DAO Biotech Club

COVID-19 Vaccine Newsletter

DEC 22, 2020 VOLUME 1, ISSUE 3

Moderna Vaccine Receives Second FDA Authorization [1]

On Friday, Dec 18, the FDA granted an Emergency Use Authorization (EUA) to Moderna, the second COVID-19 vaccine approved for mass vaccination. The Moderna vaccine has a 94.5% efficacy rate in clinical trials with 30,000 participants. The FDA decision came a day after its Vaccine Committee recommended authorization, with a vote of **yes** (20 members – 95%), **no** (0 members – 0%), and **abstain** (1 member – 5%) on the only voting question posed: *Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine outweigh its risks for use in individuals 18 years of age and older?* Moderna's vaccine is for 18 years and older, hence there were no complaints from the pediatricians who were reluctant to authorize Pfizer's vaccine (for 16 years and older). The one abstention came from an infectious disease expert who was uncomfortable with the overly broad age range (18+ years). Like Pfizer's, the most common side effects of the Moderna vaccine are fatigue, headache, and muscle pain for the first 1-2 days after the injection. Moderna also reported cases of Bell's Palsy (3 cases in the treatment arm, 1 case in placebo). However, it is not thought to be related to the vaccine, since the number of cases is statistically still within the normal incidence rate. Bell's Palsy is caused by inflamed facial nerve that caused temporary weakness or paralysis of the muscles in one side of the face.

The Moderna authorization came amid a handful of reports of severe allergic reaction and anaphylaxis among healthcare workers in the U.K. and U.S. Anaphylaxis is a severe allergic reaction that cause the immune system to release a flood of chemicals in the body, resulting in low blood pressure and blocked breathing. Vaccine recipients with know allergic reaction are strongly advised to have their epi-pens ready for rapid injection of epinephrine. The U.S. government has purchased 400 million doses of Moderna and Pfizer vaccines and hope to vaccinate up to 20 million Americans by year end.

Mass Vaccination Update - 14 States Complain [2, 3]

The relatively successful first week of Pfizer's vaccine distribution to all 50 states hit a snag when officials at 14 states learned that next week's shipment of the vaccines would contain fewer doses than the first week. Iowa's public health department stated that their shipment will be 30% less. Oregon state health officials said they will receive 38% less. Initially, officials with Operation Warp Speed, the federal entity charged with Covid-19 vaccine distribution said they had allocated only 2 million doses for next week, down from 2.9 million doses delivered this week, due to concerns that Pfizer would be unable to guarantee supply for the second shot. The move created anxiety among state officials, who are scrambling to adjust their plans and created doubts if the government can reach its stated goals of vaccinating 20 million Americans by year end. After days of confusion about the uneven pace of vaccine distribution, Warp Speed Chief, Dr. Moncef Slaoui, pinned the snafu on an administrative lag of two days between FDA approval and the time the vaccines can be shipped. He said the mistake had been corrected, and that on Dec 21, the government would ship 5.9 million doses of Moderna vaccines and another 2 million of Pfizer vaccines.

Vaccine Highlights

- Moderna Vaccine receives second FDA EUA
- Fourteen states complain on Pfizer vaccine distribution delays
- Comparisons between Pfizer and Moderna vaccines show cold storage requirements as the main difference
- Pfizer vaccine causes severe allergic reactions in a few recipients with allergy history
- Nanoparticle lipids in the vaccine is the suspected culprit for allergic reactions
- A more infectious virus mutant circulates in southeastern England, causing global panic
- The Sanofi/GSK vaccine clinical trial is unsuccessful so far

Inside this issue:

1. FDA grants authorization to Moderna's Covid-19 vaccine, the second in the U.S., STAT News, Dec 18, 2020
2. States Complain of Smaller Vaccine Shipments Than Expected, New York Times, Dec 17, 2020
3. The official leading Operation Warp Speed pins the blame for vaccine shortfalls on an administrative error, New York Times, Dec 20, 2020

Side-by-side Comparison between Pfizer & Moderna Vaccines [4]

	Pfizer Vaccine	Moderna Vaccine
Vaccine Type	mRNA	mRNA
Indicated for	16 years and older	18 years and older (testing in 12-17 years)
Efficacy Rate	95% (equally effective across all age, racial, and ethnic groups)	94.5% (slightly lower in elderly)
Dosage	30 micrograms	100 micrograms
Doses Required	2 doses	2 doses
Interval Between Doses	3 weeks	4 weeks
Side Effects	Common effects (pain, fatigue, headache, etc.) and allergic reactions or anaphylaxis	Common effects (pain, fatigue, headache, etc.) and allergic reactions or anaphylaxis
Safety for Pregnant/ Lactating	Not tested	Not tested
Storage Temperature	-70 C (ultra-cold freezer)	-20 C (regular freezer)
After Thawing, Vaccine Good for	5 days, stored in fridge (< 4 C)	30 days, stored in fridge (< 4 C)
Minimum Purchase Order	975 doses	100 doses
Doses in Vials Shipped	5 doses	10 doses
Doses Ordered by U.S. (as of Dec 22)	100 million doses + another 100 million in December	100 million doses + another 100 million in December
Durability of Protection	Uncertain, presumed min. of 6-12 months	Uncertain, presumed min. of 6-12 months

ON DEC 24, DR. ANTHONY FAUCI CELEBRATES HIS 80TH BIRTHDAY. WELL PAST RETIREMENT AGE, DR. FAUCI SHOWS NO SIGN OF SLOWING DOWN, REGULARLY PULLING 18 HOUR DAYS.

HAPPY BIRTHDAY DR. FAUCI !

4. A side-by-side comparisons of the Pfizer/BioNTech and Moderna vaccines, STAT News, Dec 19, 2020

Nanoparticles in Pfizer's vaccine may cause allergic reactions [5]

Lipid nanoparticle lipid (LNP) used in the encasing of the mRNA vaccines has been identified as the possible culprit of severe allergic reactions and anaphylaxis in healthcare workers receiving the Pfizer vaccine. LNP wraps the active ingredients of the mRNA vaccine and act as an adjuvant, a vaccine ingredient that bolsters the immune response. The LNPs are chemically attached to PEG (PolyEthylene Glycol) molecules that cover the outside of the particles and increase their stability and life span. The PEG material, used in both Pfizer and Moderna vaccines, have never been used in approved vaccines, but is common in many drugs that have occasionally triggered anaphylaxis. The National Institute of Allergy and Infectious Disease (NIAID) is currently collaborating with FDA to analyze the response to the vaccine in people who have high levels of anti-PEG antibodies or have experienced severe allergic reactions to drugs or vaccines before. Alkis Togias, Branch Chief at NIAID stated, "Until we know there is truly a PEG story, we need to be very careful in talking about that as a done deal." Pfizer is also actively investigating the root causes of allergic reaction and advocates availability of epipens in vaccination sites. Anaphylaxis reactions happen with any vaccine, but typically are extremely rare, about one per 1 million doses. As of Dec 19, there have been only 6 cases of anaphylaxis recorded among the 272,000 COVID-19 vaccine recipients in the U.S.. Since both the Pfizer and Moderna vaccines use the new mRNA platform, the few allergic cases have received enormous attention from the media and created public anxiety. "Patients with severe allergies are getting nervous about the possibility that they may not be able to get vaccinated, at least with those two vaccines," Togias said. The public anxiety goes beyond people with known severe allergic reactions. A large proportion of the general population suffer from mild allergies in the presence of pollen, pets and peanuts. Public Health officials are worried that vaccination hesitancy rates may rise with additional reports of severe cases.

Dr. Fauci receives the Moderna COVID-19 vaccine [6]

During a live broadcast on Dec 22 at the National Institute of Health (NIH) campus in Bethesda, Maryland, Dr. Anthony Fauci was vaccinated with the Moderna vaccine, which was co-developed with NIH scientists. Rolling up the sleeve of a blue dress shirt, Dr. Fauci called his public vaccination "a symbol to the rest of the country that I feel extreme confidence in the safety and the efficacy of this vaccine." Further signaling his confidence in the vaccines, he stated, "I want to encourage everyone who has the opportunity to get vaccinated so that we can have a veil of protection over this country that would end this pandemic." Dr. Francis Collins, the Director of NIH, was the next person to receive the vaccination, followed by all frontline workers at the N.I.H Clinical Center. They will receive the second dose of the Moderna vaccine in 28 days. President-elect Biden has received the Pfizer vaccine on Dec 21 and Vice President-elect Kamala Harris is expected to receive her vaccine after Christmas. For national security reasons, their vaccination schedule is staggered.

Dr. Anthony Fauci, the U.S. government's top infectious disease expert, received the Moderna vaccine at NIH Auditorium.

Mutant coronavirus in the United Kingdom sets off alarms [7]

On Dec 8, U.K. public health officials were alarmed to see surges of coronavirus cases in southeastern England. Half of the cases were attributed to *B.1.1.7*, a specific variant of SARS-CoV-2, the virus responsible for COVID-19 infection. Less than 2 weeks later, this variant caused mayhem in U.K, mainland Europe and now, in the U.S. U.K. Prime Minister, Boris Johnson has announced stricter lockdown measures to contain spread of *B.1.1.7*, which appear to be more effective in spreading the virus between people. The news has caused many countries to halting all flights from U.K. and closing their borders. Scientists are working hard to determined if B.1.1.7 is indeed more adept at human-to-human transmission. They are also trying to figure out how it can evolve so fast, acquiring 17 mutations all at once, a feat never before seen. The biggest concern is if the current approved vaccines will no longer be effective against this strain. That would necessitates developing variations of current vaccine.

5. Suspicions grow that nanoparticles in Pfizer's COVID-19 vaccine trigger rare allergic reactions, Science, Dec 21, 2020
6. Dr. Anthony Fauci receives the Moderna Covid-19 vaccine, New York Times, Dec 22, 2020
7. Mutant coronavirus in the United Kingdom sets off alarms, but its importance remains unclear, Science, Dec 20, 2020

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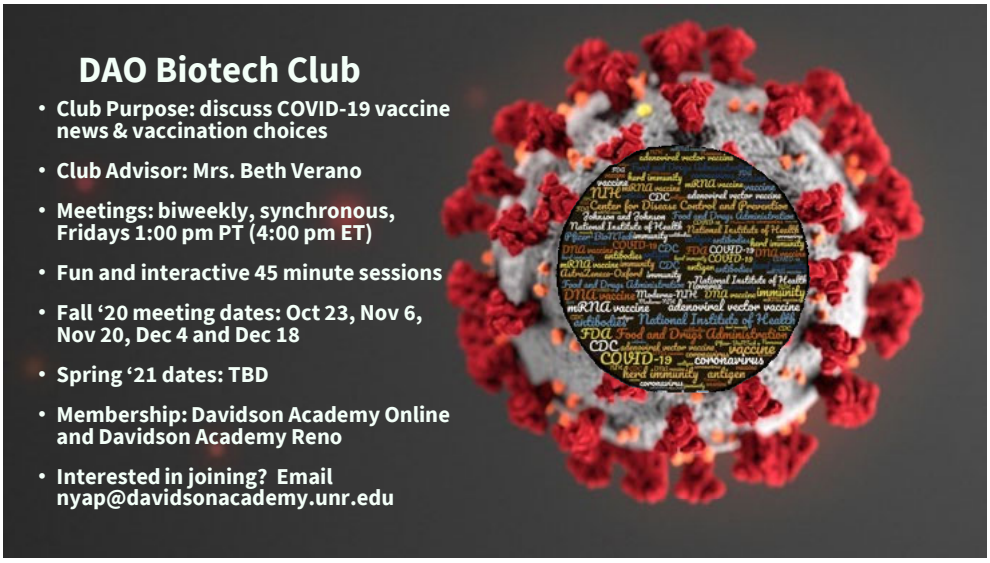
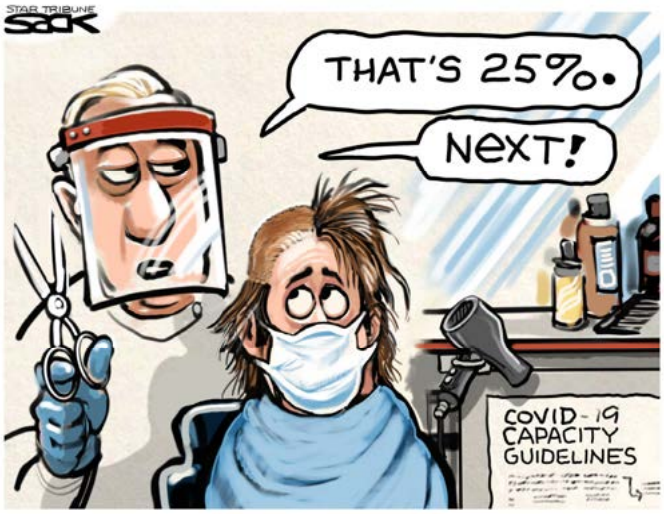
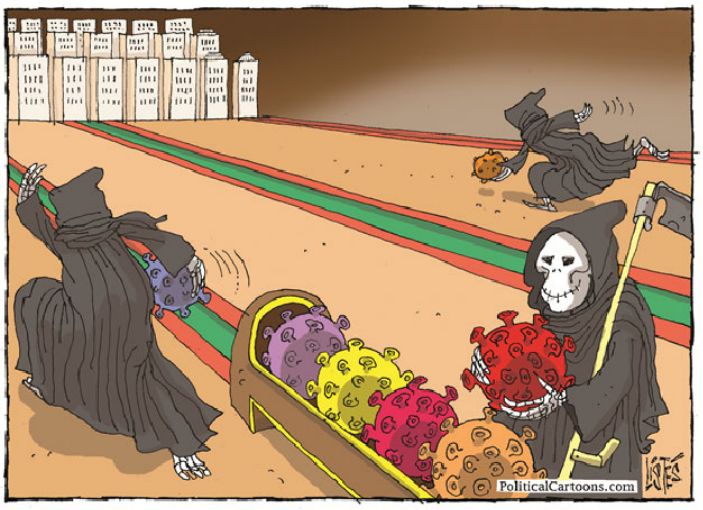


COVID-19 Humor





Sanofi/GSK Vaccine Suffers Setback [8, 9]

Sanofi/GlaxoSmithKline's vaccine has shown to be unsuccessful in their Phase 1/2 clinical trial results, so far. Although their adenovirus vaccine worked on participants ages 18-49 years old, it failed in some older adults. Likely because of an insufficient concentration of the antigen, low immune responses in these older adults were recorded. In a press release, Sanofi and GSK stated that they need to refine the concentration of the antigen to provoke a strong immune response in all age groups. They plan a new Phase 2b study with an improved antigen formulation. This modified trial will compare their vaccine to a vaccine already authorized (e.g. Pfizer or Moderna vaccine, with ~ 95% efficacy) instead of a placebo, further raising the threshold for FDA authorization. The setback delayed the planned deployment of Sanofi/GSK's vaccine from the first half to the second half of 2021.

8. Sanofi suffers major setback in development of a Covid-19 vaccine, STAT News, Dec 11, 2020

9. Sanofi and GlaxoSmithKline delay plans for a trial after experimental vaccine fails in some older patients. New York Times , Dec 15, 2020