DAO Biotech Club

COVID-19 Vaccine Newsletter

DEC 15, 2020 VOLUME 1, ISSUE 2

FDA Authorizes Pfizer COVID-19 Vaccine [1]

On Friday, Dec 11, the FDA granted a historic Emergency Use Authorization (EUA) for Pfizer's COVID-19 vaccine, setting the stage for immediate rollout. The FDA's decision came a day after its Vaccine Committee voted to authorize the vaccine. The Committee voted **yes** (17 members - 77%), **no** (4 members - 18%), and **abstain** (1 member - 5%) on the only voting question posed: *Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its risks for use in individuals 16 years of age and older?* The biggest surprise of the day: a number of pediatricians in the Committee did not feel comfortable authorizing the vaccine for the 16-17 years-old age group, since there were very few participants, and some instances of moderate inflammation in the group were reported. There was tremendous effort to modify the vote question and increase the minimum age to 18 years old. However, the FDA suggested to vote for the 16-years-and-older group first. At the end, it passed for the 16 years-and-older group, but with a number of **no** votes, because some members were hoping that there would be a second round for the 18-years-and-older group. Although Pfizer included participants in the 12-15 years-old age group since October, there were insufficient data to support inclusion in its current EUA application. Pfizer could amend the EUA to include this age group, once enough data become available, likely in the spring. The Pfizer vaccine has a 95% efficacy rate in clinical trials with more than 43,000 subjects. The most common side effects are fatigue, headache, and muscle pain for the first 1-2 days after the injection. There were reports of 4 cases of Bell's Palsy in the treatment arm, but not thought to be related to the vaccine. The Committee discussed the guidelines for who can safely get the Pfizer's vaccine, including those who are pregnant, lactating, severely allergic, asymptomatic, and immune-compromised. The campaign started on Monday, Dec 14, with the vaccination of frontline healthcare workers and residents of long-term care facilities in multiple states. Next in line are 75+ residents and essential workers in grocery stores and schools. Currently Pfizer has a contract with the U.S. Government to supply 200 million doses by June next year.

U.S. Starts Mass Vaccination Campaign [2]

The United States started a mass vaccination campaign on Dec 14, after the FDA authorized Pfizer vaccine on Dec 11. This summer, Pfizer made an agreement with the U.S. government to provide 100 million doses by March 2021, enough to vaccinate 50 million people (as two doses are needed). Despite Pfizer's urgings, however, the U.S. government did not order additional doses to cover the nation's large population until mid-December. A negotiation is being worked out for Pfizer to provide an additional 100 millions doses by late spring or early summer 2021. Pfizer's vaccines must be stored at -70 C. Large hospitals and clinics across the country have set up larger super cold fridges for storage. Pfizer has created GPS-tracked coolers filled with dry ice to distribute. The frozen vaccine is packaged into 2 milliliter glass vials, which is good for five doses after dilution. Once thawed, the undiluted vial can be kept in a regular fridge for up to five days.

Vaccine Highlights

- FDA has issued the first emergency authorization of a COVID-19 vaccine for immediate use
- The Pfizer-BioNTech vaccine, for 16 years and older, was authorized on Dec 11 and started the mass vaccination campaign on Dec 14
- Vaccination is prioritized for frontline healthcare workers and residents of long-term care facilities
- The next priority is for senior citizens 75+ years and essential workers in grocery stores, postal service and schools
- Other Americans can expect vaccination (at local clinics, Walgreens, CVS, etc.) starting around April 2021, with priority determined based on job, age and health
- Americans have many questions about the vaccines, some are addressed on page 2 and 3

Inside this issue:

1. FDA Advisory Panel Endorses Pfizer/BioNTech COVID-19 Vaccine, STAT News, Dec 10. 2020

2. U.S. and Pfizer Are Negotiating Deal for More Vaccine Doses Next Year, The New York Times, Dec 15, 2020

Answers to your COVID-19 Questions [3]

Who will get the vaccine first?

Health care workers and people in long-term care facilities: Health care workers and elderly people living in long-term care facilities will go first, starting in December. Initially, there won't be enough doses to vaccinate all health care workers, so states will prioritize based on exposure risk.

Frontline essential workers and people 75 and older: Those with a substantially higher risk of exposure to the virus will be in the second priority group, possibly starting in January. People 75 and older will also be included in this group.

Other essential workers, adults with medical conditions and people over 65: The C.D.C. is recommending all remaining at-risk adults and sectors considered essential by the government to be prioritized for a third wave of vaccination.

All other adults: Adults in the general population are at the back of the line. The vaccine hasn't been approved in children yet.

"IT'S LIKELY THAT WHEN THE GENERAL PUBLIC STARTS GETTING VACCINATED IN APRIL, SHOTS WILL BE SCHEDULED THROUGH DOCTOR'S OFFICES, CVS, WALGREENS AND OTHER PHARMACIES — THE SAME WAY PEOPLE GET FLU SHOTS."

-ABBY GOODNOUGH & REBECCA ROBBINS, NYT

How long will it take to work?

You won't get the full protection from the Pfizer-BioNTech vaccine until about a week after the second dose, based on clinical trial data. The researchers found that the vaccine's protection started to emerge about ten days after the first dose, but it only reached 52 percent efficacy, according to a report in the New England Journal of Medicine. A week after the second dose, the efficacy rose to 95 percent.

Sandra Lindsay, a critical care nurse from Queens was among the first NYC health-care worker vaccinated

How will the rest of us get vaccinated?

It's likely that when the general public starts getting vaccinated in April, shots will be scheduled through doctor's offices, CVS, Walgreens and other pharmacies — the same way people get flu shots. However, final plans will depend on what other vaccines besides Pfizer's and Moderna's have been approved. With or without insurance, the vaccine should be free, but you may have to watch out for hidden fees. If you are in the first group of people vaccinated, your booster shot (second dose) will be set aside for you and won't be given to someone else. Later when supplies are more plentiful, reserves probably won't be necessary, but there will be backup doses anyway.

Will it hurt? What are the side effects?

The injection into your arm won't feel different than any other vaccine, but the rate of short-lived side effects does appear higher than a flu shot. While these experiences aren't pleasant, they are a good sign that your own immune system is mounting a potent response to the vaccine that will provide long-lasting immunity.

People with severe allergies who have experienced anaphylaxis in the past should talk to their doctors about how to safely get the vaccine and what precautions to take. Among those who participated in the Pfizer trials, a very small number of people had allergic reactions.

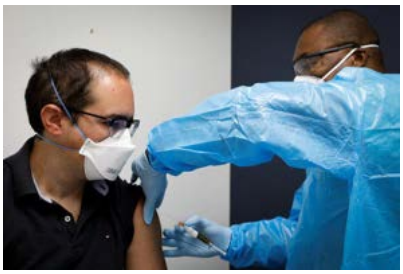
Once a vaccine starts to reach large numbers of people, it's possible (and not uncommon) for a small number of severe "adverse events" to occur. While everyone should be prepared to hear about these reports, they should not be a cause for worry or prompt you to delay getting the vaccine.

3. [Verbatim, summarized] Answers to Your Questions About the New Covid Vaccines in the U.S., The New York Times, Dec 14, 2020

Answers to your COVID-19 Questions [3]

Why not take my chances with the virus?

COVID-19 is by far the more dangerous option, even if you are young and at low risk. Although people who are older, obese or have other health problems are at highest risk for complications from COVID-19, younger people can become severely ill, too. In a study of more than 3,000 people ages 18 to 34 who were hospitalized for Covid, 20 percent required intensive care and 3 percent died. And as many as one in three people who recover from Covid have chronic complaints, including exhaustion, a racing heart and worse for months afterward. Covid vaccines, in contrast, carry little known risk.



What if I forget to take the 2nd dose on time?

Both the vaccines from Pfizer and Moderna require two doses, with the booster shot coming a few weeks after the first. Pfizer's second dose comes three weeks after the first, and Moderna's comes four weeks later. The second dose provides a potent boost that gives people strong, long-lasting immunity.

If for some reason one fails to get the second shot precisely three weeks after the first, then there I no need to start all over again with another two-dose regimen. "The second dose can be picked up at any time after the first. No need to start the series over," said Dr. Paul Offit, a professor of pediatrics at the Children's Hospital of Philadelphia and a member of the F.D.A.'s vaccine advisory panel.

When will vaccines be available for children?

So far, no coronavirus vaccine has been approved for children. New vaccines are typically tested on adults before researchers launch trials on children, and coronavirus vaccine developers are following this protocol.

In September, Pfizer and BioNTech began studying their vaccine on children as young as 12. Moderna followed suit in December, with 3,000 participants aged 12-17. If these trials yield good results, the companies will recruit younger children. The FDA will then have to review these results before the vaccines can get emergency authorization.

Vaccines are typically tested on adults first in the interest of safety. But once a vaccine is shown to be safe and effective in adults, researchers have to run more trials on children to adjust the dosage for their bodies. Another factor in the wait for a vaccine for children is that they are far less likely to die from Covid-19 than adults are.

What will life be like after vaccination?

Masks will still be required for a while, even after the vaccine is widely available.

The coronavirus vaccines are injected deep into the muscles and stimulate the immune system to produce antibodies. This appears to be enough protection to keep the vaccinated person from getting ill. But what's not clear is whether it's possible for the virus to bloom in the nose — and be sneezed or breathed out to infect others — even as antibodies elsewhere in the body have mobilized to prevent the vaccinated person from getting sick.

Public health officials estimate that 70 to 75 percent of the population needs to be vaccinated before 'herd immunity' is achieved and people can start moving freely in society again.

It's possible that coronavirus vaccinations will become an annual event, just like the flu shot. Or it may be that the benefits of the vaccine last longer than a year. We have to wait and see how durable the protection from the vaccines is.

"THE SECOND DOSE CAN BE PICKED UP AT ANY TIME AFTER THE FIRST. NO NEED TO START THE SERIES OVER,"

DR. PAUL OFFIT, CHILDREN'S HOSPITAL OF PHILADELPHIA

3. [Verbatim, summarized] Answers to Your Questions About the New Covid Vaccines in the U.S., The New York Times, Dec 14, 2020

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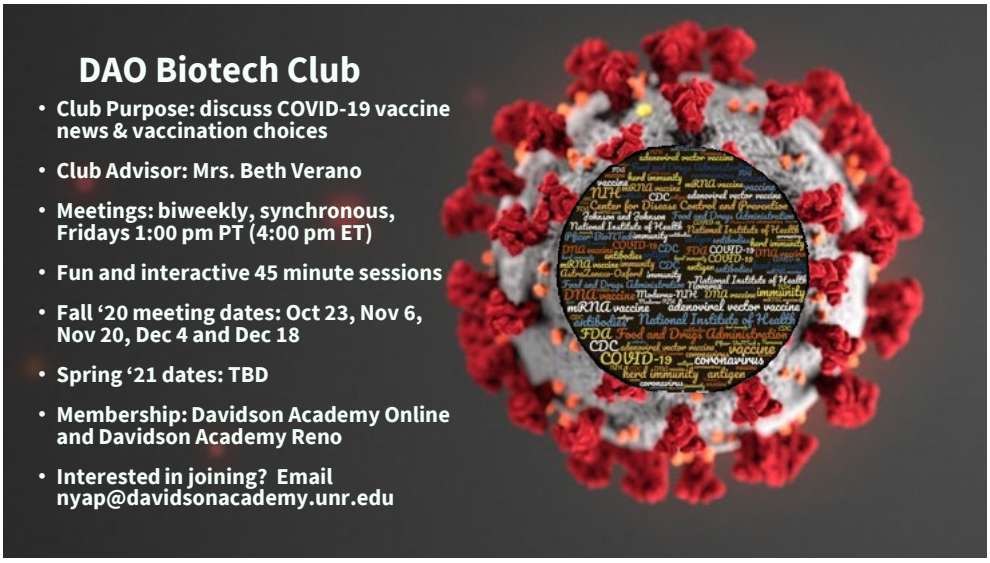
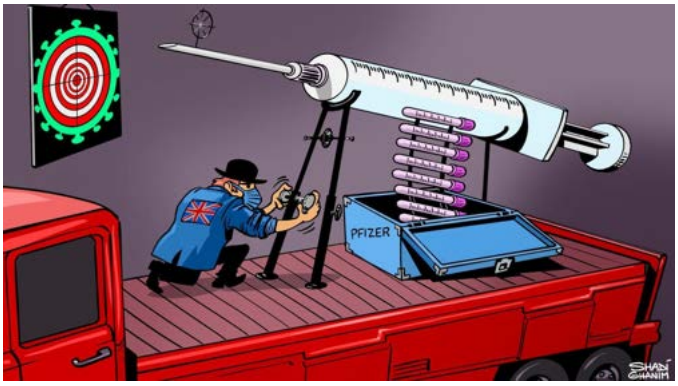


COVID-19 Humor



AstraZeneca Partners with Sputnik Vaccine [4,5,6]

As reported last week, AstraZeneca made a dosing error in their Phase 3 clinical trials. Surprisingly, the group with the dosage error (half a dose for the first shot and a full dose for the second shot) has a much better efficacy rate (90%) compared to the group that received the correct full dose (62%). There was no reasonable scientific explanation to explain the results. We have since learned that there was no participant over the age of 55 in the group with the better efficacy rate. In contrast, the group with the lower efficacy rate has participants over the age of 55, which is known to be more susceptible to COVID-19 infections, and suffer a more severe health consequences when infected. AstraZeneca is now preparing a new clinical trial with the half-dose + full dose regiment. Additionally, AstraZeneca is partnering with the Russian Sputnik vaccine for a new study with the half dose + full dose vaccine in an attempt to boost efficacy. They have agreed to combine a component of the Sputnik V vaccine (which skipped clinical trials) with their AZD1222 vaccine. Both are adenovirus vaccines that use adenoviruses as vectors (vehicles) to transport and deliver target antigens to the body. AZD1222 uses chimpanzee adenoviruses, while Sputnik V uses human adenoviruses. Using adenoviruses carries the risk that there will not be an immune response, if the body already developed an immunity to the adenovirus delivering the genetic material. Hence, the vaccine would be ineffective. Thus, mixing two different adenovirus vaccines may produce a stronger or longer-lasting immune response against the virus. The Russian Direct Investment Fund stated that clinical trials of the new vaccine would start by late-December.

4. Oxford/AstraZeneca vaccine to undergo new global trial, The Guardian, Nov 26, 2020
5. AstraZeneca to test combination of AZD1222 and Sputnik V vaccines, European Pharmaceutical Review, Dec 14, 2020
6. Covid: Trials to test combination of Oxford and Sputnik vaccines, BBC, Dec 11, 2020