



MASSACHUSETTS MEDICAL SOCIETY

Every physician matters, each patient counts.

June 25th MMS /DPH Call: DPH Update and Summary of Q & A

On June 25, the MMS hosted its eleventh, and last scheduled, COVID-19 conference call for physicians with the Massachusetts Department of Public Health (DPH). Should the circumstances surrounding the pandemic warrant, future calls will be scheduled. Dr. Larry Madoff, Medical Director of the DPH's Bureau of Infectious Disease and Laboratory Sciences and Kerin Milesky, Director of DPH's Office of Preparedness and Emergency Management, participated. Member questions to DPH officials were both submitted in advance and answered during the call.

Dr. Madoff provided an update on COVID-19 case numbers and testing in the Commonwealth:

- On behalf of DPH, Dr. Madoff expressed appreciation for the opportunity to hear from physicians and for all of the hard work that physicians in the state are doing during the pandemic.
- The Commonwealth's COVID-19 dashboard is now 27 pages in length and includes a lot of information every day. In addition, on Wednesdays, additional data are provided, including city and town breakdowns and some of the information on individual long-term care facilities.
- As of today, there are 226 newly reported cases bringing our total to 107,837 confirmed and probable cases in the Commonwealth. 25 new deaths were also reported today.
- 10,318 molecular tests that were done and roughly 1,000 new antibody tests were performed.
- Massachusetts reopening metrics, which are also reported on the dashboard, continue to be largely favorable. Our percent positive tests continues to trend down and is now at 1.8% based on a seven-day moving average.
- The number of hospitalized patients also continues to fall. As of June 24, there were 905 hospitalized COVID patients in Massachusetts hospitals. There are still four hospitals that are continuing to work at surge capacity. This is also way down from our initial number, certainly, at the peak.
- The three-day average of COVID-19 deaths is also continuing to trend down. We are now several weeks into the initial phases of reopening-- we're continuing to see favorable metrics.
- The results of the screening testing that was done in response to the mass gatherings showed about 17,000 people were tested and there were only about 400 new positives that were detected. The rate of positivity in those settings was not far off from our overall positive test rate that we're seeing in the state as a whole, which was somewhat reassuring because there was, of course, concern that the mass gatherings might result in new cases. That, of course, may still happen as this 2 days of testing was relatively early after some of the large protests occurred. If the trends do not continue to be favorable or we see upsurge in cases, we will consider other measures to ensure that the case transmission goes back down.

Ms. Milesky provided an update from DPH's Office of Preparedness and Emergency Management:

- In total, as of this week, DPH and MEMA have made 6,727 deliveries of PPE and supplies to health care facilities and others across the Commonwealth with 16.8 million pieces of PPE being pushed out since the pandemic began,

- Ventilators. We received ventilators from the Strategic National Stockpile and then also received ventilator equipment from our colleagues in New York and New Jersey. That allowed us to push out a total of 679 ventilators to hospitals in Massachusetts to support the surge. The highest use that we recorded on any day in terms of ventilators was 1,100.
 - DPH OPEM and MEMA are now planning for what we might need for the future. As of today, we have collected back those 679 ventilators from the hospitals who were utilizing them and examining them and decontaminating them. We have returned the borrowed ventilators to New Jersey, and next week the ventilators borrowed from New York will go back to them.
 - We are now in a position, in terms of events, of determining what we want as a Commonwealth for a stockpile and are making plans through our Operational Services Division, which is our procurement arm, to purchase 650 ventilators so that we can have them on hand for the Commonwealth should they be needed and not be in a position, as we were several months ago, of needing to completely rely on assets from the Strategic National Stockpile.
- Remdesivir: We've also stood up operations to be able to allocate shipments of remdesivir that we've received from the federal government for our hospitals across the state. And Drs. Bharel and Madoff put together a remdesivir working group, which helped provide guidance on what would be an equitable distribution of remdesivir to hospitals. What we've landed on is that we are taking a proportion of the seven-day admissions of COVID positive patients and utilizing that as the allocation strategy. To date, we've distributed 31,952 doses of remdesivir to hospitals and, just yesterday, learned that we will have a final allocation next week of somewhere in the vicinity of 5,000 additional doses that we'll be able to distribute.
- In terms of the future, DPH is doing a lot of work now around PPE-demand modeling. While we have seen some relaxing of the shortages that we had experienced this spring, we are still seeing some challenges around being able to procure certain sizes of N95 masks, particularly extra small and small masks, and some challenges around procuring gloves. The Department is working very hard on that. I'm sure some of you may be experiencing some of the same challenges. The Department and the Commonwealth has done a lot of work with manufacturers that are pivoting their work. If any of you are having challenges with your traditional vendors, I would direct you to the reopening webpage. And there's a banner across the top of mass.gov, where you can find a list of those manufacturers that have pivoted their operations to PPE who might be another resource for you.
- The Commonwealth has done a tremendous amount of procurement. We do have many months of PPE that are on hand now in the event that there is a second wave and we need to respond in a similar footing as we did over the last several months. DPH is monitoring that closely, and then also doing the work to determine, at least on the public health and health care side, what we want to maintain as a stockpile going forward and what strategies there might be to ensure that we are cycling that PPE so it's not just sitting on a shelf, but partnering with some health facilities to be able to do that.

Dr. Madoff's responses to questions the MMS submitted to DPH in advance of the call.

Question: *Please provide a brief summary of DPH's COVID-19 Health Equity Advisory Group's findings and recommendations?*

Dr. Madoff: This problem, of course, is not unique to Massachusetts, but is one that has been seen throughout the US- the disproportionate impact of COVID-19 on populations of color. At a very high level, Black non-Hispanics represent about 7.2% of the Massachusetts' population but double, 14.4% of the cases, in terms of the proportion of COVID cases seen in Massachusetts. Similar, even more striking distribution in Hispanic populations, which represent about 12% of the Massachusetts population but more than double the proportion of cases at 29%. This is quite striking. This disproportionate impact has been seen elsewhere. Numerous factors account for that, and as a country coming to terms with systemic racism and how race

relates to health care. In broad strokes, the first category of recommendations is on data and metrics. Race and ethnicity are missing from much of our data and this has, frankly, been a problem not just with COVID-19 but with many of the data that we collect at DPH, is that we are missing key demographic information, including race, ethnicity in many of our reports. I would remind MMS members and other providers that a lot of these data come from you when you fill out either case report forms, which has not been a huge part of our COVID reporting, but, more importantly, lab forms, which are often missing these data and are the main source of our data in terms of COVID 19, so we would ask you to be mindful of that in your reporting. Another category is around COVID-19 mitigation -making sure that disadvantaged populations have equitable access to PPE, to housing, to care, to community safety and that our workforce is diverse and culturally appropriate, are all measures that were raised by the Advisory Group. The third broad category was community engagement and support and making sure that we adequately and equitably reach out to the most affected communities and that there is an understanding of the risks and how to improve both the protection of the communities and access to care and treatment. Those were the major findings. The full report, which contains a lot of very good, but troubling, data and also the findings and recommendation of the group.

Question: *What are DPH's primary concerns as the Commonwealth continues to reopen? Infections are soaring in California, Texas, Florida, and Arizona numbers – what are your thoughts on why those states are seeing increases and what can MA do to prevent or minimize a resurgence of cases as reopening progresses?*

Dr. Madoff: California, Texas, Florida, and Arizona are seeing really alarming numbers of cases. These were areas where there really weren't a lot of cases, at least in some of these states, early on in the outbreak. So, seeing them now as these states reopen, of course, is alarming. It does definitely give us pause at DPH and it is why we are so carefully monitoring the metrics of the health of Massachusetts in the case numbers and hospitalizations of COVID-19 along all kinds of other data we have access to, for example, hospitalizations, not just census numbers but also daily hospitalization rates for COVID-19 and the use of ICU beds are things that we monitor carefully. Of course, we are concerned that reopening could lead to a resurgence in cases and we're grateful that that hasn't happened. We believe that some of the other measures that are taking place account in part for that, for example, social distancing measures, attention to hygiene, and attention to crowd control, and so forth, at facilities that are reopening. I do see a widespread use of facemasks which we believe, and there's increasing evidence to support, does reduce transmission. I attribute some of our success to the widespread use of facemasks. Of course, our contact tracing efforts are essential. As the case numbers decline, we are able to actually reach out to a greater proportion of cases and their contacts. I believe this effort also is helping because we're able to isolate and quarantine appropriately as the outbreak moves forward. Personally, I remain worried and concerned. We are all mindful of the possibility of increased case numbers or even of the feared second wave that could happen and we're keeping a close eye on things and doing what we can to reduce the risk. We count on you, as providers, to be alarm bells and to notice if you're seeing cases or clusters or other items that we should be concerned about. So please do stay in touch with us.

Question: *The Commonwealth launched a revamped testing website, "Get Tested MA" Are there any notable/new changes to DPH's testing recommendation guidance for molecular testing?*

Dr. Madoff: There are not major changes in our testing recommendations. We are still prioritizing testing for symptomatic individuals and even those with minimal symptoms who, with their provider, should and we hope, decide to get tested and, if symptomatic, to isolate while awaiting testing results. Our second highest priority for testing is asymptomatic contacts of cases and the Contact Tracing Collaborative and local boards of health are recommending that all such contacts be tested as soon as possible. We recognize that, given the natural lags in the system, the time it takes for a test result to come back positive, the time it takes for that to get reported, the time it takes to engage with contact tracing usually a few days has elapsed. That's plenty of time for an asymptomatic contact to have become virologically positive, so that's what we do recommend. Now, just to remind people, even if the PCR test on an asymptomatic contact is negative, that individual still needs to be quarantined for the full 14 days since their last exposure to the positive case. Moving down the

categories of testing. Other people who should consider testing include asymptomatic individuals who had high-risk situations where they believe they may have been exposed. These include, for example, individuals who participated in large gatherings or who continue to participate in large gatherings. Other people who in consultation with their providers feel that they're at increased risk of exposure should be tested even if they're asymptomatic. Others who we are prioritizing testing for are people who are entering high-risk settings so, for example, people who work in long-term care facilities. We are going to be rolling out recommendations for routine testing of staff in long-term care facilities, particularly staff who have not previously tested positive. One piece of guidance that is in our testing document is that we recognize that people who have a positive test can remain positive for a prolonged period of time. In one study from South Korea, there was an individual who was positive, remained positive for, I think, 80 days after their initial positive test. So, we don't recommend retesting at least within six weeks of resolution of COVID-19 in individuals who are asymptomatic. That's an important addition to our testing guidance.

Question: *Are there any notable/new changes to DPH's testing recommendation guidance for antibody testing?*

Dr. Madoff: I think there's some good news in the antibody testing front. The best news in terms of antibody testing is that in the initial days of antibody testing, it was a little bit of a wild west and there were a lot of not very good lab tests out there that were not very sensitive, not very specific. The FDA has reigned those in quite a bit and the large commercial testers have brought on board what I think are high-quality tests, in other words, tests that have specificities that are greater than 99%, that do not cross react with the community-acquired respiratory coronaviruses, and that, therefore, have a reasonable sensitivity and specificity and good predictive values in community settings. I think it's still important to remember that antibody tests are limited in what they tell us. As far as I know, none of the antibody tests that are commercially available report on neutralizing antibodies, so they're not necessarily indicating protective antibody. We continue not to know whether the presence of antibody correlates with protective immunity. I hope that we will have answers to those questions soon, but at this point in the absence of knowing that, it's hard for me to understand what the clinical indication for antibody testing would be. I think it can somewhat reliably answer the question of whether someone has had prior infection with COVID-19. We really don't know the extent, duration of immunity that either infection or antibody confers beyond sort of the immediate short-term following infection. There are some indications. For example, children with the multi-system inflammatory syndrome, many of those children who have that syndrome related to COVID are actually virologically negative at the time that they develop the syndrome. It's thought to be an immune response to the syndrome. Therefore, an antibody test is useful in attributing that syndrome to COVID in making that diagnosis. There probably are some other limited clinical indications for antibody testing, but we still do not generally recommend it.

Question: *The testing rate in Massachusetts is significantly below the Commonwealth's reported ability to conduct 30,000 tests each day – the data show Massachusetts has been using roughly one-third of that capacity what explains the difference? Does DPH have any suggestions on how to improve the turnaround time for COVID test results?*

Dr. Madoff: It is true that we have the capacity in Massachusetts now, between our state lab, our commercial testing, testing that's available in health care facilities, to test tens of thousands of individuals daily and yet we are only currently testing about 10,000 people on average on a daily basis. I think this reflects, namely, decreased demand for testing. Certainly, there are many fewer symptomatic individuals who are requiring testing and, therefore, fewer contacts of those individuals who require testing. Where I think we are likely to see is increased testing as it becomes routinely available in certain settings like workplaces and colleges and universities. As the reopening continues and people return to workplaces, we're going to see more testing that's performed as part of workplace surveillance and school college and university testing. So, I do expect to see increases overall and in our testing. Unfortunately, have an answer for the question about turnaround time. The turnaround time depends on who's doing the testing. Unfortunately, some of the commercial labs

have long turnaround times for their test results. I assume that, as their testing capacity improves, as their systems and logistics improve because turnaround times will also decrease. I would urge you, as providers, to find testing facilities that have more rapid turnaround times and use them because there are differences between commercial testing sites. I know that, here at the state lab and at the Broad Institute that we partner with, turnaround time is pretty speedy, certainly within a couple of days. There's no reason that a PCR test can't be turned around more quickly.

Dr. Madoff then mentioned results from a recent clinical study: One other thing which wasn't on the questions provided in advance, but I think that it's an important clinical development, was the results of a large British study demonstrating the effectiveness of dexamethasone in treatment of severe COVID-19. This was a large randomized controlled trial, over 2,000 participants. Participants received 6 milligrams per day of dexamethasone. It was given to patients who were hypoxic and/or mechanically ventilated. The results were pretty strikingly positive for recipients of dexamethasone, I believe, a 30% reduction in mortality. So, it was the first clinical pharmacological intervention to show reduced mortality and also a reduced duration of illness in the recipient population. Unfortunately, it was first revealed by a press release, which just gave a broad outline, but there is now a manuscript available for review. In reviewing the manuscript, what was interesting is that there was not a benefit to the study drug given during the first seven days of illness. It was primarily in the late phases of illness, which you can think of as sort of a non-viral part of the clinical disease. Also notable in that study was that there was not a clear benefit to those over age 70 who were recipients. This is a British population. There were a lot of details that are available in the paper, but those were a couple of the more interesting points that I wanted to mention on this call today.

DPH officials' responses to questions the MMS received from physicians during the call:

Question: *There's a tremendous fear out there in the community. A lot of it is not rational. For example, I already know that, if I put a soda bottle on the shelf for a week and touch it, I'm not going to get the virus, but people still don't believe it. They're looking for somebody on high like the health department to for guidance. A few weeks ago, the WHO recommended that senior citizens and people at risk use medical masks.. I know MMS put out a list of companies and, of course, the disclaimer naturally. Is there some way to vet a couple companies that sell masks?*

Dr. Madoff: I think those are both good comments, and I thank you for them. I don't know that we have the capacity to evaluate commercial vendors who are providing PPE. In the Commonwealth, we are not recommending the use of medical masks outside of the health care setting.

Question: *I've been told that there's different tests being offered at different locations. Has there been any evaluations as to the tests that are being done and if there are differences between the tests as far as positive predictive value in the different areas that they're testing the population?*

Dr. Madoff: Thank you for that question. There is a pretty big universe of tests that are available. I would say there's three broad categories. The first category would be the real-time reverse transcriptase PCR, which is the molecular test, if you will, for a detection of viral RNA, which is a highly sensitive and quite specific test that indicates the presence of the virus. Of course, in real life, the testing sensitivity doesn't match what's seen in a lab validation and that is what is generally on the package insert of each test. By the way, you can look at it/download the package insert of any FDA-approved commercially available PCR test and see what the performance characteristics of that assay are. There are many of them and they vary. In general, the laboratory performance of all of those tests' sensitivity exceeds 99%. and the specificity does as well. In real life, we know that, given the timing of testing the actual physical testing that's done, the sensitivity can be much lower. The Infectious Disease Society recommends a second test if a PCR is negative in someone in whom COVID is highly suspected. So, there's both the laboratory performance of a test and the real-life performance. All of the tests that are out there are FDA approved and do have pretty good performance

characteristics. Some of the more rapid tests, and there are a lot of them now have a somewhat lower threshold in terms of detection of virus. They're sensitive and specific in use but somewhat lower than the laboratory-performed tests that are out there.

The second broad category of tests that's available is antigen detection. I have to say, I'm much less familiar with them. These are similar to flu diagnostics or strep diagnostics. The antigen tests are highly specific but less sensitive, so a negative test really needs to be confirmed with a PCR in my mind. These tests are good if they're positive and not so useful if they're negative. The third category is the antibody test, which I've spoken about already. Again, you can look at the performance characteristics of any given assay by downloading their package insert.

Follow-up: When would you recommend to follow-up testing be done? Is there any protocol as to how many days after if it was negative?

Dr. Madoff: That's a good question. I don't have the IDSA guidelines in front of me. In general, by the time you get the first test results back, it's enough time to do a second test.