOS^{TM}) will be moving to the commercial market at some point this year.

Once commercialized, MDPH will need to supply the Mpox vaccine for VFC-eligible individuals. Since MDPH will be required to supply the Mpox vaccine for VFC-eligible individuals should it be universally supplied?

There is a limited pediatric indication since the VFC Program ends at age 18. Massachusetts currently does not have an adult vaccine program. Once it is commercialized, it will need to be privately purchased for adults.

Dr. Fowler presented information about the Mpox vaccine in the absence of the manufacturer having their medical affairs staff available for the meeting.

The global Mpox outbreak started in 2022. Mpox cases continue to be reported both domestically and globally.

In a multi-jurisdictional case-control study, both partial and full vaccination with Jynneos showed effectiveness against Mpox, regardless of administration route.

The adverse events most commonly reported to VAERS have been injection site symptoms (redness, swelling, pain, itching).

The vaccine is approved for use in persons 18 years of age or older who are at increased risk of Mpox. A National Institutes of Health (NIH) trial is underway to evaluate safety and immunogenicity for persons 12-17 years of age.

Two doses of the vaccine are recommended, 28 days apart.

CDC guidance for coadministration of JYNNEOS™ with COVID-19 vaccines:

- There is no required minimum interval between receiving any COVID-19 vaccine and JYNNEOS™ vaccine regardless of which vaccine is administered first.
- People, particularly adolescent and young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines.
    - Observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID- 19 vaccines and the hypothetical risk for myocarditis and pericarditis after JYNNEOS™ vaccine.
    - However, if a patient's risk for Mpox or severe disease due to COVID-19 is increased, administration of JYNNEOS™ and COVID-19 vaccines should not be delayed.

Mpox vaccine is not currently available through the VFC Program. The Mpox vaccine currently remains under the Health and Human Services (HHS) Mpox program.

Discussion

Laura Efros, Bavarian Nordic, noted that plans are underway to commercialize the Mpox vaccine. Bavarian Nordic is aiming for the end of Q1, 2024. The aim is to get people vaccinated

before the summer. Until that time, the vaccine will continue to be available under the Emergency Use Authorization (EUA) from the U.S. government.

Dr. Goldstein inquired about the cost of the vaccine. Mr. Baxter, Bavarian Nordic, noted that the most likely cost for Medicare/Medicaid plans will be $270.

Mr. Talebian noted that once it is commercialized, MDPH will purchase the Mpox vaccine off of the federal CDC contract.

Discussion ensued about the vaccine rollout. It is a requirement for all universally recommended pediatric vaccines to be stocked by providers, but this vaccine is likely to be exempt as it is not universally recommended for all. Practices seeing high risk patients (such as CHCs and sexual health clinics) should stock the vaccine routinely.

Dr. Goldstein noted that people will probably get the vaccine at a sexual health clinic and probably not from a pediatrician.

Dr. Fowler noted that vaccine supply was an issue early in the outbreak. Currently there are no supply issues.

Ms. Otenti noted that equity should be considered when deliberating inclusion of the Mpox vaccine MDPH's universal pediatric vaccine program.

Deliberation

Ms. Otenti made a motion that the Mpox vaccine should be included in MDPH's universal pediatric vaccine program. There was Council consensus that the Mpox vaccine be included in MDPH's universal pediatric vaccine program once it becomes available through the VFC Program.

Discussion Regarding Future Topics for Consideration

The next Council meeting is scheduled to be held on Thursday, March 14. Council members with agenda items for the next meeting should email them to Mr. Talebian.

If there are no agenda items for the March 14 meeting, the next meeting will be postponed until June 13.

The meeting was adjourned.

Future Meeting Dates:

Thursday, March 14, 2024
Thursday, June 13, 2024

MVPAC webpage:

https://www.mass.gov/service-details/massachusetts-vaccine-purchasing-advisory-council-mvpac