COVID-19 Vaccine Safety: A Fireside Chat with CMS, CDC, and AHCA December 30, 2020

Panelists

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CMS will post the recording at
https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit

Some healthcare workers are concerned about taking the vaccine and have questions. This session reviews some of the most frequently asked questions and answers from these experts.

Q: This vaccine was developed quickly. Was it rushed? How do I know it is safe?

A: The methodology has been studied for many years and the technology was already under development so the basics have been developed over time. The rapidity of the roll out is due, in part, to the fact that the FDA, HHS and the vaccine companies worked together to quickly enroll 30,000 people in trials for each of these products. That is as many or more people than for other vaccines. Manufacturing began while the trials were underway in order to be able to release doses as soon as the data was reviewed and emergency approval given. The vaccine itself is pretty simple, and it is composed of Messenger RNA surrounded by a few lipid particles. There are no preservatives or other types of ingredients. Frankly, many drugs commonly prescribed for infections, high blood pressure, etc. have much greater side effects.

Q: If it wasn't rushed why did these vaccines receive an Emergency Use Authorization rather than full approval?

A: That is mostly a question of the regulatory review steps and the speed at which they were done. Most of the participants in the study were followed for two months before data was submitted. For full approval a smaller cohort is usually followed for longer – from 4-6 months. However, now many of the trial participants have been followed for that long. And, it is likely that the firms will be requesting standard approval at some point.

Q: What are the side effects?

A: The side effects are generally quite mild and may include pain in the injected arm, fatigue, aches and a low -grade fever for a day or two. These are NOT COVID – there is no live virus. Rather they are the body mounting an immune response.

Q: What do we know about long -term side effects?

A: Some people have been followed for 6 months and there have been no serious problems. For all types of vaccines, 99% of side effects occur within 6 weeks of vaccination.

Q: Who should not get the vaccine?

A: People who have severe allergies to the ingredients in the vaccine should not receive it. The list of ingredients (which are several types of lipids) are on the manufacturers' websites.

Q: Should I get the vaccine if I have allergies?

A: People with seasonal allergies, food allergies, etc. should get vaccinated. If you have had an anaphylactic reaction to an injected medicine, talk with your physician first. If people have history of previous anaphylaxis or severe reaction to an allergen, they should be watched for 30 minutes after vaccination, rather than the standard 15 minutes. Severe reactions are very, very rare. We will have more information as more people are vaccinated – adverse effects are being monitored. If you have an allergic reaction to the first dose, you should not get the second dose.

Q: What about people with auto-immune conditions or other medical conditions?

A: People with many types of medical conditions were enrolled in the trials and there was no difference in response between those who received the placebo and those who received the vaccine. There were not many people with auto-immune disease enrolled, so those individuals should discuss with their physicians. There does not appear to be a contraindication at this time.

Q: Should pregnant women receive the vaccine?

A: The trials did not enroll women who were known to be pregnant. However, there were 20-30 women in each trial who either were pregnant and did not know or became pregnant between the first and second doses and there were no problems. 1,500 pregnant women have been vaccinated and are being followed closely. There is no biological reason that the vaccines should be a problem for pregnant women or have any effect on fertility. And, there are significant risks to contracting COVID and many people will have long term consequences from that. It should be a personal choice for pregnant women, but it is certainly recommended for frontline healthcare workers. People need to balance the potential risks of taking the vaccine vs. the effects of getting COVID.

Q: Is it true that the vaccine can affect fertility?

A: There is no biological reason that should be the case and there have been no reported effects on fertility. The vaccine is not circulating throughout your body. The vaccine is injected into muscle. Lipids then help it get to nearby lymph nodes where the immune response occurs. There can be systemic side effects in response to the injection as it boots immune response.

Q: If I get vaccine and have had COVID will I have worse side effects?

A: There is no evidence of this in the data. People who have had COVID should get the vaccine because we don't know how long having had COVID protects a person. The vaccine produces longer -term protection, though we don't yet know for how long. It may be that people will need to get vaccines on a periodic basis, which is consistent with the need to get tetanus booster, yearly flu vaccine, etc.

Q: Will you test positive if you get the vaccine?

A: PCR and antigen tests will not come back positive, but it is possible that antibody tests may.

Q: **What about this new strain of the coronavirus– will these vaccines work on that?**

A: We think so and are monitoring that and are monitoring many things such as the duration of protection. People who receive the vaccine should register with VSAFE so that they can contribute to the learning.

Q: **Should I wait and watch before getting the vaccine?**

A: **No!** This virus is so readily transmitted and we are in such a surge, that people on the front lines are highly at risk for the foreseeable future. All of the data is so positive about the vaccines – there is no reason to wait, and there is lots of risk in waiting.

Q: **If I get the vaccine can I stop wearing PPE, social distancing, etc.?**

A: **No!** We don't know if vaccines stop transmission. We know it protects the person who is vaccinated, but not whether the vaccinated person can transmit the virus to others.