DAO Biotech Club

COVID-19 Vaccine Newsletter

DEC 8, 2020 VOLUME 1, ISSUE 1

FDA Authorization for the First COVID-19 Vaccine Expected This Week [1]

Could it be that the end of the pandemic is on the horizon? This coming Thursday, Dec 10, the FDA Advisory Committee for Vaccines is scheduled to meet and review Pfizer's application for EUA (Emergency Use Authorization) for its COVID-19 vaccine. It is widely expected that the FDA will quickly give the green light, within a day or two, should the Advisory Committee recommendation be favorable. For the time being, the authorization would be for age 16 and above, based on the EUA application that was submitted on Nov 20. However, in the near future, we can expect the authorization to be expanded for the age group of 12 to 16 years. The delay is to satisfy FDA's requirement to track the safety of subjects involved for at least 2 months after the last shot. The Pfizer vaccination requires 2 shots, separated by 28 days. In clinical trials, the Pfizer vaccine has proven quite effective in protection from COVID-19 infection, with a 95% efficacy rate in a late stage (Phase 3) clinical trials conducted at 150 clinical trial sites with 43,661 participants in U.S., Germany, Turkey, South Africa, Brazil and Argentina, including 608 adolescents ages 16-17 and 266 ages 12-15. Efficacy was consistent across age, gender, and race demographics, with an observed efficacy of 94% in adults over 65 years of age. Importantly, the vaccine protects the recipients from developing a severe case of COVID-19, when infected. Out of the 10 severe cases observed in the trial, only one was in the vaccinated group. Pfizer expects to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion does by the end of 2021.

Moderna's COVID-19 Vaccine is Next in Line for FDA Review [2]

Trailing closely after Pfizer's vaccine expected green light from the FDA this week, Moderna's Advisory Committee meeting has been scheduled for Thursday, Dec 17, with an emergency authorization expected shortly thereafter. Moderna is a decade old startup based in Cambridge, MA, which until now never had a product approved by the FDA. Their core competence is in the proprietary mRNA platform technology to develop therapeutics and vaccines. Currently all mRNA-based vaccines require super cold temperatures for storage and distribution. Moderna's vaccines need to be stored at minus 20 C, but can stay for a month at fridge temperatures (below 4 C). Pfizer's vaccines require even colder temperatures, at minus 70 C. Reportedly, large hospitals have been buying industrial size super-cold fridges for vaccine storage. In contrast, smaller clinics, especially in the rural areas, do not have the financial resources to follow suit, creating access inequalities to mass vaccination in the economically deprived rural areas.

In a clinical trial with 30,000 participants, Moderna's vaccine was found to be have a 94.5% efficacy rate. Out of the 11 severe cases observed, none were in the treatment arm. The trial was done in the U.S. only, with a diverse age range (18 and older) race, jobs and health conditions. A 3,000 subject follow up trial for adolescents 12-17 years is expected to start soon.

Vaccine Highlights

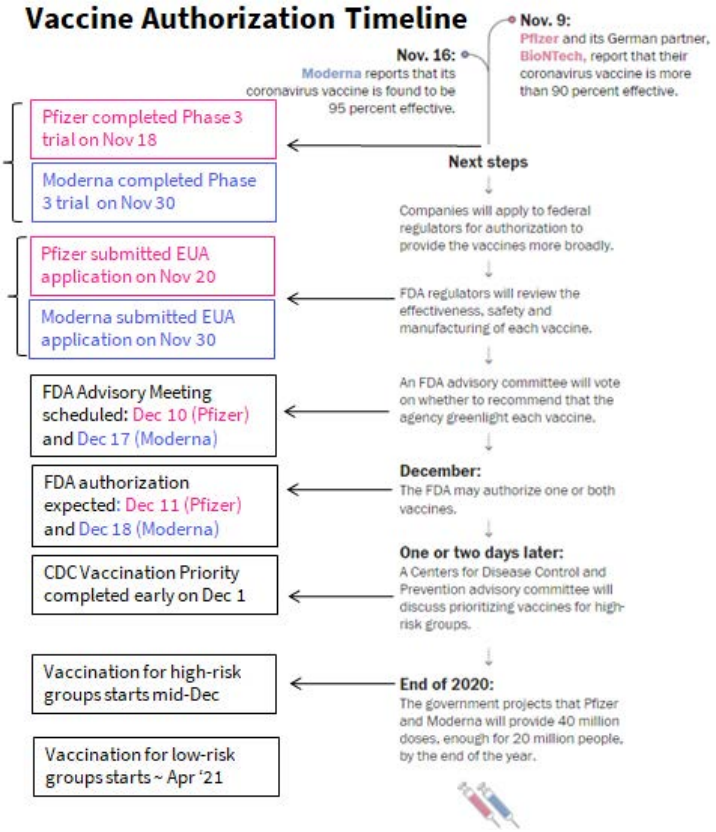
- Two COVID-19 vaccines are expected to receive U.S. FDA's green light this month: Pfizer on Dec 11 and Moderna on Dec 18
- Initially, Pfizer's vaccine is for 16 years and older. Moderna's vaccine is for 18 years and older
- Vaccination is prioritized for frontline healthcare workers and residents of long-term care facilities. Other Americans can expect vaccination (at local clinics, CVS, etc.) starting around April 2021, with priority determined based on job, age and health
- Both vaccines have been developed using mRNA technology, which has never before been used for vaccine development
- The mRNA vaccines require super cold temperatures for storage and distribution (Pfizer's at minus 70 C and Moderna's at minus 20 C), creating formidable logistics challenges

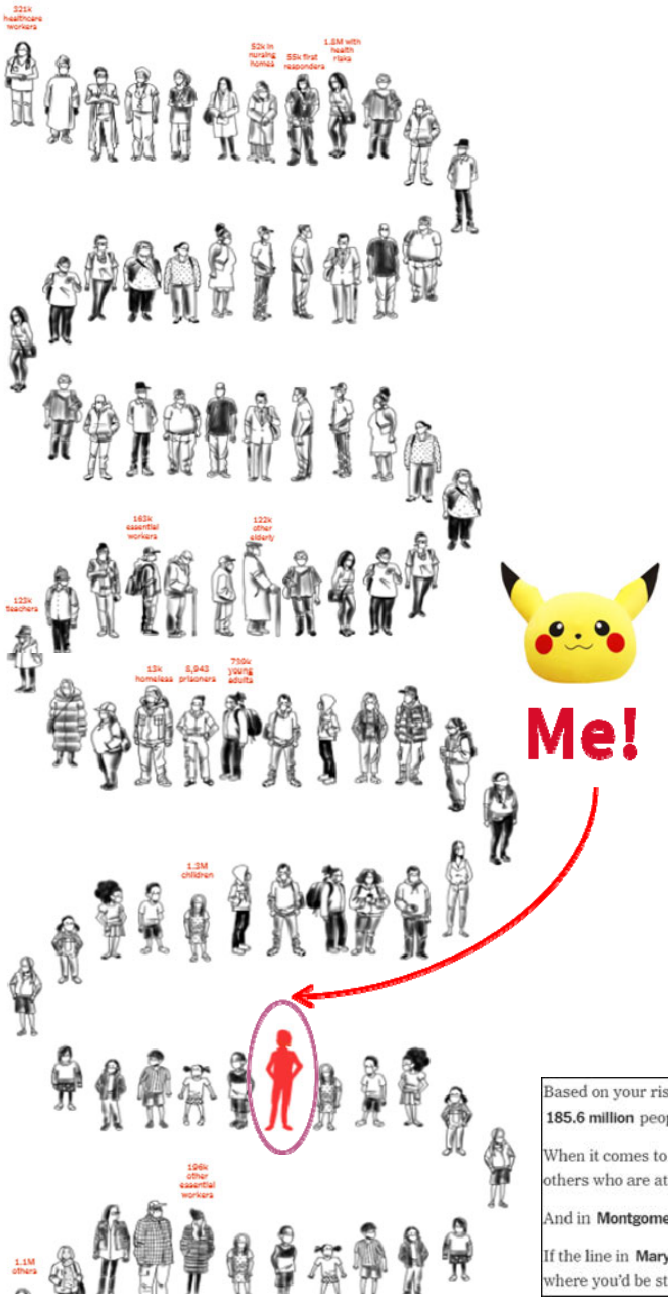
Inside this issue:

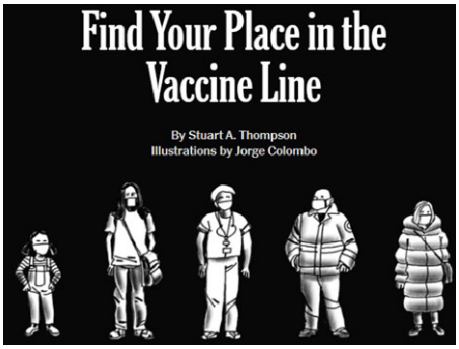
1. Pfizer Press Release, Nov 18, 2020 https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine
2. Moderna Press Release, Nov 30, 2020 https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-primary-efficacy-analysis-phase-3-cove-study

COVID-19 Vaccine: The Road to Emergency Authorization [3, 4]

This week is shaping up to be the most important for COVID-19 vaccine "approval." On Dec 10, the FDA Advisory Committee on Vaccines will hold a public hearing that will determine the fate of Pfizer vaccine. In case you are interested in attending virtually, press CONTROL and click here for the link.







Q: When will I be able to get vaccinated?
A: It depends on your job, your age and your health

JOB: priority for high-risk occupations

AGE: priority for senior citizens

HEALTH: priority for those who are immuno-compromised or with chronic conditions (asthma, diabetes, etc.)

Based on your risk profile, we believe you're in line behind **185.6 million** people across the United States.

When it comes to **Maryland**, we think you're behind **3.4 million** others who are at higher risk in your state.

And in **Montgomery County**, you're behind **497,600** others.

If the line in **Maryland** was represented by about 100 people, this is where you'd be standing:

3. Covid-19 Vaccine – What You Need to Know, Washington Post, Nov 17, 2020 https://www.washingtonpost.com/health/2020/11/17/covid-vaccines-what-you-need-to-know/?arc404=true
4. Find Your Place in the Vaccine Line, New York Times, Dec 3, 2020 https://www.nytimes.com/interactive/2020/12/03/opinion/covid-19-vaccine-timeline.html

CDC's ACIP Issued Recommendation for Vaccination Priority [5]

On December 3, The Advisory Committee on Immunization Practices (ACIP) issued its recommendation for COVID-19 vaccination priority in the U.S., with two groups singled out to be first in line for the initial vaccination campaign: **frontline healthcare workers** and **residents of long-term care facilities**. Frontline healthcare workers are defined as paid and unpaid healthcare personnel serving in a healthcare setting with potential for direct or indirect exposure to COVID-19 from patients or infectious materials. Approximately 21 million personnel work in hospitals, outpatient clinics, home health care, long term care facilities and pharmacies. As of December 1, more than 850 deaths and 245,000 cases were recorded amongst this group. Residents of long-term care facilities are mostly senior citizens, but also includes younger age groups who require 24/7 life-care support. Approximately 3 million adults reside in these facilities. Because of multiple comorbidities, this group is particularly vulnerable and has taken the brunt of COVID-19 fatalities in the U.S., with 70,000 associated deaths and half a million cases, as of November 15.

"THE BLIP FROM THANKSGIVING ISN'T EVEN HERE YET. SO WE'RE GETTING THOSE STAGGERING NUMBERS OF NEW CASES AND HOSPITALIZATIONS BEFORE WE EVEN FEEL THE BRUNT OF THE THANKSGIVING HOLIDAY,"

DR. TONY FAUCI, NIAID

U.S. Records Highest Daily Coronavirus Hospitalization [6]

[CNN Dec 7, 2020] More than 14.9 million confirmed cases have been reported in the US since the pandemic began, and more than 283,000 people have died.

And with the recent spike in cases, record hospitalizations have followed. On Monday, December 7, 102,148 patients were in the hospital with the virus, according to the Covid Tracking Project -- the sixth consecutive day the US surpassed 100,000 hospitalizations.

The Thanksgiving surge could begin to show itself in the coming week, Fauci said, because it generally takes about two and a half weeks from the time of the event until a surge in new positive test cases and potential hospitalizations.

"The problem is, that's going to come right up to the beginning of the Christmas, Hanukkah potential surge," he said.

The middle of January "could be a really dark time for us," Fauci added.

Three Questions in Everyone's Minds [4]

Are these vaccines safe and efficacious?

The clinical trial result for Pfizer and Moderna vaccines showed that these vaccines are safe and efficacious. However, historically the full long-term safety and efficacy profile of a vaccine can not be fully determined until at least hundreds of thousands people have been vaccinated and sufficient time have passed (6 - 12 months).

Which vaccine is best for me?

In the initial phases of the vaccination campaign, this question is largely moot, since vaccine availability is limited and one will have to take whichever vaccine is available in the geographic region. The Pfizer and Moderna vaccines are both mRNA based and have similar efficacy rate. For now, Pfizer EUA is for min.16 yrs and Moderna EUA is for min. 18 yrs. After additional trials, likely both vaccines will be available for 12 yrs and older

When can I get vaccinated?

CDC's ACIP has issued recommendation for vaccination priorities. When you can get vaccinated depends mostly on your job, age and health status.

To see where you stand in the queue line, press CONTROL and click here for the link

For illustrative purposes, a sample result is shown for a 13 year old male student, living in Montgomery County, Maryland (see page 2)

5. CDC MMWR, Vol. 69, Dec 3, 2020 https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm?s_cid=mm6949e1_w
6. [All text, verbatim] Fauci says the full brunt of Thanksgiving on US Covid-19 data isn't here yet, CNN, Dec 7, 2020 https://www.cnn.com/2020/12/07/health/us-coronavirus-monday/index.html

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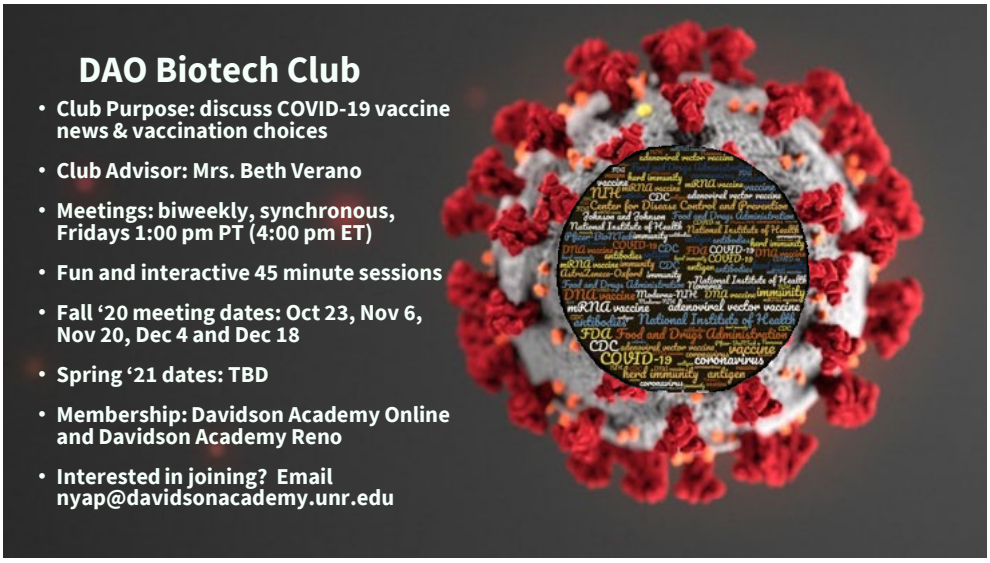

COVID-19 Humor

AstraZeneca Announced Clinical Trial Result [7]

On Nov 23, AstraZeneca announced its vaccine AZD1222 has met primary efficacy endpoint with an average of 70% efficacy rate in a large study in the UK and Brazil with 11,636 participants. The good news was tampered by AstraZeneca's revelation that a dosing mistake was belatedly discovered in 2,741 participants (approx. 25% of total). The treatment arm of this group mistakenly received only a half-dose for the first shot and a full dose a month later. However, it has a surprisingly better efficacy rate of 90% compared to the 62% efficacy rate obtained by the other 8,895 participants who, as planned, received a full dose for the first and second shots. So, the group which received the incorrect half-dose for the first shot is actually faring better than the group which received the full dose! How could that happened? So far, no one can provide a scientifically plausible explanation, not even AstraZeneca's scientists and doctors. In the past there were known rare cases when a lower dose vaccine is actually more effective than a full dose, for complex reasons. Importantly, the dosing mishap rattled the industry's confidence in AstraZeneca's ability to manage large clinical trials within a compressed timeline. The question in everyone's mind is if a dosing mistake can happen to thousands of participants, what other mistakes might be revealed in the future? Unfazed, the company has announced plans to start a new study with the more efficacious half dose, claiming that their "serendipitous finding" will lead to a more efficacious and safe vaccine "for more people" (half the dose!).

7. AstraZeneca Press Release, Nov 23, 2020 https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222hlr.html