

# COVID-19 VACCINE NEWSLETTER

JAN 26, 2021

VOLUME 1, ISSUE 5

## *Biden Signs 10 Executive Orders to Fight Pandemic*<sup>1, 2</sup>

One day after his inauguration, President Biden has signed 10 Executive Orders to put his administration's plan fighting the coronavirus in place. First among the executive actions is to **mandate use of masks** on federal property and on public transportation, including planes, trains and buses. Governors and local leaders are encouraged to enforce mask wearing and social distancing. Second, **international travelers** are required to present a negative Covid-19 results prior to entering the U.S. and will be quarantined upon arrival. Third, the wartime **Defense Production Act** will be invoked to compel companies make supplies in short supply, such as the low dead-space syringe needles capable of extracting a sixth dose of Pfizer vaccine from vials. Fourth, more funding will be provided to **support**

**state and counties** in administering 100 million vaccine shots in Biden's first 100 days. Fifth, the White House has established a national **COVID-19 Response Office** to coordinate local pandemic response efforts. Sixth, to **improve federal data collection and sharing**, CDC will publish Covid-19 cases at the county level. Seventh, **strengthen research on innovative Covid treatments** (e.g. antivirals), and emphasis on **diversity in clinical trials**. Also, expansion on programs to support

recovering Covid patients. Eight, expanding **rapid Covid diagnostic testing** programs to slow the spread of the virus. Ninth, provide national guidance on worker safety standards to support **reopening of schools and businesses**. The tenth executive action is establish an **Equity Task Force** to ensure **equitable distribution** of vaccines, treatments and PPEs, including the hard-hit communities of color. The president expressed confidence that the executive actions will put the pandemic under control around



## *Biden Unveils National Plan to Tame Coronavirus*<sup>3, 4</sup>

As the nation suffered from the worst infection and fatality rates, it became abundantly clear that there are not enough vaccines produced and distributed to the states to meet vaccination goals. As of Jan 21, only 16 millions have been inoculated, well short of the goal to have 20 millions Americans vaccinated by the end of December. Even with the limited supply they received, most states struggled with administering the vaccine, since there is no detailed national vaccination plan in place, nor dedicated

federal funding allocated. On Jan 21, President Biden released a 200 pages national strategy plan to tame the pandemic and address the urgent need to boost up vaccine availability. Long-term strategy is to invest \$25 billion in a vaccine manufacturing and distribution plan that guarantees cost-free

vaccination for every American. Negotiations are under way to buy more doses from Pfizer and Moderna to cover all Americans by the end of summer. Short-term strategies: stop holding vials in reserve, with confidence that enough will be produced for second shots; reduce Pfizer minimum shipment size for rural hospitals; invoke the Defense Production Act to produce more vaccines, and manufacture low dead-space needles and the lipid nanoparticles needed for manufacturing the mRNA vaccines.



## VACCINE HIGHLIGHTS

- ◆ President Biden unveils National Plan to fight the pandemic and signs 10 executive orders to urgently increase vaccine availability; invokes the Defense Production Act to increase supply of high efficiency vaccination syringe needles
- ◆ CDC changed its guideline, now allows the interval between the first and second doses to be extended up to 6 weeks
- ◆ CDC also approves mixing the use of Pfizer and Moderna vaccines as a last resort
- ◆ Merck permanently shelves the development of 2 vaccine candidates due to inferior immune response in clinical trials

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1. The Biden-Harris Plan to Beat COVID-19, The White House, Jan 21, 2021 <https://www.whitehouse.gov/priorities/covid-19/>

2. Here are the 10 Executive Orders Biden Signed to Combat the Covid Pandemic, CNBC, Jan 21, 2021

3. National Strategy for the COVID-19 Response and Pandemic Preparedness, The White House, Jan 21, 2021

4. Covid-19 Vaccine Supply is Running Low. Here's How Biden Hopes to Fix That, STAT News, Jan 21, 2021

## Answers to Covid Vaccine Distribution Questions <sup>5</sup>

Excerpts from an article by Helen Branswell, STAT News

### Why is the vaccination process moving so slowly?

It takes time to get vaccination programs up and running. It's expensive to do this work, but U.S. states have only started receiving significant federal funding for their vaccination delivery efforts in the past couple of weeks; it was tied up in the months-long delay in getting Covid-19 relief funding through Congress.

**Distribution is also just complicated.** The two vaccines currently in use need to be shipped and stored frozen. One of them, the vaccine made by Pfizer, has to be kept at an ultra-cold temperature, -94 Fahrenheit. After thawing, it has to be used within five days. These vaccines are difficult to use and easy to waste through spoilage.

Finally, there isn't that much vaccine available yet. The vaccination programs are becoming more efficient, but the flow of vaccine doses from manufacturers isn't growing exponentially at this point.

### Why aren't there more doses now?

Part of the issue is that vaccine manufacturers overpromised what they could produce.

Another part of the issue is that only two vaccines have been authorized for U.S. use so far, Pfizer and Moderna. If more vaccines are authorized by FDA that will increase the amount of vaccine available for use, though the increase won't be immediate. Janssen Pharmaceuticals, the vaccine arm of Johnson & Johnson is expected to release the interim analysis of its Covid vaccine by the end of January.



Johnson & Johnson Covid vaccine

### When will we get more vaccines?

Unfortunately, it's not clear when large amounts of vaccine will be available in the United States. Operation Warp Speed, the government program to fast-track development and distribution of vaccines, had promised to deliver 300 million doses by Jan. 1. **That didn't happen — not by a long shot.** A spokesperson for the Department of Health and Human Services said recently the agency's best prediction was that the government will have received 40 million doses in total by the end of January, and 200 million doses by the end of March. That's only enough to vaccinate 20 million and 100 million people, respectively.



### Will other vaccines become available?

We expect to see clinical trial data this week or next on a one-dose vaccine made by Janssen Pharmaceuticals, Johnson & Johnson's vaccine division. If the vaccine is protective enough, the company can apply for an emergency use authorization from the FDA. If all goes well, that EUA could be issued in mid-February. In addition to the one-dose shot, J&J is testing a two-dose vaccine, but data from that part of its clinical trial will take longer to come in. One dose is easier than two and a delivery of, say, 100 million doses will protect twice as many people as the same number of doses from a manufacturer making a two-dose vaccine. Next up should be the AstraZeneca vaccine, which has already been authorized for emergency use in Britain and India. An EUA application to the FDA will likely be submitted in early March. After that, Novavax may be in a position to apply for emergency use clearance in late March or early April.



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- HELEN BRANSWELL  
STAT NEWS

5. [Verbatim, summarized] Covid-19 vaccine basics: Why the rollout is so slow, who can get doses, and what about side effects, STAT News, Jan 25, 2021

## Answers to Covid Vaccine Impact Questions <sup>5</sup>

Excerpts from an article by Helen Branswell, STAT News

### What do the new variants mean for the vaccines now?

Mutations in the virus's genome can change its appearance.

***The fear is that the antibodies generated in people who have been vaccinated won't be able to identify the virus if it's changed.***

That said, the vaccines still have some tricks up their sleeves. For one, they induce the immune system to mount a "polyclonal" response, replete with different antibodies that can home in on different parts of the virus. Changes in the viral genome for one of those parts shouldn't keep the rest of the antibodies from recognizing and fighting off the virus.

Experts also stress it's not a black-and-white question of whether vaccines work or not. It's a matter of degrees. It's possible that a particular mutation, or, more likely, a particular combination of mutations, will have some impact on the effectiveness of vaccines. But both the Pfizer

and Moderna vaccines produced such stellar levels of protectiveness in clinical trials that experts are heartened that even if the shots lose some of their potency, they will still broadly be able to protect people from Covid-19.

As the number of mutations accrue, experts say vaccines should be reformulated to better suit dominant strains, as it's expected that people will get booster shots every few years.

***Updating the vaccines is a process that should just take weeks to months in terms of design.*** Scientists are stressing that the infectious diseases and regulatory communities need to prepare for this now, to figure out what kind of data will be required to green light such vaccines, how to shift manufacturing operations, and when to make the call that vaccines need to be tweaked.

### Once I get the vaccine, can I live normally again?

No. We still don't know whether people who have been vaccinated can be infected with and shed the SARS-2 virus. We'll need to see how well the vaccines work to protect against the new variant viruses.

As long as there is a lot of SARS-2 virus making the rounds, people will need to continue to take precautions. That means consistent use of face masks in public places, maintaining proper social distancing, and minimizing attendance in large public gatherings.



### Do vaccines prevent infection and transmission, or only symptomatic disease?

The goal for clinical trials was to find out as quickly as possible if the vaccines would prevent symptomatically severe disease, and save lives. Finding out if vaccinated people were developing symptom-free infections and were therefore emitting infectious virus would have been a big additional piece of work.

The answer to the transmission question will only come over time, as researchers study how effective the vaccines are in the real world. But a number of experts are quietly confident that the vaccination will cut back substantially on transmission.

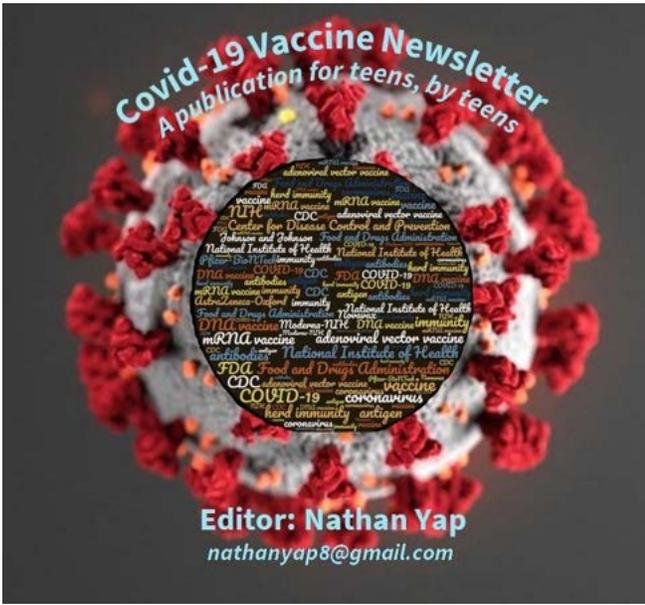
"I've been called an optimist before, but I feel that vaccines that can prevent 95% of symptomatic infections have got to be preventing infection in the nose and therefore transmission should be reduced," said Akiko Iwasaki, a virologist and immunologist at Yale University.



**"VACCINES THAT CAN PREVENT 95% OF SYMPTOMATIC INFECTIONS HAVE GOT TO BE PREVENTING INFECTION IN THE NOSE AND THEREFORE TRANSMISSION SHOULD BE REDUCED."**

**- AKIKO IWASAKI  
YALE UNIVERSITY**

5. [Verbatim, summarized] Covid-19 vaccine basics: Why the rollout is so slow, who can get doses, and what about side effects, STAT News, Jan 25, 2021



**CDC Quietly Changes Vaccination Guidelines** <sup>6, 7</sup>

On Jan 21, CDC has provided new guidance allowing stretching the interval between the doses up to 6 weeks, and “in exceptional situations” to mix the use of Pfizer and Moderna vaccines for the first and second shots. The change was to support release of all available vaccine supplies. The recommendation changes were issued despite lack of large clinical trial studies to validate the clinical effectiveness of the new approach. In December Pfizer and Moderna vaccines received FDA authorizations for administering the second shot at 3 weeks and 4 weeks interval, respectively. The interval period was designed to optimize boosting the immune response after the second shot.

Since the interval stretching was done off-label, the clinicians administering the second shot bear the clinical responsibility for the decision. Ironically, earlier this month, there was criticism from the U.S. medical community on U.K. regulators decisions to do the same, stretching the interval for AstraZeneca and Pfizer vaccines up to 12 weeks. AstraZeneca has supported this decision, based on clinical data showing a ‘sweet spot’ for 8- to 12-week gap. Pfizer, however, has warned that it does not have any clinical evidence that its vaccine continues to be protective if the second dose is provided beyond the recommended 3 weeks.

**COVID-19 Humor**



**Merck Vaccine Fails** <sup>8</sup>

On Jan 25, Merck announced stopping development of its two Covid vaccine candidates, due to inadequate immune responses in phase 1 clinical trials. Both vaccines were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other Covid vaccines. Specifically, they produced lower levels of antibodies against SARS-CoV, including binding antibodies and neutralizing antibodies, that is seen in the blood of individuals who have recovered from Covid-19. In comparison, the Pfizer/BioNTech and Moderna vaccines authorized in the U.S., generate antibody levels several times above those seen in people who recovered from Covid-19. The AstraZeneca/Oxford vaccine, approved in the U.K. and India, generates antibody levels roughly equivalent to those seen in people who recovered from Covid-19.

was developing are unique in that they use a virus that attach to human cells at the ACE-2 receptors, typically in abundance at human’s nasal passages that have lots of cells with these receptors. Muscle cells, however, do not. Since the Merck vaccines were injected intramuscularly in the clinical trials, this might explain why the antibody levels generated were insufficient.



*‘I must have the Pfizer vaccine. It’s not for me, it’s for my mink coat’*

The vaccines were developed in partnership with the International AIDS Vaccine Initiative (IAVI) to see if using a different route of administration would improve effectiveness. The vaccines Merck

6. As the U.S. vaccine rollout stumbles, the C.D.C. tweaked recommendations for second doses, despite a lack of data, the New York Times, Jan 21, 2021  
 7. U.K. vaccine roll-out speed up but doctors want quicker second dose, Reuters, Jan 23, 2021  
 8. In a major setback, Merck to stop developing its two Covid-19 vaccines and focus on therapies, STAT News, Jan 25, 2021