This Is Why the COVID-19 Vaccine Is Going to Take Longer Than You Think

By Karen Pallarito | Updated December 3, 2020

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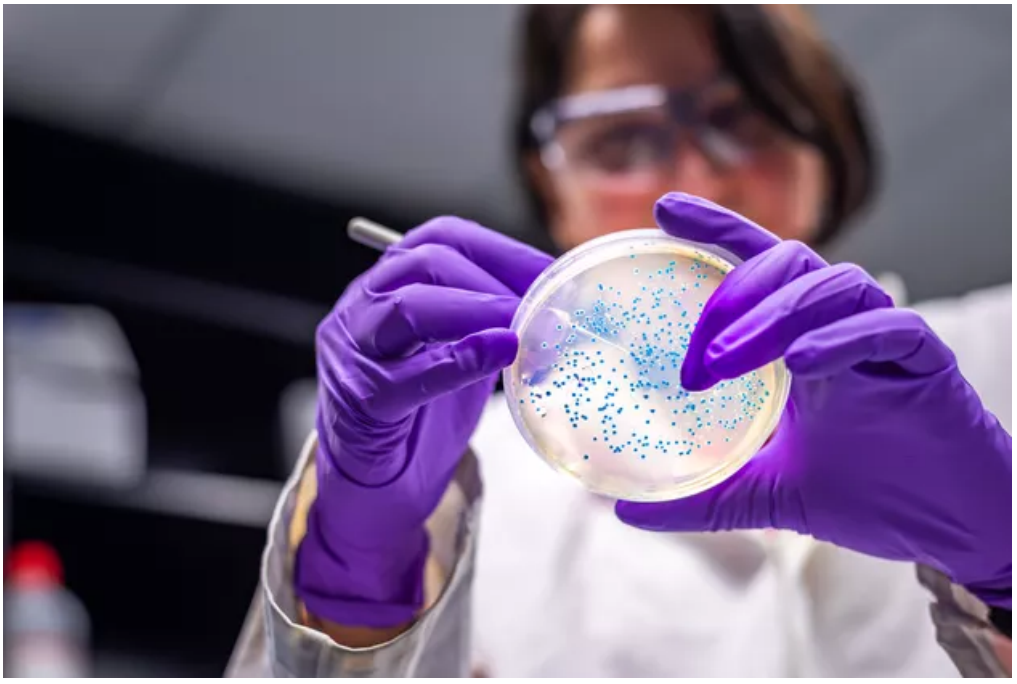

Researchers have made incredible strides toward a COVID-19 vaccine in a short amount of time, but we won't be lining up for shots just yet.
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If you believe the hype, a COVID-19 vaccine is just weeks away in the U.S. Experts say widespread vaccination could help bring the deadly pandemic to its knees, so let's hope a safe, effective vaccine emerges from clinical trials. But don't count on getting your shots just yet.

A year ago, the world hadn't even heard of COVID-19, much less SARS-CoV-2 (the novel coronavirus that causes the illness). When you consider that vaccine development typically stretches over years, not months, it's remarkable that we're even talking about closing in on a vaccine.

Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases, is optimistic that an experimental vaccine from pharmaceutical giant Pfizer Inc., the furthest along in clinical trials, may be cleared for use before year's end. The vaccine was approved in the U.K. December 2. Still, in a CNN interview, America's leading infectious disease expert cautioned that it's not a done deal.

Developing, manufacturing and deploying hundreds of millions of doses of vaccine is a mammoth undertaking, and there are bound to be slowdowns and other glitches along the way. Here, experts describe some of the challenges a COVID-19 vaccine must overcome.

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History Shows There's No Guarantee of Success

Vaccine development is a painstaking process, and it doesn't always pay off. A March 2013 *PLOS One* study looked at risks involved in vaccine research and development and found that the average vaccine takes nearly 11 years to develop and has a 6 percent chance of entering the market.

Sometimes even the most concerted efforts fall flat. An August 2013 *Vaccine* review traces global initiatives to develop a vaccine against human immunodeficiency virus, the virus that causes HIV/AIDS. After more than three decades, we still don't have a vaccine to prevent these infections.

Hoping to shorten the time it takes to develop and deploy vaccines, the federal government in May launched Operation Warp Speed, an unprecedented initiative allowing vaccine developers to perform certain tasks simultaneously, rather than sequentially. The aim is to accelerate vaccine development "without curtailing the critical steps required by sound science and regulatory standards," according to an October 2020 editorial in the *New England Journal of Medicine*.

Still, these things take time to get right, and the path to an effective vaccine is typically filled with twists and turns.

It Has to Be Protective

No vaccine is 100 percent effective, according to the World Health Organization. Annual flu vaccines, for example, reduce the risk of influenza by 40 to 60 percent, per the Centers for Disease Control and Prevention (CDC).

So, what level of protection should a COVID-19 vaccine provide? The U.S. Food and Drug Administration (FDA) is looking for vaccines that can prevent disease or decrease its severity in at least 50 percent of people who are vaccinated.

"That's the minimum threshold for emergency use authorization," says Amesh Adalja, MD, senior scholar at the John Hopkins Center for Health Security in Baltimore.

But is that good enough?

Using computer modeling to simulate the spread of COVID-19, researchers recently looked at the effect a vaccine could have under various conditions. Assuming 75 percent of the population gets vaccinated, a vaccine must have an efficacy of at least 80 percent to snuff out an ongoing epidemic, they reported in the July 2020 issue of the *American Journal of Preventive Medicine*. That's what would be needed to return to normal — meaning no more masks, no more social distancing.

That doesn't mean a vaccine with lower efficacy isn't useful, the study authors say. Even if it fails to wipe out the epidemic, "it can still save a considerable number of lives, hospitalizations and costs," they explain. Plus, vaccination could be combined with other mitigation measures, like mask-wearing, the authors point out.

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Proof of Safety Is a Must

Vaccine development in the U.S. involves multiple levels of safety checks, beginning with testing in cells or tissues and animals, according to the College of Physicians of Philadelphia. Only promising vaccine candidates move on to human trials.

Phase 1 trials look at safety and the immune response a vaccine candidate provokes in a small group of people. Phase 2 trials involve several hundred people. In phase 3, tens of thousands of people are randomly assigned to receive the experimental vaccine or a placebo.

Success in early human trials doesn't mean a vaccine is destined for approval. Phase 3 trials can reveal certain rare side effects that might not surface in smaller phase 1 and phase 2 studies, per the College of Physicians of Philadelphia.

To assess the risk versus benefit of a COVID-19 vaccine, the FDA intends to review at least two months of phase 3 data after trial participants have completed their final dose. So far, there's reason to be cautiously optimistic, says Hana El Sahly, MD, associate professor of molecular virology and microbiology at Baylor College of Medicine in Houston, a phase 3 testing site for Moderna's investigational vaccine.

"Usually most side effects of vaccines happen in the first four to six weeks," she tells LIVESTRONG.com.

Once safety data is reviewed and the FDA gives the nod, "we're pretty sure that there aren't going to be adverse events popping up left and right," says Arthur L. Caplan, PhD, professor of bioethics at the New York University Grossman School of Medicine in New York City.

Also, it's in companies' best interest to assure their vaccines are safe. "If they put out a vaccine and it gets into safety trouble, they're going to lose a lot of money and they're going to lose a lot of investors," he tells LIVESTRONG.com.

In early November, Pfizer and its German partner BioNTech announced preliminary results from its phase 3 trial. The data suggest its vaccine candidate is more than 90 percent effective in averting symptomatic cases of COVID-19 compared with people on a placebo. So far, the companies say no serious safety concerns have emerged.

The companies continue to collect additional safety data required for emergency use authorization by the FDA. And as with all vaccines, they'll have to look at secondary outcomes, like how many people become seriously sick or hospitalized after getting the vaccine. These outcomes might show, for example, that people who get vaccinated *can* still get infected but can also survive the infection more easily.

But even if Pfizer's vaccine gets the nod before the end of the year, experts say the first vaccines would go to high-risk frontline health care workers. It will be months before the general public could begin lining up for their shots.

Separately, Moderna Inc. says it is preparing to submit early data from its phase 3 trial to the independent Data Safety Monitoring Board for review and analysis. The submission will include data on more than 53 of the trial's 30,000 participants.

Compliance May Be a Problem

Most of the COVID-19 vaccine candidates in phase 3 trials require two doses. After the first shot, a second is given three to four weeks later. The problem is that some people may not bother getting a second shot or presume they're done after the first dose. In the history of vaccines, "anything that's been a two-shot vaccine has turned out to be a pain in the neck. People don't comply," Caplan pointed out during a media briefing on the topic.

Some people might sit out vaccination altogether. Only about half of U.S. adults are willing to take a COVID-19 vaccine once it's available, according to Pew and Gallup polls. That's down 21 and 16 points, respectively, from surveys the two research outfits conducted in the spring and summer. The polls suggest public support for a COVID-19 vaccine may not reach 70 percent, the minimum level experts say may be needed to achieve "herd immunity."

To overcome vaccine hesitancy, public health officials might want to consider outreach strategies to address the concerns of people who are more susceptible to the infection, researchers conclude in an October 2020 study in *JAMA Open Network*.

People May Need a Booster Shot

How long will a COVID-19 vaccine last? It's a question vaccine researchers — people like Kirsten Lyke, MD, professor of medicine at the University of Maryland School of Medicine in Baltimore — are trying to answer.

She's been on the front lines of clinical trials of two different vaccines. Each uses messenger RNA, an approach she likens to delivering a bit of computer code into a cell, instructing it to make spike protein (the type found on the surface of SARS-CoV-2). When the body's immune system encounters the protein, it makes antibodies. It's teaching your immune system to recognize COVID, she says, so that when you encounter the virus, your immune system ramps up quickly.

"We know that it can make good protein and we know it can make good neutralizing antibodies, which are really key for respiratory viruses, but we don't know how long that'll last," Dr. Lyke says.

What if a vaccine is approved but immunity only lasts six months? People would need booster shots, creating additional expense and distribution hassles, Caplan points out. We might even learn that the vaccine lasts for a shorter period of time in certain populations. It may fade faster in older adults, for example. "You might have to re-vaccinate them every three months," he says.

It's a Huge Logistics Challenge

In a typical year, the CDC distributes vaccines for more than 80 million people, according to director Robert Redfield, MD, who testified before a Senate subcommittee this summer. In an emergency, the CDC can scale up to distribute up to 900 million vaccine doses, he noted. So, if a two-dose vaccine gets the green light, do the math: It will take 660 million doses to vaccinate all 330 million Americans.

Under Operation Warp Speed, manufacturing has already begun. The goal was to stockpile hundreds of millions of doses by the end of the year, according to the *New York Times*. In reality, the number of doses that will be ready to go may be far fewer.

Speaking at a Johns Hopkins University and University of Washington symposium in October, Moncef Slaoui, PhD, chief adviser to the project, said tens of millions of doses would be stockpiled by November. Between 20 million and 30 million doses of each of the leading vaccine candidates (Moderna and Pfizer) will be ready by January, he predicted.

Making enough vaccine is one challenge; getting it out to the masses is another. "Distributing potentially hundreds of millions of doses of COVID-19 vaccines rapidly, effectively and equitably represents a public logistics effort on a scale not seen in the U.S. before," according to a Kaiser Family Foundation analysis.

Vaccines must be kept under tightly controlled temperatures from the time they're made to when they're administered, explains Anna Nagurney, PhD, professor in the Department of Operations and Information Management at the University of Massachusetts Amherst. Some COVID-19 vaccines require freezing temperatures — a frigid minus 94 degrees, in the case of Pfizer's vaccine. Maintaining the "vaccine cold chain" will require careful coordination and investment.

"Not every health care facility is equipped with very low-temp refrigerators," she tells LIVESTRONG.com.

There's Big Money Involved

Congress has already committed $10 billion in taxpayer money to COVID-19 vaccine development and manufacturing, according to the U.S. Department of Health and Human Services. A Bloomberg report suggests, however, that Operation Warp Speed's budget may have swelled to as much as $18 billion.

Frontrunner Pfizer did not receive government money to develop or manufacture its two-dose vaccine. But under a $1.95 billion agreement with the U.S. Department of Health and Human Services and Department of Defense, it will deliver 100 million doses to the government. And the government has an option to purchase an additional 500 million doses.

Vaccine doses purchased with taxpayer dollars will be given to Americans at no cost, according to the CDC. If there's a fee for administering the shot, it'll be reimbursed by insurance, it says. Public health clinics may offer free vaccines for people who are uninsured.

So, while most people, at least initially, won't have to pay out-of-pocket for their first doses, with the Pfizer vaccine, "you might," Caplan says.

When Can People Get Vaccinated?

While vaccine developers appear to be on track to deliver a safe, effective vaccine in record time, it may be a while before the first doses are widely available. HHS Secretary Alex Azar recently predicted that there would be enough vaccine for all Americans who want one by spring 2021, per CNN.

If that timeline holds up, it would be an amazing accomplishment. By this time next year, perhaps multiple vaccines will be available, experts say.

In the meantime, we all need to do our part to slow the spread of the infection, and that means continued mask-wearing, hand-washing and social distancing.

Concerned About COVID-19?

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Is This an Emergency?

To reduce the risk of spreading COVID-19 infections, it is best to call your doctor before leaving the house if you are experiencing a high fever, shortness of breath or another, more serious symptom.

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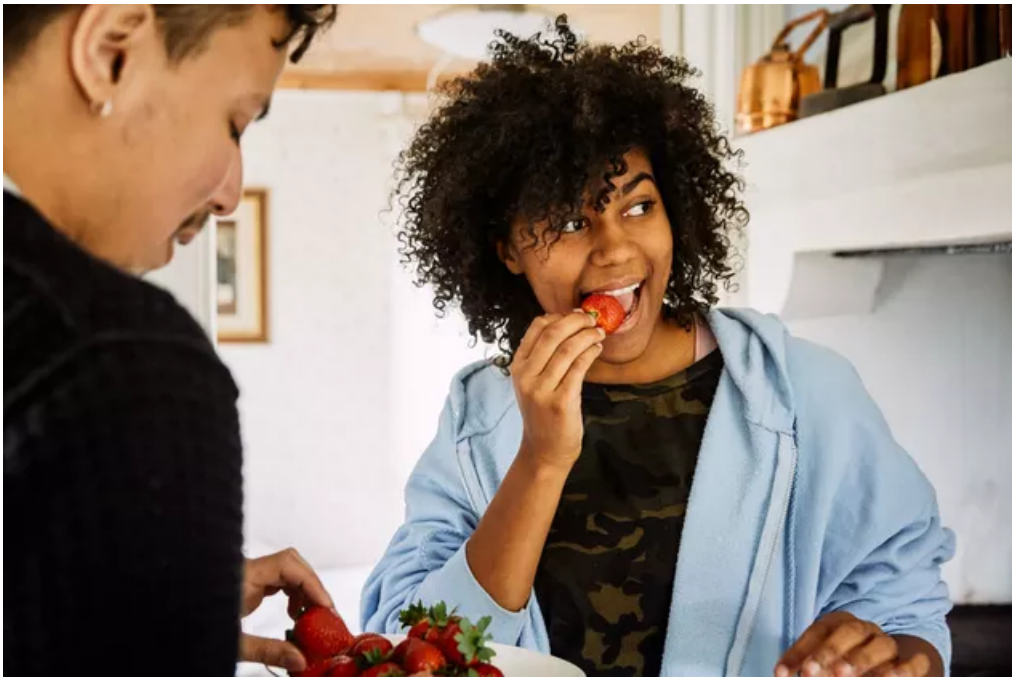

Following the Noom program takes just five to 10 minutes per day.
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If there's one universal truth about weight loss, it's that there are *a lot* of different diets out there. And since there is no singular approach that works for everyone, trial and error is inevitable — which can lead to frustration.

"When diets 'fail,' people tend to turn on themselves as they start to feel inadequate or see themselves as the failure, despite starting something that was inevitable to fail," says Andreas Michaelides, PhD, chief of psychology and head of coaching at Noom. "People can be very hard on themselves when this happens, berating their failures, and feel guilty when they fall back into old habits."

To avoid this, it's important to find a plan that makes you feel empowered and educates you on the most effective weight-loss methods — like Noom, Michaelides says. "Noom isn't a diet in the traditional sense; it's a program that empowers users to make changes by equipping them with the right tools to do so," he says. The Noom toolkit includes a science-backed curriculum, a personal coach and a fully-loaded app with resources to help you monitor your progress when it comes to food and exercise.

And while there is no one *right* way to lose weight, there are a few wrong (either unsafe or ineffective) ways to go about weight loss. Here, Michaelides breaks down

three common misconceptions.

Misconception 1: Weight Loss Is a Linear Process

Even if you're sticking to a diet religiously, your weight likely won't decrease consistently. "Plateaus are completely normal and frustrating, but they do not mean you are doing anything wrong or not making progress," Michaelides says. "Plateaus are multi-faceted and can be dependent on numerous factors, so the key here is to hold strong and focus on the non-scale victories you are achieving, like having more energy or feeling more confident in your favorite pair of jeans."

As part of the Noom plan, users weigh themselves every day in order to overcome scale anxiety and to get used to seeing slight or no fluctuations in their weight, Michaelides says. That way, if the number ticks up slightly, they won't be tempted to throw in the towel, and if it hasn't changed in a while, they can chat with their Noom coach for encouragement.

Misconception 2: Fad Diets Work

"Despite the widespread trend, we know it can be dangerous to cut out certain food groups," Michaelides says. "It is actually more important to focus on portion size rather than depriving yourself of a specific food or food group."

Beside not being sustainable long term, restrictive diets can be damaging both physically and psychologically, he says. Noom encourages users to make small changes over time and equips them to learn how to deal with setbacks.

Misconception 3: Weight Loss Should Happen Quickly

"Chances are, the weight you'd like to lose didn't appear overnight — losing it won't happen overnight either," Michaelides says. "At Noom, we encourage clients to focus on their holistic health, and celebrate small victories off the scale as well as on."

He suggests making thoughtful, attainable goals and thinking of each goal as a small building block — over time all your small successes can lead to big changes.

"If you're looking for a quick fix, or something extreme/restrictive, Noom might not be the place for you," Michaelides says. "Though extreme diets might result in faster short-term weight loss, that weight is often gained back just as quickly. Noom's focus is on creating a lifestyle change, so while the results aren't overnight, they are much more likely to stick." And that's the ultimate goal, right?