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Follow the Science with Dr. James Avery, MD, CMD, FAHHPM, FACCP, FACP

1. If you have already had COVID-19 do you still need to take the vaccine? Should we be tested for antibodies to "prove" we have had the virus? Is there any quarantine necessary after vaccination?

According to the CDC, people who have tested positive for COVID-19 in the past three months and recovered do not have to quarantine or get tested again as long as they do not have any new symptoms.

The CDC hasn't commented on quarantine and vaccinations but, most likely, people will not have to quarantine or get tested again as long as they do not have any new symptoms. The duration of the vaccine is not clear but Moderna's CEO recently thought at least a year.

Antibody testing before getting the vaccine is not needed.

2. If a person takes the vaccine, can they still be infectious – can they spread it to others?

While unlikely, a person who has the vaccine can transmit it to others after being exposed. In other words, during the short time that their body is fighting the virus from the exposure, they can infect others.

3. How long will this vaccine effectiveness last?

Most experts think the vaccine will last a year or two. The most recent studies show good antibody and T-cell responses eight months after an infection. Reinfections within three months are extremely rare.

4. If we receive the vaccine, will masks still be required?

Yes. Even though you have received your vaccine, most of the people around you have not. We know the vaccine prevents disease in the vaccinated person, but it still may be possible to transmit the disease to others, until the vaccine is in widespread use. And, of course, wearing a mask, social distancing, and practicing hand hygiene protects those who have not been vaccinated, especially our those at high risk.

5. Do you have to take it more than once?

The Pfizer vaccine both require two doses. The second Pfizer dose is given three weeks later and the Moderna vaccine is given four weeks later.



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6. How long will it take for the vaccine to be effective?

From the data presented by the companies, both vaccines are already effective 7 days after the second dose although most experts expect protection to occur sooner.

7. Does taking the vaccine mean you cannot be a carrier of COVID?

It typically takes a few weeks for the body to build immunity after vaccination. For the Pfizer vaccine, full protection occurs one week after the second injection. (Studies show that some protection starts 10 days after the first injection.)

That means it's possible for a person to be infected with the COVID-19 virus before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection.

Once the vaccine has time to stimulate enough antibodies, an active infection is much less likely. But, if a person, who had a vaccine were to be exposed to someone with COVID-19, they possibly could shed virus for a day or two while their body fights off the virus. This would be a rare situation and the duration of active shedding would be very short.

8. Can a COVID-19 vaccine cause you to test positive on COVID-19 viral tests? Vaccines currently in clinical trials in the United States won't cause you to test positive on viral tests like the antigen or PCR tests, which are used to see if you have a current infection.

If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

9. Why does the Pfizer vaccine have to be stored at -70 and the Moderna vaccine doesn't?

The fundamental problem is that mRNA is easily destroyed, and that's because there are many, many enzymes that will just break it apart. Here's a simple analogy: Think of the vaccine as a chocolate bar that melts easily. Just as there are ways to keep the chocolate from melting into goo, there are things the drug makers did to protect their COVID-19 vaccines.

- The first step was to modify the mRNA nucleosides the "building blocks" of the RNA vaccine. They've used modified versions because those are more stable. This would be like changing the chocolate recipe so it's not quite so melty.
- The next step was to use lipid nanoparticles, which, is kind of like putting your chocolate inside a candy coating you have an M&M, so the chocolate



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doesn't melt. But even with the stabilized building blocks and lipid coating, the mRNA could still fall apart easily, which is why the vaccine is frozen.

Bottom line: Everything happens more slowly as you lower the temperature. So your chemical reactions — the enzymes that break down RNA — are going to happen more slowly. Because the specific formulations for both companies are secret, it's not clear exactly why these two mRNA vaccines have different temperature requirements but "cold" makes sense.

10. What is the research showing for those who are pregnant taking the vaccine?

Women who are pregnant or breastfeeding should strongly consider getting the vaccine. Here's the logic:

- 1. COVID-19 infections tend to be more severe during pregnancy. In a study of 23,000 pregnant women with symptomatic COVID-19, the CDC reported pregnant women were 2.9 times more likely to end up in the ICU or on mechanical ventilation, respectively. I find it reassuring, though, that the absolute risk remains low; only one pregnant woman with COVID-19 out of 100 ends up in an ICU.
- 2. Vaccines are, in general, safe and well-tolerated during pregnancy.
- 3. Neither the Pfizer nor the Moderna COVID-19 vaccine contains the live SARS-CoV-2 virus, so there is no risk of the pregnant woman or her fetus developing COVID-19.
- 4. The mRNA used in both vaccines to stimulate a protective immune response never enters a cell's nucleus. That means it doesn't interact with the DNA that encodes the mother or fetus's human genome.

The caveat is that safety data is lacking for the COVID-19 vaccines because phase 3 studies of the Moderna and Pfizer vaccines excluded pregnant women. (This is a routine practice for new medications and vaccines.)

Despite the absence of clinical trial data on the Pfizer and Moderna vaccines in pregnant and breastfeeding women, both the CDC and the American College of Obstetricians and Gynecologists have recommended that vaccination be a personal decision of women who are pregnant.

There is no concern that the vaccines will interfere with lactation and no reason not to be vaccinated if you are breastfeeding. The Children's Hospital of The King's Daughters milk bank accepts breast milk from mothers who have been vaccinated.



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Again, both the American College of Gynecology and the Society for Maternal-Fetal Medicine recommend that pregnant or breastfeeding women have a discussion with their doctors on the pros and cons of the mRNA vaccine. Both suggest the vaccine should be given in most of these patients.

If You Are Pregnant, Breastfeeding, or Caring for Young Children | COVID-19 | CDC:

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

11. Is there a risk of causing infertility to young women?

Social media platforms have been flooded recently with concerns about an alarming headline purporting that Pfizer's coronavirus vaccine cause infertility in women. But experts all agree these claims are baseless.

"It's a myth, it's inaccurate — there's no evidence to support their perception," said Saad Omer, a vaccine expert at Yale University.

The rumors about infertility were fueled by an article published by a blog called Health and Money News, which falsely claimed that Pfizer's vaccine contained ingredients capable of "training the female body to attack" a protein that plays a crucial role in the development of the placenta. But experts say there is no evidence to back the infertility claim.

The key ingredient in Pfizer's vaccine (as well as a similar vaccine made by Moderna) is genetic material that instructs human cells to make a coronavirus protein called spike. The production of this protein teaches the body to fight off the coronavirus. There are no placental proteins, or genetic material that instructs the manufacture of placental proteins, in Pfizer's vaccine.

The misleading blog piece drew a comparison between coronavirus spike and a type of placental protein. The similarities were strong enough, it contended, that a vaccine could dupe the immune system into confusing the two proteins and attacking the placenta.

Stephanie Langel, an immunologist and expert in maternal and neonatal immunity at Duke University, pointed out that coronavirus spike and the placental protein in question have almost nothing in common, making the vaccine highly unlikely to trigger a reaction to these delicate tissues. The two proteins share only a minuscule stretch of material; mixing them up would be akin to mistaking a rhinoceros for a jaguar because they are wearing the same collar.



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Langel also pointed out that the human body has evolved to quash immune reactions that might harm its own tissues. "If we didn't have that, we wouldn't even make it past Day 1 of life," she said.

Pfizer pointed to a recent study that found the coronavirus did not seem to raise the risk for pregnancy-related problems. "There are no data to suggest that the Pfizer BioNTech vaccine candidate causes infertility," the company said in an emailed statement.

Langel and Omer both noted that researchers would continue to monitor the well-being of vaccinated people as Pfizer's products and others are rolled out around the world. There remains a dearth of data in people who are pregnant, Langel said. But baseless discussions about how vaccines could cause infertility, she added, was "particularly damaging" to the scientifically backed efforts to protect people with vaccines.

- **12.** Is the vaccine safe for those who are allergic to eggs/shellfish? Completely. Both the Pfizer and Moderna vaccines are messenger RNA vaccines and do not use eggs or shellfish in the manufacturing process.
- **13. What are the current side effects of the vaccines mentioned?** For the Pfizer Vaccine: Fatigue (3.8%), Headache (2.0%)

For the Moderna Vaccine: Fatigue (9.7%), Myalgia (8.9%), Arthralgia (5.2%), Headache (4.5%), Pain (4.1%), Injection-site redness (2.0%)

14. What are the adverse reactions or rate of complications for people of color as they are most impacted from COVID 19?

The vaccine should work the same on everyone in the human race. One postulated reason for the increased vulnerability of some races of the virus appears to be related to the way the virus enters the cells - that is not an issue for either vaccine.

15. If someone received the vaccine and then started showing symptoms because of a previous exposure would the vaccine provide some relief? Also, if the symptoms are from the vaccine wouldn't they test negative anyway? The vaccine does not provide any protection for at least 10 days so if someone got exposed at the same time they got the first dose of the vaccine, it would not provide any benefit. And, yes, to your second question: if the symptoms are from the vaccine, the patient would test negative on antigen and PCR tests.

16. Does the vaccine change your DNA? Is there an easy way to explain how an RNA vaccine works?

Only to say that mRNA – all mRNA (not just the vaccine mRNA) cannot enter the nucleus of the cell. And the DNA is located within the nucleus so it is impossible for



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mRNA to alter anyone's DNA. The following pictures show that the mRNA vaccines do not contain any virus particles at all - just mRNA. The mRNA stimulates the muscle cells to produce the spike protein and then our body produces antibodies to the spike protein. Then, when a real virus comes along with the spike protein all over its surface, the antibodies are already present and armed and they attack and eliminate the virus swiftly.

17. What if a therapist was not symptomatic and feeling fine when she got the vaccine. Then hours later develops symptoms (chills and muscle pain). How can we differentiate this from a new COVID-19 infection? Should the nurse go into quarantine and/or be tested?

The best way to differentiate a new COVID infection from a vaccine reaction is to consider three variables: timeline, environmental/individual risk, and symptoms:

1. Timeline: Reactions to the vaccine will occur a few hours after the vaccine and last 24 - 36 hours. Almost all reactions are gone by 24 - 36 hours. So, consider following up persistent symptoms with an antigen test. (Remember: the vaccine does not affect the PCR or antigen tests at all.)

- 2. Environment/Individual Risk: If someone had a recent exposure 3 6 days before the symptoms started, a COVID-19 infection could be the cause. Similarly, someone working in an environment where there are widespread COVID-19 infections would be more likely to have a COVID infection. In other words, those with symptoms consistent with a vaccine reaction without exposure or definitive risk should be assumed to have a vaccine reaction.
- 3. Symptoms: The symptoms are very similar (joint pain, muscle pain, fever, fatigue, achy feeling) except for a few. Loss of smell, loss of taste, cough, and shortness of breath are more likely with a COVID infection and are unlikely with a vaccine reaction.

If you factor in all three of these variables, I think the answer will be fairly clear in most cases. It is safe to assume symptoms are due to the vaccine if they started in the expected vaccine time frame ... unless they have a terrific story pointing to something else (exposure, loss of smell, etc.) As far being off from work, we are leaving it up to each employee. We are writing on our screening tool that the symptoms being reported are due to the vaccine, and they are permitted to work.

18. One of our therapists is scheduled to get a routine TB skin test in January. Should she still get the COVID vaccine or wait?

The screening tuberculin skin test does not affect the safety or efficacy of the vaccine, but the vaccine may interfere with the reading of the skin test (make a positive test appear negative). Therefore, it is best to get the TB skin test before getting the vaccine or wait 4 weeks after the vaccine's 2nd dose.



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Here are the actual statement and link from the CDC on this question: Inactive vaccines (like the Pfizer and Moderna vaccines) do not interfere with tuberculosis (TB) test results. There is no immunologic reason to believe either a Tuberculin Skin Test (TST) (administered by intradermal placement of 0.1 cc of purified protein derivative) or blood draw for interferon gamma release assay (IGRA) would affect the safety or effectiveness of mRNA COVID-19 vaccines. We have no data to inform the impact of the COVID-19 mRNA vaccines on either TB test for infection (i.e., TST or IGRA).

For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive an mRNA COVID-19 vaccine:

- Perform TB symptom screening on all healthcare personnel or patients.
- If utilizing the IGRA, draw blood for interferon gamma release assay prior to COVID-19 vaccination.
- If utilizing the TST, place prior to COVID-19 vaccination.
- If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after COVID-19 vaccine 2-dose completion.
 - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For healthcare personnel who require testing for other reasons:

- Perform TB symptom screening on all healthcare personnel
- Test for infection should be done before or at the same time as the
 administration of COVID-19 vaccination. If this is not possible, prioritization of test
 for TB infection needs to be weighed with the importance of receiving COVID-19
 vaccination based on potential COVID-19 exposures and TB risk factors.
 - Healthcare personnel with high-risk conditions for TB progression should be fully evaluated as soon as possible.
 - Healthcare personnel without high-risk conditions for TB progression should proceed with contact tracing (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation) but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination.
 - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

<u>Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine | CDC</u> [cdc.gov]



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19. If a team member receives the vaccine, the family does not and becomes COVID positive, will the team member still be required to quarantine?

The CDC and CMS have not commented on this and we need to keep in mind the team member is not full protected until one week after the second dose. But, I think we can make some assumptions regarding future guidelines based on current guidelines. Currently, people who have been infected with COVID-19 within the past 3 months do not have to quarantine if they come in close contact with someone who has COVID-19. It just makes sense that a similar guideline will come out with the vaccine eventually ... and the time period will probably be longer.

20. Do we know if the centers and individuals will need to continue with the frequent COVID testing?

The CDC and CMS have not commented whether team members who get vaccinated will need to be tested. But, based on current guidelines for those already infected, testing for vaccinated team members will probably stop one week after the second vaccine. As far as center testing: it will probably continue until infection incidences drop in that region.

Human Resources

21. Is the vaccine going to be mandatory? If the vaccine is required and I refuse what happens?

HPH strongly encourages staff to take the vaccine once available in order to protect our patients, fellow staff members, families and friends. However, HPH will NOT be requiring the vaccine for any of its staff as a condition of employment. Should a state or customer require the vaccine and a staff member refuses, it will jeopardize continued employment with that customer. In that instance, we will make every effort to seek alternative positions and solutions, should they exist.

22. Would a medical form support the refusal of the vaccine?

Like the flu shot, if a staff member has a documented medical condition making it unsafe to receive the vaccine, HR will review the appropriate paperwork to determine the potential for reasonable accommodation. Again, if the state or customer require the vaccine, the aforementioned process related to continued employment will apply.

23. If a customer requires the vaccine but I refuse, can I still use FMLA?

The qualification criteria for FMLA have not changed. The Family Medical Leave Act (FMLA) entitles eligible employees to take unpaid, job-protected leave for specified medical reasons. An example of covered absences (certified by a medical provider)



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are birth of a child, to care for an immediate family member with a serious health condition, your own serious health condition or surgery, etc.