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Warning of Shortages, Researchers Look to Stretch Vaccine Supply

The N.I.H. and Moderna are examining whether doses of Moderna's coronavirus vaccine can be halved to double the supply, while scientists look for other ways to extend availability.

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WASHINGTON — Federal officials and drugmakers, faced with a slower-than-expected rollout of the coronavirus vaccine, are racing to find ways to expand the supply, looking at lowering the required dosage and extracting more doses from the supplies they have.

Just weeks into the vaccine program, scientists at the National Institutes of Health and the drugmaker Moderna are analyzing data to see if they can double the supply of the company's coronavirus vaccine by cutting doses in half. The study, though long planned, is increasingly urgent in the face of looming shortages as the country tries to fight off a surging pandemic.

Officials are also rushing to find supplies of more efficient syringes that could extract an additional dose from vials of the Pfizer-BioNTech vaccine. That could bolster the Pfizer supply by 20 percent.

With more than 355,000 Americans already dead of Covid-19, nearly 21 million cases reported in the United States and hospitals overflowing, the need to inoculate people grows more urgent every day. The nation is facing twin problems. At the moment, it has only enough vaccine on order to cover 185 million Americans by the end of June. At the same time, doses that vaccine makers rushed out of their factories are sitting unused and are in danger of expiring.

The Trump administration has shipped more than 15 million vaccine doses, and millions more are already in the federal government's hands. Yet only 4.5 million people have received them so far. State and local public health officials, already overwhelmed with rising infections, are struggling to administer the vaccine to hospital workers and at-risk older Americans while most people remain in the dark about when they might be protected.

Countries in Europe are grappling with their own rocky vaccine rollouts, only adding to a sense of panic as a new, more contagious variant of the novel coronavirus spreads across the globe.

“The total supply of vaccine has always been a concern,” said Dr. John R. Mascola, director of the N.I.H.’s Vaccine Research Center, adding, “It’s important to do these analyses that we’re doing, and have all that data in our pocket in the event that there’s a need to use it.”

The Moderna dosage research, which also involves scientists from Operation Warp Speed, the government’s vaccine initiative, could take two months, said Dr. Mascola, who described the work in an interview Tuesday. Any dosing changes would have to be approved by the Food and Drug Administration.

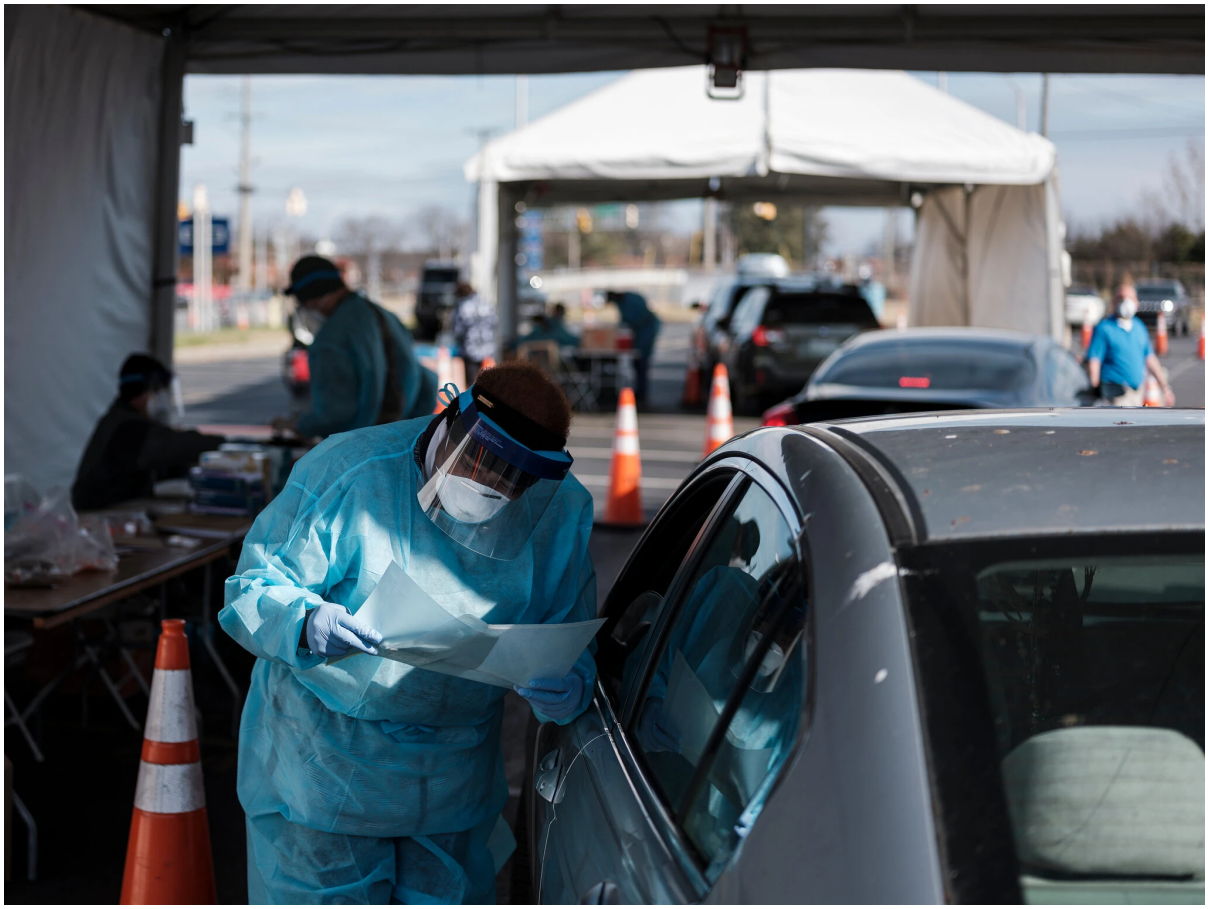
For the moment, the biggest problem is not a shortage of vaccine, but the difficulties that state and local governments face in distributing the doses they have. But in interviews, both Dr. Mascola and Dr. Anthony S. Fauci, the government’s top infectious disease expert, warned of possible shortages to come.

“To me, what appears to be the imminent problem that’s right in front of us is getting people vaccinated with the doses that we have,” Dr. Fauci said. “That could change.”

Those struggles will be global. Already, Italy, Greece and other countries are reporting shortages of needles. Spain has not trained enough nurses. France has only managed to vaccinate around 7,000 people. Poland’s program was rocked by scandal after it was revealed that celebrities were given preferential treatment. There are calls in Germany to take control over vaccine purchases from the European Union authorities. Nearly every country in Europe has complained about burdensome paperwork.

In Washington, congressional Democrats are demanding an explanation for vaccination delays. Senator Patty Murray of Washington, the top Democrat on the Senate Health Committee, said in an interview on Tuesday that states needed more support and guidance from the federal government — an issue she said she raised on Monday with Gen. Gustave F. Perna, the chief operating officer of Operation Warp Speed.

President Trump “wants us all to just give him a lot of credit for having a vaccine this fast,” Ms. Murray said. “But as the Trump administration has done with testing and everything else, it’s, ‘We did this — now it’s up to the states.’ Well, the states don’t have capacity, and there isn’t stability in the supply chain.”



A testing site in Nashville in December. With more than 355,000 Americans already dead of Covid-19, and nearly 21 million cases reported in the United States, the need to inoculate people is becoming more urgent. William DeShazer for The New York Times

Dr. Jerome Adams, the surgeon general, conceded on Tuesday that the vaccine rollout was going slowly, and urged states not to stick rigidly to the Centers for Disease Control and Prevention guidelines about whom to vaccinate first. If fewer health care workers are willing to be vaccinated, he said, states should "move quickly to other priority groups," such as people older than 75 and essential workers.

"Your headline today really should be, 'Surgeon General Tells States and Governors to Move Quickly to Other Priority Groups,'" Dr. Adams said on NBC's "Today" show. "If the demand isn't there in 1a, go to 1b and continue on down. If the demand isn't there in one location, move those vaccines to another location."

Some states, like Texas and Florida, have already begun offering shots to people 65 and older who are not nursing home residents, and to those of any age with medical conditions that raise their risk of dying if they contract Covid-19. That has led to a desperate scramble among those eager to get vaccinated.

"People want to know: When is my turn? Is this happening? Where do I go?" Ms. Murray said.

Even if distribution kinks smooth out, a vaccine shortage looms in coming months because only two products so far — one developed by Moderna and the other by Pfizer-BioNTech — have been authorized for emergency use. Both vaccine makers have committed all their doses until midyear. That still leaves uncovered about 60 million of adult Americans eligible to be vaccinated.

Officials also have high hopes for a third, single-dose vaccine from Johnson & Johnson. The company is finishing its clinical trial this month and its vaccine could be authorized for emergency use in February. But even if it passes those tests, it is unclear how many more doses will be ready for distribution and by when.

Covid-19 Vaccines ›

Answers to Your Vaccine Questions

Am I eligible for the Covid vaccine in my state?

Currently more than 150 million people — almost half the population — are eligible to be vaccinated. But each state makes the final decision about who goes first. The nation's 21 million health care workers and three million residents of long-term care facilities were the first to qualify. In mid-January, federal officials urged all states to open up eligibility to everyone 65 and older and to adults of any age with medical conditions that put them at high risk of becoming seriously ill or dying from Covid-19. Adults in the general population are at the back of the line. If federal and state health officials can clear up bottlenecks in vaccine distribution, everyone 16 and older will become eligible as early as this spring or early summer. The vaccine hasn't been approved in children, although studies are underway. It may be months before a vaccine is available for anyone under the age of 16. Go to your state health website for up-to-date information on vaccination policies in your area

Is the vaccine free?

Can I choose which vaccine I get?

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

Will my employer require vaccinations?

Where can I find out more?

With the proper syringes, federal officials hope to extract an extra dose from Pfizer's vials that were initially believed to contain only five doses, stretching Pfizer's vaccine further. But the government has yet to sign contracts to supply enough of those syringes, according to two experts familiar with the vaccine distribution system.

That has made the prospect of doubling the supply of Moderna doses that much more tantalizing. Dr. Moncef Slaoui, the head of Operation Warp Speed, said Sunday on the CBS program "Face the Nation" that data from Moderna's clinical trials demonstrated that people ages 18 to 55 who received two 50-microgram doses showed an "identical immune response" to the standard of two 100-microgram doses.

Both Dr. Mascola and Dr. Fauci confirmed that research.

But Dr. Slaoui went a step further, saying that the F.D.A. and Moderna were already discussing the possibility. The F.D.A. issued a statement on Monday that called the proposal "premature and not rooted solidly in the available science," although worthy of clinical research.

The finding Dr. Slaoui cited came from an early Phase 2 clinical trial, which involved 600 people and was meant to test only for immune response, and not for the effectiveness of the vaccine, according to Dr. Fauci and others. It compared the immune response in people given 50 micrograms with those given 100 micrograms.

The larger Phase 3 trial that found the vaccine was 94 percent effective involved 30,000 people, half of whom were given the 100-microgram dose and half of whom were given a placebo.

To provide the F.D.A. with the kind of data it would need to approve a change in dosing, scientists must first study blood samples from patients who participated in the Phase 3 trial to determine precisely what immune response correlates with protection against Covid-19.

Then, Dr. Mascola said, researchers would have to either look back at patients from the Phase 2 trial, or conduct a new one, to demonstrate that patients who received the 50-microgram dose developed the threshold immune response. If the results looked promising, he said, "all this then needs to be put together as a data package for review and discussion with F.D.A."

Because the vaccine was developed in a climate of intense partisan polarization, any effort to shift the dosing schedule must proceed cautiously and be balanced against the risk that it could scare those who have been hesitant to to be vaccinated, experts said.

“There would need to be a very strong rationale to shift off of the dose that was used in the study, and my concern would be that it would confuse people just as acceptance is increasing for a vaccine that’s 95 percent effective,” said Dr. Joshua M. Sharfstein, a former deputy commissioner of the F.D.A. who now teaches at the Johns Hopkins Bloomberg School of Public Health.

Dr. Richard E. Besser, a former acting director of the Centers for Disease Control and Prevention, said rigorous scientific research, clear communications about the findings and a public discussion by outside experts would be essential to making changes.

“Public trust is in short supply right now with these vaccines to begin with,” he said, “and the more that there can be transparency around any changes to the approach to vaccination, the more you will be able to maintain and expand on that trust.”