September 22, 2021
MMS/DPH Call Summary and Q & A

On September 22, 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, Catherine Brown, DVM, MSc, MPH, State Epidemiologist and State Public Health Veterinarian, and Kerin Milesky, Director, Office of Preparedness and Emergency Management participated. DPH officials provided updates on COVID-19 cases, current hospitalizations and resurgence guidance, booster planning and coadministration of vaccinations. DPH officials also responded to member questions asked during the call.

COVID-19 Update
Dr. Madoff:

- I recently spent one week as an infectious disease consultant doing inpatient infectious disease at UMass Memorial which afforded the opportunity to see the issues that providers are facing here in the Commonwealth.
- The recent surge is very much alive and with us in the Commonwealth. Massachusetts is reporting over 1,800 new confirmed cases today. It is hard to tell exactly where we are in the surge. It is always hard to tell until afterwards when a surge has actually peaked. Massachusetts seems to have a slight downward movement, at least in the trajectory of cases. Massachusetts is experiencing ongoing transmission -almost entirely the Delta variant.
- Massachusetts continues to have impressive vaccination outreach:
  - 4.6 million people in the Commonwealth are now fully vaccinated
  - In the over 65 age group, over 94% fully vaccinated, and for all adults, over 80%
  - For those 12 to 15 and 16 to 19 years of age, a little over 70% are fully vaccinated
  - Vaccination is continuing with close to 10,000 new vaccinations per day here in the state, and DPH expects that pace to continue.
- There are questions about what’s going to happen with booster doses. DPH does not don’t know yet.
  - DPH is waiting for recommendations from the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP).
  - The ACIP is meeting today and tomorrow. They have scheduled a vote on booster doses for 2:00 PM tomorrow.
  - Their recommendation will need to be made official by CDC before the Commonwealth would begin to implement anything.
The U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted to advise booster doses only for high-risk individuals, particularly those over 65. VRBPAC expressed an interest in health care workers as well.

Some skepticism about the need for boosters was expressed during the ACIP call held today as well as an understanding of the need for booster doses in at least some populations. It is not entirely clear how they will vote and what the outcome of tomorrow’s meeting will be.

DPH does not believe it’s possible for ACIP to expand beyond what’s approved by FDA. The likelihood is that there won’t be booster doses outside of those populations (those who received the Pfizer vaccine as their primary series and are over 65 or in a high-risk population of some other sort, for example, health care workers).

- There has been a lot of attention given to monoclonal antibodies which are an approved treatment for those with early COVID-19 (within the first 10 days of a positive test or symptom onset and who are in a high-risk category as defined in the emergency use authorization (EUA): those over 65, those with a high BMI, and those with certain other risk factors).
  - Those individuals can receive either an infusion of the Lilly product or the Regeneron combination monoclonal antibody product and/or can receive subcutaneous injection of the Regeneron product.
  - The supply of those monoclonals are somewhat constrained right now, and Massachusetts is back to a system of allocation from DPH. Facilities are going to be requesting allocations on a weekly basis, and those will be filled by DPH’s Office of Preparedness and Emergency Management (OPEM). So far, it looks like the supplies that we’re getting in the state and the supplies that we have on hand will meet the existing demand. But of course, we don’t know how that demand will change, case numbers will obviously impact that demand.
  - Both the Lilly product and the Regeneron product are also approved as post-exposure prophylaxis for individuals who are exposed to COVID-19, close contacts or in a facility where there’s an outbreak of COVID-19. Either of those products can be administered as post-exposure prophylaxis for those who are either unvaccinated or who are vaccinated but unlikely to adequately respond to vaccination. And so that is another possible use, and I have to say that these agents do offer us an available modality to treat people. And I would encourage their use when appropriate.
  - There is a federal website that lists all of the available infusion sites. Providers can reach out to the infusion sites listed to refer a patient that meets the EUA criteria.
- The CDC has given the green light for coadministration of influenza vaccine and COVID vaccine. Originally, there was a recommended 14 day interval between COVID vaccine and other vaccines, but the CDC's guidance has changed on that and now coadministration is allowed. There is now no required interval. The flu shot may be given at any time before or after COVID vaccine.

Hospitalization Update
Ms. Milesky:
- There has been a dramatic increase in confirmed COVID hospitalizations – a 701% increase in confirmed COVID hospitalizations since July 4, 2021. That being said DPH is seeing some flattening of the numbers. Today’s dashboard has 618 COVID hospitalizations with 170 of them in the ICU. This is a decrease from the most recent surge that we had seen earlier in the month, where cases had reached 707.
• Acute care hospitals continue to be very constrained with 19 of them reporting either using their med-surg or ICU space within their facilities. This is a somewhat complex situation in that this is not all surge due to COVID. There are significant high acuity non-COVID patients within hospitals, there are, of course more COVID patients, there are significant staffing issues, there are behavioral health issues, as well as challenges in placements in post-acute settings.
  o To help support hospitals, DPH reissued its resurgence planning guidance last Friday. The resurgence guidance puts in place a regional planning structure to provide situational awareness and support for load balancing and resource sharing. All hospitals in our 5 regions in the state are currently in tier three of that resurgence plan guidance. That means that they're meeting a minimum of 2 times per week to be able to share situational awareness and support one another.

**Vaccine Distribution and Planning for Booster Doses**

Mr. Cranston:

• DPH has made available, to primary care practices, including pediatricians, smaller dose amounts of COVID-19 vaccines in response to feedback that smaller dose amounts are easier for practice-based clinicians to manage and store and administer.
  o DPH is managing this effort out of the state public health laboratory and our vaccine unit, where we are ordering and then breaking up trays for redistribution. Clinicians can order Pfizer doses as small as 10 vials, which is 60 doses, Moderna doses at 5 vials, which is 50 doses, and Janssen (J&J) down to 5 vials, which is 25 doses. We have had some encouraging news from Pfizer that they are planning for a smaller dose trays relatively soon, as small as 300 or maybe even 100 dose trays.
  o The vaccine unit does need to work their way through the existing 1,170 dose trays. They need to use those up before they shift to that lower level of distribution, but that will allow clinicians and other vaccinators to order directly through the MIIS for those smaller allocations of Pfizer doses which is very welcome news.

• In terms of overall booster planning, not knowing what VRBPAC was going to say last Friday or what the ACIP is going to rule on tomorrow, we have been planning all along for the possibility of a 5, 6, or 8-month interval between the last primary series dose and the booster dose for Pfizer. We are also planning for all populations to be eligible (at least the 18+ population to be eligible).
  o DPH has conducted significant surveying. Many physicians may have received and hopefully responded to our surveys which were aimed at trying to assess capacity for ordering, storing, and administering booster doses. There was a very robust response across all sectors - health systems and hospitals, primary care, local boards of health, urgent care, mobile providers, and, in particular, the pharmacy sector, which indicated a capacity to administer doses at the order of hundreds of thousands per week. Our overall capacity appears to be several hundred thousand per week.
  o Current estimates, if the 65-plus and those at-risk or severe complications from COVID-19 end up being the recommendation coming out of ACIP, are on the order of 600,000 to 650,000 individuals. Based on the capacity identified in the surveys, it looks like that need could be met if done efficiently and everyone presents for booster, which is an uncertainty.
  o DPH continues to work with all sectors, and it is making some additional investments in the mobile provider sector to particularly meet the needs in geographic areas where there appears to be some vaccination deserts. DPH won't be having the mass vaccination sites on the order
that we saw back in the winter and spring, but some of these vendors will be able to produce staff capacity to administer up to 1,000 doses a day in some selected areas to supplement the other sectors.

- Moderna has submitted data to the FDA for consideration of an additional dose. In addition, press reports from J&J have spoken to at least internal evidence of enhanced immunogenicity following a second dose of J&J. As of at least an hour ago, those data had not been presented to the FDA for consideration, so I still think we’re several weeks out on Moderna and maybe the longer time frame on J&J.

- One question about the booster doses that comes up is whether they are expected to help prevent infection or do they still mainly work to prevent severe disease and death? This was a topic of significant discussion, both at the FDA and I suspect that the ACIP. While the universal goal to prevent as many infections as possible in order to control the pandemic is front and center, DPH’s read of those discussions is that the focus really has primarily been on preventing severe disease and death. That has been a top priority throughout our vaccination strategy. When the vaccines first became available in December and January, DPH significantly prioritized the prevention of severe disease and death. DPH is hopeful that enhanced immunity in all populations will also ultimately turn the tide on levels of infection population-wide.

- DPH is anticipating a decision for the Pfizer vaccine, or at least consideration of data that's been submitted for the 5- to 11-year-old age group, by the end of October. The planning for the pediatric piece is not as developed as it has been for the booster piece. DPH is looking to pediatricians, community health centers that have pediatric practices embedded in them, as well as a larger health system, and the urgent care centers have recently been reactivated as partners in our vaccination effort. Pharmacies also will play a role in addressing the vaccination needs of younger children.
  - The federal Public Readiness and Emergency Preparedness Act (PREP Act) authorized pharmacists to administer COVID-19 vaccines down to age 3. Our joint policy with the Board of Registration and Pharmacy follow the PREP Act in that regard. However, on a practical level, what we've heard largely from pharmacies and pharmacy associations is that the youngest children will probably best be served in pediatric practices, but children aged 5 and up are likely to be welcomed into pharmacies as well to supplement the significant procedural challenges that pediatric practices may face in meeting the needs for what we think will be a highly motivated group of families bringing their children in for pediatric vaccinations when they are approved.

**DPH responses to questions asked during the call:**

**Question:** It's sometimes difficult to find places to test young children. That means they have to stay out of daycare, or the parents have to stay out of work. Is that something DPH can help us get out more information about or help identify other sites for that kind of testing?

**Dr. Madoff:** There is the [mass.gov testing website](http://mass.gov/testing) that has dozens and dozens of locations that are available for testing. There were over 100,000 molecular tests done yesterday in the Commonwealth, so there's a lot of testing going on. I recognize that there are some sites that won't do young children, but many will. The best resource is looking on that website.

**Dr. Brown:** I want to acknowledge that we have been hearing some concerns about people being able to make appointments, not just for kids but in general. What I will share with you is that, when we investigate particular complaints, it usually turns out to be that the person is being very specific about where they will go
for testing. For example, they will only go to the CVS in their town. I believe there are 466 different testing sites in the Commonwealth. What I encourage people to do is just to acknowledge that they might have to be a little bit more flexible about which location they might go to. I understand that people are looking for convenience, but I encourage people to pick more than one location that they’re willing to go to.

**Question:** In addition to the latitude around flu and COVID-19 coadministration or sequential administration without a prescribed gap, what about other vaccines? Some patients are really motivated now to get vaccinated, particularly Shingrix, and Pneumovax and Prevnar 13. I’m wondering if we can feel as free to tell our patients that they can get those at the same time, or within a few days of the COVID-19 and flu vaccine?

**Dr. Madoff:** As I said, the CDC has removed the restriction on coadministration of other vaccines. There is still some cautionary language around the use of multiple vaccines, and I’m sure you’ve all experienced this with the variety of vaccines, that giving several reactogenicity vaccines at the same time can be problematic. There is language about using good clinical judgment around, for example, a very reactogenicity vaccine like Shingrix and a fairly reactogenicity vaccine like COVID-19 vaccines at the same time which might be problematic. It’s important to think about which ones can be safely and acceptably, from a side effect standpoint, given at the same time. There’s no hard restriction, no contraindication, to giving even multiple other vaccines along with the COVID vaccine. Certain immunization can have some complexities to the schedule. I would urge you to check the details of the immunization schedule online or to call us at DPH and one of our epidemiologists or nurses can try to walk through some of these questions if they’re complicated.

**Question:** Regarding monoclonal antibody infusions for patients, I found on your’re the DPH website something about the September 16 memo from FDA with the newest indications for the antibody administration for higher-risk patients. I’m wondering if that is the most current document and where can people look to find the information? If it’s posted on your website. How would we find it?

**Dr. Madoff:** We are doing our best to push out accurate information, but sometimes the FDA is ahead of us. There have been a lot of recent changes in monoclonal antibody information. Two changes I think I mentioned on the last call are that bamlanivimab and etesevimab administered together is now reopened for EUA because the Delta variant is susceptible to that antibody combination. It had been taken off of EUA use for a few months, June until later in the summer. The other change is information that bamlanivimab and etesevimab administered together may be effective for use as post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death. We at DPH are going to try to get out some clinical guidance around this in the very near term. It's hard to stay up to the minute and the FDA, the emergency use authorization language that is posted online from each of the manufacturers and from Regeneron is probably the most up-to-date information that it’s available. Finally, the HHS federal website gives you a way of searching for monoclonal antibody distribution sites and gives you the contact information for each of those sites.

**Question:** Some epidemiologists and infectious disease people have recommended abandoning cloth masks and using a KN95 or even an N95 which may be much more available now. Someone also put a KF94 from Korea in the same category as the KN95. Is the KF94 mask equivalent to a KN95 mask?

**Dr. Madoff:** I don’t know the answer. It’s something that we could look into, but I don’t even know where I would get that information. I think it’s important that people wear masks when they’re supposed to. That includes on transportation, health care facilities, crowded situations, and in certain municipalities and locations where indoor masking is required or strongly recommended. Of course, masks are recommended for those who are unvaccinated. There is a school of thought that better masks are better and more protective of
the individual, that filtering respirators that are like N95s provide additional protection, but I think it's probably the source control that's the most important thing that masks provide. Getting more people to wear masks where appropriate would probably be more important than the quality of the mask, at least on a population basis. I don't know if that answers your question, but it's the best I can do.

**Dr. Brown:** I did some quick googling so take this with a grain of salt. It looks like there is a new, sort of a bad comparison between the two types of masks, and so it may not be possible to say whether one is significantly better or different. In addition to everything that Dr. Madoff said, which I completely agree with, the other thing to think about is that FDA evaluated, and approved masks are probably better because at least you have some quality control information on them. The two things that I say about masks in general, and I'm generally pro-mask, is that how a mask fits really matters. You could wear an N95 mask badly and it will be possibly less effective than even a cloth mask worn well. I would also say that the best mask is the one that you can actually wear. You don't want something that's so uncomfortable that you are adjusting it or touching it all the time because that interferes with the efficacy of any mask if you're always having to adjust it. For example, wearing an N95 mask for a long period of time is pretty uncomfortable.

**Question:** I've been asked questions about whether or not it makes sense to use alternate boosters from the original vaccine that you have had to provide some measure of alternate protection, with the idea that the different vaccines support the immune system in different ways. Is there any logic to that?

**Dr. Madoff:** There is some logic to that. In fact, there was a line of questioning about that on the ACIP call today. I think there is research to support the idea that a heterologous boost may offer different or may offer better protection in some cases, but the data are quite limited. I don't know how the recommendations from ACIP are going to go exactly, but my expectation is that they will stay with homologous boosters that they'll recommend Pfizer, which is the vaccine that is under consideration right now, for those who have previously received the Pfizer vaccine. That's where the best data are, but there are theoretical reasons and some research data to support what you're saying.

**Question:** Where are we on this surge? Are we plateauing? Is there any indication we're going to hang at a plateau until the pediatric immunizations get out or is there hope that we can continue to mask and distance and see that we could plateau and maybe start to head down? I'm looking for some epidemiologic and real data on where we in this surge are.

**Dr. Brown:** I really appreciate the question, but I think you are looking for more than just data, you are looking for a crystal ball. I can tell you what the current data show, but I find it much harder to answer your deeper question about whether we going to be stuck sort of at some level of plateau until we can start vaccinating children. Two weeks ago, it looked like we were tipping over onto a plateau and I think people were generally sort of excited about that. We were still seeing hospitalizations increase at that point, but because there are a lagging indicator, that made sense. One of the things that we saw happen with last week's data is that all of a sudden there were more tests, surveillance tests being done, both in the K through 12 setting and in the higher education setting. That did a couple of things. One is that it greatly increased the number of tests that were being done per day, which made our percent positivity go down, sort of artificially, perhaps. It also revealed additional cases that might not have been recognized otherwise. We saw a relatively, significant increase in our daily cases last week. This week, and it's only Wednesday, that does not seem to have continued. If fact, it didn't plateau at that level. It's dropped down a little bit from last week's numbers. But it is too early for us to know if we are really at the top of this surge, and definitely too early for me to say anything with confidence about whether and when we will head back down. There are a couple of things that have happened. One is that the Delta variant has been around for a while now. We certainly have seen lots of
infection both in unvaccinated and vaccinated people. In unvaccinated people, hopefully it is providing some level of temporary immunity. In vaccinated people, one would assume that it's creating kind of a booster dose. But I think those benefits are potentially going to be outweighed by the fact that kids are entirely back in school, higher education is back, and the weather is going to start getting colder and people are going to move indoors, which is obviously going to support transmission. I wish that I could give you a better answer, but I would be lying if I said that I really knew what was going to happen. The best thing I can do is assure you that we are continuing to collect the data and monitor it and make as many educated guesses based on it that we can.

Question: October 1 isn't that far off. We know the schools have mandated masking until then. Do you have a sense of what the criteria might be to relax mitigation efforts like that for schools? Is there a certain percentage of kids who need to have been vaccinated in order to relax that recommendation?

Dr. Madoff: There is guidance on that. We don't know what's going to happen after October 1. Until October 1, all students and staff in schools are to be wearing masks. After October 1, there was some discussion about allowing schools that have achieved an 80% vaccination rate among students and staff to relax the mask mandate. I think that's still up for discussion, but what would happen at that point is that only unvaccinated individuals would be required to wear masks after that time. This is still something that we're going to have to see how things are going before we get there.

Question: My question relates to an office building of 20 people in open space where 100% of the people are vaccinated and 100% of the people wear masks all the time. One of the employees came down with a symptomatic case of COVID. I'm trying to get advice on what do you tell the other 19 employees who were sitting with her? Do they get tested, and if they get tested, do they have to stay home from work until they get the test results? Do you close down the office?

Dr. Brown: The recommendations are the same whether whatever setting you're in. Essentially, what you want to identify is which people in the office could have had close contact with this individual and close contact is being defined as spending more than 15 minutes being within six feet of that individual. That 15 minutes is cumulative over that period of about 24 hours. If you think about a workday, would they have spent more than 15 minutes being interacting at a distance of six feet or less? The other piece that matters is whether or not people are vaccinated. There is no current recommendation for vaccinated individuals to quarantine. In Massachusetts we also do not have a standard recommendation for those individuals to get tested, but we do recommend that they monitor themselves for that 14 day possible incubation period. If they develop any symptoms, even mild symptoms consistent with COVID, they should get tested. People who are unvaccinated and who meet that definition of a close contact should actually quarantine at home and should not be out in public for the period of the quarantine. Quarantine length gets a little bit complicated. There's an option for getting a test at day five and if that's negative they can leave quarantine on day eight. They can leave quarantine on day 11 if they haven't had any symptoms, even if they haven't had a negative test. Anyone who becomes symptomatic needs to stay in quarantine for the full 14 days. Again, it's complicated. This is definitely something that the local board of health should be involved in as part of that case investigation and contact tracing and then making recommendations. In Massachusetts we really ask people to be very vigilant for the next 14 days after exposure and if they develop any symptoms that are consistent with COVID, even mild symptoms, we recommend that they get tested at that time. I will also say that despite all of the conversations about vaccine breakthrough disease, the data still show that in Massachusetts and nationally, people who are vaccinated get COVID at much lower rates than people who are unvaccinated.
**Question:** I'm curious now that home testing kits are available, for example, from Abbott Labs. What is the quality of these tests and what is the reliability of them for patients to use for at-home testing rather than getting formal testing from a testing center?

**Dr. Brown:** One of the problems is that there are multiple assays out there. The Abbott BinaxNOW at-home, the over-the-counter version is the same as the non-over-the-counter version and so probably the quality of the assay is pretty good. I'm less confident about the quality of the people doing their own assay at home. It's not quite as easy as Abbott would like us to believe. There are just innumerable other brands, and we don't have as much experience with all of them and so can't really answer that question. I think that over-the-counter tests done at-home testing are going to become more and more common and that people are going to increasingly use them. I think there will be some benefit to that. It does mean that somebody who is asymptomatic can test themselves at home and they don't have to go out somewhere, potentially exposing other people to get tested. There are disadvantages. One is that we don't have as much quality control over how that test is conducted. The FDA regulatory oversight of these is limited. They're approving tests based on very limited data and then, because they're at-home tests, there aren't really studies happening to see how they perform. Those are a few of the problems. Then the other problem is that most of those tests are not actually reportable to public health. In fact, there is no good way to report them to public health. In general, I am supportive of at-home testing. We at the state have a responsibility to try to help give people guidance about what they should do once they have a positive test, but the fact that it is not reported to public health means they don't get into the case investigation and contact tracing pipeline. We just talked through the office situation, and the complexity of identifying who is close contacts and then how long an isolation or a quarantine period should last is so complicated that it is very hard to make that simple and turn it into sort of an easy tool for people to use to kind of police themselves following a positive test. This is something we're going to have to deal with and address, but there are multiple layers that need to sort of be handled to make it a really good option.