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COVID-19 UPDATE: Vaccine News

(Summary by Dr. Ari Brown, MD, FAAP)

It's exciting to discuss the launch of the upcoming national immunization program which, ultimately, will lead to return to our normal lives.

There is certainly plenty of information out there about the COVID-19 vaccines, but we hope to curate it, give you a clearer picture of the safety and efficacy data, and reassure you that yes, getting this vaccine is a good idea.

A bit of housekeeping first: The basis for this information comes from the Food and Drug Administration FDA Advisory Committee Meeting held on Dec 10, 2020, Centers for Disease Control (CDC), Advisory Committee on Immunization Practices (ACIP), and the American Academy of Pediatrics. We highly recommend you seek any additional information from these trusted resources because vaccines (including this one), are a lightning rod for science-skeptics. We also hope that you will trust us when we tell you that as a healthcare provider, we will be in the highest priority group and will gladly roll up our sleeve to get vaccinated.

So, let's get on to the burning questions!

COVID-19 VACCINE RESEARCH

What kind of COVID-19 vaccines are available or being researched now?

The Pfizer brand is the first vaccine to receive emergency use authorization by the FDA after a study involving 42,000 participants demonstrated 95% effectiveness in preventing symptomatic COVID-19 infection and almost 100% protection against severe disease. The Moderna brand will go through a similar process with the FDA this week. These two vaccines are both "mRNA" vaccines. Two other manufacturers, Astra Zeneca and Johnson and Johnson (Janssen) are actively doing vaccine trials using a slightly different method to achieve immunity using "adenovirus vector" biotechnology. Those, and several other vaccine candidates are a bit further away from being authorized for use.

How does the mRNA vaccine work?

The mRNA is a tiny instruction code or recipe that gives the body instructions to produce one very specific part of the COVID-19 virus called the spike protein. Once our body produces that protein, our immune system sees that protein and mounts antibodies to it. The mRNA then gets broken down very quickly in the human body and is eliminated. That is the unique part of this particular vaccine. Like all other vaccines, our body makes antibodies before seeing an actual threat of virus/bacteria, so when we do encounter it, we recognize it, and prevent it from causing infection at all or causing serious infection.

Can I get COVID-19 infection from the vaccine?

No. There is no virus in this vaccine. You do not become infected by getting the vaccine and you cannot spread infection to others by receiving the vaccine.

How long will immunity last?

Right now, we know protection lasts at least 2 months. There is optimism that the vaccine immunity will be longer lasting than natural disease-immunity. This will continue to be studied. Experts are looking at the body's T cell memory after receiving vaccination, which if activated, could mean protection lasting perhaps 1-3 years.

Will it completely protect against infection?

Great question. No vaccine is 100% effective. The mRNA vaccines (Pfizer and Moderna) show about 95% effectiveness in protection from illness from COVID-19 virus. In other words, the vaccine is excellent at protecting you from getting sick! That was the goal of the initial research trials. What we do not know yet, is if vaccinated people will still potentially be able to become infected, not have symptoms, and transmit the virus to others. That should be known in the next few months.

Should I worry that this type of vaccine technology has never been used before?

No worries. This technology has been used for over a decade as a cancer vaccine. It is just new to the infectious disease space. The initial concern (prior to the formal vaccine research studies) was whether it would provide an adequate immune response—it was already felt to be very safe after a decade of experience with it.

Will the mRNA alter my genetic code?

As parents, we all wish we could have eyes on the back of our heads, but no, we won't grow another set after getting this vaccine! The mRNA is basically a self-destructing recipe for our bodies to make what looks like the coronavirus spike protein. The mRNA is very unstable— meaning it disintegrates quickly, which is why it needs to be so darn cold and packaged in fat (lipid nanoparticle) to remain stable and enter your body. But once it has done the job, it is gone. To take you back to 7th grade science class, the mRNA enters the cytoplasm of our cells, not the nucleus where our DNA resides. It is not even remotely capable of entering our DNA and altering our genes.

Why do we need to get two doses of the vaccine?

This is common for optimal immune response and protection for several other vaccines that you may be familiar with in the childhood immunization series such as whooping cough or flu vaccine for infants. For the Pfizer and Moderna vaccines, the studies show that the first dose primes the immune system and the second dose leads to much higher protection. For the Pfizer vaccine, the timing is 2 doses given 21 days apart. It is possible to get the 2nd dose as early as 17 days after the first one. If more than 21 days elapse, a person can still receive the 2nd dose and the series does not need to be repeated. For the Moderna vaccine, the timing will be 2 doses given 28 days apart.

Are the vaccines interchangeable to get the 2nd dose?

No. If you get the Pfizer vaccine, you will need to get a booster dose of the Pfizer vaccine. The Johnson and Johnson (Janssen) vaccine is the only product in development that needs only one dose for protection.

Can I get the COVID-19 vaccine if I just got a vaccine for something else?

The Advisory Committee on Immunization Practices advises receiving the COVID-19 vaccine at least 14 days apart from other vaccinations.

Once I get vaccinated, when will I potentially be immune?

It looks like most people show robust immunity 1-2 weeks after receiving the second dose of vaccine. You should continue to practice social distancing and mask wearing, for the near future, however.

If I had COVID-19 infection, can I still get the vaccine?

Yes. Experts believe natural infection will not lead to lifelong immunity, but will provide about 3 months of protection. There is no need or recommendation to test for prior infection before getting the vaccine. But if you have had COVID-19 infection within the past 3 months, it is okay to delay getting vaccinated until after that window of time passes. You should NOT get the vaccine while you have an active infection with COVID-19 or if you have been recently exposed and in a period of quarantine.

I am immunocompromised, can I get the vaccine? Yes. People with HIV and other health issues that make them immunocompromised are at high risk of severe disease with COVID-19 infection. But you should discuss your medical history with your healthcare provider.

VACCINE DISTRIBUTION

When will the COVID-19 vaccine be widely available?

In the US, residents and caregivers in nursing homes and people who work in hospital settings have the highest priority for getting vaccinated. As more vaccines receive emergency use authorization and vaccine supply increases, it should become widely available in the next six months.

KIDS, PREGNANCY, & BREASTFEEDING

Is the COVID-19 vaccine approved for children right now? No. The Pfizer vaccine has been approved for ages 16 and up. The FDA advisory committee meeting expressed some concern about the limited data on 16 and 17 year olds in the initial study, but ultimately felt that the benefit to teens with health issues in that age group was greater than the potential risk. Pfizer has enrolled children down to age 12 in ongoing studies, and Moderna and Janssen plan to enroll children ages 12 and up as well. Astra Zeneca plans to enroll children ages 5-12 in the UK but none are included in the US study thus far. Younger children will likely be included in these studies over the coming months.

Where will I be able to get the COVID-19 vaccine?

National pharmacy chains, independent pharmacies, doctors' offices, and clinics will begin offering COVID-19 vaccine when it is widely available. Note: the Pfizer vaccine is shipped in minimum quantities of 1000 doses and must be used within 5 days—which is easier for hospitals or large pharmacies to manage. The Moderna vaccine ships in minimum quantities of 100 doses and has a longer shelf life so it will be more practical for use in smaller medical practices.

Is there any COVID-19 vaccine data for pregnant women?

Well...Pregnant women were not recruited for the initial research studies, but guess what, stuff happens! So, yes, there are some (12) inadvertent pregnancies in the vaccinated group and those women will be followed for birth outcomes. No pregnancy-related data has been released yet. Animal DART (Developmental And Reproductive Toxicity) studies are currently underway and results will be available in the near future.

Is there any COVID-19 vaccine data for breastfeeding women?

No. But, the American Academy of Pediatrics says it is “not likely” to be a problem for breastfeeding women or any risk to the child, based on how these vaccines work. The Advisory Committee on Immunization Practices concurs, but admits there is no data to confirm that.

I am a healthcare provider and I am pregnant, should I get the COVID-19 vaccine?

According to the Advisory Committee on Immunization Practices (ACIP), you should discuss the risks and benefits with your healthcare provider. But you certainly can choose to be vaccinated if you are in a high priority group for other reasons. There is no need to test for pregnancy prior to receiving the COVID-19 vaccine. We know that pregnancy is a risk factor for more severe COVID-19 infection and an increased risk of preterm delivery. If you get the vaccine and develop a fever, ACIP advises taking Tylenol (acetaminophen) as fever during pregnancy carries a slight risk of adverse pregnancy outcomes.

COMMON SIDE EFFECTS

I've heard that many people feel sick after receiving the vaccine. Will I need to take the day off of work after getting vaccinated?

Maybe, especially after the 2nd dose of the vaccine when more people report bodyaches, chills, and fever. This is called reactogenicity and is part of the immune system mounting a robust response to vaccination—so while you may feel bad you can feel good that your body is doing what it is supposed to do. You may want to consider taking the day after vaccination off. It occurs more in people ages 18-55. Note: people receiving vaccine do NOT experience cough, shortness of breath, or loss of smell and taste. If you develop these symptoms, you should consult your doctor and get tested for COVID-19 infection.

Can I take Tylenol if I feel crummy after getting vaccination?

Yes, but ACIP recommends NOT taking Tylenol (acetaminophen) routinely at the time of vaccination. It may impact the antibody response to the vaccination. So, if you absolutely need it, take it, but limit use if possible.

SAFETY MONITORING

I've heard about the potential for allergic reactions with this vaccine. I have a peanut allergy, is it safe to get the COVID-19 vaccine?

Yes. The UK quickly issued a warning about two patients who developed an allergic reaction after receiving the COVID-19 vaccine last week. In the US, the Advisory Committee on Immunization Practices has provided more specific guidance:

>People with a history of food, pet, insect, venom, seasonal allergies, oral medications (e.g. Penicillin) CAN receive COVID-19 vaccination but should be observed for 15 minutes afterwards

>People with a history of severe allergic reaction (anaphylaxis) to an injectable medication or another vaccination MAY receive COVID-19 vaccination after a risk assessment and should be observed for 30 minutes afterwards.

Experts are looking at an inactive ingredient in the vaccine called polyethylene glycol (PEG) as the possible cause of rare allergic reactions to it. PEG is found in other injectable medications and vaccines, which is why the advice is to stick around for 30 minutes after vaccination if there is a history of significant allergic reaction with injectable medications. Stay tuned on this one.

How will vaccine safety be monitored?

As with all vaccinations, healthcare providers are required by federal law to report adverse events that occur after vaccination to the Vaccine Adverse Event Reporting System (VAERS). This system collects data as part of the US vaccine safety post-licensure monitoring system. Note: VAERS is only a data collector. VAERS does not determine if the adverse event was caused by vaccination. Other entities review the data and look for any concerning trends. Texas law also requires adverse events to be reported to our state immunization registry, ImmTrac2. The CDC has also launched a V-Safe App to allow COVID-19 vaccine recipients to submit health information after being vaccinated. (The app will also send a reminder when it is time to get dose #2 of the vaccine). That said, there are various ways that vaccine safety will be tracked as more people get vaccinated. If there is any significant issue that arises, we will know about it very quickly!

How do we know if this vaccine has any long-term safety issues?

All Pfizer study participants completed their two dose vaccination series at least two months ago. We know from other licensed vaccines that significant adverse reactions, if any, occur during within two months of being vaccinated. Study participants will be followed for two years to monitor for any potential issues.

TESTING AFTER RECEIVING VACCINATION

If I get the vaccine, then potentially have symptoms of COVID-19, will rapid testing be accurate?

Yes. Rapid tests are not impacted by receiving vaccination.

If I get the vaccine, will antibody testing be accurate for detection of disease? This gets kind of technical, but stick with us. Since the goal is to create spike protein antibodies with vaccination, having spike protein antibodies does not differentiate between immunity after disease or immunity after vaccination. The proof of true infection in a COVID-19 vaccinated person will be a blood test for IgM/IgG for the nucleocapsid protein.

STUFF YOU'LL SEE ON THE INTERNET...

I heard some people died who were in the Pfizer COVID-19 trial. Is this true?

Yes. There were 6 study participants who died during the research trial. But 4 of them were in the placebo group, meaning they did not get the vaccine. The two deaths were in people over 55 years of age. One person had a heart attack 62 days after getting the 2nd dose of vaccine and one had a vascular event due to arteriosclerosis 3 days after getting the 1st dose of vaccine. The number and cause of deaths in the age group being studied was a similar rate to the general public and not statistically significant.

I heard 4 people developed Bell's Palsy after vaccination. Is this true?

Yes. But again, there was no greater chance of developing Bell's Palsy after vaccination than the incidence that occurs in any other population of 44,000 people.

Is there a chance that the vaccine could make you get more severe illness if you are later exposed to the actual virus?

There is no evidence currently to support the concept of vaccine-enhanced disease or antibody mediated enhancement with the COVID-19 vaccine. In fact, study participants who received the vaccine and later developed infection had milder cases of illness. But the FDA and other advisory groups are monitoring for this closely in ongoing clinical trials.

Is this vaccine being rushed out too fast?

No. The clinical trials (Phase 1, 2, and 3) are identical to other vaccine research studies prior to clinical use. This vaccine got to bypass the usual red tape as well the financial risks that make other vaccines take longer to get to the finish line. While it would be nice to have longer term data, we know that with virtually all other vaccines on the market the most significant and common adverse reactions occur within two months of being vaccinated. With 300,000 US deaths at this point, the safety and efficacy data demonstrate the benefit of emergency use authorization far outweighs the risk of not proceeding.

Remember, the vaccine is only effective if people get it!! For now, keep masking up 🦺

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