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COVID-19 Vaccine Q&A: Your Questions, Expert Answers

Sep. 30, 2020 - [Katie McCallum](#)

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Vaccines aren't anything new to us. Well, they shouldn't be. You're getting your flu shot every year, right?

In addition to the influenza vaccine, we rely on many vaccines to keep us healthy over the course of our lives, including vaccines against tetanus, measles, mumps, rubella, hepatitis B, whooping cough, polio — and the list goes on.

What *will* be new to us, however, is a vaccine against the coronavirus that causes COVID-19.

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Scientists and doctors are working tirelessly to bring a COVID-19 vaccine to the public as quickly as possible. And with several vaccine candidates in the final phase of clinical testing, you likely have some questions.

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When will a COVID-19 vaccine be available?

Dr. Sostman: Right now, there are 29 COVID-19 vaccines being tested in multiple clinical trials around the world. Among these, six different COVID-19 vaccines are being tested in the final phase of clinical trial testing, three of which are funded by the U.S. government. You can [track the COVID-19 vaccine clinical trials](#) currently underway here.

We are optimistic that one of these vaccine candidates will prove to be safe and effective, and will be ready to distribute in 2021.

Vaccine distribution plans are moving more quickly than in the past. Typically, it can take months to years to scale up manufacturing of a vaccine for widespread distribution, but the U.S. government has provided vaccine manufacturers with a head start on this. Our government is fronting the cost associated with manufacturing several promising vaccine candidates while these candidates are still being tested. This approach is unusual, but it means that vaccine distribution can begin very quickly — if and when a vaccine is approved by the FDA.

Once a vaccine is approved and distribution begins, it's very likely that frontline workers will be vaccinated first.

How effective is the COVID-19 vaccine expected to be?

Dr. Sostman: There are many questions surrounding the effectiveness of each potential COVID-19 vaccine, and each one will likely vary slightly. The FDA has stated that it will only approve vaccines that prevent disease, or reduce disease severity, in at least 50% of people who are vaccinated. This level of effectiveness is similar to the annual influenza vaccine.

In many cases, multiple doses (commonly referred to as "boosters") may be needed to increase the effectiveness of a particular COVID-19 vaccine. And it will take about two weeks for a person to build immunity after being vaccinated.

Fortunately, we are beginning to see evidence suggesting that cellular immunity to COVID-19 is very consistent and robust after both natural infection and vaccination. While this is not yet proven, it is cause for optimism. We know that people who become infected with COVID-19 can continue to show some level of immunity up to 125 days post-diagnosis, but further surveillance and testing will be needed before we understand how long a vaccine remains effective.

It's also still unclear how effective the COVID-19 vaccine will be in the elderly, who we know typically need higher-dose vaccinations to achieve protective immunity.

Regardless, getting vaccinated remains crucial. As the saying goes, "An ounce of prevention is worth a pound of cure."

Can COVID-19 be stopped without a vaccine?

Dr. Sostman: A COVID-19 vaccine will be an important leg up, so to speak, in achieving herd immunity, so it's important that everyone get vaccinated. Without a vaccine, we would probably achieve some level of herd immunity, *eventually*, but at the cost of many thousands of hospitalizations and deaths — as well as the economic strain of an ongoing pandemic.

Some of the common concerns with the vaccine are side effects, getting COVID-19 from the vaccine itself and lack of effectiveness of the vaccine, but here's why these concerns shouldn't stop you from getting vaccinated:

- **Potential side effects will be well documented and made clear to the public.** So far, the most common side effects of the COVID-19 vaccine include fever/chills, headache, sore arm and fatigue. These side effects are generally less severe than the symptoms experienced in even a mild case of COVID-19. Very few severe reactions have been reported so far, and those were typically in response to doses higher than what would be administered clinically.
- **There's no risk of getting COVID-19 from the vaccine.** Many of the most promising vaccine candidates are made using synthetic, noninfectious viral components, with no live, infectious virus ever being used in the vaccine manufacturing process. The only vaccine candidates that do use live virus in the manufacturing process kill the virus before incorporating it into the vaccine.
- **Even imperfect protection is better than none.** Given that the new coronavirus that causes COVID-19 can elicit severe symptoms or complications in even seemingly healthy people, any chance we have as a community to prevent infection must be

taken seriously. Although immunity from the vaccine may wear off over time, researchers will be working to understand how often boosters are needed. In addition, a vaccine will probably lead to less severe disease if you do become infected and develop COVID-19.

Are COVID-19 vaccine trials safe?

Dr. Sostman: Typically, vaccine development, testing and manufacturing is a slow process that spans years or decades. However, given the critical need for a COVID-19 vaccine, researchers around the world are working at an unprecedented pace to develop a safe and effective COVID-19 vaccine as quickly as possible.

While this process is moving much more rapidly than previous vaccine development, we can feel comfortable that safety is not being sacrificed.

Throughout development and testing, the COVID-19 vaccine trials are being monitored for safety by independent boards that are overseeing each individual trial and regulatory agencies — such as the FDA in the U.S. and corresponding agencies in the UK and the EU. Vaccine trial findings will be readily available for independent review.

The three main reasons that COVID-19 vaccine development has progressed so rapidly, without sacrificing safety, are:

- 1. Researchers were able to leverage previous coronavirus and vaccine research.** The new coronavirus that causes COVID-19 is very similar to previous coronaviruses that have made the jump from animals to people (SARS and MERS), as well as the coronaviruses that cause common colds. These similarities, as well as previous research into new vaccine strategies that are quicker to develop, allowed researchers to begin testing vaccine candidates just three months after this new virus appeared in humans.
- 2. Hundreds of vaccine candidates are being developed and tested simultaneously.** Bringing a COVID-19 vaccine to the public has become a true global effort. Creating a safe, effective vaccine comes with a lot of trial and error, but with several dozens of vaccine candidates in clinical trials — and even more in preclinical testing — the trial-and-error nature of vaccine development is being overcome by the sheer number of vaccine candidates being tested at the same time.
- 3. Newer vaccine technology is being used and there is unprecedented financial support.** Although some of the new vaccine approaches, such as mRNA vaccines and nonreplicating viral vector vaccines, haven't previously been approved for use, they're safe, easy to develop and quick to manufacture. And because governments across the world are providing tremendous financial backing to ensure a safe, effective vaccine is developed as quickly as possible, researchers were able to push these new technologies through development with little financial risk and at a much faster pace. In addition, government funding has allowed pharmaceutical companies to begin manufacturing their vaccines before receiving approval — eliminating the financial risk if a vaccine candidate fails to clear regulatory approval.

How is the COVID-19 vaccine made?

Dr. Sostman: There's not just one COVID-19 vaccine being developed and tested right now, and we will likely see several vaccines approved over the next year.

There are several different types of vaccines, but the goal of each is the same: to stimulate a person's immune system to create the specific, protective antibodies and immune cells needed to recognize and respond to the virus quickly and effectively — preventing, or reducing the severity of, disease.

Of the COVID-19 vaccines currently being developed, there are several different types — the major players being DNA-based and mRNA vaccines, nonreplicating viral vector vaccines, inactivated viral vaccines and protein-based vaccines.

Each type of vaccine has its own advantages and disadvantages, and each one also works a little bit differently:

- **DNA-based and mRNA vaccines** – introduce synthetic, noninfectious viral genetic material that your cells can then use to create viral components. Since these components do not assemble into a complete virus, they can't actually make you sick. But, they can stimulate an immune response to the virus. RNA- and DNA-based vaccines are easy to develop, but use new technology not previously licensed in a vaccine before. There is a lot of optimism that these techniques represent a new breakthrough in making vaccines faster.
- **Nonreplicating viral vector vaccine** – prepared by injecting genetic material from the new coronavirus into another live, but noninfectious, virus, such as adenovirus. This

genetic material then can be used by your cells to produce inactive viral components, which in turn can help stimulate an immune response. This approach has a long history of success in gene therapy, but hasn't previously been licensed for use in a vaccine.

- **Inactivated viral vaccine** – produced by rendering the new coronavirus uninfected via chemicals, such as formaldehyde, or heat. This type of vaccine is effective, but, because it requires starting with large amounts of live virus, manufacturing large quantities of an inactivated viral vaccine can take time.
- **Protein-based vaccine** – introduce noninfectious viral components that, when chosen strategically, can stimulate your immune system. This type of vaccine often requires what's called an adjuvant, an additional immune-stimulating molecule, as well as multiple doses. Additionally, this type of vaccine can be produced by creating virus-like particles that mimic the outer shell of the virus, but contain no genetic material inside the shell. These can trigger a strong immune response, but can be difficult to manufacture on a large scale.

How is the COVID-19 vaccine tested?

Dr. Sostman: As with any new medical test or treatment, each COVID-19 vaccine candidate is being rigorously tested for safety and effectiveness through a multistep process.

Vaccine development begins with preclinical studies in a lab, where researchers test the vaccine candidate in cell and animal models to determine if it can successfully stimulate an immune response and is safe. If a vaccine candidate performs well in preclinical testing, researchers can then move the vaccine into clinical trials.

A clinical trial is used to validate whether a COVID-19 vaccine is both effective and safe for use in people. A clinical trial typically has three phases:

- **Phase 1 study** – initial safety study in which the vaccine is given to a small group of people to check if it's safe.
- **Phase 2 study** – includes more people and is used to further gauge safety, identify any potential side effects, determine the appropriate dosage and assess the strength of the corresponding immune response. To expedite a trial, the first two phases are sometimes combined as a Phase 1/2 trial.
- **Phase 3 study** – enrolls thousands of people across different ages, demographics and locations to determine how many people who are vaccinated contract COVID-19, as compared to those participants who aren't vaccinated (known as the placebo group). The results indicate how effective the vaccine is at reducing infection — also referred to as a vaccine's efficacy.

After the three phases are complete, regulators review the trial results and decide whether to approve the particular COVID-19 vaccine for widespread use in the general public.

To be considered effective, the FDA announced in June that a COVID-19 vaccine will need to "prevent disease (or decrease its severity) in at least 50% of people who are vaccinated." The FDA will soon announce additional clinical trial requirements, such as following all participants for more than two months and having a certain number of severe infections show up in the placebo group.

While there are several promising vaccine candidates in the final (third) phase of clinical trials, no COVID-19 vaccine has been approved yet for use in the U.S.

Overall, the progress that researchers around the world have made toward developing and testing a COVID-19 vaccine is truly amazing. Once a vaccine is made available, it will be our turn, as a community, to take our civic duty seriously and reap the benefits of this powerful COVID-19 prevention tool.

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