

COVID-19 TOWN HALL Q&A – December 16, 2020

MEMBER QUESTIONS		AAFP RESPONSES
QUESTION TOPIC INDEX		
<ul style="list-style-type: none"> • Advocacy and Government Relations • Health of the Public and Science 		
<p align="center">Thank you for joining our informative discussion with Lee Norman, MD, FAAFP, secretary, Kansas Department of Health and Environment, and Jonathan Temte, MD, PhD, associate dean, public health and community engagement, University of Wisconsin School of Medicine and Public Health.</p>		
MEMBER QUESTIONS		AAFP RESPONSES
ADVOCACY AND GOVERNMENT RELATIONS		
Workers in skilled nursing facilities and others in senior group living situations are so very important to be vaccinated early. Is the AAFP advocating for them?	<p>The AAFP has called for equitable distribution of the vaccine and that all family physicians receive the vaccine, regardless of whether they treat patients at an in-patient or outpatient setting.</p> <p>Distribution of the vaccine is being determined at the state level and the AAFP is monitoring state distribution plans to ensure that chapters have the latest information.</p> <p>Each state and/or jurisdiction has a different plan for vaccine distribution. The AAFP has created the State COVID-19 Vaccine Distribution Plans to help you navigate your state's plan.</p>	
HEALTH OF THE PUBLIC AND SCIENCE		
Is there any information or studies about the Pfizer or Moderna vaccine for women who are pregnant or mothers who are breastfeeding?	Pregnant women were not in the studies. However, they are not excluded from receiving the vaccine. These individuals should discuss the risks and benefits of the vaccine with their physician.	
Can you get the vaccine if you had Guillain-Barre syndrome (GBS) with the flu shot in the past?	According to GBS/CIDP Foundation International , there is no contraindication to the COVID-19 vaccine and those with a previous GB reaction to the flu shot.	
How can outpatient family physicians get vaccinated if they are not affiliated with any hospital system? Our county health department doesn't have information about that.	<p>The AAFP has called for equitable distribution of the vaccine and that all family physicians receive the vaccine, regardless of whether they treat patients at an in-patient or outpatient setting.</p> <p>Distribution of the vaccine is being determined at the state level and the AAFP is monitoring state distribution plans to ensure that chapters have the latest information.</p> <p>Each state and/or jurisdiction has a different plan for vaccine distribution. The AAFP has created the State COVID-19 Vaccine Distribution Plans to help you navigate your state's plan.</p>	

<p>What information or evidence is there about the vaccine and what happens to the spike protein once it is expressed on the myocyte? What stops the translation of the messenger ribonucleic acid (mRNA) to protein? Are we sure that only the myocytes express the spike protein? Is it truly safe to be expressing antigen on our own cells?</p>	<p>The mRNA is safe, as is the process of displaying the spike protein on the surface of cells. Our cells are displaying antigen on their surface all the time. When immune cells recognize that antigen as a host, nothing happens. But when they recognize it as foreign, they become activated and respond. For these vaccines, only part of the spike protein is made and displayed. It is then rapidly broken down, as is the mRNA.</p>
<p>How can we encourage essential staff to get the vaccine if they are hesitant?</p>	<p>Studies have shown that a strong recommendation from a trusted physician increases vaccine confidence. AAFP members are encouraged to share news with patients and staff when they get the COVID-19 vaccine. If you're sharing your vaccination on social media, use the hashtags #FamDocs4Vax and #WhyWeVax.</p>
<p>Do patients need to register in order to get the vaccine?</p>	<p>Each state and/or jurisdiction has a different plan for vaccine distribution. The AAFP has created the State COVID-19 Vaccine Distribution Plans to help you navigate your state's plan.</p>
<p>I haven't seen anything scientific that says the myocytes expressing the spike protein are broken down rapidly. The Centers for Disease Control and Prevention (CDC) is focused on how fast the mRNA is degraded. Is there evidence for the former?</p>	<p>All proteins are recycled by our cells pretty quickly. Once the mRNA is degraded, more protein is not made. The main cells involved in presentation of the antigen are the monocytes, and dendritic cells present near the site of injection.</p>
<p>With regard to side effects, I've had a lot of questions from my patients today about this report from Alaska. Does the AAFP have any comment on this?</p>	<p>The Food and Drug Administration (FDA) and the CDC are working with local officials in Alaska, as well as with the United Kingdom, to learn more about these reactions. AAFP staff continue to monitor the situation and participate in calls with federal agencies. As more information is available, staff will communicate major changes in vaccine administration to members via the AAFP COVID-19 Vaccine webpage and other channels, such as the COVID-19 Rapid Response Member Exchange and the COVID-19: Member Communications webpages.</p>
<p>What are the AAFP's thoughts on health care workers who are pregnant opting in or opting out of the COVID-19 vaccination? What about mothers who are breastfeeding?</p>	<p>Pregnant women were not included in the trials, but they are not excluded from getting the vaccine. They should talk with their physician about the risks and benefits of vaccination. The same suggestion goes for women who are breastfeeding. There were no trials that included them either, but there are no exclusions from getting the vaccine.</p>

<p>Our clinic is treating sick patients and swabbing them for COVID-19 every day with inadequate personal protective equipment (PPE). How do we get our doctors and staff vaccinated?</p>	<p>Each state and/or jurisdiction has a different plan for vaccine distribution. The AAFP has created the State COVID-19 Vaccine Distribution Plans to help you navigate your state's plan.</p>
<p>There reports about delays for rural sites and locations in some states getting an adequate supply of vaccines. How are states ensuring there is parity?</p>	<p>This question was answered live during the Town Hall session. Please see response at the 46-minute mark in the video replay.</p>
<p>Are there any issues with giving the COVID-19 vaccine with, or in a specific time frame, of other vaccines?</p>	<p>Patients will need to wait 14 days from other vaccine administration.</p>
<p>Some health care organizations are discussing incentives or forcing strategies for health care workers to improve vaccination rates. Are there guidelines to address these questions or concerns?</p>	<p>No guidelines were found related to this concern. Per the FDA at the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting, vaccines available under an emergency use authorization (EUA) can't be mandated by employers without specific instructions from the secretary of the FDA.</p>
<p>For those of us who will not be getting the vaccine for a while (i.e., medical students), what are some other ways to get accurate information to others and to encourage the general public to get vaccinated?</p>	<p>Information is available on the AAFP COVID-19 Vaccine Patient Education webpage with strategies to communicate with patients to boost vaccine confidence, as well as this helpful COVID-19 Vaccine FAQ.</p> <p>The AAFP's patient-facing website, familydoctor.org, has information for a patient audience, along with videos and other resources to help address vaccine hesitancy.</p>
<p>Are there any recommendations for adjusting the dosage for patients on chronic steroids (stress doses) when getting the vaccine?</p>	<p>There is no information specific about stress doses of steroids with the vaccine. However, the CDC has stated routine prophylactic administration of anti-pyretic or analgesic medication for the purpose of preventing post-vaccination symptoms is not currently recommended. Information on the impact of such use on the Pfizer-BioNTech COVID-19 vaccine-induced antibody responses is not available at this time.</p>
<p>Are there plans to proceed with pediatric vaccine trials, and how is our inability to vaccinate those under 12 years anticipated to affect short- and long-term social distancing and mask recommendations in the future?</p>	<p>Both Pfizer and Moderna have begun enrolling in trials children and adolescents 12-16 years. Based on the data so far, most of the transmission in schools is due to adults and not young children. Dates for inclusion of children under 12 in the trials have not been provided by any manufacturers.</p> <p>All individuals receiving the vaccine will still need to wear masks and practice physical distancing, as the vaccines will be effective at preventing the disease, but it may not prevent virus spread.</p>

<p>Can you tell us about physicians who recently received bamlanivimab (an investigational treatment for individuals 12 years and older with mild to moderate symptoms who are at high risk for developing severe COVID-19 symptoms) in the last month due to symptomatic COVID-19? Should the vaccine be delayed? How long?</p>	<p>The current recommendation is to wait 90 days.</p>
<p>I heard that recipients of the vaccine shed virus. How long does that occur and how much of a risk are they to others? My son is a health care worker and his wife is three months pregnant. Would he be putting her at risk?</p>	<p>The vaccine does not contain virus, so it will not lead to viral shedding. However, people who are vaccinated may still be able to transmit the virus if they get infected. Masking and physical distancing will still be very important.</p>
<p>Can you offer advice if my health department doesn't have a plan for vaccinating outpatient doctors who are not affiliated with any hospital systems?</p>	<p>The AAFP has called for equitable distribution of the vaccine and that all family physicians receive the vaccine, regardless of whether they treat patients at an in-patient or outpatient setting.</p> <p>Distribution of the vaccine is being determined at the state level and the AAFP is monitoring state distribution plans to ensure that chapters have the latest information.</p> <p>Each state and/or jurisdiction has a different plan for vaccine distribution. The AAFP has created the State COVID-19 Vaccine Distribution Plans to help you navigate your state's plan.</p>
<p>What are the components of the vaccine so people can determine if they are allergic to any of those?</p>	<p>This question was answered live during the Town Hall session. Please see response at the 54-minute mark in the video replay.</p>
<p>Does the spike protein encoded by the mRNA promote an antibody response that leads to immunity to one or multiple strains of SARS-CoV-2?</p>	<p>The mRNA vaccine is specific for SARS-CoV-2. Cross reactivity of an antibody response for other coronaviruses is not known at this time.</p>
<p>I already have patients requesting exemptions from the vaccine. Other than anaphylaxis to the components of the vaccine, are there any contraindications for which exemption would be medically appropriate?</p>	<p>This question was answered live during the Town Hall session. Please see response at the 40-minute mark in the video replay.</p>
<p>What is the current thinking about vaccinating patients who are pregnant? What is the evidence behind that? Do we know whether mRNA crosses the placenta?</p>	<p>This question was answered live during the Town Hall session. Please see response at the 41-minute mark in the video replay.</p>

<p>If a health care worker or long-term care patient recently had COVID-19, how long are they considered immune and can they safely wait to get the vaccination in a later round?</p>	<p>The length of immunity after infection with the virus is not known. Individuals who have previously had COVID-19 are eligible to receive the vaccine.</p>
<p>Should individuals be tested for COVID-19 prior to receiving the vaccine?</p>	<p>Testing for COVID-19 is not required for receipt of the vaccine.</p>
<p>Will private physician offices receive vaccines?</p>	<p>The AAFP has called for equitable distribution of the vaccine and that all family physicians receive the vaccine, regardless of whether they treat patients at an in-patient or outpatient setting.</p> <p>Distribution of the vaccine is being determined at the state level and the AAFP is monitoring state distribution plans to ensure that chapters have the latest information.</p> <p>Each state and/or jurisdiction has a different plan for vaccine distribution. The AAFP has created the State COVID-19 Vaccine Distribution Plans to help you navigate your state's plan.</p>
<p>Since the trials were so large, why are there so few patients actually having COVID-19 in either arm in the released studies?</p>	<p>Trial participants were encouraged to continue risk mitigation practices like masks, hand hygiene, and physical distancing. Additionally, both trials used an endpoint of COVID-19. Neither trial used routine testing of participants, so there may have been some asymptomatic infections. It is important to note that the vaccine is effective at preventing disease and has not been demonstrated to prevent infection at this time.</p>
<p>How soon after having a positive COVID-19 test should a person get the vaccine and/or should they get the vaccine at all?</p>	<p>Persons with a positive COVID-19 test should delay receiving the vaccine until they have completed the recommended duration of isolation and are not symptomatic. This will help avoid unnecessary exposure to those administering the vaccine. Individuals who have had COVID-19 previously are eligible to receive the vaccine if they desire.</p>
<p>Is there a vaccine information sheet (VIS) about the vaccine yet?</p>	<p>Please find the emergency use authorization (EUA) fact sheet here.</p>
<p>Where can we get the list of ingredients in the vaccine so we can ask patients about the specific allergies?</p>	<p>Please find the emergency use authorization (EUA) fact sheet here.</p>
<p>What is the risk of Bell's palsy and do we treat it with steroids? Are there any other severe side effects that last more than 24 hours?</p>	<p>In the Pfizer-BioNTech trial, Bell's palsy was reported by four vaccine recipients and none of the placebo recipients. This is similar to what is seen in the general population, so there is no increased risk. Most systemic post-vaccination symptoms are mild to moderate in severity, occur within</p>

	the first three days of vaccination, and resolve within 1-2 days of onset. These symptoms are more frequent and severe following the second dose and among younger persons (aged 18-55 years) compared to older persons (aged >55 years).
Is there any guidance for females of childbearing age? Is there the potential for the vaccinations to cause infertility?	Women who are pregnant were not included in the trials, but they are not excluded from getting the vaccine. They should talk with their physician about the risks and benefits of vaccination. The same suggestion goes for women who are breastfeeding. There were no trials that included them either, but there are no exclusions from getting the vaccine .
Should our clinicians and staff continue to wear PPE when seeing patients once everyone in our staff is vaccinated? Is there guidance on how we start opening up as the vaccine is distributed?	Yes. While the vaccines provide protection against COVID-19, they have not been shown to prevent infection, so people who are immunized may still be able to transmit the virus. Additionally, the 95% efficacy in preventing the disease was not observed until several weeks after the second dose. Everyone will still need to wear a mask and practice physical distancing until a large section of the population have developed immunity, which may not be until late 2021. Even then, more data will be needed to see how long immunity lasts. Additional rounds of immunizations may be needed.
Is there a central vaccine registry to track and provide documentation of the vaccinations?	Each state/jurisdiction will have a reporting system in place. Please refer to your state plan here .
Children are at lower risk of severe disease, but they are still in congregate settings (schools). Are there studies ongoing or planned, and is there an intent to eventually get this group vaccinated?	Both Pfizer and Moderna have begun enrolling children and adolescents 12-16 years in trials. Based on the data so far, most of the transmission in schools is due to adults and not young children. Dates for inclusion of children under 12 in the trials have not been provided by any manufacturers.
Is there any estimation on the timeline for availability of the Pfizer and Moderna vaccines? Specifically, to have enough vaccines to get through all of phase one? Is that timeline February or March? When do we expect to see phase two?	The timeline is dependent on several factors, such as the amount of vaccine available from the manufacturer(s) and the speed at which the different populations are able to be vaccinated in each area.