MMS Virtual Member Forum
COVID-19 Vaccine in Massachusetts
December 14, 2020

On December 14, 2020, the Massachusetts Medical Society (MMS) hosted a 90-minute live, virtual forum on COVID-19 Vaccine in Massachusetts. Dr. David Rosman, President, Massachusetts Medical Society, served as moderator.

Presentations covered the science behind the COVID-19 vaccines and an overview of the Commonwealth’s phased plan for vaccine distribution. Expert panelists addressed vaccine availability, safety, tracking, adverse reaction reporting, and concerns for specific at-risk populations. The challenges of vaccination in communities of color that struggle with trust in the health care system was also discussed.

Summary of Presentations

Forum Speaker 1 – Dr. Eric Rubin—Update on the science of the COVID vaccine. Dr. Rubin’s slides from the program are posted.

Dr. Rubin began by mentioning that the Pfizer vaccine has started to arrive at hospitals in Boston and that the Moderna vaccine on the horizon. He said we could have a couple more vaccines soon. However, even with these two, there is not going to be a sufficient supply.

He stated that there are several different ways to make vaccines and almost all of them are being used right now in one vaccine or another, including many late-stage vaccine candidates. Some try to stimulate a non-specific immune response, or trained immunity, with vaccines like BCG. For many diseases, attenuated strains of the organism are used, but that really isn't a strategy that's gone very far. However, there are several vaccine candidates, which are either purified proteins or inactivated viruses. A few of those are being distributed in other countries already even though we don't have the phase three information about them. He noted that there are also many vaccine candidates, including these late-stage candidates, which use an attenuated virus, an adenovirus, to carry the gene for the SARS-COV-2 antigen to our own host cells. Dr. Rubin said some of these are already being used in other countries, even though we don't have final data for them. The vaccine from AstraZeneca was reported in an article in The Lancet a couple of weeks ago (Dr. Rubin noted he is using the manufacturer’s name because the names of the actual
vaccines are difficult to remember) The results for that vaccine are a little bit confusing because there were some issues with the trial, but it does seem to be effective, perhaps not as highly effective as the two mRNA vaccines. There is also one candidate that's still in early phase trials that is a DNA vaccine that carries the SARS-COV-2 gene on naked DNA.

Dr. Rubin then talked about the two vaccines we will initially have in Massachusetts, one from Moderna and one from Pfizer. The Pfizer vaccine has received an emergency use authorization (EUA) in the United States and in a few other countries. What do we know about it? It is a SARS-COV-2 protein, the spike protein, which is encoded on a messenger RNA, and that messenger RNA is specifically modified to provide some chemical stability to it and delivered in a lipid formulation so it can get into cells. It requires two doses spaced at three-week intervals. In addition, the Pfizer vaccine requires ultra-cold storage. Not only does it require that storage, but it doesn't last that long after it's been diluted. The data for this has all been reported, both in the FDA filing and in a paper published last week.

The Pfizer trial was designed to look at whether or not it was efficacious seven days after the second dose. Although, as you'll see, we know more information about it. That trial also looked at the safety of the vaccine. It looked at a wide range of ages, from 16 to 75, and there were several exclusions. One was a history of anaphylaxis to a component of the vaccine, but not a general history of anaphylaxis. We suspect there were people in the trial who had anaphylaxis to other antigens, but not to a vaccine in the past. Pfizer also excluded people who had been diagnosed with COVID-19, but there were many people in the trial who likely had asymptomatic infection. It was a very large trial. There were more than 18,000 people in each group. The trial went until they accumulated 164 cases. They are continuing to follow patients for safety endpoints, and they are still collecting efficacy data.

Dr. Rubin stated that there are several ways of looking at safety and directed attendees to some simple representations. He displayed a bar graph showing how many people had local reactions (the graph happened to be the age over 55 group, but Dr. Rubin noted that it looks fairly similar to a younger age group). Many people had some local reactions, pain or redness, or swelling, but particularly pain, injection pain, and almost all resolved fairly quickly. There were some systemic reactions, but nothing particularly striking. He added that the spectrum of adverse events looked very similar to most other vaccines. The important thing is that it worked. 95% efficacy. Dr. Rubin pointed to two pieces of information in the graph. First, noting that it really works. People who got the vaccine (shown by the red line) really didn't develop infection, or symptomatic infection, whereas people in placebo continued over the course of the trial to develop infection. Not only did the vaccine protect, but it protected fairly shortly after the first dose. They didn't have to wait until the primary endpoint, which is way out at 28 days. If you look at the first week
or two, you can see what looks like very good protection. Right now, however, we don't know how long that protection will persist. It seemed to work across subgroups. A lot of these numbers are small, but it did appear to work consistently at least, as far as you can tell with small numbers.

Dr. Rubin then turned to what we don't know, which, he acknowledged is a lot. We don't know how long immunity will last. There are some encouraging results looking at the Moderna vaccine as much as three months out suggesting that the antibody responses do persist, but we don't know if those correlate with protection. One big logistical question is how do you deliver two doses, and what happens to the people who miss the second dose? We know that one dose produces what looks like very good immunity. Again, what we don't know is how long that will last. That's a big question. Is it going to remain safe when we go beyond 20,000 people? We don't know. We only know that the threshold of 20,000 looked pretty good. Is it safe in pregnancy? Pregnant women were excluded from this trial; therefore, we don't know. Is it safe in children? No one under 16 was in the initial trial, however, there is a group of 12 to 16-year-olds undergoing vaccination now. Dr. Rubin expects that we will have some more information about that age group soon. Finally, because this is a large group with a lot of subgroups, what happens in nursing home residents? What happens in people over 75? We don't know the specific answers. Right now, we can only extrapolate from what we have.

Dr. Rubin wrapped up by saying there are a lot of things we're going to learn as we start administering this vaccine. He added that, for now, we have something that works and at least within the confines of our ability to test in a group of 20,000 people and it is pretty safe.

**Forum Speaker 2 - Dr. Paul Biddinger - Overview of the state's vaccination plan and recommendations. Dr. Biddinger did not have slides.**

Dr. Biddinger began by saying that it is an honor and a privilege to work with an incredibly talented group of clinicians, academics, community representatives, and government representatives on the governor’s advisory group. He added that he wished that everyone participating tonight would have been able to listen in on the thoughtful discussions that went into thinking through how best, how most effectively, how most equitably, and most ethically the state could approach allocating initially limited quantities of vaccine.

He thanked Dr. Merchant, Dr. Wildes, Dr. Madoff for their contributions to the discussions. The basic problem is that even as we are starting to have more vaccine candidates that receive emergency use authorization, we just won't have enough supply initially. This is due to both manufacturing reasons and also product availability.
Dr. Biddinger stated that many are hopeful that Moderna will be added to the Pfizer product in having an emergency use authorization. The hope is that other vaccines will be given EUA as well. Since we are facing the problem of limited amount of supply initially, the state’s advisory group on vaccine started with some basic ethical principles of fairness, transparency, maximal benefit, prevention of death and disability, and preservation of functioning of essential elements of society.

Dr. Biddinger mentioned the National Academies of Science, Engineering, and Medicine (National Academies) report that was published in October. The report goes into detail on both the ethical principles, as well as the goals of their framework for how one could consider allocation of limited supplies of vaccine. After the National Academies document was published, there were also several presentations that came out of Centers for Disease Control’s (CDC) Advisory Committee on Immunization Practice (ACIP). Both groups, the National Academies and the ACIP, started with prioritization of the health care workforce as well as prioritization of residents and staff in long-term care facilities. There has been disproportionate death in the long-term care community, especially elderly residents in long-term care congregate settings. He added staff in long-term care have also had significant illness and death, and that often the staff that work in those settings come from vulnerable backgrounds themselves, whether it is low income, minority or other disadvantaged status. In addition, the ways in which they need to commute to and from work where they are otherwise exposed to higher risk conditions makes them vulnerable. Dr. Biddinger stated that he didn’t think there was any controversy about prioritizing the long-term care, both the community of patients and the staff that care for them.

On the health care worker side, he commented that it's really important to think about why health care workers are prioritized for vaccination. Obviously, it is the essential role of health care workers play in preserving life and supporting health. He noted that the advisory group talked a lot about the dilemma of believing in personal protective equipment (PPE) and the safety of the medical workplace, yet still prioritizing health care workers. Dr. Biddinger said that sometimes there's a misunderstanding that health care workers are prioritized because of the risk of infection they're facing moment to moment. He stated that you can't deny the fact that health care workers, in fact, are around COVID virus more than most anyone else, but the data has shown that personal protective equipment, when properly worn and when protocols are followed, are indeed protective. He believes the real reason that health care workers need to be prioritized is to make sure that they are there for what we do every day, which is to care for those who need us.

Dr. Biddinger said that unfortunately there are rising numbers of COVID cases in the Commonwealth, both in the outpatient and inpatient settings. Our health care system is under significant strain from these rising number. Dr. Biddinger stated that it does, in fact, make a lot of sense that the health care workforce should be prioritized with
vaccines so that we can continue to do our jobs whether we're exposed in the community or exposed at work. He said when the group had its deliberations, and ultimately when they presented the recommendations to state government, there was strong agreement with the prioritization of the health care workforce and the prioritization of the long-term care community.

Dr. Biddinger then explained that within the health care workforce we will not have enough vaccine in the first few weeks to months to vaccinate every health care worker at the same time. Therefore, it was necessary to make some really hard choices about how best to approach immunization of the workforce. The discussions centered around the fact that with rising COVID numbers, prioritizing what we call the “COVID-facing” health care workforce was important in order to make sure those people who are in our primary care practices, urgent care centers, emergency departments, inpatient units, and ICUs caring for patients with known COVID are able to show up and continue to do their jobs. That care is simply not deferrable.

Ultimately, the recommendation given to the state starts with “COVID-facing” health care workers with a focus on equity. Dr. Biddinger pointed out that from the very first moment, it was very clear that all members of the health care workforce in a similar setting had equal priority to a vaccine. That means in an urgent care center, it's not just the nurse or the physician or the advanced practice provider, but it's the clerical staff, it's the environmental services staff, it's everyone working in that same area because they are all essential to the care of the patient. He explained that we can't care for patients if we can't clean rooms or can't deliver food or can't do the needed registration and documentation. Equity is a fundamental component of the plan. He remarked that we have seen how much inequity there has been in the impact of COVID in our communities and on society and therefore the recommendation is that all health care workers in a similar setting receive vaccine at the same time.

Dr. Biddinger then said that the advisory group recognizes that congregate care settings are extraordinarily high risk. There have been significant outbreaks in prisons, in homeless shelters, in other group home settings where we have large numbers of residents near one another. A single infected individual can result in a large number of cases. With that in mind and going beyond what was initially recommended in the National Academies document, the advisory group elected to consider all congregate care settings with high priority because of the risk of spreading transmission so quickly to so many people including staff as well as patients and residents.

Next, Dr. Biddinger mentioned that the plan also recognizes that the first allocation be inclusive of our public safety representatives. Fire, police, and EMS who are in people's homes. They must respond in emergencies, they must respond quickly and often don't have time to fully don their PPE, or to fully assess the risk of a situation. Because of this
risk, as well as because of the duties they're called to perform to support all of us, they belong in that top category.

Dr. Biddinger also explained that from an equity standpoint, there was a lot of discussion about the home health community. The home health community spans from personal care attendants, to formal home health nurses, to other more formalized home health services. These are professionals of various levels of training and various levels of experience who are in and out of people's homes and in and out of vulnerable patients' homes. For their own personal protection, as well as for them as potential vectors of transmission, it was thought to be extraordinarily important to include them high on the priority list. Once again, from an equity perspective, Dr. Biddinger noted that the group was mindful that many members of the home health workforce come from hard hit communities (racial and ethnic minorities, low-income) with high prevalence. For their personal protection as well as to limit transmission, they were specifically called out as important in the priority list. After these groups, it is clear that all of us in health care are providing essential services. That is part of what it is to be in medicine. There is a need to continue to protect, support, and value the role of the medical care clinician in our rollout of vaccination. That is the state’s priority criteria during phase one. It includes primary and specialty care in the inpatient and outpatient settings, and it includes all the staff who are required to make that care happen. For example, food service and even food prep in hospitals, the chefs and others, are included because if we can't feed our patients we can't run inpatient hospitals.

Based on what Massachusetts has been told about the availability of vaccine coming to Massachusetts, it is estimated that we should be able to get through phase one through February 2021. Dr. Biddinger noted that there are dependencies. Clearly, a lack of vaccines moving through the federal approval channel to get EUA could affect that. Likewise supply chain disruptions could affect that as well. He said that it's the hope, that in roughly the first three month, we get through phase one. He added that Massachusetts has now received just shy of 60,000 doses of vaccine, and by the end of this calendar year, we expect to receive 300,000 doses. It's important to remember that generally speaking, when speaking about doses in a public setting, we're talking about first doses, and therefore, you don’t have to divide by two. Dr, Biddinger added that a second dose of both the Pfizer and the Moderna vaccine is needed. In the allocation framework provided by the federal government, when a first dose of vaccine is allocated to a state, automatically the second dose is allocated as well. Therefore, health care systems and practices are automatically slated to receive that second dose as soon as they've been allocated their first dose.

After phase one, Dr. Biddinger stated that it is obviously extraordinarily important that we vaccinate other individuals who are at high risk and/or have particular need for vaccination in society. Massachusetts followed, in large part, the National Academies risk
framework. First in phase two are individuals who have two or more comorbidities as listed on the CDC's website. These are individuals who have a scientifically documented, or strongly suspected comorbidity based on the evidence and are at risk for greater complications or death from COVID-19.

After high-risk individuals, there's a need to prioritize workers in critical settings that are in high-risk situations. This includes education, transportation, grocery, food and agriculture, etc. He stated that is easy to understand why these workers are prioritized; noting that our children are having difficulties not being able to go to school and that anything we can do to restart the educational system is extremely important. Likewise, food, transit, agriculture are also fundamental elements of society.

Dr. Biddinger then explained that the second part of phase two will include certain other categories of at-risk individuals including those greater than 65 and individuals with one comorbidity as listed by the CDC list. Phase two, based on the expected estimates, would go roughly from February to April and then more broadly into late April or a little after depending on vaccine supply. After that, vaccination opens up to the members of the general public. Based on modeling, in order to get close to herd immunity, Dr. Biddinger expects that about 60% plus of society will need to be vaccinated.

Dr. Biddinger pointed out that it is the Commonwealth's stated goal to get to 80% vaccination across the state. It is the strong hope that by late spring, early summer we can start getting close to that kind of vaccination rate. A concerted effort to continue make sure that the virus has as few opportunities as possible to be passed from person to person is really what it's going to take for us to drive down prevalence as well as protect individuals from the risk of serious illness or death.

Dr. Biddinger remarked that there are a lot of dependencies and complexity to the plan. He knows there have been a lot of questions about how workers in critical roles and other elements of subgroups fit within this prioritization framework and he expects that the Department of Public Health (DPH) will be rolling out additional guidance and additional definitions in the coming days and weeks. Dr. Biddinger ended by sharing that the governor’s vaccine advisory group will continue to work with the state to try and help with implementation efforts and to represent the medical community.

Summary of Question & Answer Session

Dr. Eric Rubin, Dr. Paul Biddinger, Dr. Larry Madoff, Dr. Simone Wildes and Dr. Asif Merchant responses to questions received from attendees.
How is COVID-facing defined?

**Dr. Biddinger:** This is a really good question. Obviously, it's one that everyone has been struggling with. I think all of this is a matter of degree. It's pretty easy to say that anyone could be considered COVID-facing because in a disease with so much, either minimally symptomatic or asymptomatic presentation we do struggle to know who could have COVID. Our group really tried to identify those medical settings in which either someone has clearly been diagnosed with COVID such as the emergency department, inpatient ICU setting, or if the health care system has set up a specific clinic or practice for care of known COVID positive patients during their infectious period. For those who are in the process of diagnosing, we really have wanted to focus on those places where it's a significant portion of your practice to see patients with symptomatic fever and respiratory illness symptoms compatible with COVID and you're in the process of testing and medically evaluating for it. If it's something that can happen from time to time, or you can't rule it out, that really isn't something that we consider COVID-facing. However, if it's really part of your practice, you're making the diagnosis, you're testing, you're providing either acute care or inpatient care for COVID-facing, or for COVID positive patients that's COVID-facing.

How do health care workers who aren't at a hospital get their vaccine?

**Dr. Biddinger:** The roll out of the vaccine is one of the many, many things that makes this so incredibly tricky. The first vaccine, the Pfizer vaccine, as Dr. Rubin said, is one that has significant complexity to it. It needs ultra-cold storage in a specialized freezer if you're going to store it for longer than five days and it comes in allocations of 975 doses at a time, which is really too large for many smaller practices to vaccinate their staff in any appropriate way. The Moderna vaccine which hopefully is coming soon does not have that requirement. It comes in 100 dose allocations, which makes it easier for smaller practice settings. Certainly, practices that are hospital-affiliated should be working with their hospitals and their occupational health clinics to figure out what those processes are. My understanding from the state, as they get more Moderna vaccine that's available to smaller practices, that will allow them to start vaccinating their staff who are COVID-facing according to the definitions that we talked about. Again, hopefully, within a month or two, we can quickly move to the non-COVID-facing medical care community and make sure that we're broadening the reach across all of medicine. Some practices (the pediatric practices have been especially good about this) have come together to create group arrangements to request Moderna vaccine for one of their sites assuming they've been registered with the state's vaccination program for COVID.
Are Community Health Centers (CHCs), like other practices, going to have to wait for the Moderna vaccine as well?

Dr. Biddinger: That is correct. I do want to emphasize how important CHCs are going to be overall to our vaccination effort in Massachusetts. CHCs will be getting Moderna vaccine as soon as it is available. They play a huge role in some of our most vulnerable communities. They communicate well. They are leaders in communication to the communities they serve, and they have access that many of us otherwise don't have. I know that DPH sees them in a very prominent role allocating vaccine, certainly for staff, but very soon too patients when we move forward.

What do we know about long-term side effects of getting an mRNA therapy of any kind?

Dr. Rubin: While it's true we have other RNA therapeutics, mostly antisense RNAs or things which modulate splicing of RNAs, we don't really have anything that's gone into this large number of people. 20,000 people is certainly unusual, and this will go into millions. I think we don't know if there's something special about mRNA. I would say that, as well as the RNA, remember that there are other components to the vaccine, and those may be as much of an issue or, perhaps, more of an issue than the RNA molecules themselves. For example, the anaphylactic reactions that we've heard about in Great Britain would seem more likely to be due to the lipid formulation than to the RNA itself, although we don't know that.

Can a vaccine can be integrated into the genome?

Dr. Rubin: As far as integration of the RNA into the genome and having persistent expression, that seems to be very unlikely. It would require a reverse transcriptase, which do exist in cells, but, in addition, it requires that the RNA be a good template to be turned into DNA and then integrated into the genome. Reports are that the modifications made to these RNA molecules don't allow reverse transcription to occur very efficiently. I don't think there's been any evidence of it. Most of the artificial RNAs persist for only a few days and get cleared. They're relatively unstable molecules. We don't know precisely for either of these molecules because they have proprietary modifications.

For people who have been already infected by COVID, is there's any science that we know about how the importance of them getting the vaccine?

Dr. Rubin: There is emerging evidence that people who have been infected are at least partially protected, but we don't know the magnitude of that protection yet. The trial that
Pfizer did allow people who had evidence of an antibody response to the virus, suggesting that they'd been previously infected, to be enrolled. Those people did really about as well as people who didn't have antibody evidence. There doesn't seem to be danger in giving vaccine to people who were previously infected based on, admittedly, a relatively small number of people. It's not clear that they needed quite as much. We just don't know the numbers or the magnitude of the protective efficacy. Dr. Biddinger might want to comment on policy considerations.

**Dr. Biddinger:** I think that's exactly right. There was some discussion in some of the CDC documents about whether people who had had a documented COVID infection might want to wait 3 months before receiving their vaccine. However, that really was much more about just sequencing and trying to manage the queue of people waiting for a vaccine rather than any medical contraindication or medical reason for waiting. I think many health care systems, my own system included, are not going to be asking people who have had a recent infection to wait. Anyone who's had a documented infection, as long as they've recovered, as long as they otherwise would have been able to come to work with our return-to-work criteria will be eligible for vaccination.

**How will we be able to track how we're doing and how our own community is doing regarding uptake of the vaccine? Are there going to be DPH dashboards to understand how many people in a community have gotten vaccinated?**

**Dr. Madoff:** The state is dedicated to transparency and we want to get the information out to providers and to the public as we move through this program. We put out our COVID dashboard indicators on a daily basis and put out more public health metrics on a weekly basis. We also want to do that with COVID vaccination. We are formulating exactly what that's going to look like, how to best put that information forward, how to show the groups that are being vaccinated, how we're reaching our goals of equity that are so important. We also have in place systems for very closely tracking vaccines. This applies not only to COVID vaccine, but to every vaccine. Every vaccine administered in the state is reported to the Massachusetts Immunization Information System (MIIS). Many of the providers on the call are probably familiar with that system. Every single dose that goes into any individual in Massachusetts will be tracked and will be maintained in our database. Therefore, we will have access to that information, access to the demographics around who is vaccinated, and DPH will commit to making that information available as we move through the program. I just want to add that there's so much that we don't know yet. This is the first day of the vaccine being available and we
are still very much engaged in a whole number of work streams to get the vaccine rolled out.

**There is a considerable and understandable mistrust of health care and particularly vaccination in communities of color. What can we be doing as a medical society, as a DPH, as a governor's group, and as physicians in order to earn back trust in the long-term, and what can we be doing now, in order to help with the vaccine distribution?**

**Dr. Wildes:** Thank you for that timely question. We really have to try to do everything we can to rebuild trust in the communities of color. In order for us to do that, I think first we need to understand the history. I know we all think about the Tuskegee Syphilis Study as the main study, but there have been many others that have caused a lot of pain to people of color. In order to move forward, I think we really need to take certain steps at evaluating where we made mistakes. We need to interact with the patients, listen to their stories, understand their concerns. I think people really build a relationship with you when you spend time with them. We have to be very transparent in all our undertakings, so they know what we're doing. Another thing that really helps is having people that look like them and sound like them. That makes a big difference. That's really a very critical part of this whole equation. Finally, I think having partnerships with people that have trustworthy relationships in the community can really help to strengthen the trust in these communities. It's a long-time coming. We have a lot we need to do, but I think these steps can help us to move forward, not only now for COVID, but just getting ahead to building trust in these communities so that we can get better health care to these communities of color. The Massachusetts Medical Society can definitely help to lead this charge.

**For community physicians, whether they're working in private practice, not affiliated with a larger group or hospital and who perhaps might not have access to be giving vaccines as a group, how they go about getting involved and getting themselves to be able to get vaccines for them and their staff and how does that equitably extend to all people working to support those locations?**

**Dr. Biddinger:** I would say, the answer is going to end up being multifactorial, and it's still a bit in evolution. Clearly, for an undertaking this complex where we're trying to vaccinate an unprecedented number of people in an unprecedently short period of time. I think it really takes a lot. Commercial pharmacies are actually going to start playing a significant role. I also think that some members of the health care workforce will ultimately utilize commercial pharmacies for their vaccinations. I also know that the state
is in the process of looking at larger vaccination venues as a way to support other key role groups. We haven't really talked about fire, police, and EMS. For some systems, EMS will be able to vaccinate their workforce and the other public safety responders. Paramedics are allowed to do vaccination in Massachusetts with the current system, but they may be asked to do the EMTs or firemen, or police officers, et cetera, but not everywhere. There will be some centralized clinics that are made available for those staff as well as for some of the critical workers in high-risk settings. As those sites expand, (Dr. Madoff can certainly correct me on this) I believe those sites are going to be made available to smaller practices as well as independent practitioners who don't themselves have access to vaccination. It's a variety of methods, What I would say is that some will work with their affiliated hospitals, some will work with their local health departments, some will work with state large scale vaccination clinics, some will work with commercial pharmacy vendors. In the coming couple of weeks, as we start to have more product coming, especially the Moderna product that can be distributed to health centers, to small practices, to other sites around the state, and as the state starts to set up these larger vaccination sites, hopefully that will give the medical community many more options to seek their vaccination.

As a follow-up question, if I'm a primary care doctor, and I'm in private practice, and I see myself as a first wave person because of the urgent care that I provide, is my first move to make sure that I've gone to the MIIS in order to sign up there, or do I have access in some other way?

Dr. Biddinger: To be clear, the MIIS is the documentation system by which medical professionals document that they have administered vaccine. There's a separate system (this is a federal system and was outside of the state's control) that is required for individual practices to sign up to be vaccination sites for the Commonwealth. If you're an independent practitioner and you want to be administering vaccine both for yourself and your patients, make sure you've gone to the state's immunization program website, fill out their form, and sign up as a COVID vaccine vaccination provider. Even if you provide influenza or other vaccines, you need this specific COVID form. Sign up there, and as more product becomes available, you will get allocation directly from the state.

One of the very high priorities is long-term care facilities. Help us understand how they're going to be getting access?

Dr. Merchant: For long-term care, it's a separate channel from the federal pharmacy partnership program and all the facilities across the country were asked to choose a pharmacy. The federal government has partnered with CVS and Walgreens and in certain
other states, a few more different pharmacies that have a tremendous presence in long-term care. Physicians and staff at long-term care facilities and the residents and post-acute patients will all get vaccinated through this federal program where the pharmacist from either CVS or Walgreens will come into the facility and vaccinate everybody. So far, they have said that they will come in three times and try and vaccinate everybody there.

**For the patient population studies that were in people over the age of 75, do we know whether or not their response to the vaccine will be different? Are they more or less likely to have the same level of immunity from the vaccine?**

**Dr. Rubin:** The Pfizer study didn't include for efficacy. The phase three study didn't include patients over 75 years old, so we only can extrapolate. We haven't seen the Moderna study data yet. They're not yet public, but they did include patients over 75. I expect we'll have some better idea from that study. There have been a couple of efficacy studies of a variety of vaccines, including at least one of these (I can't remember which one) that looked at the immune response, not protection, but the immune response in older people, and it looked to be consistent across age groups. That result is encouraging, but the real efficacy data we're going to have to wait on. I assume that the FDA data will become public. The submission for Moderna will become public tomorrow.

**There is vaccine skepticism among health care workers as well. Some physicians are wondering whether or not they should get vaccinated as there's not yet long-term data. Younger physicians may feel that they are young and healthy with good hygiene, so do they really need to be getting the vaccine now?**

**Dr. Rubin:** Different people will have different answers. The question is how do you become immune to COVID-19? Right now, we know of two ways. You can either get infected or you can get the vaccine. If you get infected, what are the risks? We know the risk of getting hospitalized, for a younger person, it's going to be around 5%, and the risk of death is going to be very small, but it might be half a percent, 0.3%, something like that. The risk, if you look at vaccine from what we know so far, and admittedly, we don't long-term data, your risk of ending up in the hospital is less than 1 in 20,000. Your risk of death is less than 1 in 20,000. I don't think this is a tough calculus. I think it is pretty simple right now.

**Dr. Biddinger:** If I can add to Dr. Rubin's comment, I would say, and I'll take this one personally as a flaw. We've done a not-so-great job of making the case for collective action throughout this entire pandemic. People who are young and healthy have said,
well, I don't need to follow the rules as much because if I get sick, it's not such a big deal. Yet, the more of us that are infected, the more prevalence there is in the community, the more dangerous it is for all of us, and the more dangerous it is for the highest risk of us. There's a personal imperative to protect yourself, as Dr. Rubin said and I think there's a collective imperative that if we really want to get on the other side of this pandemic and make it through, we have to drive prevalence down. The only way we're really going to make a noticeable difference in driving prevalence down is to decrease the number of susceptible hosts that have the opportunity to become infected with the virus. So, there are reasons we do it for ourselves, reasons we do it collectively to get past this pandemic.

**Dr. Merchant:** I consider myself young and healthy. Of course, it's debatable, but I have elderly parents at home and every day I see patients. I want to make sure that I keep them safe and I don't expose them. As a geriatrician, I see the susceptible population, and I don't really want to take it back to them.

**Dr. Madoff:** Another important reason to be vaccinated, and one that came up on the advisory group, is that we lead by example. If we want to get to 80% of the population being vaccinated, I think we as physicians have an obligation to show our desire to get the population vaccinated by example, by showing that we, ourselves, are willing and able and eager, even, to get vaccinated. That is another important reason for physicians to get vaccinated.

**Dr. Wildes:** As an African American, my group is disproportionately affected. I have family members at home that have underlying conditions. I need to be an example and lead by example so that they feel more encouraged. They need to have more confidence in taking the vaccine because the impact is so devastating. I can be the one to lead the charge to help them to be convinced to get the vaccine because it's safe and it's effective.

**One component is trust, and a second is about prioritization. How do we ensure that there's equitable access to the vaccine within priority groups as outlined in the state's plan since racial disparities and structural racism pushes other people to the back of lines? How do we make sure that we get that right this time?**

**Dr. Wildes:** I have to just thank Dr. Biddinger for doing such an awesome job as the chair for the advisory committee. We really had great discussions, and he led the charge very well. One of the things which he has alluded to is how important it was for the advisory group to really address the underserved community and how we need to make sure that equity is at the front of all the decisions we're making. One of the things we also used along with making that decision was looking at the Social Vulnerability Index and
also the prevalence of COVID within these communities. The state has allocated 20% of vaccines to help this group. The state is really working to make sure that we address the needs of these individuals. A vaccine needs to be accessible to them, and we need to provide ways and means for these individuals so there's no reason they cannot get the vaccine like everyone else. Again, the Massachusetts Medical Society can really help to break down some of these barriers, to help this group to make sure that they get the care they so deserve.

We are supposed to get a second dose of the vaccine. What happens if there is a production or distribution delay with getting the second dose of vaccine? How do we deal with that as a state and what do we know about how that may impact efficacy?

Dr. Madoff: Dr. Biddinger mentioned, that the federal government is allocating the vaccine and is tracking how many doses are administered as a first dose and are at the same time allocating that second dose so that those doses will be available to the same site that administered the first vaccine after 21 days. It is built into the system and I really fully expect that that will happen. A few other things I would add. The second dose for the Pfizer vaccine is optimally delivered at 21 days. There's a little bit of a window. At least a week around that, so four days plus and four days minus that are considered acceptable times for the vaccine to be given as a second dose. There is a little bit of wiggle room there. Beyond that, we don't know exactly what the range is when a second dose could be successfully administered. We just know what we know, what's been available from the clinical trials. Certainly, we're going to learn more as vaccine rolls out. I have to say, there's a lot of optimism today, and it's a really happy day in that less than a year after this disease was first found that we're able to begin immunizing people here in the US and here in Massachusetts. I do want to say that there, almost inevitably, will be snags. There will be problems that will pop up. We’ve seen this with every immunization program. We see this with every vaccine, that there are issues, and there are problems that arise. We're going to have to be nimble, and we're going to have to be flexible, and we're going to have to work hard to keep everything running as smoothly as possible.

What do we know about people's carrier status once they have been vaccinated, whether or not they remain vectors of the disease and once people are vaccinated, and let's assume that there's seven days past the second dose, what do we expect that their behaviors should be and so far as mask wearing, social distancing?

Dr. Rubin: The Pfizer trial was set up to look at asymptomatic infection, not transmission. They haven't analyzed those data yet and there are some oddities about the
original data that might make it difficult to understand that part of it. We don’t know but hopefully we will learn more. As for behavior, I'll turn that over to Dr Madoff.

**Dr. Madoff:** We don't know yet is the answer. We don't know how protected people will be, whether they will still be able to acquire and transmit asymptomatic infection. 5% of people will be able to get symptomatic infection. No vaccine is 100% effective, and this isn't either. I think our guidance will evolve as it has almost continuously since the beginning of this outbreak as we learn more. For the moment, I would strongly advise people to maintain all of the precautions that they do now and not assume anything about their own immunity or ability to get the virus or to transmit the virus. For now, we would expect people to use the same measures that they currently do after being vaccinated.

**Dr. Rubin:** Getting back to what other people have mentioned as far as being examples for our community. When we walk into the grocery store, no one knows that we received vaccine. We should be behaving by the norms, even if we did know that we weren't likely to shed. Even if we thought the vaccine was pretty good and not perfect, we should be behaving in the way that we'd expect other people to behave.

**What about reduced doses for the elderly? Is anything known in that space, or whether the dose remains the same regardless of age?**

**Dr Merchant:** There is no reduced dose. It's one dose. I should say two doses, actually, a series of two doses. The strength doesn't change.

**Some people are in nursing homes and long-term care facilities, but some, of course, are short-term in nursing home. How do people who are short-term in nursing home make sure they get the appropriate second dose? How do they follow up that way?**

**Dr. Merchant:** Some of that is yet to come. We have raised this issue. Dr. Madoff has discussed this with me and my colleagues. I was also on the CDC call on Friday and asked this question. It's not clear yet, but I think we'll have to be innovative. Perhaps either call back a short-term resident who has been discharged before the second dose just for an outpatient clinic visit or perhaps can get a second dose through CVS. It may be left up to the community or their Primary Care Physician (PCP) when they have an allotment. I would love to see if Dr. Madoff has anything he can add.

**Dr. Madoff:** We don't know the answer to that yet. The vast majority will be able to get their second dose in the same setting where they got the first dose, and we're going to have to see for those individuals who leave the long-term care how to get them vaccinated in some other setting, but they will still need to be vaccinated. I just want to
mention one of the pluses of the vaccine in the elderly is there seems to be a diminished reactive immunogenicity. In the studies, at least those over 55 had a lower rate of adverse events following vaccination, including fever and other inflammatory signs. That's one silver lining.

What about patients that are either immunosuppressed because of some process in their body or immunosuppressed because of medications they are taking. What do we know about them and whether or not they should be receiving the vaccine?

Dr. Rubin: The group that were in the Pfizer trial, which is the one we have the most data from, included patients with what they described as stable disease. That included, for example, some HIV patients who had well-controlled HIV. The results, though, weren't broken out by those individuals and, in fact, the numbers are very small. It’s going to be hard to determine. On the efficacy side, I think we don't know. On the safety side, there's not a theoretical reason why these, at least these mRNA vaccine should be any riskier in that group than in any other. Chances are that these are going to be as safe in these immunocompromised populations as anyone else, and how well it will work is really going to depend to some extent on the degree of immunocompromised and the specific condition that those patients have.

How do people identify themselves by their cohort? In other words, there are some people who are a certain age or have a certain number of comorbidities. What's going to be needed in order to prove one way or the other about who we are, what we do, and whether or not we're allowed, as it were, in order to be able to get the vaccine?

Dr. Wildes: A big part of that is going to be people being really honest. There are guidelines that the state has provided, which we use as guides. We’re hoping that people adhere to these principles so that everyone can get the vaccine at the appropriate time because there are some people who are higher risk that should be ahead of the younger population. I think the key is that people really just follow the guidelines that have been given. DPH will probably help us by telling us when we're ready for the next phase that way people will know what stage we are in the process so they can go for their vaccination.

We don't know yet whether the vaccine is safe in children. What studies are forthcoming, and how young will we eventually be able to immunize if the studies turn out to be positive?
Dr. Rubin: It's a great question. There are studies, there’s already at least one study I'm familiar with which is enrolling 12-year-olds. There are plans for younger children studies, but to my knowledge, I don't know that any of them are underway right now. It's been raised repeatedly in discussions at the FDA how little we know and how important it is to learn that. Manufacturers are being urged to do these, but it's going to take a little while before we know.

If a COVID-facing health care worker who gets vaccinated then gets fevers or aches after the vaccination, how should they approach things? How can we if it’s from the vaccine or from COVID. Do they need to quarantine? Do they need to get tested?

Dr. Madoff: It's a very good question. Certainly, it's going to be important in the health care setting where the first people are being vaccinated because we don't want to see 10% or 20% of our health care workers excluded because they have side effects of the vaccine. CDC has just put out guidance on this point, actually. If people have an illness that doesn't include a respiratory component, for example, fever, low grade fever, even higher-grade fever, and don't have cough or shortness of breath or loss of sense of taste or smell, other more specific symptoms suggestive of COVID that we consider just screening those individuals looking for evidence of COVID, and perhaps, allowing them to continue to work, or to come back to work soon after that exposure. Clearly, we're in the midst of a pretty bad outbreak right now, so it's going to be difficult to know if somebody has a fever whether it's from COVID or from the vaccine. We need to be cautious, but we also don't want to lose a large percentage of our health care workers. The CDC guidance on this is pretty good and asks you to look at a number of factors in considering whether it's COVID or a vaccine reaction.

When we have conversations about equity, we often think about gender, race, and ethnicity, but people often forget to include disability. Where does disability fall in the phased plan for vaccination?

Dr. Merchant: The advisory group discussed whether disability should be included in one of the phases or not. It seemed to many members that disability was of many different kinds. Defining disability is hard. A variety of situations can cause disability.

We chose not to go there and stick to what we know is high-risk including age, comorbid conditions, and COVID-facing health care workers. Are you high-risk because of your job or are you high-risk because of the comorbid conditions or age? We chose to stick with that. That’s what the National Academies and the ACIP did as well.
The Pfizer efficacy rate was originally reported as 90% and then 95% later, and wondering why that was? These are impressively effective. Is there anything that we know about mRNA that is making these particularly effective, or is it this particular coronavirus that is making these particularly effective?

**Dr. Rubin:** Those are both excellent questions. Remember that the data were looked at twice. There was an interim analysis and then a final analysis. The interim analysis had fewer patients, a smaller number of infections, and the final analysis was triggered when they reached a certain number over 162 or so infections, something on that order. In fact, they had a few more than that when they did the analysis. The numbers came out about the same. The 90% and the 95% are really within the same confidence intervals. The 95% is probably a little more precise than the 90%. Yes, that’s extraordinarily effective. Now, we have a lot of other vaccines that are extraordinarily effective, too, and it's going to be hard to sort out whether this is the modality, the messenger RNA, or the virus. The only comparator we have is the AstraZeneca vaccine, which is based on a different technology and that didn't appear to produce as good efficacy as both mRNA vaccines did. It is conceivable that it's something about mRNA, but it's also equally possible that it's got to do with all the other myriad details involved in making a vaccine.

**People have asked about volunteering and aiding in distribution of vaccine and giving vaccine. Are there opportunities for physicians who are retired or quasi-retired to be able to help in vaccine distribution?**

**Dr. Madoff:** The spirit of volunteerism and assistance that we're getting from the medical society and its membership has been amazing. Yes, there will be opportunities. If you haven't already, you can join your local Medical Reserve Corps (MRC). The MRCs throughout the state enlist health care providers and work with local health departments or regional health departments. That's a pool we will draw on at DPH. There will be other opportunities. Stay tuned for those. We will be looking for vaccinators. This is really an all hands on deck situation. As we stand up mass vaccination clinics that Dr. Biddinger alluded to, there will be a need for additional vaccinators. Joining your MRC, if you haven't, would be a good place to start right now.

**We heard about anaphylaxis related to the Pfizer vaccine in the UK. For people with a history of anaphylaxis, but not to vaccines or any of the components of the vaccine, is there any protocol to test for administration, or is there any way that these people who want to get the vaccine can with a history of unrelated anaphylaxis?**
**Dr. Rubin:** Honestly, I haven't read the EUA that came out. Some of the other panelists may know better. As I said before, it's rather unlikely that anyone with anaphylaxis to anything is at particular risk of the vaccine. For the people who received the vaccine in the trial, over 20,000 people, there apparently weren't any cases that looked like the cases in England. If you take a random assortment of 20,000 people, a few of them carry an EpiPen, so it's probably likely that a lot of people got it. Having said that, it's not the kind of reaction that you want to see. In the trial, the only exclusions were people who had a history of vaccine anaphylaxis rather than to anything else. It's probably relatively safe.

**Dr. Madoff:** The EUA recommendations I think only specified anaphylaxis to one of the vaccine components. The CDC, the ACIP recommendations, which I'm not even sure are finalized, have been a little broader than that. Anaphylaxis to a previous vaccination, a previous immunization, is a relative contraindication. Finally, people who have had any kind of anaphylactic reaction, people who carry an EpiPen, as you suggest, should be observed for 30 minutes following vaccination, more than the routine 15 minutes. Again, this is something that we're learning more about daily. I would say we need to stay tuned, but those are the current guidance documents.

**As we near the end of our time, is there something that hasn’t been asked that needs to be added?**

**Dr. Wildes:** I just want to make sure that as we get ready to go ahead with the vaccine, especially for the communities of color. We want to make sure that we do everything we can to encourage that particular community to get the vaccine. Also, we also want to think about the undocumented immigrants. That's also a very important group. Remember, the vaccine is free, so we want to make sure that we to get the messaging out, because we all want to get back to normal, whatever that is going to be.

**For undocumented immigrants, we know the vaccine is free, but we're going to be keeping track of who gets a vaccine and where so that they can get a second dose. Is there anything that we can be doing to reassure the undocumented population that they're not jeopardizing themselves by revealing themselves in some database?**

**Dr. Madoff:** We obviously track people very closely in the MIIS. That information is extremely confidential and safeguarded. We share that information only with a patient's provider. That information is confidential. We certainly don't consider documentation or immigration status in making any kind of immunization decisions in Massachusetts. It does require some trust on the part of participants. I hope we can get that message out there.
**Dr. Merchant:** I just wanted to add one more thing. I hear every day, particularly among nursing home staff, people telling me. “I'll take it if my PCD recommends it”. I hope we can use this forum to have PCP's educate their patients because this is such an important issue, and we have a responsibility to society, not just to our patients.

**Dr. Rubin:** If I can echo that. We've been handed a sort of gift. I mean, this extraordinarily short cycle in which we're going from nothing to having a vaccine that seems to be highly effective against disease. That was a very hard part, but there's still a very hard part, which is trying to get people to take it. We are the ambassadors for vaccination as many have referred to. It’s on us right now to make it all work because nothing else seems to be working in this epidemic in this country. This is our opportunity.

**Dr. Madoff:** Nothing is more important to vaccine acceptance than a strong endorsement from the provider.

**Notes**

Each of the physician panelists who were a part of this program indicated they plan to be vaccinated for COVID-19 when their turn comes.

A video recording of the forum is available at: