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

Date: Thursday, March 13, 2025 Time: 4-6 PM Location: Massachusetts Medical Society, 860 Winter Street, Waltham, MA 02451

Attendees

Council Members In-Person Council Members: Lloyd Fisher, MD, FAAP Angela Fowler, MD, MPH Robbie Goldstein, MD, PhD Hemant Hora, MD, FACP

Additional Attendees

In-Person DPH Larry Madoff, MD Lynn Squillace, JD, MPH Pejman Talebian, MA, MPH Susanna Bächle Holly Burke Bill Daileanes Sue DeRemer Kimberly Fredericks Alexi Kimura Brett Lown Benjamin Kruskal, MD, PhD, FAAP, FIDSA Everett Lamm, MD, MHCDS, FAAP *Virtual* Vandana Laxmi Madhavan, MD, MPH, FAAP

Cynthia McReynolds Andrew Rennenkamp Sherry Schilb Tim Temple

Virtual

Stephen Boksanski Marla Campbell Kim Daly Ali Lydon Sandra Ribeiro

Agenda

DPH Updates/Announcements

Commissioner Goldstein welcomed attendees.

In-person attendees introduced themselves. Virtual attendees introduced themselves.

Commissioner Goldstein acknowledged the current uncertainty in the national landscape, noting the cancellation of recently scheduled Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) meetings.

He confirmed that at the state level Massachusetts is committed to its values and to immunization of its residents.

Vaccine preventable diseases (VPDs) are with us, as made clear by more than 200 cases of measles nationwide.

While Massachusetts has high immunization rates, it must be prepared to meet the challenges that VPDs could present.

Commissioner Goldstein reviewed the meeting agenda:

- 1. A brief presentation reviewing Massachusetts' vaccine infrastructure.
- 2. Open discussion among Massachusetts Vaccine Purchasing Advisory Council (MVPAC) members about challenges to this infrastructure and how the Council could be utilized to address these challenges.
- 3. Discussion of future meeting topics.

Review of the current immunization landscape

The current immunization infrastructure was reviewed.

The United States (US) government significantly funds the current immunization infrastructure. The government funds the FDA and regulatory bodies to evaluate clinical trial data, determine vaccine efficacy and to make recommendations about immunization administration. FDA approval of a vaccines allows for the Advisory Committee on Immunization Practices (ACIP) to make recommendations to the CDC on how to use vaccines to control vaccine preventable diseases.

Other bodies, such as the World Health Organization (WHO), the American Academy of Pediatrics (AAP), and MVPAC (Council), may have a role in recommending vaccines and how best to use them to protect children.

Approval of a vaccine allows for it to be purchased and distributed. The US government currently funds and manages purchase and distribution of pediatric vaccines through the CDC's Vaccines for Children (VFC) Program.

The CDC pediatric vaccine contract has been useful for getting vaccine to pediatric healthcare providers who then administer them to children at a significant cost savings from private market prices.

This process is complicated, and the pieces need to work together for a robust manufacturing and distribution system. This system is at crosshairs with the current administration.

The Council discussed how it could pick up some of the national immunization work at the state level.

Commissioner Goldstein noted that while the Council is not set up to do the work of the National Institutes of Health (NIH), the Council is comprised of experts who have made vaccine recommendations to the Massachusetts Department of Public Health.

Dr. Kruskal: What would be the launching point to make this task more concrete? With the recent cancellation of a recent meeting of FDA's Vaccines and Related Biological Products Advisory Committee (VRPAC), which makes annual recommendations for seasonal influenza strains, what is the future of the flu vaccines?

WHO has completed its strain selection process for the 2025-2026 influenza season. Life sciences companies are currently producing or getting ready to produce the 2025-2025 influenza season vaccines.

Will the ACIP meet this summer? Will the flu vaccine recommendations for the 2025-2026 season change in the fall? Will adequate flu vaccine supply be available?

In the absence of a VRPAC meeting, FDA can approve the flu vaccine strains. Pathways are available in the process for flu vaccines to make it to market without VRPAC's recommendation.

Dr. Fisher: If the ACIP does not meet, CDC could make a recommendation. Is there a pathway with FDA approval? MVPAC could make a recommendation.

If the normal approval process is not available, what would insurers do?

Dr. Homa: Could a consortium be created in states that have universal pediatric vaccine supply programs?

Could collaborations be created with other states in the absence of FDA approval?

Commissioner Goldstein: It is possible to create a collaboration, but the work that CDC and ACIP does is a lot. It would be difficult for a state to do this on its own (cost and staffing).

Mr. Talebian: The Association of Immunization Managers (AIM) has been meeting to discuss these issues. On a national level, AIM and some of its partner organizations are looking for organizations/committees like the AAP's Infectious Disease Committee to fill this gap. The AAP has a process and committee structure to fill this gap for pediatric vaccines. It is unclear what would happen in the adult vaccine world. A group like the Infectious Disease Society of American (IDSA) might be able to take this on for adult vaccines.

Dr. Madhavan: Is there any possibility of MA making recommendations for influenza and COVID vaccines this fall without FDA approval?

The void filled by not having ACIP recommendations might be able to be filled, but the gap created by not having FDA approval is more concerning.

Dr. Rennekamp (CSL Seqirus); The FDA has an extensive lot release program. This happens annually and is needed for a vaccine to be approved. Safety considerations are important.

Dr. Fowler: Would it be possible to partner with another country, like Canada? Their approval process and bodies are similar.

Commissioner Goldstein: There are parallel processes in other countries, but there would be issues around reimbursement.

Dr. Fisher: How different are US/non-US products?

Dr. Rennekamp (CSL Seqirus): The products can be very different.

Dr. Fisher: I would be concerned about messaging for providers on the front line when a product has not gone through the "normal" process. It might undermine the message that the system works.

Dr. Hora: This process has been a selling point.

Dr. Kruskal: For example, say that the manufacturing process is the same as it has always been, such as the regulatory pieces for lot inspection release approval. Can the pieces of the system be replicated? If not, this might be a problem.

The vaccine safety network is very extensive. Can the safety of this system be maintained? Or how would this system be rebuilt?

Vaccine Information Statements (VIS), National Vaccine Injury Compensation Act (NVICA) and the Vaccine Adverse Effect Reporting System (VAERS) are tied to FDA-licensed vaccines. Recreating all of this infrastructure would be a significant undertaking.

Commissioner Goldstein: It would be a large amount of work to do these things. But we are well-positioned in Massachusetts to have the Council, a group which can work through some of these issues.

Commissioner Goldstein asked Council members whether they believe in the value of immunization in Massachusetts and the additional work that would need to be done by the Council in the absence of a functioning federal system.

The Council's role would be increased – additional meetings, etc., to weigh the benefits and risks.

General consensus from all members was that they were willing to take on this charge.

Dr. Fisher: Would legislative action be required to change the Council's scope? The Council is a statutory constituted body.

Mr. Talebian: DPH is reviewing whether statutory changes would be needed. If yes, DPH will work with the legislation on these changes.

Dr Kruskal: On the payor side, if the vaccines are the same and the price is not substantially increased, it is likely that BCBS of MA would cover them. However, this might be difficult for non-profit organizations.

Dr. Hora: If the processes (testing, regulation, etc.) are equally effective and safe and the prices are similar then yes.

Kim Frederick and Sue DeRemer (GSK): GSK is working directly with FDA on the flu vaccine strains for the 2025-2026 season. There is no indication that they are not moving forward with business as usual. Pre-booking is underway.

Sherry Schilb (Sanofi): Ongoing currently to get ahead of the game – the development of talking points about the flu strains.

Andrew Rennekamp (CSL Seqirus): Seqirus is awaiting information from FDA for strain selection.

Dr. Kruskal: It is a two-part effort. If information is not coming from the federal government, what's the next step?

Commissioner Goldstein: Despite uncertainty on the federal level, DPH is actively planning its talking points.

Mr. Talebian: [questions from the Zoom chat]: what if CDC contracts are dissolved? Could mixed multi-state contracts be used to keep vaccine flowing?

MDPH is planning for possible dissolving of CDC contracts and direct purchasing or in collaboration with other states.

Dr. Kruskal: Aside from flu vaccines, how long will the current structures and supplies last before plans for new vaccines are needed? Most non-seasonal vaccines come with at least a 18 month shelf life.

Kim Frederick (GSK): It is safe to assume that approved vaccines are on the shelf/ready to use. An approximate 18-month supply is available.

In the absence of ACIP meetings/recommendations, it can be assumed that the immunization schedule will stay the same outside of specific actions by CDC to change it.

Dr. Madhavan: Specifically, I also wonder about measles, mumps, and rubella (MMR) vaccine supply if we end up giving more second doses early (and 6-11m doses) in the setting of the broadening measles outbreaks.

Kim Frederick (GSK) – There is currently plenty of MMR vaccine supply. Licensing is not an issue.

Dr. Kruskal: How long will this work need to be done at the state level? If there is not a government mechanism to make up for the CDC and the FDA, how long will it be before we start to run out of vaccines? Could it be less than four years?

Tim Temple (Pfizer); It is unclear what will happen with COVID-19 vaccines. If the seasonal update to track COVID-19 mutations are not continued, will the same lot be used in the fall? Current lots of COVID-19 vaccine are due to expire in September 2025.

CDC still can make vaccine recommendations without ACIP deliberations.

Commissioner Goldstein noted that the discussion at this meeting can be taken to start the work to create a pathway outside the box, with a focus on maintaining high levels of vaccination without relying on the traditional system.

Dr. Kruskal: I can spread the word to other Blue Cross payors across the country.

Dr. Homa: The word should be spread to universal supply states.

Marla Campbell (AstraZeneca): Other countries will continue to manufacture vaccines for the rest of the world.

Dr. Homa: Most organizations are in a wait and watch mode right now.

Andrew Rennekamp (CSL Seqirus): Seqirus wants to support the Council as will be helpful.

Commissioner Goldstein: Thank you for industry's assistance as we move forward. We need to know what risks manufacturers are facing. I appreciate this open and honest discussion. We will take it back and come to this group to see how we can engage.

Tim Temple (Pfizer): Addressing misinformation on social media is important.

Commissioner Goldstein: Countering misinformation is important. Messaging at all Massachusetts government levels is crucial.

Discussion regarding future topics for consideration

Dr. Fisher: Future topics are pending awaiting ACIP's future.

Topics which had been planned for ACIP discussion at its February meeting included changes to the meningococcal vaccine recommendations.

Dr. Kruskal: zero cost share for vaccines operating outside of the ACIP framework.

Mr. Talebian noted the Massachusetts law covering the Vaccine Trust Fund can be utilized for future planning, although the ACIP-specific language may need to be changed.

Commissioner Goldstein adjourned the meeting.

Future Meeting Dates:

Thursday, June 12, 2025 Thursday, October 9, 2025

MVPAC webpage:

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