May 14th MMS /DPH Call: DPH Update and Summary of Q & A

On May 14, the MMS hosted its eighth COVID-19 conference call for physicians with the Massachusetts Department of Public Health (DPH). Commissioner Monica Bharel, 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.

Commissioner Bharel provided an update on COVID-19 in the Commonwealth:

- The Commissioner expressed her appreciation for the opportunity to be on the call with MMS. DPH is committed responding to physician questions on COVID-19. DPH continues to learn more each day. The science is rapidly growing, and we are all doing our best collectively to stay on top of and share the latest information.
- As of May 14, the Commonwealth reported 80,497 total confirmed cases, 5,315 confirmed deaths, and 410,032 total patients tested to date. More details are available on the COVID-19 Dashboard.
- The end of April was Massachusetts’ peak followed by a very long time of plateauing for several weeks. In the last few days, there has been a slight decline, which DPH is following very closely as it has a little bit of a sawtooth pattern. It is possible that Massachusetts is now on the other side of the peak.
- On May 11, Governor Baker announced a “Four-Phase Approach to Reopening Massachusetts”. The Reopening Advisory Board developed Mandatory Workplace Safety Standards to reduce the risk of COVID-19 transmission as employees and customers begin to return to workplaces during the first phase of reopening. These standards, which include many of the concepts those in health care are familiar with, are applicable to all sectors and industries that will be open in phase one. The new workplace standards include requirements for social distancing, hygiene, staffing and operations, and cleaning based on the data and evidence that is currently available about COVID-19 and how to contain its spread.
- As the state looks towards the opening, DPH’s first priority is to be able to ensure the Commonwealth has the health care capacity that we need.
- DPH released revised COVID-19 testing criteria on May 13. The guidance expands testing recommendations for COVID-19 in commercial and clinical laboratories including molecular testing of all COVID+ close contacts, regardless of symptom status. The expanded criteria allows DPH to increase its capacity to do both testing of presumed asymptomatic individuals as well as to better understand this illness and help individuals isolate as needed.
- DPH has issued a notification on pediatric multi-system inflammatory syndrome (PMIS) and is requiring all clinicians under their existing reporting structure and authority to report the cases to DPH so the Department can begin to better track and understand this illness. In New York, they've reported over 100 cases. In Massachusetts, DPH currently has anecdotal knowledge, from pediatric clinicians, of less than 10 cases.
DPH officials’ responses to questions the MMS submitted to DPH in advance of the call.

**Question:** We have heard that the federal government sent remdesivir to some MA hospitals, but not others and some hospitals decided to share the supply using DPH as the agent for distribution. If this is the case, with regard to remdesivir use and distribution -How does DPH allot doses? Will there be enough to meet the need? Are controlled studies still happening and, if so, do they include placebo controls? Is DPH impressed with the evidence that remdesivir is a helpful/effective treatment?

**Dr. Madoff:** I want to back up for a minute. We were heartened by the news from Tony Fauci about the improvement in clinical status in patients who received remdesivir in the NIAID-sponsored clinical trial. The outcome of the trial showed decrease in duration of disease from an average of 15 to 11 days. We learned that there was not a statistically significant difference in mortality, but that the study was, we believe, stopped early because of the clinical improvement that it showed. As far as I know, we still have not seen the data from this trial and data from other trials of remdesivir have been underpowered or haven’t shown a benefit from its use. I just want to let you know that we certainly are waiting for additional information about the benefit of remdesivir, and how it works, and who it would be most beneficial for.

With regard to the distribution of remdesivir in Massachusetts. We learned about a week ago now that the manufacturer, Gilead, had released its remaining supplies of remdesivir after the FDA EUA was issued and that these doses would be distributed by the federal government. Some of that supply was released to hospitals to, really, a handful of hospitals in Massachusetts. DPH worked with these hospitals to redistribute the remdesivir to all hospitals in the state. We convened a working group of infectious disease specialists, critical care specialists, and ethicists, and, under the Commissioner’s guidance, developed a system for allocating the supplies of remdesivir that have come to Massachusetts. The system is based on the numbers of COVID-19 patients at each hospital such that the doses of remdesivir would be distributed according to the numbers of COVID-19 patients at each of the hospitals throughout the state. As of today, DPH has distributed somewhat over 900 courses of remdesivir to most of the hospitals here in Massachusetts- 58 hospitals. So, they’ve actually received doses of remdesivir thus far with this allocation system. DPH is really grateful to the hospitals and the people on this working group who are providers in the state for working with us closely and helping us come up with what we think is an equitable system for distributing what, so far, is a scarce commodity. We expect that the demand for this will continue, as it is the only treatment, thus far, that’s been shown to have benefit in treatment of COVID-19.

**Question:** Where are the new cases in Massachusetts coming from? From the daily dashboard, it looks like 25% of all new cases are coming from LTC, but what about the other 75%? Are they health care workers and their families? Are they grocery store workers? Are they people not social distancing adequately?

**Dr. Madoff:** I would say is that there is a lot of information that's available on the dashboard that I would ask you to look at. We released, just yesterday, the distribution by cities and towns in Massachusetts. It is apparent that much of the burden, as was mentioned, is in long-term care facilities. We’re also seeing a disproportionate burden in areas that are the most population dense in the state. That's really not unexpected and something that's been seen everywhere but has been particularly hard-hitting some of our urban areas and more congested parts of the state. Beyond that, we really don't have answers at this point or more precise demographic information, and that's something that we are actively working on and hope to learn more about. We are heartened by the fact that we appear to be past the peak of our case numbers. The case numbers, at least, have shown a persistent trend downward. Certainly, our rate of hospitalization and the occupancy of hospital beds has continued to fall. I think that that's attributable, in large part, to the social-distancing measures that we're all living and working under during these very difficult circumstances.
**Question:** It has been reported in news outlets that the Covid-19 virus has mutated with several strains that are more infectious than the original Chinese strain. The east coast of US has a European strain and the west coast of US has Asian strain. Is this true? Also, will that affect the effectiveness of the vaccines that are already in phase one trials since they are using the RNA coding of the original Chinese strain? Will new vaccines have to be developed that incorporate the new RNA codes?

**Dr. Madoff:** The data I've seen do suggest that. Beyond that, and speaking to virologists and molecular epidemiologists, I think it’s hard to make further inference from those data. Some people have suggested that maybe the European strain is more transmissible, accounting for some of the large east coast outbreaks, for example, New York City and state, metropolitan New York. I think there are so many other factors at play that I would be hesitant to attribute that to changes in the virus. It would really be hard to tell- to make those conclusions, and there is so much new information that comes out every day that I would be hesitant to draw that conclusion from the data.

One of the corollary questions to that question is whether vaccines will have to be developed to incorporate the new strains of virus. Again, I think that that would be getting way ahead of where the science is at this point. I will say that, while we have seen some genetic variation in the virus, it has not varied a great amount. The variation that we’ve seen does not appear, at this point, to be changing the antigenicity of the virus, at least as far as we can tell. This is something that is likely to be the subject of intense scientific inquiry, and we should all stay tuned as this data develop. I always have to sit back and just remember that this virus is only a few months old, and there are still viruses that are much older that we can't even answer those questions for.

**Question:** With regard to PPE, we understand DPH’s role is to “bridge” PPE needs. Are you seeing any improvement in the supply lines, and does DPH anticipate serving an ongoing supply role for PPE moving forward? Do you have advice for practices that may expand operations in the coming weeks?

**Ms. Milesky:** We do have a resource process set up at the department to be able to support PPE and other supply requests from health care facilities in the light of the severe shortages that you've all been working through. Just to give you a sense of what our little unit has done since it was stood up and received our first Strategic National Stockpile (SNS) assets on March 12. We've pushed out on 2,200 deliveries to hospitals, nursing homes, and other health-care providers. 665 ventilators have gone to hospitals. As Dr. Madoff mentioned, we've made delivery to 58 hospitals of the remdesivir, that we were so fortunate to receive in this state. So, some incredible work there from all of my colleagues at the Department that is outside of our normal day-to-day work.

With regard to what we are seeing in terms of the supply chain. We are, in fact, seeing some loosening of the supply chain. Much of this is anecdotal, but particularly, among larger facilities, we are absolutely seeing fewer requests coming in for PPE resources. I would say that there is still a scarcity of gowns and N95 respirators that we are still very aggressively working with our procurement team to be able to source, so I'm quite certain that hospitals and other facilities are seeing the same. I want to encourage and remind everyone about the Battelle decontamination system equipment that we're so fortunate to have available to us in the state. So, as you're looking at ways to be able to mitigate the shortage of N95 masks, certainly thinking about contracts with Battelle, if that's an option for you, may help to address the shortages of N95. We are also following, very closely, those manufacturers that are pivoting their operations and we have seen some movement around gowns, so I am hoping, as we're all looking at forthcoming information around reopening, that there'll be some additional information that's able to be shared around some of those pivoting manufacturers. Another question that's come up, and we have received some anecdotal feedback, is around price gouging. That there are masks and other items available, but they're at a cost that's quite a bit higher than what the market has demanded in the past. We would certainly encourage any of you, if you believe that there is price gouging practices going on, to report that to the Attorney General's office so that they can follow up and do any necessary investigations.
DPH officials’ responses to questions the MMS received from physicians during the call:

**Question:** A week ago, I believe I asked if the DPH was collecting data around the numbers of presumptive deaths. And the next day in the Boston Globe, they reported that you were, and so I wonder if you have any numbers on that yet. And my second question is what is the R0 now for Massachusetts as we head into a time when we’re thinking about opening up? Some epidemiologists have suggested that an R0 less than 1 is the time to do that. I just wondered where our R0 was over the last couple weeks?

**Dr. Madoff:** We are working on looking for deaths outside of those that have been recorded as COVID deaths, but we don't yet have results on that. Stay tuned, and we will try to answer that maybe in the next week's call. The question about the transmission coefficient. During an outbreak what the transmission is also an interesting and challenging one. I was just on a phone call with someone who is a real epidemiologist, a card-carrying academic epidemiologist. They, too, are trying to grapple with that question and haven't been able to precisely answer it. I think that as our numbers of cases have, on average, declined, if we look at it as a moving average over days, then I think it's safe to say that R0 is less than 1, at this point, as defined by a falling number of cases. Beyond that, the precise estimate of ours is hard to make. I think that is one of the criteria that many have stated for the reopening is to have falling numbers of cases, falling hospitalizations, and reduced levels of infection in the community. How exactly to calculate R0 is a question that's challenging even for people who better epidemiologists are than I am. I'm just going to have to say that I think that it's less than 1 at this point, but I can't give you a more precise number.

**Question:** I'm at a primary-care office, and I'm getting questions from family members that are out of state who want to come to Massachusetts to see their elderly parents. What is the recommendations that we should be giving them? And my other question is, what exactly do I need, as far as PPE, in order to reopen my practice?

**Dr. Madoff:** The question about coming from another place to visit your elderly parents. I think that all of us would approach that quite cautiously at this point. I'm sure that the last thing that a family member would want to do is risk exposing a vulnerable individual. Anybody in that situation should be very cautious and might want to, perhaps, quarantine themselves, or at least separate themselves, from a vulnerable individual for a period of time prior to coming into close contact with them. That would be my advice to a family member who is going to be approaching an elderly relative regardless of whether they were coming from out of state. We do still have a recommendation from Massachusetts that anybody coming from out of state quarantine for 14 days.

In terms of the PPE required to open. You, of course, know your patient volume and what you would need to do. With regard to what kind of PPE you would use ideally and what's acceptable in the current shortage situation, in a health care situation, any encounter, certainly the provider should be wearing, at a minimum, a surgical face mask. In most situations now, where COVID is widespread in the community, and where it's possible that any patient could have COVID, certainly, someone who is seeking health care, I think it would be reasonable to also wear eye protection during any patient encounter. In an exposure situation, certainly if seeing an ill patient, or perhaps any patient, the patient should also be wearing face coverings at least as much as possible. That would also enhance the level of protection. Beyond that, obviously, hand hygiene is extremely important and something that we should be routinely practicing. Those would be the routine patient-management expectations in an office practice for someone who doesn't seem to have COVID and for which an aerosolizing procedure isn't happening. I know it's still challenging to get PPE. Ideally, fresh face masks should be obtainable for each encounter, and that's something that we're certainly looking forward to having. For the situation where a patient has COVID or COVID-like symptoms, CDC guidance suggests that a respirator, such as an N95 mask that's been pit tested, in addition to a gown, gloves, and eye protection. Again, this is what we would ideally plan to have and hopefully, we're beginning to see supply chains loosen up for PPE.
**Question:** Are there any research studies that are happening right now in Massachusetts, and/or surveys that are being conducted? And do they need IRB approval?

**Dr. Madoff:** Thanks for that question. As you know, Massachusetts is home to a wealth of academic institutions. We, at DPH, are only aware of some of the research that’s going on. Some of it is being done collaboratively with DPH and many, many other research studies are being done in health care institutions by academic colleagues at the universities and other institutions of higher education throughout the state. There certainly is some work going on here at DPH either that we had instigated or are collaborating with others around. Anything that is defined as research, research that is beyond just public health surveillance activities that we perform ordinarily that we need to gather strictly for public-health purposes, is subject to approval by an institutional review board (IRB). DPH has its own IRB. Several studies have been reviewed and approved by our IRB and many other investigations that are going on throughout the state have been instigated or approved by individual IRBs, for example, at a hospital or hospital system, or educational institution. We are only aware of some of them. There is also, here in Massachusetts, an organization that was started a couple of months ago called the Massachusetts Consortium on Pathogen Readiness, I believe, which has been formed by many of the hospitals and academic institutions in Massachusetts, including Harvard. That organization has been a really useful consortium for combining and collaborating on projects that are all over the map, in terms of the epidemiology, serology, virology, molecular epidemiology. That’s been a very worthwhile organization that DPH actually participates in and is part of. One of the ways that organization works is by allowing for the sharing of biological specimens (samples, and sera, and virus) that have been obtained throughout the state. It allows all of the participating consortium members to be eligible to use those items in a cooperative way. So, there is a great deal of research going on in the state. DPH is privileged to be part of some of it and, of course, we are doing a great deal investigation that's part of our public health work.

**Question** My question is, as people, patients, start to think about going to healthcare providers in person, I realize this is a little premature, but one question that’s coming up is access to institutional specific nosocomial COVID-19 infection rates. I'm wondering if you might direct me to a source for that information, even statewide?

**Dr. Madoff:** You are looking for information beyond just how many cases of COVID have been hospitalized in an institution. But for health care associated infection (HAI) rate at institutions among health-care workers and patients, but particularly among the patients. To my knowledge, we don't have that information at a specific level. Now, we do track actively the numbers of patients in the hospital, we track all cases reported of COVID, but even understanding what that rate is very difficult because in the setting where we are seeing so much COVID in the community, we're coming up to 80,000 just lab-confirmed cases in the state, it's not usually clear where somebody gets COVID, regardless of whether they're a health care worker. We are certainly aware of clusters and this has been particularly a problem in long-term-care facilities, as you know. Some of that information about long-term-care facilities that have cases of COVID is posted on our dashboard. We have not yet compiled nor have clear answers to HAI rates and I'm not sure even how we would find those data at this point. Certainly, there are examples of it that we've seen, where health-care workers have become infected, we believe, on the job. Those were more apparent early in the outbreak, when there was no evidence of community-level spread, but at this point, it would be really hard to even figure that out. We do track the numbers of health care workers as best we can when we find a positive test result. Each of the occupational health services at hospitals keeps track of their health care workers who are either exposed or infected, but I don't believe we have, or are likely to be able to come up with, very good estimates of HAI in this setting -it's one that we will continue to work on.

**Question:** With the new information about the pediatric multi-system inflammatory syndrome associated with COVID, similar to Kawasaki disease, what we should be looking for, especially out in the community?
Dr. Madoff: I'll start by acknowledging that I'm not a pediatrician and that this syndrome is new to all of us. We really just became aware of the existence of this syndrome, perhaps a week ago, when an pediatric intensivist group in the UK released an alert that they were seeing some cases of this syndrome. I can tell you what little I know about it. First of all, the context is that COVID, at least symptomatic or severe COVID disease, fortunately, appears to be quite rare in pediatrics and represents a very small proportion of the cases that we've seen to date in Massachusetts and in the US, which is a good thing. These cases, as you noted, appear, perhaps, to be a post-infectious syndrome and perhaps an immune-mediated phenomenon. Again, because it's only in the New York experience, about 30% of the patients who have had a compatible syndrome were PCR-positive for SARS COVID-2 and the remainder had detectable antibodies. Since we know viral shedding persists for quite a while, it suggests that people with this illness, perhaps, are having a late response to COVID rather than an acute manifestation of the disease. The alert that DPH just sent out includes much of the clinical information that you're asking about. The syndrome is said to have features that overlap with both Kawasaki disease and toxic shock syndrome. The patient population is said to be somewhat older than a typical Kawasaki population, which is generally quite young. Fever is a pretty common feature, which, of course, is the common feature in pediatric illness in general, but inflammatory markers are notably elevated throughout, many inflammatory markers that are seen beyond what are usually seen. Coagulopathies have been seen. Myocarditis is a relatively common manifestation. Rashes are said to be common. Then, shock and end-organ dysfunction is part of this. As the Commissioner mentioned, at this point, we have less than 10 cases in the state that meet this very broad case definition. Probably, some of those are not related to COVID. Of course, the other criterion for inclusion in this is the absence of another known etiology for the syndrome. So, someone who is having bacterial sepsis, for example, could have many of these manifestations, but not fit the case definition. This is such an area of active work, and I would be hesitant to try to go beyond the little that I know, at this point.

Question: Are the contact tracers asking any questions to try to identify where cases may have been exposed and in what type of situation they may have been exposed? Is this information being collected by any location? The numbers I've been involved with are fairly small, but anecdotally, recently, they've been mostly in health-care work or their family members?

Dr. Madoff: That's it's a very good question. As far as I know that is not currently part of the contact tracing, but I think it's a very good idea. Something that we would like to pursue is trying to get a handle on where cases are occurring. Most of the efforts on contact tracing have been on identifying their contacts, as the name implies, so public health action can be taken. Clearly, we note where, geographically, these cases are occurring and get demographic information, but understanding where these cases come from is an excellent thought. It is challenging at the level of the numbers of cases that we have right now today to try to collect all of that information, but something that is worthwhile.