## **COVID-19 Vaccines**

January 21, 2021

#### #Whatsyourwhy

Best #2 I've Ever Had!





#WhatsYourWhy "Because I'm a CNA on 6 North and because of my mom. I want to see her, and all this is scary. She's older, and I don't want anything to happen to her. I'm looking forward to being with my family again." Mattie Jenkins, CNA

Nursing Assistant, Progressive Care Unit

#### **COVID-19 Vaccines**

Manufacturer	Biotechnology	Status
Pfizer	mRNA	Emergency Authorization Granted
Moderna	mRNA	Emergency Authorization Granted
Jansenn	Adenovirus	Phase III, expected results late January
AstraZeneca	Adenovirus	Middle of Phase III
Novavax	Recombivent	Phase III began, expected results late Jan

### The Vaccine Testing Process

The COVID Vaccine is held to the same safety standards as other vaccines

Phase 1 20-100 Healthy Volunteers



Researchers try to answer these questions:

- Is this vaccine safe?
- Are there any serious side effects?
- How does the vaccine dose relate to any side effects?
- Is the vaccine causing an immune response?

Phase 2 Several Hundred Volunteers



Researchers try to answer these questions:

- What are the most common short-term side effects?
- What's the body's immune response?
- Are there signs that the vaccine is protective?

#### Phase 3 1000+ Volunteers



#### Researchers try to answer these questions:

 How do disease rates compare between people who get the vaccine and those who do not?

 How well can the vaccine protect people from disease?

#### Phase 4 Vaccine is Approved



Researchers try to answer these questions:

 FDA approves a vaccine only if it's safe, effective, and benefits outweigh the risks.

 Researchers continue to collect data on the vaccine's long-term benefits and side effects.

# There have been intentional efforts to recruit volunteers from diverse backgrounds



- National Medical Association, COVID-19 Taskforce on Vaccines and Therapeutics
- reviewed data in search of differences in health outcomes that would place the Black community at higher risk of unfavorable outcomes
  - 10% (total 7,400) enrollees were Black
  - Number sufficient to have confidence in health outcomes
  - Efficacy and safety were observed and consistent across age, gender, race, ethnicity, and adults over 65.

https://www.nmanet.org/news/544970/NMA-COVID-19-Task-Force-on-Vaccines-and-Therapeutics.htm

#### mRNA Vaccines



Coronavirus contains studded proteins



Lipid nanoparticles surrounding mRNA



mRNA is harmless material Used to create proteins. The mRNA is enveloped in a lipid bubble

This is injected into muscle

Your body uses the mRNA to make a version of the spike protein **T T T T T T** This prompts the immune system

This prompts the immune systen to produce antibodies and activate T cells



If your patient encounters Coronavirus, the antibodies and T cells will quickly recognize the protein and begin destroying the cells

#### **mRNA Vaccines**



• You cannot get COVID-19 from the vaccine

• The mRNA vaccines <u>DO</u> <u>NOT</u> interact with your DNA in any way.

#### How Well Does the Vaccine work?

- Clinical Trials show:
  - Pfizer- 95% efficacy after second dose
  - Moderna-94.1% efficacy after second dose
- This means that people who got 2 doses of the vaccine got symptomatic COVID-19 infection 94-95% less often than people who did not get the vaccine.



Image by <u>Sammy-Williams</u> from <u>Pixabay</u>

### What are the side effects?



- Common Side effects may include:
  - Injection Site pain
  - headache
  - muscle aches
  - Tiredness
  - Fever
- This is a sign that the immune system is gearing up
- No serious adverse events observed, small number of treatable allergic reaction after millions of doses

Copyright free photo from Christian Emmer http://frontiersmag.wustl.edu/2020/11/20/from-cowpox-to-covid-19-a-brief-overview-of-vaccination/

# What about the long-term effects of the Vaccine?

- Serious side effects to vaccines are rare and occur hours or days after vaccination, not months or years
- At least 8 weeks of safety data were gathered in the trials. Unusual to see side effect more than 8 weeks.
- Risk of COVID-19 infection is much higher



## How will the vaccine be monitored for safety?

#### <u>V-Safe, CDC</u>

- Smartphone-based,
- Uses text messages and web surveys.
- Provides second dose reminders
- <u>Vaccine Adverse Event</u>
  <u>Reporting System (VAERS)</u>,
  CDC-
  - Adverse reactions tracked and reported.
  - Information is public.

- National Healthcare Safety Network (NHSN), CDC- Acute and Long-term care facility monitoring system
- FDA: Other large insurer/payer databases
- Vaccine Safety Datalink (VSD), (CDC)
- Clinical Immunization Safety Assessment (CISA), CDC
- Biologics Effectiveness and Safety System (BEST), FDA



#### How much does the vaccine cost?

- They are free to everyone, even if you don't have health insurance.
- The federal government is covering the cost.
- No ID requirement, citizenship status doesn't matter



DFCisneros, CCO, via Wikimedia Commons

#### **COVID-19 Vaccine Distribution**

# North Carolina receives shipments of COVID-19 vaccine each week.



Federal government decides how much vaccine each state receives based on the state's population NC DHHS determines which providers will receive doses based on reaching prioritized populations Manufacturer ships the vaccines to local providers Providers safely store and handle vaccines North Carolinians are vaccinated in phases, as vaccine is available



#### **COVID-19 Vaccinations:** Your best shot at stopping COVID-19.

#### SPOT. SHOT.

You have a spot, take your shot. A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. To save lives and slow the spread of COVID-19, independent state and federal public health advisory committees recommend first protecting health care workers, people who are at the highest risk of being hospitalized or dying, and those at high risk of exposure to COVID-19. Keep practicing the 3 Ws—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to get vaccinated.



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## How many people have received the vaccine?



#### See How the Vaccine Rollout Is Going in Your State



https://covid19.ncdhhs.gov/dashboard/vaccinations

https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html

## How Many People Have to Get Vaccinated to Reach Herd Immunity?

- Experts predict 70-90% of the population
- How fast we get there depends on:
  - Vaccine Supply
  - Vaccine Demand



https://www.nytimes.com/2020/12/24/health/herd-immunity-covid-

coronavirus.html?fbclid=IwAR2PdGBadTM\_OhWQ9ETRM6t4DwGq6VamcwAXh6oCkEC2czSd-aNKQtI2IX

https://www.statnews.com/2020/12/17/calculating-our-way-to-herd-

immunity/?fbclid=IwAR2oL\_ZIAvL5p-FXfCab75STY07YsmUuF8OGBDT8jnZpsJmKItaOhzCnc

Image by Gerd Altmann from Pixabay

## I thought vaccine development took years. How did it get developed so fast?

- mRNA vaccines are faster to produce
- Manufacturing began while clinical trials are still underway.
- FDA and CDC are prioritizing review and authorization



### Why Do you Need 2 Doses?

- 2 Doses Provide Greater
   Protection

• "Prime-Boost" Principle

Images: by Max Porstmann from Pixabay

# Do I still need to wear a face mask if I get the vaccine?

#### lt's a two-way street Masks protect you & me

When we all wear masks, we take care of each other



- Yes
- Unsure how much the vaccine prevents transmission
- Continue your safety precautions
- Recommendations may change depending on:
  - How many people get vaccinated
  - Rates of Spread in the community

https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/pdfs/321378-A-\_Masks-protect-you-and-others-Final.pdf

# Why do I need the vaccine if I have already had COVID?

- It is recommended that you receive the vaccine, even if you have already had COVID-19
- Immunity to natural SARS-CoV-2 infection is variable
- If currently infected, wait until you have recovered



# Can I get the Vaccine if I am pregnant or breastfeeding?

- The vaccine is offered to pregnant and breastfeeding individuals
- Pregnant and BF mothers not included in trials
- Individuals who got pregnant during the trial had no complication related to vaccine
- Vaccinated rats had no complications
- mRNA vaccines not thought to be a risk to breastfeeding babies

- Talk to your provider and discuss:
  - Level of COVID-19 spread in the community
  - Whether you have any medical conditions that elevate your risk of COVID-19 complications
  - Your comfort level in taking the vaccine



Image by gdakaska from Pixabay

## When will kids get vaccinated?

- Adults go first in safety trials
- Then older children
  - A few trials now include older children (12+)
- Then younger children
- Timeline: experts hope for Fall 2021



### **Special Populations**

- Known previous COVID infection
- Received monoclonal antibody or convalescent plasma
- Pregnant or breastfeeding
- Immunocompromised
- Known severe allergy to polyethylene glycol or other vaccine component
- Known severe allergy to other vaccines or injected meds, or anaphylaxis to anything

### Vaccine Hesitancy

- ACKNOWLEDGE concerns, don't immediately disagree/dismiss but normalize it, because patient concerns are often legitimate and demonstrate the patient cares about their health.
- ASK respectful questions about their concerns, ask if they want more info. Ask what are reasons to get vs. not get vaccine, and reflect it back without judgement
- PERSONALIZE yourself to patient- explain your own emotions about the topic and your own research and your own motivation to know the truth and help people
- TELL THE TRUTH about science behind the research- what we know and what we don't know- and compare that to other common topics in health. Use simple, straightforward language. Share info resources.
- **GIVE YOUR ADVICE!** Give a direct recommendation.

### Vaccine Hesitancy

#### I heard on tv that vaccines cause autism

- Corroborate: There's certainly been a lot of coverage on television about vaccines and autism so I can understand why you have questions
- About Me: I always want to make sure I'm up to date on the latest information so that I can do what's best for my patients, so I've researched this thoroughly. In fact, I just returned from a professional conference...
- Science: The scientific evidence does not support a causal link. The CDC, the AAP, the NIH, the IOM (etc) all reviewed the data and all reached the same conclusion. Dozens of studies have been done. None show a link. In fact, the latest autism science indicates...
- Explain/Advise: Vaccines are critical to maintaining health and wellbeing. They prevent diseases that cause real harm. Choosing not to vaccinate does not protect children for autism, but does leave them open to diseases. Kids need these vaccines.



I'm concerned because the vaccine is so new. What resources are available to help me make an informed decision?

#### **Trusted Resources**

- CDC COVID-19 Vaccine
- NCDHHS COVID-19 Vaccine
- Buncombe County Health and Human services
- World Health Organization
- FDA
- Advisory Committee of Immunization Practices (ACIP)

#### **Evaluate Online & Social Media Resources. Ask yourself:**

- Was the information written recently?
- Who is the author?
- How Does it Compare with other resources? Is it based on scientific research?
- Why does the site exist? Is there a motive behind it?

#### References

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