December 2, 2020 MMS/DPH Call Summary and Q & A

On December 2, the MMS hosted its monthly COVID-19 conference call for physicians with the Massachusetts Department of Public Health (DPH). 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 were asked to provide an update on COVID-19 in the Commonwealth. They also responded to MMS member questions that were submitted in advance as well as those asked during the call.

DPH Update on COVID-19
Dr. Madoff remarked that the Commonwealth is in the middle of a second surge and is seeing more cases than Massachusetts had during the spring surge. On a daily basis, Massachusetts is seeing increases in hospitalizations, increases in ICU bed occupancy, and increases in the number of intubated patients. Dr. Madoff noted that at the same time, in general, we are not seeing the same severity of illness that the Commonwealth experienced during the spring surge. This is attributable to a number of factors including the fact that, overall, a younger population is being affected as well as improvements in medical care for infected patients together with the availability of newer therapeutics. Hospitals are beginning the roll out of monoclonal therapeutics for COVID-19. At least 11 hospitals have indicated the ability to infuse these products safely into patients meeting the EUA criteria. DPH has issued guidance for putting patients over the age of 65 and/or with a BMI of greater than 35 in the top tier to receive those antibody products. Dr. Madoff anticipates that providers will continue to hear more about monoclonal therapeutics as these therapies are rolled out.

Dr. Brown concurred that we are seeing concerning trends in Massachusetts. She added that although our case numbers are getting to points that are higher than what they were in the spring, there is also much more testing than back then, so the numbers include a surveillance artifact that is difficult to account for. The data are not showing that transmission is currently being driven by specific age groups or by specific transmission settings. Dr. Brown stated that we are seeing increases across the board in all age groups in all areas in all sectors, all settings and in all parts of the state. This is very consistent with what most other states across the country are seeing.

Ms. Milesky shared that the DCU field hospital in Worcester is opening on Saturday, December 6, at 7:00 a.m., and is anticipating taking transfers from both emergency departments and inpatient units from hospitals across the county. More information about the process for transferring patients is can be accessed at 508-334-4111. One challenge Massachusetts is facing in this second surge, that we didn't have in the first surge, is staffing. During the first surge PPE was a limiting factor, but Massachusetts was able to bring in staff from across the country to help support hospitals, field hospitals, and nursing homes. Those staff just aren't available now with COVID widespread across the country. UMass Memorial has set up a webpage for health
care personnel interested in helping and supporting the DCU field hospital. Individuals who are interested can visit Umassmemorialresponds.com to sign up to help staff, or take a shift at, the field hospital.

**DPH responses to questions received in advance of the call:**

**Question:** As DPH continues to prepare for the second surge in cases that may strain Massachusetts health care system capacity, please explain how the DPH Resurgence Planning and Response Guidance for Acute Care Hospitals (tiering system) may impact physicians and the patients they care for in the outpatient/community setting?

**Ms. Milesky:** In early November, DPH issued resurgence planning and response guidance for acute care hospitals. DPH contemplated the preparation of this guidance before we were in the second surge, as a resurgence was anticipated. The planning was done within the framework of the Phase 3 Reopening Guidance still being in effect for both hospitals and health care providers. The guidance established a regional planning process at the Department of Public Health at the Health and Medical Coordinating Coalition (HMCC) level. Massachusetts has six HMCCs. For the purpose of this planning process, the MetroWest and the Boston regions were combined resulting in five regions that have come together and who are meeting regularly to address capacity constraints within their regions. One of the things that DPH learned from the first surge when the switch was flipped to turn everything off was that, at that time, everyone in the state was at different levels in terms of the impact that the pandemic was causing. This regional process allows for an analysis of what’s going on in the region, the impact there, and provides an opportunity for the hospitals in the region to work together to be able to address some of those issues. Each hospital across the state was required to identify a senior leader with clinical and operational expertise and could also identify other individuals if they wanted someone else to participate. The hospitals come together on a regional basis. DPH is producing a regional dashboard of disease indices and capacity indicators that are reviewed, and responded to, regularly. Based on the data within that dashboard, DPH designates each region a color-coded capacity tier. There are 4 tiers ranging from Tier 1, which is gray, and indicates that measures suggest low-risk for health system assets or capacity constraints, all the way up to Tier 4, which is red, and indicates active ongoing constraints, and where DPH might potentially need to make some interventions in terms of closing elective services. The goal is to prevent that from happening by having the regions work together on an ongoing basis to be able to assist and support one another. The regions began the process by meeting every other week. Now, some regions are meeting daily due to the surge. Region 3 was raised to Tier 2 earlier this week because of some specific constraints there. Overall, it has been an extremely productive process where the hospitals are coming together, sharing situational awareness, and then offering possible solutions or interventions to be able to help support each other.

**Question:** Please update us on the status of vaccine planning in Massachusetts including expected vaccine availability timeline, who will be dispensing the vaccine, and who is in the initial priority group/s?

**Dr. Madoff:** Two vaccines have been submitted to Food and Drug Administration (FDA) for Emergency Use Authorization (EUA), the Pfizer vaccine and the Moderna vaccine. Both are messenger RNA vaccines, which are new platforms. Both of them showed very promising and frankly, remarkably similar results from their Phase 3 trials. I want to say upfront; I do not have access to any data that you all haven’t seen. The Advisory Committee on Immunization Practices (ACIP) has been meeting and discussing the vaccine roll out and deployment. The FDA meeting is on December 10. We expect to hear something very shortly after that and expect the initial doses of vaccine, the Pfizer product, to be available in the state within a few days of that
release if it all goes according to plan. As you may have seen, the British government approved emergency use of the Pfizer vaccine yesterday which bodes well for the FDA authorization going forward.

Massachusetts has stood up a number of workstreams regarding vaccination including an internal vaccine group and a vaccine communications group working on communicating with the public and providers about safety and effectiveness of the vaccine. There is also an external vaccine advisory group, on which the MMS has a representative. That body has met and formulated guidance that will be reviewed by the administration. Massachusetts is expecting initial doses of vaccine available as early as December 15 with quantities gradually increasing over time. Two doses are necessary. Initial doses will go to acute care hospitals, mostly due to the need for very cold storage of the vaccine. The plan from the National Academies, and from the ACIP, and likely from the Massachusetts guidance have first wave doses going to COVID-facing acute care health providers. The ACIP has announced that residents of long-term care facilities are also in the initial phase. Subsequent allocations will expand to Community Health Centers, large multi-specialty practices, and eventually, to all ambulatory care and primary care practices in the state. Shipping and handling will be being managed by McKesson and vaccine will be allocated and deployed by the DPH.

**Question:** What happens once someone is vaccinated? What changes and what does this mean for the public health measures currently in place,

**Dr. Madoff:** There are so many fundamental questions. What we know from the preliminary data that the vaccine prevents symptomatic disease and serious illness fairly effectively. What we don't know is whether asymptomatic infection or transmission is impacted by the vaccine. We believe there will be an impact, but we don't know that yet. As we learn more about vaccines, our guidance is going to change. Initially, our guidance on isolation and quarantine and the use of PPE is not going to change. The same for travel restrictions. In the initial months, the vast majority of the population is not going to be vaccinated, so we expect to see ongoing transmission. Hopefully, it will diminish, but that's going to be due to public health measures, like masking and distancing, not due to vaccine-induced immunity.

**Question:** When will physicians have access to vaccines to give their patients?

**Dr. Madoff:** This is probably not going to be until later in the deployment. Millions of doses will be needed to vaccinate the population in Massachusetts. If things go according to plan and vaccine production ramps up as it is expected to do, we expect to see availability hopefully in early spring, but not much before that.

**Question:** What public health measures and messaging are going to be needed even after Massachusetts starts receiving the vaccine?

**Dr. Madoff:** Essentially all of them. We're all going to need to be just as vigilant and just as cautious and use the same public health measures that we use now. Including testing and isolation and quarantine and all of the preventive measures that we're used to seeing until there's really wide availability of vaccine and immunity out there.

**Question:** Does DPH have information regarding vaccine costs?

**Dr. Madoff:** Vaccines are being provided free of charge by the federal government. In Massachusetts, health providers and patients will not need to pay for COVID vaccine. The federal government is also supplying an amount of the ancillary supplies, such as syringes and needles free of charge. The costs for the immunization administration and reimbursement around immunization are still being developed.
Question: How can we build trust in the safety of the Covid-19 vaccine?
Dr. Madoff: This is a challenge, not just with new vaccine, but with many of our vaccines. We, as providers, need to really encourage vaccine confidence and lead by example. We can do this by communicating that we will receive the vaccine and that we trust it for our family members who are also being vaccinated. We know from our long experience with immunization that the best messaging to a patient is your recommendation to get vaccinated. Knowing that you plan to receive the vaccine, and that you would also provide it to your loved ones is important. DPH is also developing a comprehensive communication strategy in the Commonwealth. We work very hard to convey truthful, transparent information about the vaccine. Of course, we are going to be carefully monitoring for adverse events, which is already built into the reporting systems. That messaging is essential from trusted providers.

DPH responses to questions asked during the call:

Question: Will public health guidance change for those individuals who are vaccinated?
Dr. Madoff: I don't think we know enough yet. There are different ways that vaccines can be effective. They can decrease morbidity, they can decrease the severity of disease, and they can decrease transmission. Those are not mutually exclusive categories, so we need more data to find out what happens with transmission of the disease in a setting where we have people vaccinated. Everybody's wish is that once you're vaccinated, you are protected for 10 years. Even it was for a year, if we could say that a person is really not at particular risk and therefore doesn’t need to quarantine, that would be great, but we just don't know the answer yet. That question also applies to people who’ve recovered from COVID. We just don't know how long people are immune for after recovery. Until we learn more, we all need to follow the current guidance.

Question: I've been getting a lot of questions from members in small private practices wondering about how they themselves and their staff are going to have access to the vaccine. They are concerned that people at similar risk with similar contact who are in hospital-owned practices that are out in the community are going to have easier access than they are. Is there any thought to how these small practices who are seeing patients will be able to get vaccine distributed to them? One thought that came up is if local hospitals could be encouraged to provide vaccine to providers and staff in their affiliated practices that are not necessarily employed by those hospitals.
Dr. Madoff: There is a lot of consideration as to how the initial deployment of vaccines is going to work. By logistical necessity, the first wave of vaccines has to go to acute care hospitals given the large indivisible quantities that are going to be rolled out and the need for low temperature storage. I think there's a lot of thought going into how exactly those doses of vaccine are going to be deployed. We certainly feel that they should be deployed not only to physicians and nurses and other direct patient care providers, but to others who are in contact with patients. How vaccine will be deployed to practices affiliated with hospital systems has yet to be fully worked out. I definitely hear your concern and I know that it’s been voiced by others. I will bring that back to the vaccine distribution group to discuss further.

Question: For someone who has a proven prior infection, does that have any impact on which vaccine they get or on the timing of vaccination? Is there information about vaccine efficacy for someone who is immunocompromised?
Dr. Madoff: To my knowledge, prior infection with COVID-19 really hasn't been studied as far as use of either of the soon-to-be released vaccines. Evidence of prior infection and evidence of immunity are not currently being considered as part of the vaccine allocation or distribution. There has been some research by people
who have thought about that and considered that as a possible way of allocating vaccine, but as far as I know that is not incorporated into any of the anticipated guidance or recommendations around vaccination. We haven't even seen the total data on the vaccine trials. I expect that those may become available even before the FDA meeting and we will all be able to look and see if there have been studies in that particular population. The other question was around immunocompromised patients. Again, we don't have any specific insight into that population currently. None of the vaccines have been specifically studied in immunocompromised patients. Based on the types of vaccine, I would not expect there to be contraindication to their use in immunocompromised patients, but these are things that we need to continue to learn more about.

Question: Do you anticipate that some of the vaccine will be available and administered in retail pharmacies and that we might be directing patients there?
Dr. Madoff: Yes. As you've probably heard, the retail pharmacy chains, CVS and Walgreens, are going to be deployed to long-term care facilities to immunize residents and staff in the very early phases of the vaccine roll out. The retail pharmacy chains are very much involved, and I expect that they will play an important role in providing vaccine to the public when we get into later stages of vaccination.

Question: I have two questions. First, given the large numbers of folks who are going to be getting vaccinated in a relatively short period of time, is there any special website being set up for physicians or providers to report adverse events? (Apart from a website that may be set up by the pharmaceutical company itself) Second, is, I'm wondering if people who have recovered from COVID, like myself, could have antibody levels checked prior to being vaccinated as a way to create a database going forward to see whether or not the types of antibodies or the amount of antibody response is different in people who had been previously exposed, notwithstanding that there some people who may be COVID positive and not be aware?
Dr. Madoff: We expect a very intensive and robust multitude of systems in place for monitoring vaccine adverse events. There is currently a vaccine adverse event reporting system or VAERS, which has long been available and will continue to be available for anyone to report a vaccine adverse event. We also expect additional systems to be in place for monitoring of this vaccine. These systems are being deployed at the state and federal level. The plans for these have not been completely finalized. Your second question is a great one. We expect that in many cases, immunization of someone who already has immunity to elicit a greater immune response following vaccination, but to my knowledge, those questions have not been answered with regard to the vaccines that are coming out now.

Question: We know that for testing, the most effective timing for testing for asymptomatic exposure testing is seven to nine days post-exposure. As a primary care office, we are running into challenges with patients and employers who do not know or understand this. When they go to DPH or the CDC website, they're seeing old guidance saying people should be tested as soon as possible. Are there any plans for an update to the public DPH website so that our guidance is in alignment and we are providing them with the best information?
Dr. Madoff: Your point is totally fair, but it's more complicated than that. If somebody is only exposed to COVID on one day, then we know the best time to test them is seven-ish days maybe even a little bit earlier than following that exposure. But, if they've been exposed over multiple days, which is more often the case then testing as soon as possible still actually makes more sense. The landscape is changing. The more recent guidance that we put out around earlier release from quarantine pending and negative results from the tests taken on day 8 or later. The CDC has just come out with more interesting guidance around several different possibilities for shortening quarantine, which may change all of that. So, I would expect that our guidance is
going to change. However, I don't think it's as simple as saying somebody should just get tested once, between 7 and 9 days after they were exposed because that exposure period often occurs over a much longer timeframe. That is very helpful feedback though and I will definitely take that comment back in and add it to our discussions around how we might change our guidance.