

COVID Vaccine Update

Wednesday, January 13th, 2021

2:00-3:00pm ET

Introductions



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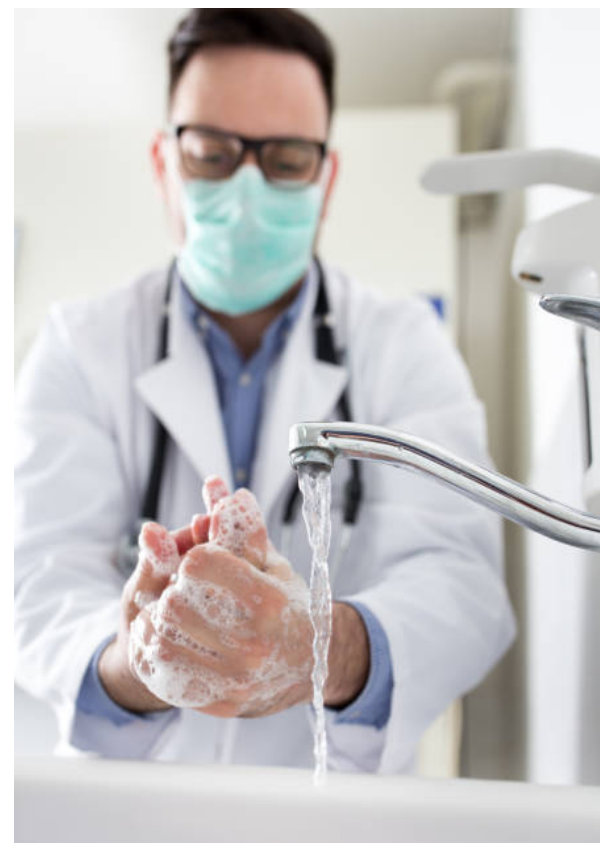
- Medical directors from mental health and substance use treatment organizations from across the country.
- Advises National Council members, staff and Board of Directors on issues that impact National Council members' clinical practices.
- Champions National Council policy and initiatives that affect clinical practice, clinicians employed by member organizations, national organizations representing clinicians and governmental agencies.

Agenda

- Scientific and regulatory processes
- Vaccination-specific concerns
- COVID-19 prevention strategies
- Answer questions asked

How To Prevent COVID-19

- Wear a mask that covers your mouth and nose
- Avoid close contact with others. Stay at least 6 feet (about 2 arms' length) from other people
- Avoid touching your eyes, nose, and mouth with unwashed hands
- Clean and disinfect frequently touched surfaces daily
- Wash hands often with soap and water
- Use an alcohol-based hand sanitizer with at least 60% alcohol if soap and water are not available



New Measures For Prevention: COVID-19 Vaccines

- Multiple COVID-19 vaccines are in development, several of which are in large scale (Phase 3) trials



- COVID-19 vaccines are being held to the **same safety standards** as all vaccines

COVID-19 Vaccines Have Received FDA Emergency Use Authorizations (EUAs)

- Two vaccines have received Emergency Use Authorizations (EUAs) from the FDA:
 - **Pfizer/BioNTech:** 2 doses given at least 21 days apart
 - **Moderna:** 2 doses given at least 28 days apart
- Both vaccines were tested in tens of thousands of adults from diverse backgrounds, including older adults and communities of color
- Clinical trial data show that both vaccines are safe and effective at preventing COVID-19
- It is unknown how long protection from vaccines might last

Sources: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine>
<https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy>

Requirements For An Emergency Use Authorization (EUA)

- Overall
 - known and potential benefits outweigh the known potential risks
 - meets reasonable thresholds for safety and effectiveness
 - people are in urgent need of care
 - effective alternatives are not available
 - Minimum of 50 % effective
- Research Data
 - all safety data accumulated from phase 1 and 2 studies completed
 - a phase 3 safety database of well over 3,000 vaccine recipients for over 1 month after completion of the full vaccination regimen
 - Effectiveness data on at least half of study participants to follow-up of at least 2-months after vaccination completed

These COVID-19 Vaccines are mRNA Vaccines

- Both are 95% effective at preventing Covid infections and the 5% that still get infected will not have a severe case
- mRNA vaccines teach our cells how to make a harmless piece of the “spike protein” for SARS-CoV-2
 - After the protein piece is made, the cell breaks down the instructions (the mRNA) and gets rid of them
- Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies. This produces antibodies to protect us from getting infected if the SARS-CoV-2 virus enters our bodies
- mRNA vaccines do not use the live virus that causes COVID-19. They **CANNOT** give someone COVID-19
- mRNA vaccines **DO NOT** affect or interact with our DNA in any way

Source: [Understanding and Explaining mRNA COVID-19 Vaccines | CDC](#)

What Does 95% Effective Really Mean?

Trial Group	Number of People	Number got COVID After Injection
Placebo Control	10,000	100
COVID Vaccine	10,000	5

Side Effects to mRNA Vaccines (Pfizer, Moderna)

- Symptoms
 - Pain at injection site – red, tender, mild swelling
 - Fatigue
 - Headache
 - Muscle ache
 - Less common – fever, chills, joint pain
- Often over in a day
- May be more severe after second dose
- Could be more accurately called “immune response” instead of “side effects”
- No significant safety concerns were identified in the clinical trials.
- At least 8 weeks of safety data were gathered in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination



Pfizer/BioNTech and Moderna Vaccines

 **2** 
30 MICROGRAM DOSES
ADMINISTERED 21 DAYS APART

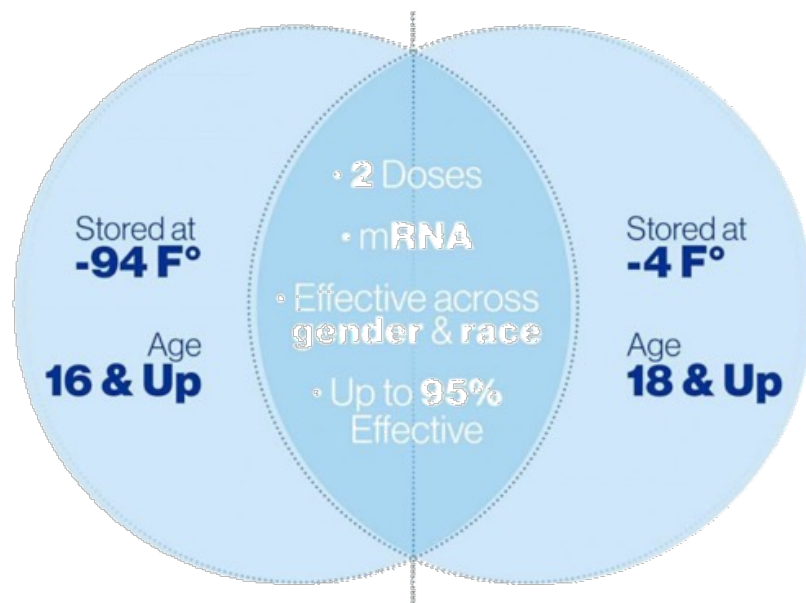
**95%
EFFECTIVE** 
AFTER THE 2ND DOSE

 **88.9%
EFFECTIVE**
AFTER THE 1ST DOSE


36,621
CLINICAL TRIAL
PARTICIPANTS
(16+ YEARS OLD)



PFIZER vs. MODERNA



 **2** 
100 MICROGRAM DOSES
ADMINISTERED 28 DAYS APART

**94.5%
EFFECTIVE** 
AFTER THE 2ND DOSE

 **80.2%
EFFECTIVE**
AFTER THE 1ST DOSE

 **30,350**
CLINICAL TRIAL
PARTICIPANTS
(18+ YEARS OLD)

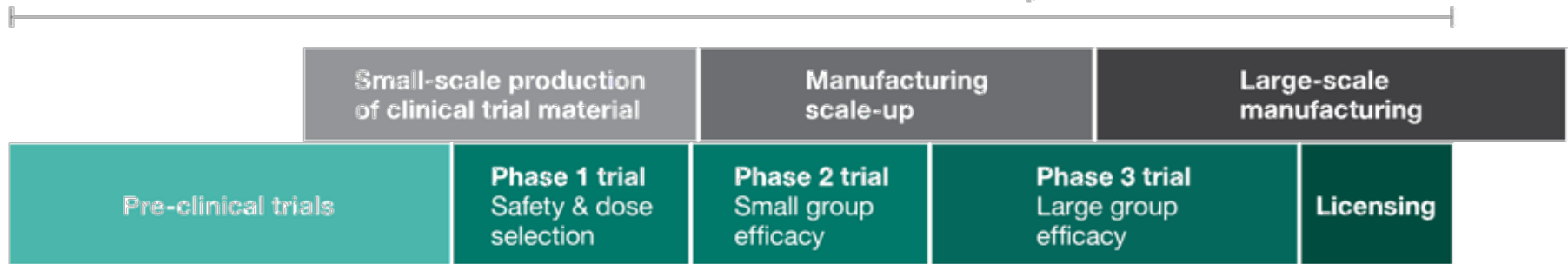
How Were COVID-19 Vaccines Developed So Fast?

- Scientists have been studying coronaviruses for over 50 years
- Recent vaccine research was underway due to SARS epidemic in 2002 and MERS in 2012
- Advances in genomic sequencing, researchers successfully uncovered the viral sequence of SARS-CoV-2 in January 2020 — roughly 10 days after the first reported pneumonia cases in Wuhan, China
- Vaccine development is expensive and difficult to get funded – but not during COVID – no time lost on small initial proof of concept studies or fund raising
- Vaccine development is a process of trial and error usually only one to a few trails at a time - but not during COVID – 87 animal studies and 55 human trials going simultaneously
- Enormous funding allowed firms to do preclinical and phase I, II and III trials, as well as manufacturing, in parallel instead of sequentially

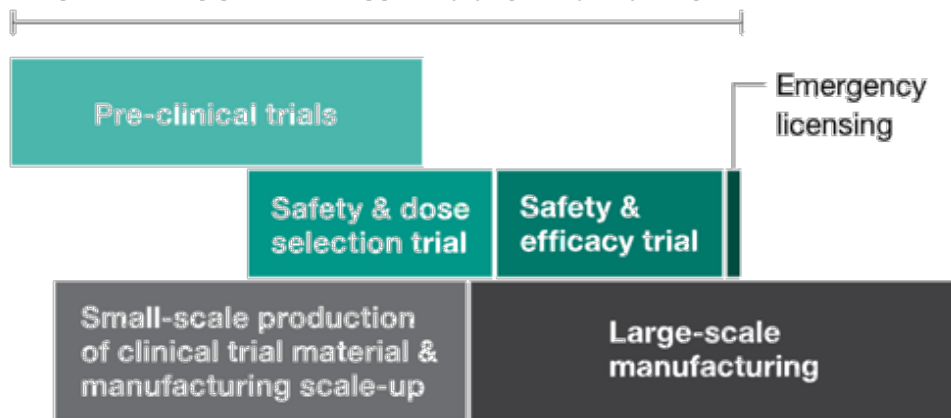


Did they skimp on safety? No. Well then how did they make the vaccine so FAST?

The fastest a vaccine has ever been made is **5 years**



Goal for a COVID-19 vaccine is under **18 months**



- It helped that COVID-19 was everywhere because firms need infections to show that vaccines work. It's hard to run efficacy trials when the diseases themselves aren't prevalent

Safety of COVID-19 Vaccines is a Top Priority.

- COVID-19 vaccines are being held to the **same safety standards** as all vaccines.



Before authorization

- **FDA** carefully reviews all safety data from clinical trials.
- **ACIP** reviews all safety data before recommending use.



After vaccine authorization

- **FDA** and **CDC** closely monitor vaccine safety and side effects.

Monitoring Vaccine Safety is a Regular, Ongoing Part of Vaccine Development.

- **Existing** systems and data sources are used to monitor safety of vaccines after they are authorized or licensed, such as:
 - [Vaccine Adverse Event Reporting System \(VAERS\)](#)
 - [Vaccine Safety Datalink \(VSD\)](#)
 - [Clinical Immunization Safety Assessment \(CISA\)](#)
 - [Biologics Effectiveness and Safety System \(BEST\)](#)
- **New** systems are being developed to monitor vaccine safety, such as **v-safe**:
 - Active surveillance that uses text messaging to initiate web-based survey monitoring
 - Any clinically important events reported by a participant would be sent to VAERS for follow-up



Risk of Severe Reactions is Very Low

- As of January 6 only 21 of the first 1.9 million of Americans to receive the Covid-19 vaccine experienced the severe allergic reaction known as anaphylaxis
- 17 had known risk factors for severe allergic reactions
- 20 known to have recovered and no known deaths
- By way of comparison
 - This rate of adverse reactions is 1.1 per 100,000
 - US Rate of death by motor vehicle crashes is 11.2 per 100,000
- CDC advises:
 - people with a history of drug allergies be observed for 30 minutes
 - All others be observed for 15 minutes after getting the shot
 - vaccination sites should have emergency equipment on hand, including epinephrine

People Who Have Gotten Sick With COVID-19 May Still Benefit From Getting Vaccinated

- While more research is needed, available evidence suggests that reinfection with this virus is rare within 90 days of initial infection
- Getting vaccinated may help to further strengthen natural post-infection immunity against COVID-19
- Pfizer and BioNTech have studied their vaccine in people with and without a history of exposure to the virus. Data show that the vaccine is safe and likely effective in persons with previous evidence of SARS-CoV-2 infection
- If someone currently has active symptoms of COVID-19, the CDC recommends they wait to get vaccinated until they've recovered and met the criteria for ending isolation



I've heard about people testing positive for COVID-19 just a few days after getting the vaccine. What's up with that?

- It takes over a week it for your body to develop immunity after you get your first vaccine injection
- They either:
 - had a COVID infection incubating before they got the vaccine that did not become symptomatic at, or
 - they contracted COVID a few days after their first vaccine dose before their body had had enough time to develop immunity to COVID as a result of the vaccine

Work Related FAQs

Can I work if I'm having vaccine side effects?

You can work as long as:

- You feel well enough to work
- You do not have a fever
- Side-effects are limited to those associated with the vaccine and not COVID-19 disease (cough, SOB, loss of taste or smell)

What if I can't come to work because I'm having side effects?

Call your manager and go through the same process as for COVID symptom call-offs. **If you have a fever or are too sick to work for more than 2 days, you should get a COVID test.**

What if I get the vaccine, but sometime in the future I have COVID-19 symptoms?

You should follow the same process as before we had a vaccine. Stay home, call your manager, and get tested. You could be the 5% that isn't immune.

What We Don't Know Yet

- How long will a COVID vaccination protect you from COVID?
 - Varies widely for other vaccines from just a year to a lifetime
- Can a vaccinated person who gets COVID infect others?
- Will there be any long-term adverse effects that don't show up until months to years later?
 - Long term adverse effects that don't show up until months to years later have not been a problem with other vaccines
 - There have been fears of this (vaccines causing Autism) but multiple large research studies have never found these fears to be correct

Fear and Uncertainty are a Challenge

- In a recent US-consumer research, 63 percent of respondents are cautious about or unlikely to adopt COVID-19 vaccination
 - The “cautious,” who comprise 45 percent of respondents (the largest segment), are those who will wait and see how a vaccine performs in the “real world” before deciding if they will get vaccinated
 - Another 18 percent say they are unlikely to vaccinate
- In High Risk Groups only a portion reported being “Interested” in getting vaccinated
 - Elderly 65%
 - Black 31%
 - Hispanic 36%
 - Earning under \$25K/yr 31%
 - Earning over \$100K/yr 60%

Persons of Color Have Real Reasons To Be Wary

- Historically, medicine has used black bodies, without consent, for its own advancement
- POC are less likely to receive treatments once proven effective
- POC reports of symptoms and pain are not taken as seriously
- Higher rates of illness and death
- This impairs the healthcare/patient partnership
 - much less likely to report trust in their physicians and hospitals;
 - are less likely to seek treatment or be compliant with recommended treatment plans

POC were Included in the COVID-19 Vaccine Safety and Efficacy trials

Pfizer/BioNTech

- **43,931** enrolled
- **150** clinical sites
 - **39** U.S. states
- Racial/ethnic distribution
 - **13%** - Hispanic
 - **10%** - African American
 - **6%** - Asian
 - **1%** - Native American
- **45%** ages 56-85

Moderna

- **30,000** enrolled
- **89** clinical sites
 - **32** U.S. states
- Racial/ethnic distribution
 - **20%** - Hispanic
 - **10%** - African American/Black
 - **4%** - Asian
 - **3%** - All others
- **64%** ages 45 and older
 - **39%** ages 45-64
 - **25%** ages 65+

Subgroup analysis specific to POC showed both vaccines to be effective for preventing COVID in POC

Source: <https://www.pfizer.com/science/coronavirus/vaccine>; <https://www.modernatx.com/cove-study>

For more information, visit www.clinicaltrials.gov



Vaccine Hesitancy: What do national surveys say?

- 59% - worried about possible side effects
- 55% - lack of trust in government to ensure vaccine safety & effectiveness
- 53% - concern that the vaccine is too new
- 51% - concern over the role of politics in the development process
- 43% - risks of COVID-19 are being exaggerated
- 37% - don't trust vaccines in general
- 33% - don't trust the health care system
- 27% - worried they may get COVID-19 from the vaccine
- 20% - don't think they are at risk of getting sick from the virus
- <https://www.kff.org/coronavirus-covid-19/report/kff-covid-19-vaccine-monitor-december-2020/>

Addressing Vaccine Concerns

- Listen
- Vaccine hesitancy is not the same as being anti-vaccination
- Acknowledge the concerns and ask for more
- Acknowledge historical and current reasons for distrust - Medical racism has left significant scars; we need to build trust
- Answer questions directly in as much detail as asked
- Share uncertainty – be OK saying
 - “We don’t know yet”
 - “Let me look for more information on that and get back to you”
- Elicit hope toward helping one’s community restore health & wellbeing
- Give time to decide later



The Facts:

COVID-19 mRNA vaccines will not give you COVID-19

- **None** of the COVID-19 vaccines in use or under development use the live virus that causes COVID-19
- The vaccines only have genetic information to make one part, the spike protein, not the whole virus
- People can experience normal side effects, such as fever, after vaccination. These side effects are signs that the body is building immunity
- It takes a few weeks for the body to build immunity after vaccination. A person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection

The Facts:

COVID-19 mRNA vaccines will not cause you to test positive on COVID-19 viral tests

- Vaccines currently authorized for use or in development won't cause you to test positive on viral tests, which are used to see if you have a **current infection**.



COVID Vaccines Cannot Alter Your DNA

- mRNA stands for messenger ribonucleic acid and can most easily be described as instructions for how to make a protein or even just a piece of a protein
- mRNA is not able to alter or modify a person's genetic makeup (DNA)
- The mRNA from a COVID-19 vaccine never enter the nucleus of the cell, which is where our DNA are kept. This means the mRNA does not affect or interact with our DNA in any way.

COVID Vaccine Mis-information Rumors

- Because of the pandemic, the pharmaceutical industry has been given permission to "skip the animal trials...we humans will be the guinea pigs."

This is false. The Pfizer BioNTech, Moderna and AstraZeneca vaccines have all been tested in animals as well as thousands of people, before they could be considered for licensing.

- There will be microchips in Covid-19 vaccines funded by the Bill & Melinda Gates.

This is false. While the Bill & Melinda Gates Foundation has financially contributed to developing a Covid-19 vaccine, there is no evidence to claims that he is implementing microchips and it has been debunked countless times.

COVID Vaccine Mis-information Rumors

- Vaccines are fake, and that press events showing people being injected have been staged. They claim fake syringes with "disappearing needles" are being used in an attempt by the authorities to promote a vaccine that doesn't exist

This is false. The healthcare professionals are using a safety syringe, in which the needle retracts into the body of the device after use. Safety syringes have been in widespread use for over a decade. They protect medical staff and patients from injuries and infection

- There was a Facebook post that a nurse died in Alabama after taking the coronavirus vaccine.

This is false. - After being alerted to the rumors, the Alabama department of public health contacted all vaccine-administering hospitals in the state and "confirmed there have been no deaths of vaccine recipients. The posts are untrue."

Protect yourself, your family, friends, coworkers, patients, and community. Get vaccinated.

- Choose to get vaccinated yourself when it is available to you.
- Participate in **v-safe** and help CDC monitor for any health effects after vaccination
- Share your experience with coworkers, friends, and family
- Know the basics about the COVID-19 vaccine
Help answer questions from your family and friends
- Visibly show you received a vaccine, such as by wearing a sticker or button



Vaccination is one measure to help stop the pandemic.

- While COVID-19 mRNA vaccines appear to be highly effective, additional preventive tools remain important to limit the spread of COVID-19
- If you one of the 5% who get COVID after vaccination you could have an asymptomatic case and infect others
- The combination of getting vaccinated and following CDC recommendations to protect yourself and others offers the best protection from COVID-19
 - Cover your nose and mouth with a mask
 - Avoid close contact. Maintain social distancing
 - Clean and disinfect
 - Wash your hands



Questions?

Thank You

for being an important part of
the National Council community.