October 6, 2021
MMS/DPH Call Summary and Q & A

On October 6, 2021, the Massachusetts Medical Society (MMS) held its informational call for members with the Massachusetts Department of Public Health (DPH). Kevin Cranston, MDiv, Assistant Commissioner and Director, Bureau of Infectious Disease and Laboratory Sciences, Larry Madoff, MD, Medical Director, Bureau of Infectious Disease and Laboratory Sciences, and Kerin Milesky, Director, Office of Preparedness and Emergency Management participated. DPH officials provided updates on current COVID-19 cases and hospitalizations, monoclonal antibody allocation, and on-going vaccination efforts and planning. DPH officials also responded to member questions provided in advance and asked during the call.

COVID-19 Update
Dr. Madoff:

- Massachusetts is still in a surge in terms of case numbers. DPH is reporting out 1,492 new positive cases today out of slightly over 100,000 molecular tests that were conducted. The seven-day average percent positivity rate is a little over 1.8%. The positive percentage is driven down somewhat by the high numbers of testing of higher education students in Massachusetts, which is part of a surveillance program.
- Although case numbers have declined a little from our peak of two to three weeks ago, Massachusetts is still not approaching the low levels seen in back in May and June. Hospitalizations also remain in a bit of a standstill.
- DPH looks at Massachusetts Water Resources Authority (MWRA) wastewater COVID detection as another leading indicator. At the MWRA facilities, this level has also been stuck at persistent, detectable levels. The levels are not as high as earlier in the summer, but they still are not returning anywhere near the baseline that we would expect.
- The Delta variant is now essentially all of the COVID that we're seeing here in the state by molecular sequencing. Well over 98% of the isolates in Massachusetts are Delta.
- Massachusetts seems to be experiencing a bit of a standoff between the highly contagious Delta variant, the return of students, and a return of many baseline mobility and activities, including restaurants and theaters and other public venues reopening, all of which are tending to push up on case numbers in combination with a high level of immunity in the Commonwealth due to the very high vaccination rates. Massachusetts continues to lead the country on vaccination. Vaccination rates are likely keeping this surge from being out of control and keeping our hospitalizations and serious morbidity and mortality down.
- On the therapeutics front, Molnupiravir, an investigational oral antiviral medicine, appears to have benefit in treatment of early mild to moderate COVID - about a 50% protective efficacy against serious
outcomes in several hundred patients), according to the press release. We don't yet know the details or the side effect profile. The efficacy of this treatment is lower than the available monoclonal antibodies, at least by report. The percentage of efficacy in the monoclonal antibodies is closer to 70%. While these oral agents are exciting, they are far from a complete answer or cure.

- The U.S. Food and Drug Administration (FDA) has announced that their Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on October 26, 2021, to look at the Pfizer vaccine for the 5 through 11 age group. Pfizer has presented data which they say is favorable.

Dr. Madoff’s responses to questions provided in advance of the call:

**Question:** What is the efficacy of the KN94 masks?

**Dr. Madoff:** I don’t know a lot about them. I've found one published report using these KN94 masks. They're filtering respirators, similar to N95 masks. The 94, you know, refers to the percentage of particulate in a certain size that is removed by the mask in normal use. This is a disposable, paper mask that's produced in Korea and is available commercially. You can buy it on Amazon and so forth. As far as I know, they are not National Institute for Occupational Safety & Health (NIOSH) approved and would not be acceptable for use in place of N95 respirators in a health care setting, but they are probably more effective at filtering than a typical disposable face mask or a cloth mask. If others know more about it, I'd be happy to hear more.

**Question:** What is the current guidance regarding social distancing in schools, and how will that evolve once mask mandates are relaxed?

**Dr. Madoff:** The current guidance requires both students and staff to wear face masks in all K through 12 settings and in early childhood settings above the age of two while in school. That guidance will remain in effect through the end of October. There is a plan that is in place that if schools achieve a vaccination rate of 80% in their students and staff, that vaccinated students and students (I believe, only vaccinated students and staff) will be allowed to not wear masks after that time. That has not yet gone into effect. There are no current social distancing requirements in schools where masks are being used. DPH recommends increased distancing, as feasible, in unmasked settings, for example in cafeterias and at lunchtime. That is really the only guidance that we have at this point. Masks are not required outside, even in the school setting. Distancing is not recommended or enforced in outdoor settings.

**Question:** We are hearing reports regarding supply challenges for pooled testing, and about staff challenges implementing test and stay policy. Can DPH provide a status update?

**Dr. Madoff:** The state made available pooled testing throughout the Commonwealth. Over 2000 schools adopted pooled testing in some form or another. The uptake among students has been variable, but in many situations, students are taking advantage of pooled testing. The test and stay program, which is another program that's been implemented by the Department of Elementary and Secondary Education (DESE) along with DPH, is a program that allows exposed students, students who have an exposure in the classroom to a case of COVID, to remain in school as long as they are asymptomatic and are tested daily with a BinaxNOW test. That program was provided by DESE and by the Commonwealth with staffing. The vendor that's been providing that, by and large, has been CIC Health, and they were able to hire about 1,200 staff to deploy this testing, but they remain short of their targeted 1,500 staff. That has been challenging and it remains a challenge in some of the schools to perform their testing, which is obviously labor intensive, requires a trained individual to administer the tests. DPH is working with DESE and with our Health and Human Services Department to try to alleviate these shortages and to try to simplify the processes as much as possible. Test
and stay has been a very popular program. It has allowed thousands of students who otherwise would be excluded from classrooms to remain, and as far as we are aware, has not yet resulted in any transmission or outbreaks in the schools. Undoubtedly, there is some transmission occurring in schools, but we haven't been made aware of clusters or large outbreaks in school settings. I remain cautiously optimistic that with all of the safety measures that are in place, that students will be able to remain in school.

Vaccination Update

Mr. Cranston:

- Massachusetts has one of the highest rates of COVID vaccination in the country. We're second of all states with one or more doses administered per capita. Among large states with 5 million people or more, Massachusetts ranks number one.
- Over 4.6 million individuals are currently fully vaccinated. On the county level, 70% of eligible individuals (people aged 12 and up) in all of our counties have at least one dose administered with many counties having 60% or more of eligible individuals fully vaccinated.
- Booster dosing for the Pfizer COVID vaccine formulation is now available. DPH is anticipating additional federal action on boosters for the Moderna and J&J vaccines as well as the expansion of the indication on the Pfizer vaccine to a younger population.
- Over 150,000 additional doses of Pfizer vaccine have been administered in Massachusetts. That number includes individuals who were previously eligible due to their immunocompromised status. The number is indicative of a fairly rapid uptake among the probably 600,000 individuals who may be ultimately eligible for those doses.

Mr. Cranston’s responses to questions provided in advance of the call:

**Question:** Does DPH have more clarity, or plan to issue further guidance, on who would may qualify in the occupational or institutional settings and/or will a self-attestation be required? May physicians/providers rely on a patient’s self-reporting that they work in a high-risk setting?

**Mr. Cranston:** DPH had some of the same questions around the occupational and institutional settings where individuals live or work that qualify for the Pfizer booster dose. The CDC has provided a partial list. They have indicated that it will continue to evolve. It includes first responders (including health care workers), education staff, food and agriculture workers, manufacturing workers, corrections workers, U.S. Postal Service workers, public transport, and grocery store workers. This list is similar to some of our prioritized populations for the initial roll-out of the primary series. However, the question is really about, are we providing additional guidance on those occupations or institutional settings, and/or will a self-attestation be required? I can answer the second part of that affirmatively, that self-attestation will continue to be the mechanism by which people indicate their eligibility for the booster dose of Pfizer. No particular documentation is needed. I would anticipate if and when Moderna and J&J become approved for booster dosing, we will similarly only require self-attestation. We do encourage individuals to consult with their health care provider about their own situation as there are some risk and benefit determinations attached to some of these recommendations.

**Question:** What can be done to increase the vaccination rate among pregnant women? What are the main roadblocks to reaching this population?

**Mr. Cranston:** The CDC made statements in the past week urging pregnant, postpartum individuals, and people planning on getting pregnant to get vaccinated. It was a very strong statement about the risk of COVID greatly outweighing any risk of the vaccination for individuals who are pregnant or postpartum.
continues to be some anxiety amongst some individuals, and maybe even some providers, regarding the relative benefits of vaccination of pregnant and postpartum individuals. We feel like the CDC statement was emphatic and strong and should serve as the basis of clinical consultation, both in the past and moving forward. We, at DPH, would be open to comments and recommendations about how we can better support the individuals making those decisions around COVID vaccination during pregnancy or surrounding pregnancy.

**Question:** Will DPH be prioritizing smaller batches of vaccine, and vaccines not needing reconstitution, to physician practices and community health centers (CHC) over pharmacies?

**Mr. Cranston:** This is a complicated question because currently, all of the, certainly the Pfizer vaccine requires reconstitution. We've indicated in previous calls that we have heard from Pfizer that they are planning on eliminating the separate diluent and providing a pre-diluted vials of vaccine. Those are not currently available. We expect them to be available possibly within the next month. They are also planning on 100-dose pediatric formulation. As you know, the pediatric formulation, once approved is likely to be a lower dose of Pfizer vaccine. We have to wait for FDA approval and the Advisory Committee on Immunization Practices (ACIP) recommendations on that, but the indication from Pfizer is when it becomes available, it will be made available to pediatric practices in 100-dose increments. Longer term, we anticipate the elimination of the 1,170-dose trays of Pfizer vaccine, to be replaced by, likely, a 300-dose adult formulation tray. All of this is going to be a great boon to physician practices and community health centers. It's not really in our place to be prioritizing one over the other. Right now, Pfizer is only available in the 1,170-dose trays. So, all orders are filled through that mechanism. As we've described in the past, we do make available smaller amounts, through the work of our own vaccine unit. Our vaccine unit breaks up those trays to make Pfizer and other formulations, Moderna and J&J, available to practices in smaller increments (60 doses of Pfizer, 60 doses of Moderna, for example) on request. We break up the trays and arrange for either pickup from the state public health laboratory in Jamaica Plain or for a courier to bring those smaller increments to physician practices and community health centers. You should note that they are not shipped in those smaller increments in ultra-cold contexts. They are shipped at refrigerated temperatures, but because of the extended shelf-life of up to 30 days, refrigerated, those should be manageable dose increments until we see the smaller increments made available by the manufacturer, in which case they will be available to all orders, physician practices, CHCs, and pharmacies equally.

**Question:** Does DPH have plans for an information campaign regarding the safety of coadministration of vaccine and influenza vaccine?

**Mr. Cranston:** Generally, we would limit that outreach to our providers because we feel that this is a clinical decision, and assurances of safety and efficacy should come from the provider. It's an opportunity for providers to indicate to an individual seeking either the influenza vaccine or the COVID vaccine that they have an opportunity to receive both in the same visit. Coadministration is clearly indicated, generally, and the CDC has recommended it with separate arms for administration. I'm happy to take that suggestion back to our communications team and ask whether there's a need for more general public communication campaign or messaging around coadministration. They have their finger on the pulse of what they're hearing from their various focus groups and concerns that are being expressed by various sectors of the population. To the degree that there may be concerns about coadministration, we may have an opportunity to also do some public messaging.

**Question:** Is or will DPH be working with DESE to implement school-based clinics or mobile vendors once pediatric vaccine is approved? Will DESE/DPH target communities with lowest vaccination rates?
Mr. Cranston: Back in July, we reached out to school districts and gave them an opportunity to opt into our mobile vaccination vendor system. We are contracting with an array of ambulance companies to provide mobile vaccination. An important component of our Vaccine Equity Initiative is providing on-the-ground vaccination opportunities to our 20 equity communities. These services are also available to schools in general, whether or not they have a school-based clinic. We're very excited about the prospect of school-based clinics being a vaccination site. They are already playing that role for older adolescents. They'll also be playing a role for the younger children. You should know that most school-based clinics are in high school settings, not exclusively, but primarily in high school settings, so they may not be available for the youngest individuals. That doesn't mean a school can't become a site for vaccination. We do encourage schools to think about offering school-site clinics, perhaps in tandem with our mobile vendors. We are fully expecting our mobile vendors to support schools and make vaccine available to younger individuals, recognizing that we expect most children to be vaccinated, either through their pediatric providers or in their pharmacy or community health center setting. It will be a fairly substantial eligibility for these vaccines if the Pfizer indication is expanded to the 5-to-11-year age group. DPH recognizes there'll be significant demand from parents and families, and that we need to have multiple points of access in order to have equitable access to these vaccines.

Hospitalization and Monoclonal Antibody Update
Ms. Milesky:

- COVID hospitalizations have plateaued somewhat with overall hospitalizations dropping to under 600 recently. Today's report was 589 COVID hospitalizations with 156 in the ICU.
- Overall serious constraints are being experienced at our acute-care hospitals. Total occupancy as reported today was 88.9%. And in the ICU, we're seeing levels of about 81% occupancy.
- All of our hospital regions are currently in tier 3 of our resurgence guidance. That means is that they are meeting on a regional basis, twice a week, to look at the need to load balance and to talk about resource issues. While COVID is contributing, there are also other drivers around workforce issues, around high behavioral health volumes, and a lot of non-COVID acute care needs. DPH is watching this closely.
- On September 15, 2021, the federal government shifted how it allocates monoclonal antibodies, moving away from direct allocations to providers. The state will now work more closely with the providers with the goal of having a better sense of where the allocation should be made in what could be a tightening supply. DPH issued updated Guidance for Allocation of COVID-19 Monoclonal Antibody Therapeutics to Health Care Providers on October 1 and also updated its OPEM Resource Request Form for monoclonal antibody therapeutics from the state supply. The guidance and form can be requested by emailing: COVID19.Resource.Request@mass.gov
- DPH has a cache of PPE available by request. If any provider is having trouble accessing surgical masks, N95 respirators, etc., they can email our resource unit at: COVID19.Resource.Request@mass.gov

DPH responses to questions asked during the call:

**Question:** Could you share with us what you're hearing about Moderna's timeline for submitting booster vaccination? I've heard a variety of different versions of this. We know where Pfizer is, and we know where J&J is, but it's harder to find out where Moderna is in the FDA, ACIP, and CDC timeline.

**Dr. Madoff:** The FDA has scheduled a meeting, I believe, on October 15 to hear about Moderna's booster program. Another VRBPAC meeting is scheduled for that day, specifically to address that. There's also a
meeting scheduled to look at J&J’s vaccine booster and also to consider mixing and matching vaccines as booster doses. Those three topics are scheduled for next week, or the following week. The Moderna booster dose is proposed to be at 1/2 of the current primary series meaning a 50-microgram dose is being proposed. Again, we have not seen any of the data, and we hope that that will come out with the VRBPAC meeting. Then, depending on the FDA action on that approval, the ACIP would meet. There are no ACIP meetings currently scheduled, but they have typically followed in pretty short order after FDA actions.

**Question:** I'd like to know if there's any guidance in administration of a booster vaccine in those who've had a proven breakthrough infection?

**Dr. Madoff:** The CDC has a very useful site called Clinical Considerations for COVID Vaccination which answers many, many of these questions. I look at it all the time because there is detailed guidance. Someone who has a COVID infection is not supposed to get vaccinated during their isolation period, typically, 10 days from the date of their positive test or symptom onset. However, there is no contraindication to vaccination if it's otherwise indicated after that period of time has passed. I think the main consideration there actually is prevention of transmission of COVID in the vaccine clinic setting, there is no evidence of harm to vaccination in people who have had COVID or have recovered from COVID. So, as long as it would be otherwise recommended to receive the vaccine. There are also now categories for booster dosing, which for some is based on clinical considerations. The CDC recommendations are that someone may receive a vaccine rather than should receive a vaccine. Those are questions that either the individual or the individual and their provider can look at and determine whether or not they should receive the vaccine. I think it wouldn't be wrong to consider a recent COVID infection as weighing into the decision in those categories. It's whether someone should be vaccinated or not. But there's no precaution or contraindication to vaccinating somebody once they have recovered.

**Question:** I was wondering if you were continuing to test for variants and if you're beginning to see any other variants come into the state or hear of any new variants in the Northeast?

**Dr. Madoff:** The variant story has become a lot less interesting recently. Almost everything we're seeing is Delta. There is a lot of sequencing going on here in the state. The state lab is sequencing about 200 isolates every week, and our partners at the Broad Institute are also sequencing, essentially, most of their positive isolates, which is a pretty big sampling around the state. In addition, the CDC contracts with a national laboratory, Helix, that samples from around the state. We see an occasional isolate that is not Delta, but almost all of the isolates are in the Delta family. In fact, they're starting now, actually, to look at variants within Delta. We may be hearing more about that by classifying certain variants that are, sort of, sub-variants within the Delta overall group. Again, for the most part, all we're seeing right now is essentially Delta.