

On January 12<sup>th</sup>, Johns Hopkins, LeadingAge, and the Baltimore City Health Department hosted a COVID-19 vaccines town hall addressing assisted living and senior housing providers.

Dr. Joshua Sharfstein moderated a panel of esteemed experts, covering the science behind vaccine development and approval, messaging strategies to address hesitancy among residents and staff, and considerations for assisted living and housing providers navigating vaccine clinics or other vaccination strategies.

Here are insights provided by each of the panelists:

**William Moss Executive Director, International Vaccine Access Center, Johns Hopkins Bloomberg School of Public Health**

*What is vaccination?*

Vaccination is a way of priming our immune system so that it is ready to fight a virus if you get exposed.

*How do we know vaccines work?*

The primary way we know they work is through an extensive process – we start off through animal studies, called preclinical studies, but where we really learn where they work are in human studies. There is a very standard way of assessing both the efficacy, whether the vaccines are protective and safe, which is really critical for vaccines because we're giving vaccines to a huge number of healthy people. We go through phases of trials where we start with smaller groups of people - a Phase 1 trial looking at some dosing, perhaps, and some safety signals. We move to a larger group of people looking at the immune responses to the vaccine. It's really in what we call the Phase 3 trials where we really look to see and measure whether the vaccines are protective and safe. For the Messenger RNA vaccines, the COVID vaccines, the United States involved tens of thousands of individuals.

*There were 30,000 or 40,000 patients in each of these studies, half of whom got the vaccine and half of whom got a harmless injection. None of the participants knew which ones they got. Then they looked to see if the groups got sick at same rate or does the vaccine actually protect the group they got the vaccine. What did they find?*

What they found was actually quite remarkable and unexpected. They found out about 95% of people who got the vaccine were protected, or what we call 95% protective efficacy after two doses of either the Pfizer or Moderna vaccines. That was really astonishing because we don't have many vaccines that are actually that protective. That protective efficacy was just as high in older adults.

*How closely was safety monitored in these large clinical studies?*

Safety is one of the paramount things that is monitored. They have people self-report any adverse events or things that occur to them after vaccination. They question people about things that

happened after vaccination. The testing of safety in these large trials is done very rigorously and very carefully.

*What are the results for the safety profile of the vaccines?*

These Messenger RNA vaccines - Pfizer and Moderna - were shown to be very safe in the Phase 3 trials. What we did see, however, is what we call reactogenicity. Those are side effects related to inflammation and that includes things like soreness at the site of injection, muscle aches, some fatigue. Some people got fever. All of this happened 12 to 36 hours after the vaccine. All were very expected. We see this with many other vaccines. These sometimes are moderately severe and people have to take a day off from work. Sometimes they have to take some an anti-inflammatory drug like a Tylenol or an Advil, but these go away. They don't cause any long term consequences. These side effects were less severe in individuals over 55 years old.

*Did these large clinical trials include a mix of ages, races and nationalities?*

Yes, they included a range of ages, nationalities, and ethnic groups. They did not include young children and pregnant women were specifically excluded.

*Do we know if the vaccine will need to be repeated year after year, like a flu vaccine, or might it be less frequently than that?*

We do not yet know the duration of protection following vaccination. We will learn as time goes on.

*Are you concerned about these new variants of the virus and whether or not the vaccine will work for them?*

It is reasonable to be concerned and to look into that. There has to be a fairly substantial changes to the virus for it to really allude the immune protection conferred by these vaccines, so I don't expect that to be the case. It is possible that there may be some decrease in the protection conferred by these vaccines. It is certainly not going to go to zero. My guess is that we're going to continue to see protective efficacy with these vaccines, but it's something that needs to be looked at and people are looking into that now.

*There have been more serious side effects, particularly allergic reactions, that have been reported among relatively few people. All of the serious adverse reactions have to be reported and then they get investigated by team of public health officials who look to see if it could be related to the vaccine or whether anything needs to be changed. On the basis of that, we have a question about whether any deaths have been reported from the vaccine and I do not believe there are any deaths that are have been associated with vaccination. Do you know otherwise?*

I'm not aware of any deaths associated with the vaccine. There have been several cases of severe allergic reactions with thought to probably be due to some of the fatty or lipid components of the vaccine in which the Messenger RNA is wrapped that is still ongoing investigations of that but no guests as, as far as I know.

*What gives people confidence in the long term safety based on what we know so far?*

We know from other vaccines that the vast majority of adverse events that are associated with that with vaccines occur in the first month or two following vaccination. So we can be very confident that we're that with the current follow up in the time upon which the emergency use authorization were based, we're capturing the vast majority of adverse events. It is true that we do not yet know because we haven't had the long-term follow up of whether there could be any rare adverse events associated with the vaccines. We did not see, for example, the severe allergic reactions in the Phase 3 trials. Those were first observed after the vaccine rollout and that's why it's so critically important the role the CDC is playing in continued monitoring for adverse events as we give these vaccines to more and more people.

*Who shouldn't get the vaccine?*

People who have had a prior severe reaction to their first dose and people with any severe allergic reactions to a component of the vaccine.

Those with an autoimmune disease CAN get vaccinated.

Those with seasonal allergies, food allergies, or a bee sting allergy CAN get vaccinated.

*What are some myths about the vaccine?*

There is a lot of misinformation about the vaccines. Myths include that the vaccines change your DNA or make you sterile. NEITHER of these are true.

**Thomas Cudjoe, Assistant Professor of Medicine, Johns Hopkins School of Medicine**

*You are taking care of patients in your geriatric practice who are thinking about getting vaccinated, what are the kinds of questions that that they have and how do you answer them?*

I care for older adults in their homes through our home-based medicine program. Responses have been heterogeneous. Some of my patients have been asking me when are we going to get the vaccine? Some of them have been more hesitant about the interest in it. It's important to acknowledge that interest in the vaccine varies for older adults.

The concerns about receiving the vaccine is not new, though I always say during these times we've been more aware of this concern and how different groups may have more hesitancy than others. One of the things that I think is important is to approach this conversation with dignity and respect while honoring individual autonomy, but lifting up our common experience and challenges amid this pandemic and acknowledging that vaccines are part of a broader strategy in our effort to mitigate the effects of the coronavirus.

*Let's say you had a patient who said "I don't know about this vaccine. It wasn't around a year ago. I know that they've done all these studies on it, but maybe I should wait a year or two to get vaccinated, just to be safe." How would you engage with a patient like that?*

I think it is important to start with understanding what their knowledge is about the vaccine, and then understanding their attitudes about getting this vaccine and the impact that it can have in their life, as well as their beliefs. Being a trusted source for my patients as well as using information that's available to me through public trusted resources is what I've relied upon.

I try to ground things in the current experience that people have had. We know older adults are particularly burdened by the coronavirus in terms of morbidity and mortality. From CDC data, we know that 8 out of 10 of the deaths that have occurred from COVID-19 have been in the 65+ population.

Throughout this whole time of the pandemic, I've had conversations with my patients about their risk and so we've already begun having conversations about the vaccine. It's important for individuals on the call to continue to rely upon the trusted sources that they've relied upon throughout the pandemic to further engage individuals in these settings on the effectiveness, the science, and answering any concerns that people have regarding the vaccine.

*If you were to speak to a patient who is concerned about the unknowns of long-term effects, how do you talk that through?*

I primarily focused on the information we have in front of us now, which is the risk of contracting the infection and the associated morbidity, mortality. You have to balance the unknown that exists against the known of the threat of COVID-19 right now. And, evidence is increasingly coming out about some of the long-term health impacts of COVID-19 for those who've experienced it and overcome it. We need to continue to monitor and our patients have contracted COVID-19 and try to support them as best we can as they navigate complications potentially associated.

**Ruth Link-Gelles, Epidemiologist, Centers for Disease Control and Prevention**

*You are in the business of getting vaccine to older adults through special kinds of partnerships. Can you tell us a little bit about that?*

The Centers for Disease Control and the Department of Health and Human Services partnered with a couple of pharmacies nationwide - CVS and Walgreens are the two biggest - to provide vaccines on site to long-term care facilities including skilled nursing, assisted living, HUD 202 IDD facilities, residential care facilities and other similar facilities for older adults. The purpose of this program is to reduce some of those barriers to vaccination. The patients are often bed bound or homebound so we need to bring vaccine to them. We also know that many of the staff members are working multiple jobs and may have other barriers to getting vaccinated out in the community. The idea is that we can increase uptake here by making this as convenient as possible for residents and staff.

The pharmacies are working with facilities that signed up themselves or that were signed up by their state health department to schedule clinics. That's already underway and most of the skilled

nursing facilities in the country have been completed, though it depends a lot on the individual state how they decided to time the program rollout.

Many of the assisted living and other eligible facilities are scheduling and starting their clinics this week or within the next couple weeks. Those are going to be a series of three clinics over the coming months. The first clinic for first doses for everyone. A second clinic for second doses and then we do have a third clinic in place for any folks who got a first dose at the second clinic needing to get their last dose. We expect the program to continue rolling out over the next couple of weeks and then facilities will have their second and third clinics throughout February and into March.

*How do assisted living and senior housing communities plug into this?*

Facilities were able to sign up throughout the month of October and into early November. Those not signed up can work directly with their state health department to get the vaccine so some state health departments are adding additional locations to the to the list that the pharmacies are using to schedule clinics. Other states have chosen to serve additional facilities, either through a local health department, through an affiliated hospital or through other means. If there is an organization that is not getting vaccine through the Federal program, I would encourage them to reach out directly to their state health department.

*If a rare allergic reaction to the vaccine occurs, are those administering vaccinations through the pharmacy partnership prepared?*

Yes, absolutely. CDC has posted a number of requirements for sites doing vaccinations to make sure that they're equipped to deal with these anaphylaxis reactions when they happen and that includes the pharmacy partners that are going out to these onsite clinics. They're working with the facilities ahead of time to make sure not just that they have equipment like an epipen and blood pressure cuff, but also that the facility can call 911 and can facilitate a transfer of an individual if there is a reaction.

*How is the CDC, at the national level, getting people information to help them understand the value of vaccination?*

The CDC is adding new resources to our website all the time. Just a week or two ago we added a long-term care facility toolkit, which includes some really great resources specifically geared toward both staff, residents and residents' families in long-term care to help with the discussions around vaccination. That toolkit is being updated all the time as new information becomes available. As we move into a phase where there's a lot more vaccine available and eventually new vaccines available, we'll be updating those resources continually.

There are a number of other media areas that CDC is using to get the word out. We had a fireside chat a week or two ago with the American Healthcare Association to talk through some of the concerns around hesitancy and safety of the vaccine and we will be continuing those types of outreach going forward.

*Have we seen staffing shortages as a result of vaccination side effects?*

There are generally more side effects with the second dose than the first dose, and since most facilities are just starting their second dose clinics this week and moving forward, we'll be keeping an eye on how that unfolds. A lot of facilities are working to try to stagger staff vaccinations just for that reason.

Juliana Bilowich: For those HUD Section 202 senior housing communities that have gotten the vaccine clinics their first clinic, we haven't heard this concern. In fact, we've heard the opposite, that the side effects are minimal. It is working very smoothly in comparison to staff getting COVID-19 and being out of work for a really long time. But just in case, that is the reason why there are not just two clinics, but three so that staff and residents can be staggered throughout.

**Juliana Bilowich, Director of Housing Operations and Policy, LeadingAge**

*How is the vaccine rollout going in different parts of the country?*

We have seen clinics start to happen in HUD SECTION 202 communities and it's so exciting. For those communities that are in the partnership and getting access, the clinics are just starting. Some are going very well. We know that there are still some hiccups to work through and it's all moving really fast.

However, that's only one segment of the affordable housing that serves older adults. We know that there are a lot of folks who aren't getting access yet to the vaccine.

*What kind of advice would you have for people who are running or living in assisted living or senior housing to make this process easy as possible for them?*

There are some special considerations for this type of housing. There are no medical staff on site, there are only a few staff at all, and they're also not in the habit of handling sensitive medical information. Just getting access to things like insurance information to pass on to the pharmacies or consent forms has been a real challenge. Tips for success include starting early and then trying to have the best communication possible with the pharmacy partner working with the site.

The other big challenge is the hesitancy that the residents and the staff feel about this vaccine. Try starting early with education efforts like putting up posters and other resources that the CDC has made available. Engage in conversation with folks to meet them where they are. Approach them with empathy and try to find a way to make use of this great opportunity.

For communities that aren't in the pharmacy partnership program, get on the radar of the states of the health departments to try to be part of other distribution strategies. That means that the education efforts aren't just limited to a vaccine clinic. It's an ongoing effort to try to improve health outcomes at these communities, just like we would the flu shot or other types of health resources.

*For communities that don't have access right now, what are you telling them to do?*

For those communities not within the partnership, try everything you can to get on the radar of your state or your health departments to try to be a part of expanded strategies for vaccine distribution as more doses become available.

States are working on strategies for individuals to go somewhere to get vaccinated and so that's another option to communicate with your residents. Of course, we think it's more efficient and safer for individuals if the vaccine comes to them in a in a in a group setting but any way that we can improve access increased access is certainly helpful.

*Can you limit certain services to senior housing residents who have gotten the vaccine and exclude those who haven't?*

We've heard some housing communities ask could we, for example, limit dining, service coordination, or occupancy to folks who have been vaccinated. We think is really problematic because as a housing provider, you're not in a position to ask somebody about their medical status. You aren't basing decisions about if somebody can live somewhere or access the services that you provide based on their medical status. That is not information you can ask or share. We just wanted to really remind providers that that's not something that HUD is allowing folks to do. If your community has a policy that everybody wears masks, then that continues regardless of somebody's medical status related to the vaccine.

**Heang Tan Deputy Commissioner: Aging and Care Services Baltimore City Health Department**

*How is this going in Baltimore?*

In Baltimore, we are currently vaccinating our first responders and healthcare workers. Our pharmacy partners are vaccinating the long-term care facilities right now and that effort is managed and handled at the state level. Our role at the local health departments is to help support these efforts. What we're seeing right now is that the uptake is not great. We are hoping to help support both on the educational side logistic side as well as being vaccinators ourselves.

*Are there any immediate lessons that you have from nursing home outreach so far?*

There needs to be a lot of education and logistical support ahead of time. One of the things that we found in the flu work is that we've had to go a couple of times into the facilities to help support, provide education, engage residents and their families, working very closely with the facilities and the administrators.

*How is the Baltimore City Health Department spreading the word about the vaccine to improve confidence more generally?*

We are building a community task force to engage community leaders and members to help develop messengers, another way of building trust, which is so important. We are developing an education campaign and training materials for building out COVID ambassadors in the community.

For the seasonal flu, what we did here in Baltimore was provide onsite and door-to-door vaccination through community health workers in partnership with our pharmacy partners. While we saw an uptick in vaccination in that work, we do know that there is a lot more work that needs to be done with education and building this engagement. Everyone here working in senior housing as well as assisted living and skilled nursing can play a role in helping facilitate that.

*What role do assisted living facilities and senior housing communities play in encouraging vaccination uptake?*

Assisted living facilities and senior housing entities each play an important role. You are trusted members of your community. You know your residents better than any other entity here so we need you to be involved in this process - anything that you can do to help prime and help support vaccination uptake and access. Please engage with your local health department to do so. Also, maybe look at potential policies about requiring your staff to have vaccinations if they can. We've seen really a lot of success in this in Baltimore City when for example, homeless shelters required every single member of their staff to get vaccinated for the flu.

**Morgan Katz** *Assistant Professor of Infectious Disease, Johns Hopkins University School of Medicine*

*How important are vaccines in the context of controlling COVID-19 and what else needs to be done?*

Nursing homes and assisted living communities have struggled a lot through this pandemic. We now have a sense that there is some sort of end in sight. A lot of that will depend on vaccine uptake while at the same time sticking with our core infection prevention practices. Until we get the community prevalence down we can't change a lot of the policies that communities struggle with like regular testing and limited visitation practices. I know that's hard because it seems like we've waited for so long but we have to cover every corner to get control. It really is going to take a team effort from every direction in order to get control of this.

*As vaccinations spread through the population and the amount of virus in the community goes down, and fewer people are getting sick, is that when you start to see some changes to those recommendations that are so difficult?*

We will see those changes as community prevalence comes down. Even after staff are vaccinated, even after residents are vaccinated, it will depend on vaccine uptake in the community. You're really shooting for 100% if you can get there. If you're only vaccinating 50% of your community, it makes it harder to get to a point where you can stop the testing. The regular testing is going to depend on prevalence in the community so it will have to continue until we get ahold of it.

*What kind of resources to answer these kinds of questions do you think assisted living and other facilities should access and how do you think about tackling this challenge of talking to people about the safety?*



It's important to talk to the residents, their families, and staff members about this. The CDC, Johns Hopkins, and LeadingAge all have great online resources available. There is still a lot of misinformation getting out there so make sure you're looking at the right sites.

*How do you explain to people who got vaccinated, that they still need to wear a mask?*

We know that the vaccine is incredibly efficacious in terms of preventing symptoms and severe disease. What we don't know is if you can still potentially be exposed, infected, and pass that on to somebody else, even if you're vaccinated and have no symptoms. Until we have more data on that, we really need to stick these core infection prevention practices – masks, physical distancing, and handwashing. We will not be in this place forever, but for the next several months until we get a good portion of this population vaccinated, that's where we are.