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## It may be time to reset expectations on when we'll get a Covid-19 vaccine

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October 29, 2020

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The ambitious drive to produce Covid-19 vaccine at warp speed seems to be running up against reality. We all probably need to reset our expectations about how quickly we're going to be able to be vaccinated.

Pauses in clinical trials to investigate potential safety issues, a slower-than-expected rate of infections among participants in at least one of the trials, and signals that an expert panel advising the Food and Drug Administration [may not](#)

[be comfortable](#)<sup>5</sup> recommending use of vaccines on very limited safety and efficacy data appear to be adding up to a slippage in the estimates of when vaccine will be ready to be deployed.

Asked Wednesday about when he expects the FDA will greenlight use of the first vaccines, Anthony Fauci moved the administration's stated goalpost.

"Could be January, could be later. We don't know," Fauci, director of the National Institute of Allergy and Infectious Diseases, said in an [online interview](#)<sup>6</sup> with JAMA editor Howard Bauchner.

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On Tuesday, front-runner [Pfizer revealed](#)<sup>8</sup> in an earnings call that the first interim analysis in its Phase 3 clinical trial has not yet occurred. That means there hadn't yet been enough Covid infections among the trial participants to take a first stab at analyzing whether the people randomly assigned to receive vaccine were infected at a lower rate than people who were assigned to get a placebo injection.

It's possible that the company will cross that threshold sooner rather than later. But Pfizer, which has been one of the most aggressive players in the vaccine race, had earlier predicted it would know by the end of September if its vaccine worked — an estimate that was later pushed back to late October. The company now projects that it could apply to the FDA for an emergency use authorization for the vaccine, which it is developing with BioNTech, in mid-November.

It is important to note that, to date, none of the vaccines being developed for the U.S. market has been proven to be effective in preventing Covid-19 disease. Early stage clinical trials have shown what appear to be promising signals; multiple vaccines have triggered production of important antibodies in people who have been immunized.

But data generated in a few hundred people aren't enough to determine whether a vaccine will actually fend off illness. That answer comes from large, Phase 3 trials, five of which are now underway in the United States. Their findings will ultimately tell us how soon vaccines may start to be rolled out to the masses.

The administration has been saying for months that vaccine would be ready for deployment before the end of the year. In fact, President Trump had been hinting vaccine could be pushed out before Election Day, which it will not be; at a campaign rally on Wednesday night, he said vaccine would be ready “momentarily.”

Other officials have been bullish in their own right. Just last Friday, Paul Mango, deputy chief of staff for policy for Health and Human Services Secretary Alex Azar, reiterated the administration’s projection that all Americans who want to be vaccinated against Covid-19 will have that opportunity by the early spring.

“We believe before the end of this year we will be able to vaccinate our most vulnerable citizens,” Mango told journalists in an update on the work of Operation Warp Speed, the government’s effort to fast-track Covid-19 vaccines, drugs, and diagnostics.

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“By the end of January, we believe we’ll be able to vaccinate all seniors. By the March and April timeframe, we believe we’ll be able to vaccinate any American who desires a vaccination,” Mango said.

In reality, that timeline has always been aspirational — probably excessively so. While Warp Speed and vaccine manufacturers and others involved in the effort have moved heaven and earth to accelerate vaccine production, at the end of the day, developing, testing, and manufacturing vaccines takes time. Vaccines are difficult to produce and there are always bumps in the road.

“While it’s unfortunate, I don’t find it surprising that the timeline is being moved back,” said Michael Osterholm, director of the University of Minnesota’s Center for Infectious Diseases Research and Policy. “Clinical trials like this routinely have unexpected occurrences that delay planned timelines. It’s just not unexpected.”

As for the idea that all Americans will have had a chance to be vaccinated by the early spring, Osterholm suggested it is going to take longer.

“For many of us, we never thought that that was doable,” he said. “I commend Operation Warp Speed for what it has accomplished in the time it has, but to have vaccinated the U.S. population by March in my mind was never a realistic goal.”

Two of the vaccines being supported by Operation Warp Speed have seen their Phase 3 trials paused to investigate unexpected illnesses among a small number of trial participants.

AstraZeneca, which in June projected it could begin to supply up to 2 billion doses of vaccine [in September](#)<sup>10</sup>, instead saw its Phase 3 trials in multiple countries put on hold when a participant experienced **neurological symptoms** that chairman Pascal Soriot said were [consistent with transverse myelitis](#)<sup>11</sup>, a serious inflammatory disorder. While regulators in Britain, India, and South Africa quickly cleared Phase 3 trials to resume enrolling volunteers, the U.S. trial was paused for [five weeks](#)<sup>12</sup>.

Johnson & Johnson, the only manufacturer among the major vaccine makers testing a one-dose Covid vaccine, also saw its Phase 3 trial paused for two weeks after a male volunteer in his 20s suffered what the Washington Post reported to **be a stroke**.

After an investigation, the FDA allowed J&J to resume the trial.

Another manufacturer, Novavax, has pushed back the start date for its U.S. Phase 3 trial to the end of November; it had earlier said the trial would start this month.

Anna Durbin, a vaccine researcher at Johns Hopkins Bloomberg School of Public Health, said the public needs to understand that Covid vaccines may be a bit further off than people have been led to believe.

“We may see efficacy in one or more trials by the end of 2020, but that doesn’t mean we’re going to have a vaccine available at the end of 2020,” she said.

“I think what people can take from this is that the process is not being rushed.... That’s a good thing,” Durbin said. “And certainly, I think the other message that has to be heard loud and clear is that even when an [emergency use authorization] is issued, we’re not going to have enough vaccine for everybody [immediately].”

**About the Author [Reprints](#)**<sup>4</sup>



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