



MASSACHUSETTS MEDICAL SOCIETY

Every physician matters, each patient counts.

February 3, 2021 MMS/DPH Call Summary and Q & A

On February 3, the Massachusetts Medical Society (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, Kevin Cranston, MDiv, Assistant Commissioner and Director, Bureau of Infectious Disease and Laboratory Sciences, and Kerin Milesky, Director, Office of Preparedness and Emergency Management participated. DPH officials were asked to provide an update on COVID-19 and the status of vaccination efforts in the Commonwealth. DPH officials also responded to member questions asked in advance and during the call.

COVID-19 Update:

Dr. Brown:

- The Commonwealth continues to be in the second surge; however, key indicators show that Massachusetts is beginning to notice a downward trend. DPH is seeing this not only in the declining numbers of cases, but also in the wastewater surveillance being conducted. The amount of virus found in wastewater has been dropping dramatically. DPH is also starting to see some decreases in the numbers of hospitalizations, and deaths. Hospitalizations and deaths tend to be lagging indicators, therefore the fact that they are coming down is good news.
- **Variants.** Dr. Brown reminded everyone that COVID-19 is an RNA virus that has a regular mutation rate. The more people who are infected with the virus the more opportunity that that creates for mutations. Therefore, everything that can be done to suppress transmission, including adhering to all of the standard risk mitigation public health recommendations and getting vaccinated is absolutely critical in order to reduce the number of people that have the virus. This suppresses the opportunity for development of mutations.
 - The virus is mutating all of the time, and not all mutations are advantageous to the virus, and not all of them are bad for people. As a result, the term “variants of concern” has arisen. There are currently three identified COVID-19 virus “variants of concern”: a variant identified in the United Kingdom (U.K.) (B.1.1.7); a variant identified in South Africa (B.1.351), and a variant identified in Brazil (P.1)
 - There is surveillance ongoing, both in Massachusetts and nationally, for these viral variants.
 - Regarding the identification of the B.1.1.7 variant, the U.K. was light years ahead of the United States in terms of genetic sequencing. The United States has not done as good a job at sequencing, but that does seem to be changing. The Centers for Disease Control (CDC) has contracted with three different national labs to do routine surveillance sequencing on a proportion of the samples that they are processing. Additionally, Massachusetts’ state public health laboratory has ramped up and it is currently able to do 100 sequences a week. DPH

continues to collaborate with the Broad Institute, and they are also ramping up their sequencing. The intent is to be able to do 1,000 sequences a week in the not too distant future. Several academic and hospital labs are doing sequencing or plan to do sequencing. The combination of in-state surveillance capacity combined with what's happening at the national level is going to give us a better window into the virus variants that are present in the United States. Unfortunately, this likely to reveal more virus “variants of concern” as this process goes on.

- In Massachusetts, seven (7) B.1.1.7 variant cases have been identified. Three of these were travel-related, and for the other four there was no indication of recent travel, either in the individual or in any of their close contacts, which is more suggestive of community transmission. At this point, there is no evidence that there is widespread community transmission of the B.1.1.7 variant. So far, neither the variant originally from Brazil nor the variant originally detected in South Africa have been detected in Massachusetts.
- Dr. Brown noted that there has been a lot in the media about these “variants of concern” and that has raised questions about whether you can still use monoclonal antibodies to treat them, whether the vaccines are still effective against them, and if the B.1.1.7 variant is more transmissible (which it does seem to be), and if there are any additional recommendations for reducing transmission. Dr. Brown reinforced that the standard public health messages about how to prevent transmission are still appropriate and important. She said that there are not any changes to the isolation or quarantine recommendations associated with identification of someone with a B.1.1.7 variant or the other variants. The 10-day isolation period and a 14-day quarantine period still apply. Dr. Brown stated that while there's some evidence to be a little concerned about some of these variants regarding the benefit of monoclonal antibodies and efficacy of vaccine, at this point, there is no evidence to suggest that the vaccines are not going to be effective. They just may be slightly less effective against one of these variants.
- **Vaccine Confidence Campaign.** Starting next week, DPH will be launching a vaccine confidence campaign. DPH communication department has done considerable research, surveys and conducted focus groups to develop this campaign. The campaign recognizes that there are particular populations, especially people of color and other minority populations, that may have understandable increased concern about receiving the vaccine. Commissioner Bharel considers health equity to be a primary priority, and therefore DPH is having additional ongoing conversations about the best ways to try to improve vaccine confidence among some of these groups that are harder to reach.

COVID-19 Vaccination Update:

Mr. Cranston:

- Current vaccine supply unfortunately does not meet demand. This is a function of the allocation that Massachusetts and other states are getting from the federal supply. This is starting to improve. Massachusetts has seen a 30% increase in our Moderna vaccine allocation, and we are expecting by next week to see that supply go from the current approximately 44,000 Moderna doses, and about the same number of Pfizer doses, to about almost 64,000 Moderna doses starting next week. The Pfizer dose count will remain stable.
- It is expected that Johnson & Johnson will be filing for Emergency Use Authorization (EUA) for their one-dose vaccine shortly. In general, there is typically at least a three-week period of review by the Food and Drug Administration (FDA). Assuming it achieves an EUA approval by the FDA and an indication by the federal Advisory Committee on Immunization Practices, the time frame to receive the

Johnson & Johnson vaccine likely will not be before March. When it does arrive, DPH is anticipating that weekly supplies will be substantial and might even rival or exceed the current amount of combined Moderna and Pfizer vaccine that Massachusetts is receiving.

- Additional sites of access for COVID-19 vaccine are coming online this coming week.
 - DPH is seeing increased pharmacy access. Eight (8) new Walgreens pharmacies and fifteen (15) new CVS pharmacies will be sites for vaccination for individuals who fall within the Commonwealth's prioritization scheme. Currently, all of Phase 1 and Phase 2, Group 1, which is people 75 years of age and older.
 - The Reggie Lewis Center in Boston and another mass vaccination site in Danvers came online this week.
 - The skilled nursing facilities are in their third week of their second-round clinics. Additionally, the first week of second-round clinics for assisted living residences and continuing care, retirement communities and rest homes is underway. Once the final doses and clinics for the long-term care program are administered, that will free up doses for other groups in the prioritization process.
- **Primary care providers access to vaccine for eligible patients.** A relatively small number of practices have been receiving vaccine through direct allocation requests via the Massachusetts COVID-19 vaccine program. Others are gaining access through their hospitals and health care systems. Mr. Cranston indicated that DPH anticipates making a broader announcement, ideally by the end of this week, about plans to create channels of access of vaccine for primary care providers and medical practices for their patient populations. He asked that physicians stay tuned, and he asked that practices give DPH a few more days to finalize those plans to make them ready for announcement.

DPH responses to questions received in advance of the call:

Question: *DPH has recommended that patients call their physician with questions about vaccine, but physicians do not always have up to date information. Could DPH provide physicians with a communication template with the information needed to respond to patients' inquiries?*

Mr. Cranston: That is a consistent recommendation because many of the questions that come to us and to other sources are individual and very particular questions about their medical situation, the impact of comorbidities, pregnancy, other health issues relating to the COVID vaccine. The particular request that DPH provide physicians with a communications template is a solid recommendation. I'd like to take that back to our internal deliberations about maybe creating a patient response FAQ for some of the major questions.

Question: *Do patients need to 'prove' the number of comorbidities they have to be eligibility for Phase 2 vaccination? What is the role of clinical judgement in assessing comorbidities for individual patients?*

Mr. Cranston: Phase 2, Group 2, includes not only people 65 and up, but will include those with two or more comorbidities or medical conditions. First, to be very clear, the definition of those medical conditions or comorbidities is the increased risk list on the CDC website. It is a fixed list at this point, but it will continue to evolve, as it has evolved in the past, as more medical information or clinical information becomes available to justify that a person with this comorbidity or one of those comorbidities is likely to have a greater risk of severe illness or death. Massachusetts will use the CDC's at increased risk, not they may be at increased risk list. When patients become eligible in Phase 2, Group 2, they will not need to provide medical evidence of their comorbidities. As we have with other populations, they will be asked to sign a self-attestation, signed either within an app or a website at scheduling, or in paper at the site of the vaccination location. We're not

asking patients to go back to their clinicians, their primary care providers for medical evidence, and we're not asking physicians to make clinical judgments. We are using that fixed CDC list.

Question: *Is DPH is aware of any consideration of moving to a single dosing model prior to getting people second doses?*

Dr. Brown: The CDC has been very clear that that is not going to be something that they are entertaining at this point. There is a lot of concern about moving away from using the vaccine in a data-driven way. The data were created or produced using a two-dose series. They've been pretty clear that they won't be making that recommendation, at least in the immediate future.

DPH responses to questions received during the call:

Question: *I've been hearing from a lot of physicians around the state that they feel like they're not hearing enough timely information coming from the DPH. They're wondering if these type of phone calls could occur more frequently while we're doing the vaccine roll out. For example, you just clarified that those at increased risk in Phase 2, Group 2 will only be those specific patients who are at high risk. That's not something that I have heard before. We've been basing our vaccine strategy on giving it to everybody on both of those lists, so how can we get more information out to people in a timelier manner?*

Mr. Cranston: We were aware that there was a lack of clarity on that particular point, and we did make an effort to change how the language was framed on our webpage. Actually, the entire section of our webpages dealing with the phases, both eligibility and mechanisms for getting vaccinated, have been revamped just over the past week, so I do urge you to take another look at that section. Please continue to give us feedback about whether it is clear enough, both for your patients and for yourself. We did try to specify that it's the CDC's at increased risk list that is being pointed to on the webpage. I will come back to my colleagues around requests for more frequent phone calls or other mechanisms.

Question: *I'm a retired physician, and I have reinstated my license for the purpose of volunteering to give shots. I would like to know what the process is for volunteering because I haven't seemed to receive any options and if I do volunteer, what would be the process for making certain that I got vaccinated because I am under 75?*

Ms. Milesky: Thank you so much for your question, and obviously for your generous offer of support for what is and will continue to be a massive effort across the state. The department does have a volunteer portal. Maresponds.org is a site that you can visit to either register with your local Medical Reserve Corps (MRC) organization. There are upwards of 40 of them across the state, or you could register as a COVID-19 response volunteer to be able to respond to larger statewide requests. In either case, if you register for your MRC or for the COVID-19 response team, you will be asked to answer a certain number of questions and put in your credentials. Then everything will be verified in advance, and you will be asked to submit a CORI application. Once you are fully vetted and accepted into the system, as we have requests for support from volunteers, you will be contacted to check on your availability.

Mr. Cranston: There's another piece of your question, which is if you were paired with a vaccination site, how would you be insured to get your own vaccinations. As you know, in Phase 1, Group 1 all vaccinators are prioritized as COVID-facing health care workers, and we would rely on the entity, organization, or site that is mounting the vaccination effort and tapping into your generous offer of service to take responsibility for ensuring you were duly vaccinated in a timely way.

Question: *I'm a primary care doctor, and one of my major concerns is how is the state and our systems going to identify the patients who are elderly, frail, don't have children or support to go online or even identify themselves in any way as needing the vaccine? There are some ways we can do that through home care programs. Many of us at systems have case managers, but I don't see a concrete plan from the state yet on how we're going to identify those patients on the fringe who are frail, elderly, don't speak English, or don't have computer internet access. I'm wondering if the state has even looked at that yet, and where you are with that?*

Mr. Cranston: We have been in conversation with Mass Health, with the private health insurance plans, as well as large medical systems, all of whom have expressed a keen interest in reaching out to their members or to their patient panels. I'm an outpatient of one large medical system, and I've gotten almost weekly communications about the current eligibility. I realize some targeted efforts, particularly for individuals who may not be as comfortable with online services may need some more direct outreach by mail, by telephone. I appreciate your referencing case managers, but recognizing that not all individuals, as you've described them, have active case management roles. It is a shared responsibility across providers, insurers, the Commonwealth, as well as local health departments to make sure that all members of our community are getting accurate and up-to-date information about the importance of COVID vaccination and their relative eligibility and mechanisms for doing so. I know we're putting up information and will be announcing some additional supports for individuals, particularly those in the 75 plus age group, who may have some difficulty navigating online or app-based services. You can anticipate some announcements on that very soon. Also, the subset of the group that you're talking about are individuals who truly are homebound, who may not be able to access a mass vaccination site, or even an appointment at a health center. We are deeply into planning for how to solve for individuals who may need the vaccine brought to them in their home. This is a large effort, and we're keenly aware of these challenges.

Question: *I'm a retired physician also, but I have an inactive license. I signed up for MA Responds about two weeks ago, and I'm going to get my final shot next Monday for vaccination. Any sense on how long it might take for the vetting process to occur?*

Ms. Milesky: Once you have entered all of your information and you have completed your CORI process, then everything is fairly automated, and it should go relatively quickly. Right now, frankly, we are just in the process of working with the larger COVID response group and identifying where the areas of need are around the mass vaccination and other sites so that we can make that linkage between individuals wanting to help and the areas where they're needed.

Follow-up: *I had asked for the response to the CORI be sent to me, and it's been two weeks and I haven't gotten one yet. Has it been taking that long to complete the CORI?*

Ms. Milesky: Did you complete the form and send it to the department?

Question: *Did I have to send one in or just have to do it online?*

Ms. Milesky: I believe you do need to send it in.

Follow-up: *I'll have to look at it again because I didn't send mine in. I just filled it out online.*

Ms. Milesky: If you go to the website, there is an email address that you can email if you have any questions. We're happy to support you.

Question: *I have a follow-up question, and it's about the pace of vaccine. I know that that's one of the great unknowns, and it's dependent on the federal government more than the state, and even where it's federal, it's on the manufacturers. As I think about the numbers, with 80,000 doses per week, that calculates out to about 80 weeks to get everybody one dose, and 160 weeks to get everybody two doses. I know that it's going to*

accelerate, but we don't have too much of a sense of how much it's going to accelerate, and in what way. How do we go about, one, finding out how much it will accelerate, and two, setting expectations in the community regarding when they might be able to get vaccine, given just to get through the 75-year-olds will take about 12 weeks at the pace that we are getting vaccine?

Mr. Cranston: One clarification on the numbers. Whenever I quote numbers of doses of Moderna, Pfizer, and ultimately Johnson & Johnson, we are talking about the first doses in that regard. For each first dose that does get allocated and administered, there is a second dose coming behind that. In recent weeks, we are close to double those numbers of the 88,000 in total doses coming in, but they're divided across first and second. It gives us a better way of talking about when people get underway, and also informs when each of the groups under the phases get prioritized. I will say that the time frames that we have posted on the website for all of the phases, we're largely on track on these. We are substantially through Phase 1, and that gave us confidence of starting to move into Phase 2. We don't need to complete one phase before starting the other. We want to be substantially through each one before moving to the next. Our assumptions for those timelines, which go out through June, and one could imagine there will still be some vaccinating going on into the summer, but the major phases will be operationalized February through March for Phase 2, and April through June for Phase 3. We are still on track for those timelines, but they are dependent on our assumptions about multiple new vaccine formulations making it through the clinical trials, submitting for FDA for EUA approval, and being available. While those are still uncertainties in the mix, we are expecting, as new vaccines come online, the supply to substantially increase and to ramp up rapidly, even as the number of eligible individuals in each of the phases becomes larger and larger.

Follow-up: *Really helpful. Thank you so much for that. Just for clarification, when we say 80,000 doses are coming in, that is always just talking about first doses. If 80,000 come in next week, that's not counting the second doses that are also coming in?*

Mr. Cranston: That is correct. Second doses are allocated by the federal government as we demonstrate that they have been allocated locally and administered. When we end up saying that 100,000 doses are coming in, that actually means that we're administering 200,000 doses. Once patients become eligible for their second dose. We should think about it in that context. That's a rolling number, of course.

Question: *There have been questions about monoclonal antibodies. It's clear that they're efficacious, but not clear that they're being used very much. Given that we are on a downturn of the disease and you never know what happens between now and later, I'm wondering whether or not there are sort of plans for recommendations or a public health model for increasing the use of monoclonal antibodies?*

Dr. Madoff: I think the evidence around monoclonals has definitely accumulated at this point to where I think we can be more than neutral about recommending their use. There are a number of studies with a number of different agents now that I think pretty clearly show benefit to patients with early, mild to moderate disease when administered as close to the time of diagnosis as possible, and particularly for those at the highest risk. Adoption of the monoclonals has been slow, as you pointed out. We have more doses on hand and available through DPH, provided to us from U.S. Department of Health and Human Services (HHS) than have been actually used or administered. I think that, unfortunately, the problem is the logistics of the administration. It does require reaching out to a patient within days of their diagnosis, finding an infusion site, it's a one-hour infusion, followed by a one-hour observation period. I think that our hospitals, in particular, were pretty tied up with rolling out vaccine to their staff in the early phases. We have seen the pace of administration pick up. We are monitoring it, and it's so far being made available to acute care hospitals that have expressed an interest to DPH. If your hospital isn't part of the dozen or so hospitals that are currently enrolled in the program, you might speak to the hospital administration about getting them enrolled and seeing what's

available in terms of infusion space for doing this therapy. We have also made monoclonals available to long-term care facilities and surveyed long-term care facilities. Initially, close to 100 facilities expressed an initial interest. We actually make the monoclonals available to those programs on kind of an on-demand basis. If they have a patient who requires administration, they can actually obtain it through DPH, so we are trying to ramp that up. We also recently had a call with Community Health Centers (CHC). We did a webinar with some academic partners from Boston Medical Center (BMC) and Massachusetts General Hospital (MGH) who talked about the monoclonals and talked about the clinical data with our CHC partners. We are trying to get the word out more on that basis. In terms of patient outreach, actually, our Community Tracing Collaborative will mention the availability of monoclonals when they make first contact with patients who have tested positive. That's another effort to try to get it out there. I do see a little bit of momentum building. Admittedly, it's at a slow rate. I also think the guidelines, for example the Infectious Disease Society of America (IDSA) and National institutes of health (NIH) guidelines around monoclonal antibody use is still pretty measured. It says that it's not a standard of care and it requires shared clinical decision-making. I think if there was stronger endorsement on those channels, it would also help adoption. Additionally, the fact is that it does require sometimes lengthy conversations with patients and their providers to come to agreement that this is something worthwhile. Remember that these are patients who are usually having pretty mild or minimal symptoms, but who might be at high risk, particularly the elderly or the high body mass index (BMI). Those are our first-tier recommendations. We are continuing to make it available and trying to expand outreach. This is something maybe we can work with the MMS to promote further.