COVID-19 Vaccine and CMT - Q & A

Disclaimer: Nothing shared on these pages should be construed or is intended to be used for medical diagnosis or treatment. It should not be used in place of the advice of your physician or other qualified health care provider. Should you have any emergency questions or concerns, please contact your physician or health care provider immediately. Always consult with your physician or other health care provider to gain clarification regarding any health care related questions. This content was sourced from the CDC, the CMTA Scientific Advisory Board, the MDA and the NY Times.

What are the side effects of the COVID vaccine? Will they affect my CMT?

The known side effects of current and likely-to-be authorized COVID-19 vaccines are similar to those of the annual influenza vaccine. These include symptoms such as: muscle soreness at the injection site, fever, tiredness, body aches and headache. It's important to note that at this time we do not know whether or not the COVID-19 vaccine will have a different or more serious set of side effects for CMT patients. You should talk to your doctor about the possibility of more serious side effects of a COVID-19 vaccine for you.

What impacts will the vaccine have on possible future gene therapy treatments or medications?

Whether the vaccine will have an adverse impact on any course of treatment that you or your loved one may be taking is something that you will want to consult with your clinician about directly. Upon the FDA authorization of the Pfizer/BioNTech vaccine, the FDA did not name any contraindications pertaining to genetic therapies or other medications particularly important to the CMT community. Should there be any contraindications that accompany future Agency decisions, we will update our information accordingly. However, this question can best be addressed by your clinician.

What safety measures are in place for the COVID vaccine?

The U.S. vaccine safety system ensures that all vaccines are as safe as possible. Learn how federal partners are working together to ensure the safety of COVID-19 vaccines.

CDC has developed a new tool, <u>v-safe</u>, as an additional layer of safety monitoring to increase our ability to rapidly detect any safety issues with COVID-19 vaccines. V-safe is a new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines.

How long will it take to work? Proof of Vaccination?

You won't get the full protection from the Pfizer-BioNTech vaccine until about a week after the *second* dose, based on clinical trial data. The researchers found that the vaccine's protection started to emerge about ten days after the first dose, but it only reached 52 percent

efficacy, according to a report in the New England Journal of Medicine. A week after the second dose, the efficacy rose to 95 percent.

You should receive a vaccination card or printout that tells you what COVID-19 vaccine you received, the date you received it, and where you received it. You should receive a paper or electronic version of a fact sheet that tells you more about the specific COVID-19 vaccine you are being offered. Each authorized COVID-19 vaccine has its own fact sheet that contains information to help you understand the risks and benefits of receiving that specific vaccine.

What if I forget to take the second dose on time?

Both the vaccines from Pfizer-BioNTech and from Moderna have two doses, with the booster shot coming a few weeks after the first. Pfizer-BioNTech's second dose comes three weeks after the first, and Moderna's comes four weeks later. The second dose provides a potent boost that gives people strong, long-lasting immunity. If for some reason you fail to get the second shot precisely three weeks after the first, you don't have to start all over again with another two-dose regimen. "The second dose can be picked up at any time after the first. No need to start the series over," said Dr. Paul Offit, a professor at the University of Pennsylvania and a member of the F.D.A.'s vaccine advisory panel. And while the two leading vaccines include a second dose, some future vaccine candidates may only require one dose. Johnson & Johnson, for example, is expecting data in January that will show whether its experimental vaccine works after a single dose. In case it doesn't, the company has also started a separate trial using two doses.

Will it hurt? What are the side effects?

The injection into your arm won't feel different than any other vaccine, but the rate of short-lived side effects does appear higher than a flu shot. Tens of thousands of people have already received the vaccines, and none of them have reported any serious health problems. The side effects, which can resemble the symptoms of Covid-19, last about a day and appear more likely after the second dose. Early reports from vaccine trials suggest some people might need to take a day off from work because they feel lousy after receiving the second dose. In the Pfizer study, about half developed fatigue. Other side effects occurred in at least 25 to 33 percent of patients, sometimes more, including headaches, chills and muscle pain. While these experiences aren't pleasant, they are a good sign that your own immune system is mounting a potent response to the vaccine that will provide long-lasting immunity.

Who will receive the vaccine first?

Because the current supply of COVID-19 vaccine in the United States is limited, CDC recommends that initial supplies of COVID-19 vaccine be offered to healthcare personnel and long-term care facility residents. Learn more about <a href="https://www.who.should.com/who.should.c

If I have allergies, should I be concerned?

People with severe allergies who have experienced anaphylaxis in the past should talk to their doctors about how to safely get the vaccine and what precautions to take. Although severe reactions to vaccines are rare, two health care workers had anaphylaxis after receiving the vaccine on the first day it became available in Britain. Both workers, who had a history of severe reactions, were treated and have recovered. (Anaphylaxis can be life-threatening, with impaired breathing and drops in blood pressure that usually occur within minutes or even seconds after exposure to a food, medicine or substance like latex.) For now, British authorities have said the vaccine should not be given to anyone who has ever had an anaphylactic reaction, but U.S. health experts have said such warnings are premature because severe reactions can be treated or prevented with medications. Because of the British cases, the F.D.A. said it would require Pfizer to increase its monitoring for anaphylaxis and submit data on it once the vaccine comes into use. Fewer than one in a million recipients of other vaccines a year in the U.S. have an anaphylactic reaction, said Dr. Paul Offit, a vaccine expert at Children's Hospital of Philadelphia.

Among those who participated in the Pfizer trials, a very small number of people had allergic reactions. A <u>document published by the F.D.A.</u> said that 0.63 percent of participants who received the vaccine reported potential allergic reactions, compared to 0.51 percent of people who received a placebo. In Pfizer's late-stage clinical trial, one of the 18,801 participants who received the vaccine had an anaphylactic reaction, according to safety data published by the F.D.A. None in the placebo group did.

What will happen if serious side effects crop up after the vaccine is rolled out?

Once a vaccine starts to reach large numbers of people, it's possible (and not uncommon) for a small number of severe "adverse events" to occur. Many existing vaccines, including the flu shot, also can cause rare complications, including Guillain—Barré syndrome, seizures and sudden unexplained death. While this sounds frightening, the risk is minuscule when considered over the millions of people who are safely vaccinated each year, and some of these complications can be triggered by the virus itself. Health officials will investigate each event to see if it's simply coincidence — or if it could have been caused by the vaccine. While everyone should be prepared to hear about these reports, they should not be a cause for worry or prompt you to delay getting the vaccine. Your risk of severe complications from Covid-19 is far higher than your risk of complications from the vaccine.

I had Covid-19 already. Do I need the vaccine?

It's safe, and probably even beneficial, for anyone who has had Covid to get the vaccine at some point, experts said. Although people who have contracted the virus do have immunity, it is too soon to know how long it lasts. So for now, it makes sense for them to get the shot. The question is when. Some members of the C.D.C. advisory committee have suggested people who have had Covid in the past 90 days should be toward the back of the line.

Will it work on older people?

All the evidence we have so far suggests that the answer is yes. The clinical trials for the two leading vaccines have shown that they work about the same in older people as younger people. As the vaccines get distributed, the vaccine makers and the C.D.C. will continue to monitor the effectiveness of the vaccine in people 65 and older who, because of age-related changes in their immune systems, often don't respond as well to vaccination as younger people do. But just as certain flu vaccines have been developed to evoke a stronger immune response in older people, it's possible that one of the new vaccines could emerge as a better option for this age group. It's just far too soon to know.

I'm young and at low risk. Why not take my chances with Covid-19 rather than get a vaccine?

Covid-19 is by far the more dangerous option. Although people who are older, obese or have other health problems are at highest risk for complications from Covid-19, younger people can become severely ill, too. In a <u>study of more than 3,000</u> people ages 18 to 34 who were hospitalized for Covid, 20 percent required intensive care and 3 percent died. And as many as one in three people who recover from Covid have chronic complaints, including exhaustion, a racing heart and worse <u>for months afterward</u>. Covid vaccines, in contrast, carry little known risk.

When will vaccines be available for children?

So far, no coronavirus vaccine has been approved for children. New vaccines are typically tested on adults before researcher's launch trials on children, and coronavirus vaccine developers are following this protocol. In September, Pfizer and BioNTech began studying their vaccine on children as young as 12. Moderna followed suit in December. If these trials yield good results, the companies will recruit younger children. The FDA will then have to review these results before the vaccines can get emergency authorization.

Cost is not an obstacle to getting vaccinated against COVID-19.

Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers may be able to charge administration fees for giving the shot. Vaccination providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund

If I've been vaccinated, will I still need to wear a mask?

Yes, but not forever. Here's why. The coronavirus vaccines are injected deep into the muscles and stimulate the immune system to produce antibodies. This appears to be enough protection to keep the vaccinated person from getting ill. But what's not clear is whether it's possible for the virus to bloom in the nose — and be sneezed or breathed out to infect others — even as

antibodies elsewhere in the body have mobilized to prevent the vaccinated person from getting sick.

The vaccine clinical trials were designed to determine whether vaccinated people are protected from illness — not to find out whether they could still spread the coronavirus. Based on studies of flu vaccine and even patients infected with Covid-19, researchers have reason to be hopeful that vaccinated people won't spread the virus, but more research is needed. In the meantime, everyone — even vaccinated people — will need to think of themselves as possible silent spreaders and keep wearing a mask.

How will we know when things are getting better?

The test positivity rate in your community will be an indicator of how things are going. This number is the percentage of overall tests given in a community that come back positive. The lower the number, the fewer new cases and the less likely you are to cross paths with someone who has the virus. "The best number is zero," Dr. Fauci said. "It's never going to be zero, but anywhere close to that is great."

Will these vaccines put a dent in the epidemic?

The coronavirus vaccines will be much less effective at preventing death and illness in 2021 if they are introduced into a population where the virus is raging — as is now the case in the U.S. A vaccine that's 95 percent effective, as Moderna's and Pfizer's versions appear to be, is a powerful fire hose. But the size of a fire is still a bigger determinant of how much destruction occurs.

According to the authors of a paper in the journal Health Affairs, at the current level of infection in the U.S. (about 200,000 confirmed new infections per day), a vaccine that is 95 percent effective — distributed at the expected pace — would still not be enough to end the terrible toll of the virus in the six months after it was introduced. Almost 10 million or so Americans would contract the virus, and more than 160,000 would die.

Measures that reduce the virus's spread — like <u>mask-wearing</u>, <u>social distancing</u> and <u>rapid-result</u> <u>testing</u> — can still have profound effects. Public health officials hope that people will continue to take these precautions at least until the country reaches a vaccination rate of 70 to 75 percent.

How long will the vaccine last? Will I need another one next year?

That is to be determined. It's possible that coronavirus vaccinations will become an annual event, just like the flu shot. Or it may be that the benefits of the vaccine last longer than a year. We have to wait to see how durable the protection from the vaccines is. Immunity from coronavirus infections appears to last for months, at least, so that may be a hint about vaccines.