



MASSACHUSETTS MEDICAL SOCIETY

Every physician matters, each patient counts.

April 21, 2021 MMS/DPH Call Summary and Q & A

On April 21, the Massachusetts Medical Society (MMS) hosted its bi-monthly COVID-19 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 provided updates on the pause of the Johnson and Johnson/Janssen COVID-19 vaccine as well as the latest on COVID-19 vaccination, hospitalization rates, and cases in the Commonwealth. DPH officials also responded to member questions asked in advance and during the call.

Johnson and Johnson/Janssen (J&J) COVID-19 Vaccine Pause Update

Dr. Madoff:

- Last week, Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) officials paused the use of J&J's COVID-19 vaccine pending further evaluation due to a very small number of clinical events that have been temporally related to the administration of the J&J vaccine.
- The safety pause is a part of the surveillance process and monitoring of adverse events, which is routine for drugs and therapies. The pause allows for additional data to be collected and information to be shared.
- Six incidents of rare blood clots occurred within two weeks of receiving the J&J COVID-19 vaccine.
 - The six cases occurred in women between 18 and 48 years of age (childbearing age).
 - Specifically, cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). Heparin is contraindicated for thrombocytopenia, which is another reason that this alarm bell was rung. The FDA and CDC wanted to pause and create a clinical alert so that physicians can be on the lookout for people presenting with this unusual syndrome and provide important guidance - [DPH CVST with thrombocytopenia after receiving the J&J COVID-19 vaccine health alert](#). It is expected that there will be more instances of this rare event, both as the index of suspicion is raised and also as more time elapses since the rollout of the J&J vaccine
- The CDC Advisory Committee on Immunization Practices (ACIP) is collecting more data and they have a second meeting scheduled for Friday, April 23, 2021 to further deliberate what will happen with the J&J vaccine.
- The clinical events are consistent with what has been seen in association with the other adenovirus vector vaccine (the AstraZeneca COVID-19 vaccine) in Europe. The European Medicines Agency (EMA) has recently decided to move forward with the AstraZeneca COVID-19 vaccine in Europe with the

addition of a warning. which caused similar, rare instances in the EU, stating that it needs a warning, which is a potential action that the ACIP could take.

- The J&J vaccine represents a very small proportion of the vaccine that's been delivered in Massachusetts, about 200,000 of the over 5 million doses received.

COVID-19 Update

Dr. Madoff:

- Over 6 million doses of COVID-19 vaccine have been delivered to Massachusetts with 5.3 million doses administered. Over 3 million people in the state have received at least one dose with a higher percentage of those vaccinated being in older individuals and more vulnerable groups.
- Between vaccination and immunity from preexisting COVID-19 illness, Massachusetts is beginning to see the impact of immunity and some positive progress with the trajectory of new cases, hospitalizations, and deaths from COVID-19 in the state.

Dr. Brown:

- Dr. Brown agreed with Dr. Madoff that the case numbers we're currently seeing in Massachusetts are encouraging.
- Since the middle of February, there has been a bit of a bump in cases, but it appears right now to have peaked and does seem to be heading downward. This may be due to the change in the weather combined with increasing rates of vaccination as well as natural immunity.

DPH responses to questions asked in advance of the call:

Question: *Does DPH expect pediatric vaccination to begin in the near future? When and how do you foresee this rolling out?*

Dr. Madoff: The Pfizer vaccine is the only vaccine which is currently approved under EUA for those under 18, specifically for those 16 and older. Ages 16 and older are now eligible for vaccination in Massachusetts, so that part of the pediatric population is already eligible. Pfizer submitted data to the FDA a couple of weeks ago on the 12 to 15 year population. Those data were released in press release form and showed there was, not surprisingly, robust immunity that was imparted by the Pfizer vaccine. In addition, there were no safety signals, so I do expect that the FDA will approve the Pfizer vaccine for that age group. The difficult decision is going to be whether to begin vaccination in those age groups, and that's something that I expect to see the ACIP develop federal policy on. I also expect we'll also work on a policy for vaccination in younger age groups. There are also ongoing clinical trials of multiple vaccines in younger age groups. It is likely, as the summer goes on, that we're going to hear more and more about potential for vaccination of pediatric age groups. We're going to have to make some strategic and logistical decisions about who to vaccinate in those age groups. We don't have policy at DPH on that at this point, but please stay tuned.

Question: *Pfizer announced that the need for a booster will be likely. How and when will the decision about whether a COVID-19 vaccine booster will be needed? Would you expect that a booster will be needed for both the mRNA vaccines as well as the viral vector vaccines?*

Dr. Madoff: I don't know honestly. We are early in vaccination to know the duration of immunity. Certainly, no one has received this vaccine more than a year ago, and very few people are even six months out from vaccination, so the numbers and the duration of immunity remains to be seen. The durability of immunity in some preliminary studies I've seen looks very good. There were a high level of antibodies seen six or seven months after vaccination with the mRNA vaccines and the curves and the decay looked very slow. So, I'm

optimistic that high levels of immunity that are induced by the mRNA vaccine, at least, will be pretty durable. Whether this vaccine becomes a part of an annual vaccination campaign and whether the composition of the vaccine will need to be adjusted in response to the emergence of variants are all things that haven't really been answered yet. We just need more data to see how that's going to go.

Question: *Do we know anything about reinfection rates after being fully vaccinated?*

Dr. Madoff: Both reinfection in people who have had prior infections, and so-called breakthroughs of vaccine have been seen in Massachusetts, nationally, and internationally. They seem to be relatively rare. In other words, we are seeing the kind of levels of vaccine induced immunity that we expected but it is not 100%. We do see breakthrough cases, most of which are asymptomatic. A few of reinfections are symptomatic and we have seen cases where individuals have become seriously ill with COVID-19 even after full vaccination. This shouldn't shock us, but it gives us a note of caution. The vaccine immunity is not complete, and we need to keep an eye on this. There has not, so far in the work that I've seen published and heard reported, been a particular increase in variance among the breakthroughs, which is an encouraging sign. If there were a lack of immunity against variants, we would expect to see more variance in the breakthrough cases. Thus far, that hasn't been what we've seen.

Dr. Brown: We have had about 1,400 breakthrough cases. That represents 1% of people that are fully vaccinated. So, I would say that the evidence supports that these vaccines are very effective. They're not 100%, but the data is very good.

Question: *How are schools doing? Have there been any cluster associated with school reopening?*

Dr. Brown: There have been some clusters in schools all the way along. What the data show now, and actually showed previously, and continue to show is that infection rates of children in school is lower than the infection rate in the surrounding community which suggests that transmission rates, at least in classroom settings, is low. The biggest exception to that among school age kids is sports. Those are more likely to be situations where people are not masked, and there may be some increased exhalations. So, when we see clusters of school age kids, they are more likely to involve some type of athletic, sports events. At this moment, we have not seen a sharp rise in cases in kids simply due to school reopening. Having said that, I would also say its early. The Department of Elementary and Secondary Education recommends maintaining 3 feet of distancing in classrooms for physical distancing when masks are worn, and other mitigation strategies are in place.

Question: *What's happening with COVID-19 around the world and how does that impact the track of the pandemic here in the US?*

Dr. Brown: One particular country is often very different from others. What we need to watch is not just where COVID-19 is happening but the variants. We need to monitor the evolution of COVID -19 and the collection of variants it accumulates. This is the case even in the face of a population that will be largely vaccinated.

Question: *With the variants of concern with increased transmissibility circulating widely in the community, are there any extra precautions people should take?*

Dr. Brown: All the public health measures that one does for COVID-19 continue to be important for the variants. This includes being fully vaccinated.

Question: *How is Massachusetts doing as far as cases and hospitalizations since the last DPH update?*

Ms. Milesky: After about 4 weeks since we saw hospitalizations begin to rise, we are now seeing some leveling off. The seven-day average of COVID-19 admissions has decreased from 716 to 708, but we do remain 18% above our COVID-19 census on March 20, 2021 which was the low point for the winter or the second surge. That increase has been most prevalent in the central part of the state, which is Region 2. We have seen a decrease, rather steadily, in Western Massachusetts, in the Northeast, and in the Boston metropolitan area. Today, for those of you who pulled up the dashboard, it was nice to see a decrease in COVID-19 hospitalizations by 22. Our single-day number today is 686 statewide. We also saw a subsequent decrease in the ICU by 12, to 156. What we're seeing is a bit of a roller coaster over the last week to two, where we're up some days and down some days, but overall, we are seeing a leveling off. All regions remain in Tier 2 of the state's hospital resurgence guidance. That means that we're meeting weekly to be able to monitor capacity constraints and any need for load balancing our systems. We also meet ad hoc as necessary, as issues come up. The hospitals have been great about meeting together, coordinating, and supporting each other. Statewide occupancy does remain high, but that's being driven both by COVID-19 and non-COVID-19 admissions. In addition, we are hearing reports of staffing challenges, particularly this week with school vacation in Massachusetts. That's likely due to high census and high acuity.

Question: *What is the state doing to improve vaccine rates in vulnerable communities? How does DPH utilize the CDC Social Vulnerability Index to identify and support vulnerable communities?*

Mr. Cranston: Our vaccine equity initiatives are particularly focused on 20 communities with a high score on the CDC's Social Vulnerability Index as well as a larger proportion of non-white individuals. Resources have gone out and are available to support and strengthen these community's vaccination efforts. We have contracted resources provided in collaboration with Archipelago Strategies Group (ASG) and Health Care for All (HCFA). Additionally, a number of providers serving those communities have recently received awards through a competitive procurement processes to deliver both navigation services and direct vaccination services trying to reach the most vulnerable and hard to reach subsets of those communities. There is door-knocking going on in localized communities (being directed by the municipalities), specialized educational forums, engagement and funding of community-based and faith-based organizations. All of those activities are underway and ramping up rapidly. We're really starting to see the effect of that in terms of a deeper level of engagement using a more face-to-face and trusted sources approach to reaching vulnerable communities, so we're anticipating seeing that emerge from the vaccination coverage data imminently.

DPH responses to questions asked during the call:

Question: *How did it go Monday with opening COVID-19 vaccine eligibility up to everyone age 16+ in the state?*

Mr. Cranston: What we're hearing is that the pre-registration system in particular has been meeting a great deal of need and reducing frustration on the part of individuals who previously were having to click on multiple websites. While it only provides access to the mass vaccination sites, those are getting a large share of the vaccine and are maintaining full rosters of appointments. As we know, the federal retail pharmacy program has also ramped up considerably. CVS, Walgreens, and other pharmacies throughout the state are offering vaccines vigorously. Collaboratives amongst local health departments are also maintaining a fairly robust and vigorous immunization efforts. Unlike other states, which have seen already started to see a drop-off in demand, we are still able to fill the appointments that are being made available. What we're hearing from the community is that multiple mechanisms for accessing appointments is far less frustrating and more

responsive. Even the news coverage surrounding that seems to be a bit more positive than it was when folks were experiencing higher levels of frustration.

Question: *I have a question about the MIIS registry and obtaining information from it about COVID-19 vaccination. Most of the time when we query through MIIS were able to see the dates that the patient has received both vaccines. There are occasions, not rare, but certainly not common, when a patient assures us that they did have one or both vaccines in the past, but we can't find it/it doesn't appear in the MIIS registry record?*

Mr. Cranston: Data quality is an eternal challenge in health care and in epidemiology. With a large number of vaccinating sites, data quality can be variable, and data timeliness can be variable, even though our requirements are that all vaccinators must enter their data into the MIIS. COVID-19 vaccines information, specifically, needs to be entered within 24 hours, but it doesn't always happen. I would suggest that you contact the MIIS helpdesk. Our data quality team can follow up on a particular record. If there's an incomplete record, they may be able to contact the vaccinator of record and check with their local record and improve or complete the entry. If the person is not entered at all, though, it would be quite difficult for us to figure it out unless the patient is able to identify the location of their vaccination- a mass vaccination site, a pharmacy, or other setting. It would be difficult for us to know where to start, in terms of who administered the vaccine, but patients generally do remember where they got their vaccine. If that information can be provided, our data quality team will reach back out to that vaccinating site and try to confirm the information and update the record.

Dr. Brown: I would encourage patients to bring and show their vaccination card when they are seeing their provider. The MIIS helpdesk number is (617) 983-4335.

Questions: *We know that New Hampshire has revised their mask mandate and some people in Massachusetts are suggesting that masks outdoors could be not required. Do you have any indication whether Massachusetts would be following that example about mask wearing in outdoor situations?*

Dr. Brown: There is a desire to review the data regarding the utility of masks outdoors, which may be more in question than indoors. At this point, we're still kind of stabilizing from our most recent mini surge. At this moment we are confident that we all need to do everything possible to continue to keep those numbers coming down as the vaccine continues to roll out. It's something where there's room for discussion in the future, but right now we definitely need to be really careful about continuing to take all the steps we need to in order to mitigate COVID-19 risk.