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

Date: Thursday, September 14, 2023
Time: 4-6 PM
Location: Massachusetts Medical Society, 860 Winter Street, Waltham, MA 02451

Attendees

Council Members:

In-Person

Lloyd Fisher, MD
Angela Fowler, MD, MPH
Kristin Jean, PharmD, RPh, CPHQ
Everett Lamm, MD
Pejman Talebian, MA, MPH

Virtual

Aditya Chandrasekhar, MD
Vandana Laxmi Madhavan, MD, MPH
David Norton, MD

Additional Attendees:

In-person

Susanna Bachle
George Coutros
John Crowley
Luke Cunniff
Kim Daly
Bob Fontenelli
Katie Kelley
Ali Lydon
Cynthia McReynolds
Mary Beth Miotto
John Powers
Andrew Rennekamp
Sandra Ribeiro
Christopher Rizzo
Sherry Schilb
Tim Temple
Melissa Williams

Virtual

Alana Arnold
Brooke Cardoso
Munish Gupta
Sandra Hennessy
Olga Hennion
Sarah Jones
Susan Lett
Katherine Lorson
Mari Nakamura
Kathleen Talbot
Trent Wilson

DPH Updates

Mr. Talebian welcomed attendees. In-person and virtual attendees introduced themselves.

Mr. Talebian noted that Kevin Cranston retired at the end of July. Dawn Fakuda is now the Assistant Commissioner and Director of the Bureau of Infectious Disease and Laboratory Sciences.

Dr. Robbie Goldstein, Commissioner of the Massachusetts Department of Public Health, will actively participate in the Council going forward. Dr. Goldstein shared his regrets that he would be unable to attend this meeting. He has provided feedback on the agenda items to Mr. Talebian. Mr. Talebian noted that he will vote on the Commissioner's behalf at this meeting.

Ordering for the updated COVID-19 vaccine will be turned on for state-supplied vaccine ordering beginning tomorrow (September 15). MDPH sent a communication about COVID-19 vaccines ordering this evening (September 14). Note: At its March meeting, the Council recommended inclusion of COVID-

19 vaccines in the MDPH formulary of state-supplied pediatric vaccines and to offer provider choice for all currently available vaccines.

Deliberation regarding inclusion of PCV20 in the universal pediatric vaccine program

Mr. Talebian noted that PCV13 and PCV15 have been state-supplied. PCV13 has been discontinued as of early September and is no longer available in the formulary of state-supplied pediatric vaccine. PCV15 currently is the only available vaccine in the state-supplied pediatric formulary.

Susanna Bächle, Field Medical Director, Vaccines, Pfizer, was introduced.

Dr. Bächle presented information about pneumococcal 20-valent conjugate vaccine (PCV20).

Dr. Bächle reviewed the Food and Drug Administration (FDA) indication for PCV20, serotype composition, safety and immunogenicity, and clinical trial data. She noted a theoretical potential annual decrease in antibiotic use and outpatient visits for the US pediatric population resulting from use of PCV20. She confirmed the Advisory Committee on Immunization Practices (ACIP) recommendation for PCV20. She also noted that the publication of the ACIP recommendation in *Morbidity and Mortality Weekly Report (MMWR)* was expected soon.

Following the presentation, the Council deliberated the following options:

1. Recommend continuing to only supply PCV15 in the formulary of state-supplied pediatric vaccines.
2. Recommend inclusion of both PCV15 (currently state-supplied) and PCV20 in the formulary of state-supplied pediatric vaccines.
3. Recommend that only PCV20 be included in the formulary of state-supplied pediatric vaccine going forward.

A motion was made by Dr. Madhavan to exclusively supply PCV20 in the state-supplied pediatric vaccine and no longer supply PCV15.

Dr. Madhavan's motion was seconded by Dr. Fisher.

Questions/Discussion

Dr. Madhavan noted that PCV20 vaccine includes 7 more serotypes than the PCV13 vaccine and 5 more serotypes than PCV15, which would result in increased coverage and there would be no need for an additional dose in high risk children who receive PCV20 (PCV15 HR recipients would need an extra dose of PCV20 or PPSV23).

Dr. Fisher noted that it would be hard to see a practice administering PCV15 once PCV20 is available.

Dr. Daly (attendee representing Merck) noted that provider choice is available for other vaccines and would not be available if only PCV20 were included in the formulary of state-supplied pediatrics vaccines. She also referenced a study which concluded that seven years following PCV 13 no significant changes in serotype 3 invasive pneumococcal disease (IPD) incidence or disease characteristics in children in Massachusetts. She added that studies show that PCV15 generated a higher antibody response than PCV13.

After discussion, the following motion was confirmed by Council members: PCV20 should be added to the formulary of state-supplied pediatric vaccine as the only vaccine for protection against invasive pneumococcal disease (IPD).

Deliberation regarding inclusion of nirsevimab (RSV monoclonal antibody) in the universal pediatric vaccine program

Mr. Talebian noted that although it is a monoclonal antibody, Nirsevimab is interpreted as vaccine by the Center's for Disease Control and is included in it's Vaccines for Children (VFC) program.

MDPH has reviewed the language of the Vaccine Trust and has determined that a monoclonal antibody can be covered by the Vaccine Trust and can be considered to be included in the formulary of state-supplied pediatric vaccine.

Since Nirsevimab has been added to the VFC program even if it is not supplied universally, MDPH will need to supply nirsevimab for the VFC eligible children.

It is not currently available for purchase through the CDC contract. MDPH will be able to supply it once it becomes available for purchase through the CDC contract which is anticipated by early October.

Dr. Christopher Rizzo, Senior Medical Director, Sanofi Pasteur, was introduced.

Dr. Rizzo discussed the annual burden of Respiratory Syncytial Virus Infection (RSV) in the United States. He noted that nirsevimab is a recombinant human IgG1 kappa monoclonal antibody. Nirsevimab targets **site 0** at the apex of the prefusion conformation of RSV F protein, locking it in place, blocking conformational change and thus viral entry. Its extended half-life allows for once per season dosing.

He reviewed nirsevimab indications and safety information, Food and Drug Administration (FDA) recommended nirsevimab dosing, and how it is supplied, handled, and stored. He added that nirsevimab may be administered concomitantly with childhood vaccines.

Dr. Rizzo reviewed ACIP and American Academy of Pediatrics (AAP) recommendations for nirsevimab.

He reviewed implementation of nirsevimab for infants entering or born during their first RSV season.

He concluded by noting that nirsevimab in all infants could prevent 500,00 medical interventions due to RSV in the US annually.

Questions/Discussion

Will there be supply chain issues once nirsevimab is available for ordering?

Sanofi noted that while it cannot promise that nirsevimab will be available for all eligible babies, they are confident that they can meet the demand to immunize babies this winter.

While MDPH has not heard any signals from CDC that there will be ordering constraints or allocation, ordering information is not available yet.

Given the cost of the product, will MDPH prioritize allocation?

MDPH has no plan to prioritize allocation of nirsevimab.

If recommended by the ACIP, how will the maternal RSV vaccine affect immunization of infants?

The ACIP is scheduled to meet on September 22. The maternal RSV vaccine will be discussed at that meeting. More will be known after the meeting.

While infants whose mother received the RSV vaccine while pregnant probably will not need to be immunized with nirsevimab, some babies may be recommended to be receive nirsevimab. For example, for babies born over the summer, six month's protection from the maternal RSV vaccine may wane by the peak of RSV season.

What is the shelf life of nirsevimab?

The shelf life is 18 months (2 years from time of filling) similar to most routine pediatric vaccines.

Dr. Fisher noted that the vaccine is costly, and uptake is unknown. If hospitals are ordering and administering the vaccine, this will affect pediatric providers. He added that a small practice might on the hook for restitution if the vaccine expires.

Mr. Talebian noted that given the shelf life is 18 months, expiration should not be a problem for pediatric practices but MDPH will still be reviewing it's restitution policy in light of the inclusion of several new costly vaccines.

He added that only 50% of Massachusetts birthing hospitals currently participate in the state vaccine program. 70% of the Hepatitis B vaccine birth dose is administered at the hospital. The cost to administer Hepatitis B vaccine is paid for (absorbed) by the hospitals that do not participate in the state vaccine program. Due to the cost of nirsevimab, hospitals will need to participate in the state vaccine program or may not supply nirsevimab.

In addition to reaching out to hospitals, MDPH is planning to reach out to the Massachusetts Health and Hospital Association (MHA) to encourage participation in the state vaccine program.

If practices private purchase nirsevimab, will they be reimbursed?

Practices will not be reimbursed for private purchase if nirsevimab is available through MDPH similar to other pediatric vaccines.

Are hospitals submitting immunization data to the Massachusetts Immunization Information System (MIIS)?

100% of hospitals submit data to the MIIS.

There will be a gap if hospitals which do not participate in the state vaccine program do not purchase nirsevimab privately. Pediatric practices will need to identify children who are discharged from the hospital without receiving nirsevimab.

For babies born in the spring and summer, it will be up to the pediatric practices to immunize. There will be trial and error in ordering. An 18-month shelf life is reassuring.

The first season will be challenging as we work through these issues. The timing and availability of nirsevimab will affect its roll out. Primary care practices may need to offer more in the first year.

Dr. Fowler made a motion to recommend that nirsevimab be added to the formulary of state-supplied pediatric vaccine. Dr. Lamm seconded the motion. Council consensus was confirmed.

Mr. Talebian noted that the Council's recommendations for PCV20 and nirsevimab are in line with the Commissioner. Once reviewed by the Commissioner, these recommendations should be implemented in the coming weeks.

Discussion regarding future topics for consideration

Topics for future discussion included:
Maternal RSV vaccine – this will be discussed by the ACIP on September 22. If recommended, it may be included in the VFC program for pregnant teenagers.

Pending the ACIP recommendation, an ad hoc Council meeting may be scheduled before the March 2024 Council meeting. The meeting may be virtual. Mr. Talebian noted that he will keep the Council informed as updates become available.

Future Meeting Dates: official

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

The meeting was adjourned.

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