

COVID-19 Vaccine Rollout: “So Many Pieces Have to Work Just Right.”

The FDA officially granted emergency use authorization for the Pfizer-BioNTech COVID-19 vaccine on Friday, writing that “in making this determination, the FDA can assure the public and medical community that it has conducted a thorough evaluation of the available safety, effectiveness and manufacturing quality information.”

“The tireless work to develop a new vaccine to prevent this novel, serious, and life-threatening disease in an expedited timeframe after its emergence is a true testament to scientific innovation and public-private collaboration worldwide,” FDA Commissioner Stephen Hahn said.

Trucks began dispatching shipments from Pfizer’s production plant in Kalamazoo, Michigan, to all 50 states on Sunday morning.

Gen. Gustavo Perna, chief operating officer for Operation Warp Speed, said during a Saturday morning news conference that 2.9 million doses of the Pfizer vaccine will be sent this week, including to 145 vaccination sites designated by the states on Monday, and an additional 491 sites on Tuesday and Wednesday.

Trump administration officials remain confident they will hit their goal of 20 million inoculations by year end.

“We’ll be getting more and more Pfizer product, and we’ve got 12.5 million [doses] of Moderna product, assuming that we get approval at the end of this week,” Health and Human Services Secretary Alex Azar said yesterday. “So yeah, 20 million vaccinations this month. And then we think we’ll be up to 50 million total vaccinations—of people—by the end of January. And 100 million shots in arms by the end of February, just with the Moderna and Pfizer vaccines.”

Most states are expected to follow CDC recommendations by administering vaccines to health care workers and long-term care facility residents on Monday. The *New York Times* reported Sunday that White House officials working in close proximity to the president will also be among the first Americans to receive Pfizer’s vaccine, but President

Trump later said he requested an “adjustment be made” so that White House officials “receive the vaccine somewhat later in the program, unless specifically necessary.”

Distributors have developed contingency plans to prepare for inclement weather, refrigeration mishaps, or logistical miscommunications that could delay shipments or destroy entire batches of the vaccine. Local government officials have also taken steps to ensure that doctors’ offices, clinics, and pharmacies are sufficiently equipped with the proper quantities of masks, dry ice, needles, alcohol swabs, and syringes required for proper vaccine administration.

“We’re launching a very complex nationwide distribution program,” Azar said Sunday. “Do it right, do it measured, get the job done right, anticipate problems. But know there are going to be hitches and hiccups as we go, and we will work to solve it. This is the U.S. military that is running this operation. It’s what they do.”

“So many pieces have to work just right,” said Yossi Sheffi, director of the MIT Center for Transportation & Logistics and author of *The New (Ab)Normal: Reshaping Business and Supply Chain Strategy Beyond Covid-19*.

The Pfizer-BioNTech vaccine must be stored at minus-94 degrees Fahrenheit, which presents unprecedented challenges to supply chain management. Cargo planes and delivery trucks have been equipped with special dry ice containers that can be opened only twice per day to preserve their ultracold temperatures.

Once the vaccine vials are thawed and diluted with a 0.9 percent sodium chloride solution, they must be stored between 35 to 77 degrees Fahrenheit and administered within six hours. “The issue is that right now, the vaccine is coming in packages of about 1,000, and you have to dilute it to get about 5,000,” Sheffi told *The Dispatch*. “So 5,000 people have to come more or less the same day at the same time, same place. If only 4,000 people show up after six hours, you throw out 1,000 vaccines.”

With the Pfizer vaccine—and the (hopefully) soon-to-be-approved Moderna vaccine—a second dose (either 21 or 28 days after the initial shot) is required to reach full efficacy. And this adds an additional level of complexity to distribution logistics. “The Johnson & Johnson vaccine has one huge advantage: You need one dose, not two,” Sheffi pointed out. “When you need two doses, you don’t only need all these 5,000 people to come to

one place at one time. Three to four weeks later, you need exactly the same 5,000 people to come to the same place at the same time.”

Early trials show that Pfizer-BioNTech’s mRNA vaccine is 95 percent effective at preventing the spread of COVID-19 when administered in two doses. According to an [FDA briefing report](#) published Thursday, that efficacy rate drops to just 52.4 percent when a person receives only one dose (though that number may be higher, it’s skewed by the trial being designed for two doses). The government’s plan, as of now, is to only distribute half the vaccines available in December, saving the other half to provide initial recipients with their second dose.

But some argue we should be getting that first dose to as many people as possible now, and trust manufacturing will ramp up enough to have additional supply later on. “The idea that we need to cut [the doses] in half and give half of it now and hold onto it, so we have supply in January to get the second dose,” former FDA commissioner and Pfizer board member Scott Gottlieb [told USA Today last week](#). “I just fundamentally disagree with that.”

The problem with that approach, however, is Pfizer and Moderna have not conducted any single-dose trials, and we don’t know the true effectiveness of the vaccines sans booster shot. Journalist Zeynep Tufekci [makes the case here](#) for beginning a single-dose trial, but most vaccine experts are hesitant to stray from the recommended guidelines.



Prof. Akiko Iwasaki [@VirusesImmunity](#)

The estimated vaccine efficacy after the 1st (82%), between 1st and 2nd (52.4%) and after the second dose (95%) are all impressive! However, high affinity Ab and long term immunity likely require the 2nd dose and we should all adhere to the recommended

regimen. (2/n)

Among all participants (regardless of evidence of infection before or during the vaccination regimen), 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared with 275 cases in the placebo group, indicating an estimated VE of 82% (95% CI: 75.6%, 86.9%) against confirmed COVID-19 occurring after Dose 1, with VE of 52.4% (95% CI: 29.5%, 68.4%) between Dose 1 and Dose 2. The efficacy observed after Dose 1 and before Dose 2, from a post-hoc analysis, cannot support a conclusion on the efficacy of a single dose of the vaccine, because the time of observation is limited by the fact that most of the participants received a

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second dose after three weeks. The trial did not have a single-dose arm to make an adequate comparison.

December 8th 2020

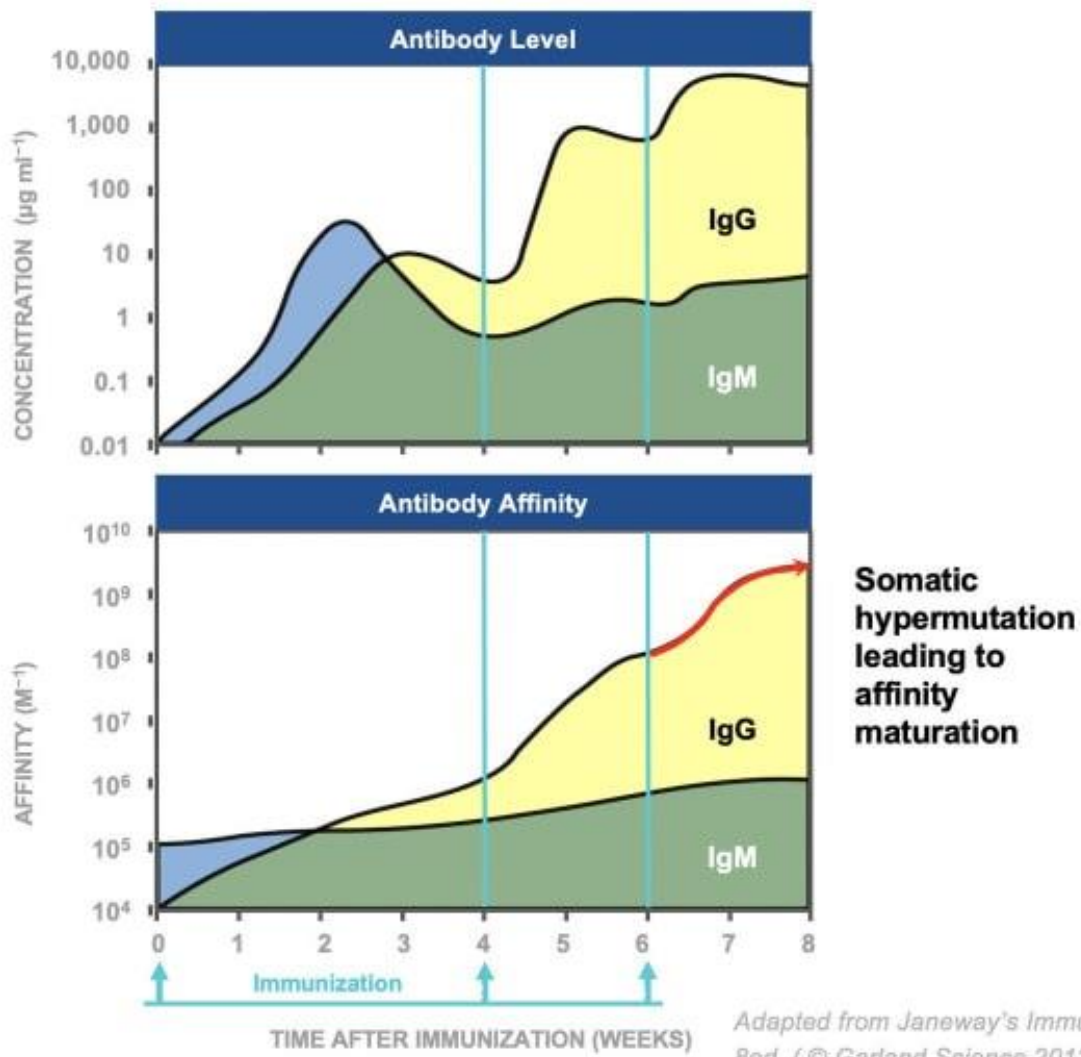
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Why do we need a booster shots? This is because B cell responses induced by first dose only generates lower levels, lower affinity and short lived antibody responses. The booster dose(s) allow stimulation of robust long-lasting immunity with high

affinity/neutralizing Ab. (end)



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The next several months will bring with them incredible amounts of pain and suffering, and it's a near certainty that things will go wrong in the vaccine distribution process. But today is a momentous day, and it could well be the beginning of the end of this dark period that began in March.

Operation Warp Speed head Moncef Slaoui told Fox News Sunday that the federal government hopes to immunize 100 million people with two doses of vaccines by the end of the first quarter of 2021. "Long-term care facility people, the elderly people with

comorbidities, the [front-line] workers, the health care workers,” Slaoui said. “[That’s] about 120 million people.”

“We need to have immunized about 75 or 80 percent of the U.S. population before herd immunity can really be established,” Slaoui added. “We hope to reach that point between the month of May and the month of June.”

Gen. Perna made clear on Saturday that the country’s nationwide vaccine campaign will be one of the largest mass mobilizations of federal resources in decades. “D-Day was the beginning of the end. And that’s where we are today,” he said. “We are not taking a victory lap. We know that the road ahead of us will be tough. We know that situations will occur. But we will figure it out together collectively.”