



# What You Need to Know About COVID- 19 Vaccines

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# Some Caveats

- I am not a physician, I have an MPH and worked over 30 years in public health, mostly respiratory diseases (Tuberculosis, Influenza). I worked with nursing homes in the management of influenza outbreaks.
- These slides are a compilation of readings and podcasts, accessible to all.
- Nobody knows everything about anything.
- These slides are based on questions I have heard which I will try to answer.

# What Happens When We Are Infected With a Pathogen?

- When germs invade our bodies, they multiply until there are enough copies to make us feel sick, have symptoms.
- Our body see these invaders as “foreign” and start fighting these invaders .
- Once infected, it may take several days or weeks for the body to mount an immune response.
- T-lymphocytes, memory cells, go into action quickly if the body encounters this same virus again. B-lymphocytes produce antibodies to attack this virus.

# What is a Vaccine?

- A substance used to stimulate the production of antibodies and provide immunity against one or several diseases.
- A vaccine gives your body a “heads up” for something, i.e. a pathogen, that you may see in the future.

# How Do Vaccines Work?

- Vaccines help our body develop immunity without our having to get the natural infection.
- Our body recognizes that the proteins made through the vaccine instructions are “foreign” and begins making T-lymphocytes and antibodies.
- If we are ever infected again in the future, memory cells will recognize and fight the virus.
- It takes a few weeks for the body to produce the B and T lymphocytes after vaccination.

# What Vaccines Are Available For COVID-19?

- Three main types
  - 1) **Vector vaccines** (contain a weakened version of a live virus).
  - 2) **Protein subunits** (harmless proteins of the SARS-COV).
  - 3) **mRNA** (Pfizer and Moderna).

# What is this mRNA technology?

- This technology has been in the works for decades and is being studied for vaccines for other diseases as well as treatment for certain cancers.
- mRNA gives our cells the genetic code (instructions) to make the spike protein that is found on the surface of the coronavirus that allows the virus to penetrate cells and cause infection.
- Our cells then make the spike protein.
- Our immune system recognizes that this protein is “Foreign” and starts making antibodies against this protein.
- Our bodies have now learned to make these antibodies and will “remember” to do so when they encounter this protein again, like when COVID infects our body.

## More on mRNA

- The mRNA does not enter the cell nucleus so does not interfere with our DNA. mRNA stays in cytoplasm.
- Our cells break down and get rid of the mRNA soon after it is finished using the instructions.
- This vaccine **does not use live or inactivated COVID-19 virus** and so **cannot make you ill with COVID.**



- Messenger RNA
- Lipids or fats that protect the mRNA, otherwise it would be broken down before delivering the genetic code.
  - The lipid portion is very fragile. That is why storage is needed at such low temperature
  - Tiny amount of PEG, polyethylene glycol: maintains the integrity of the lipid molecule. Not found in other vaccines.
  - PEG found in laxatives and oral bowel preps for colonoscopy
- Salts: keep the pH balanced
- Sugars: protect vaccine during freezing

## What are the Vaccine Components?

- According to the Phase 3 studies so far, both Moderna and Pfizer vaccine provided >94% protection against symptomatic disease and severe illness, even for people over 65.
  - Pfizer vaccine had 52% protection after first dose, 94% after second dose.
  - Over 45% of US participants were 56-85 yo, no nursing home residents.
  - Moderna had somewhat higher protection after first dose.
- The Moderna vaccine provided protection against infection, which means it may protect against asymptomatic transmission.

What Protection Do the Vaccines Provide?

# What Happens to Me When I Get The Vaccine?

- Approximately 15% of recipients experience mild or moderate short-lived (1-2 days) fatigue, muscle aches, headaches, fever, pain at site of infection.
- This occurs within 1-2 days of vaccine administration, more so after receiving second dose.
- These reactions are manifestations of your body's immune system ramping up.

# What About Anaphylaxis?

- A severe allergic reaction, occurring within seconds or minutes of exposure to an allergen.
- About 5% of people in US have ever had an anaphylactic reaction.
- Anaphylaxis has been linked to other vaccines (a rate of 1.3 per million doses).
- Of the 4 million doses of Pfizer and Moderna vaccine, a rate of 5.5 per million doses, rare, none of them fatal.

- Anaphylaxis is a rare event. As of 1/6/20, of 4-5 million doses administered, 29 cases of anaphylaxis.
- Clinical trials involved tens of thousands of volunteers; this kind of reaction may have been too rare to see in a relatively small number.
- People with previous allergic reactions may not have volunteered for the clinical trials (self-selected out).

Why Didn't  
We See  
Anaphylaxis  
Reactions in  
Clinical Trials?

# What Did I Hear About Bell's Palsy?

- Facial nerve damage: inability to move half your face resulting in a drooping face
- Symptoms resolve within 3 weeks to 3 months.
- Annual incidence is 15-30/100,000 people.
- Reports of 4 cases in Pfizer vaccination arm, 0 in placebo. Three cases in Moderna vaccination arm, 1 in placebo. Total of 7 cases/approximately 30-40,000 people, or within background rate.

# Who Should Not Get the Vaccine?

- Anyone who has allergies to any component of either vaccine.
  - Not clear what in the shots is causing these reactions.
  - Leading candidate is polyethylene glycol found in many foods, cosmetic and medications. Previously linked to a handful of anaphylactic reactions. May cross react with polysorbate, also found in food, cosmetics and vaccines.
- People who have had severe reactions to first dose should not receive the second.
- Consider referral to allergist/immunologist.

# Who Should Take Precautions to Vaccination?

- Those with a history of any immediate allergic reaction to vaccines or injectable therapies (except those related to component of mRNA COVID vaccines or polysorbate, as these are contraindicated).
- Consider deferral of vaccination and/or referral to allergist immunologist.
- 30-minute observation period if vaccinated.

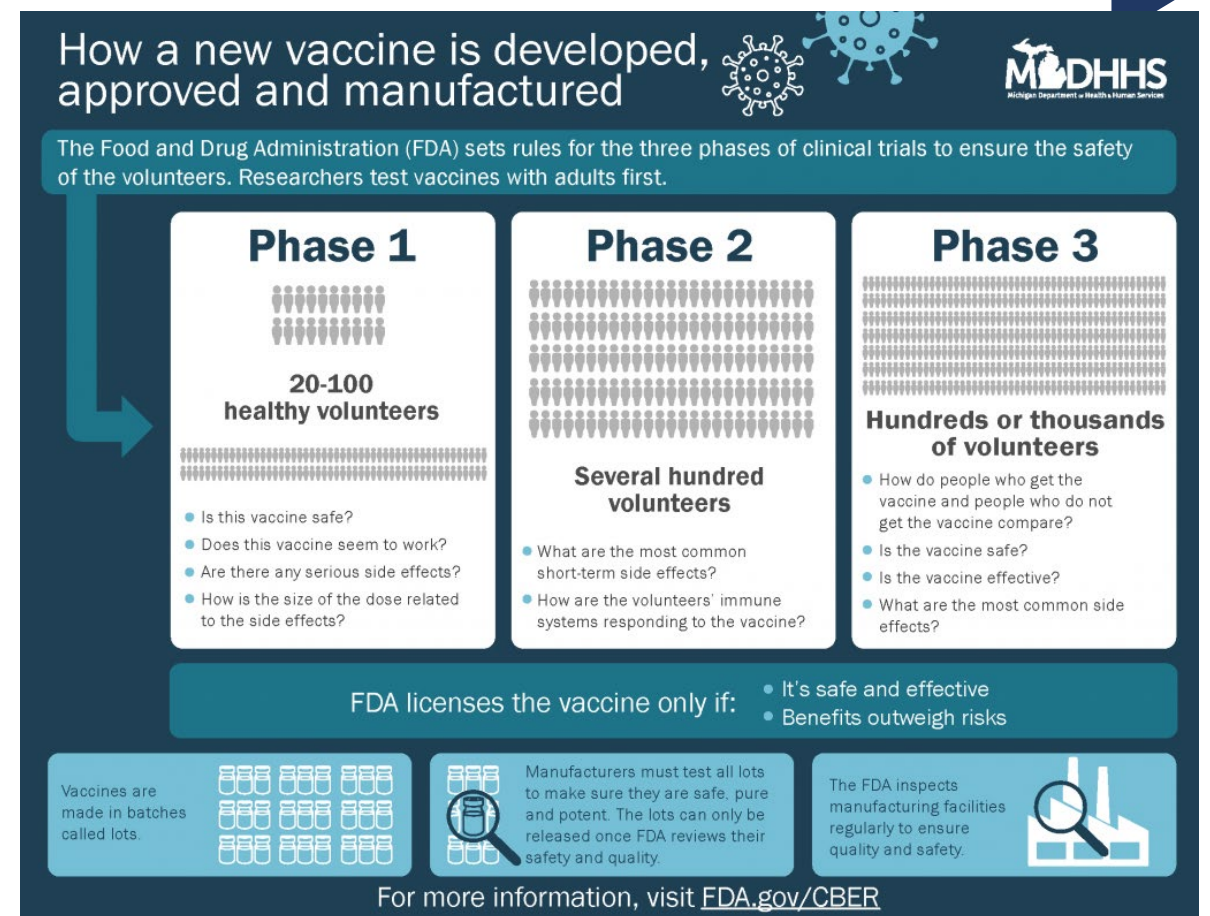


# Who May Proceed With Vaccination?

- History of allergies that are unrelated to components of an mRNA COVID-19 vaccine, other vaccines or an injectable therapy, such as:
  - Allergy to oral medication.
  - History of food, pet, insect, venom, environmental, latex, etc. allergies.
  - Family history of allergies.
  - 30-minute observation period for any person with a history of anaphylaxis.
  - 15-minute observation period all other persons.

# How Did These Vaccines Get Made So Fast?

- Operation Warp Speed
- Steps that are usually taken sequentially were now being done simultaneously such as starting manufacturing of the vaccine at industrial scale before the demonstration of vaccine efficacy and safety, increasing the financial risk but not the product risk.
- Regulators coordinated with manufacturers.
- Several advisory committees analyzed the results, so less bias.
- For Emergency Use Authorization (EUA) to be issued, questions must be answered on all aspects of vaccine production, so no short cuts.



# Can I Get the Vaccine If I Have Had COVID?

- If you currently have COVID, wait for symptom resolution before getting vaccine.
- Even if you have had COVID, the vaccine may provide additional protection
  - Some people who tested positive for COVID were later found not to have antibodies.

# How Often Will We Need to Get Vaccine?

- Not clear
- We still don't know how long immunity lasts after natural infection.
- Participants in the clinical trials will be tested every few months to look at antibody levels.

# Which Vaccine is Better?

- Not known yet
- Three other vaccines are undergoing Phase 3 Clinical trials
  - AstraZeneca
  - Janssen
  - Novavax
- Since these are different components there may be a difference in the allergic reactions.

# When Will Vaccine Be Available?

- CDC's Advisory Committee on Immunization Practices has made recommendations about a phased plan that lays out who should be eligible within each of [four phases](#): Phases 1a, 1b, 1c, and 2.
- **Phase 1a** includes high-risk health care personnel and residents of long-term care facilities.
- **Phase 1b** includes frontline essential workers (including first responders) and people 75 years or older.
- **Phase 1c** includes all other essential workers, people age 65-74, and people 16 or older with high-risk medical conditions.
- **Phase 2** includes everyone else age 16 or older (general population).

# Why Do I Need to Wear a Mask After Vaccine?

- After vaccination, it takes a few weeks for the body to produce B and T lymphocytes. Thus, you are not fully protected until a few weeks after the second dose. You could get infected with COVID while your body is in the process of building immunity.
- It is not clear yet if vaccine protects you against asymptomatic infection—that is, you may not get clinically ill with symptoms but you can get infected and transmit the infection to others.
- The Moderna vaccine may offer protection against asymptomatic shedding.

# Risk-Benefit Analysis

- In the final analysis, **only you can make a decision** about whether or not to get the vaccine, but that decision should be **based on fact** and not hype.
- Look at the science, not the myths and fake news
- One day of mild side-effects versus risk of illness, hospitalization, long-term effects, death
- Efficacy (protection) reported over 90% in clinical trials
- Consider your own risk assessment
  - Risk of exposure
  - Underlying conditions- risk of severe disease and death
  - Unknown risk of allergic reaction
  - Vaccination in setting where medical monitoring/care is available



# Let's Not Forget About Influenza (The Flu)

- Greatly decreased incidence this year over previous years.
- Flu season can extend through April or later, so not too late to get flu vaccine.
- Pre COVID
  - 10%-20% of all adults and up to 40% of children in the U.S. infected with influenza each year
  - ~226,000 hospitalizations annually
    - About half among those in persons  $\geq 65$  years of age
  - ~3,300-49,000 deaths during each influenza season
    - More than 90% are in adults  $\geq 65$  years
    - In NYC, I&P was the 3<sup>rd</sup> leading cause of death, leading to between 2,247 – 3,003 deaths/year