

COVID-19 Vaccine (Pfizer) FAQs

Mark Hamed MD MBA MPH FAAFP

Medical Director

Department of Emergency Medicine/ Hospital Medicine

McKenzie Health System



Vaccines:

Halting Wars and Bringing Adversaries Together

- In 1966, the United States and the Soviet Union were in a Cold War... and on the verge of military war
 - However, they worked together to develop a smallpox vaccination campaign to help eradicate the disease
- In 2014, in order to force Afghanistan leaders into negotiations, the Taliban blocked Afghan villages under their control from administering polio vaccinations to the local children
 - The United Nations threatened airstrikes against the Taliban leaders who then reversed course and allowed polio vaccinations to resume
- In 2017, civil war-torn Yemen experienced a resurgence of measles, killing thousands of children
 - Both warring parties halted their attacks to allow the World Health Organization entry into villages to vaccinate 11.5 million children

2020: SARS COV-2 (COVID-19)

- As of 12/11/2020
 - 71 million humans around the world infected
 - 1,600,000 deaths
- United States
 - 1st confirmed case: Jan 21, 2020
 - 1st confirmed COVID19 death: Feb 29, 2020

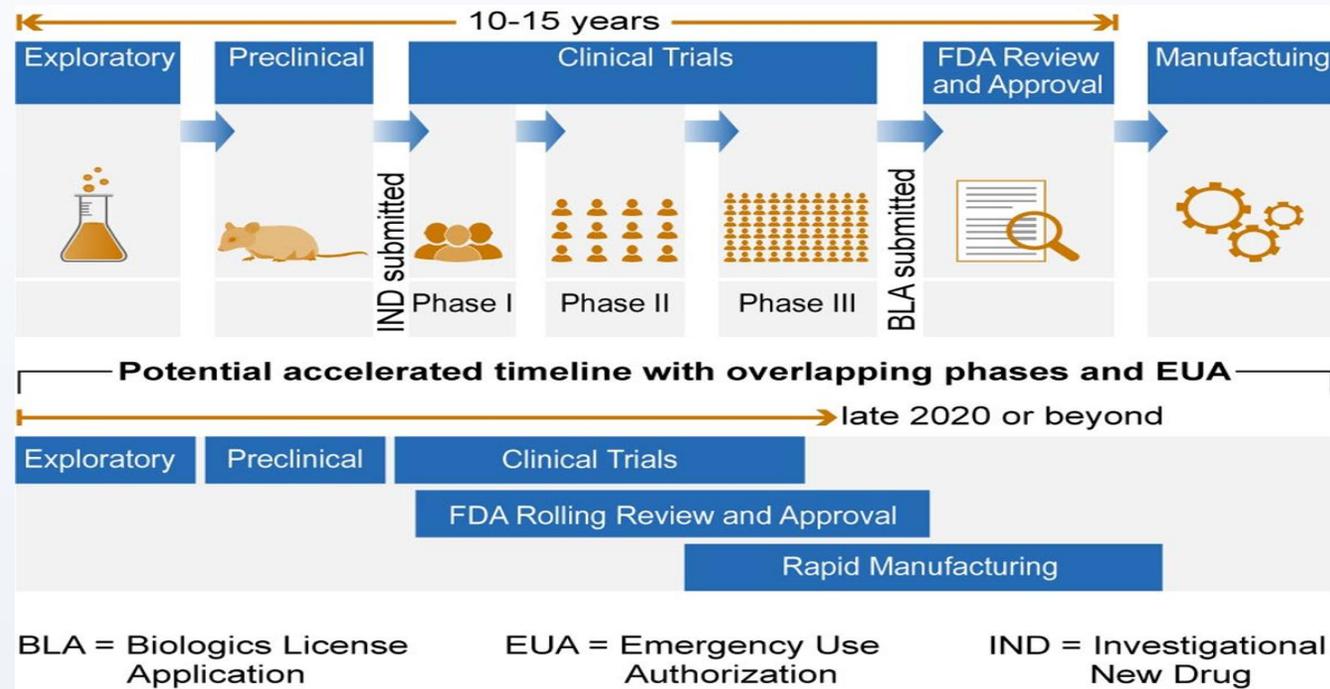
December 11, 2020 (325 days after 1st confirmed US case):

- 15.9 million Americans infected
- 296, 747 Americans dead

December 11, 2020: FDA EUA Approval

- FDA grants approval (Emergency Use Authorization) for the first COVID19 Vaccine in the United States (Pfizer)
- A 7–10-year process vaccine development process “condensed” into almost 12 months, combined with the name “Operation Warp Speed” was bound to raise questions about safety and efficacy
- The information on this presentation will hopefully give you the answers you need to make an informed decision about whether or not to get the COVID19 vaccine when it is available to you
 - **Information current as of 12/11/2020 using CDC, FDA, MDHHS and Pfizer Trial and EUA information publicly available online**

The Accelerated COVID19 Vaccine Timeline



Source: GAO analysis of GAO-20-215SP, FDA, HHS, and Pharmaceutical Research and Manufacturers of America (PhRMA) documentation. | GAO-20-583SP

Previous Coronavirus Vaccine Research: A Head Start for the COVID19 Vaccine

- Vaccine development typically takes many years.
 - However, scientists had **already begun research for coronavirus vaccines** during **previous outbreaks caused by related coronaviruses**
 - SARS (Severe Acute Respiratory Syndrome)
 - MERS (Middle East Respiratory Syndrome).
- That earlier research provided a **head start for rapid development** of vaccines to protect against infection with the novel coronavirus SARS-CoV2, the virus that causes COVID-19.

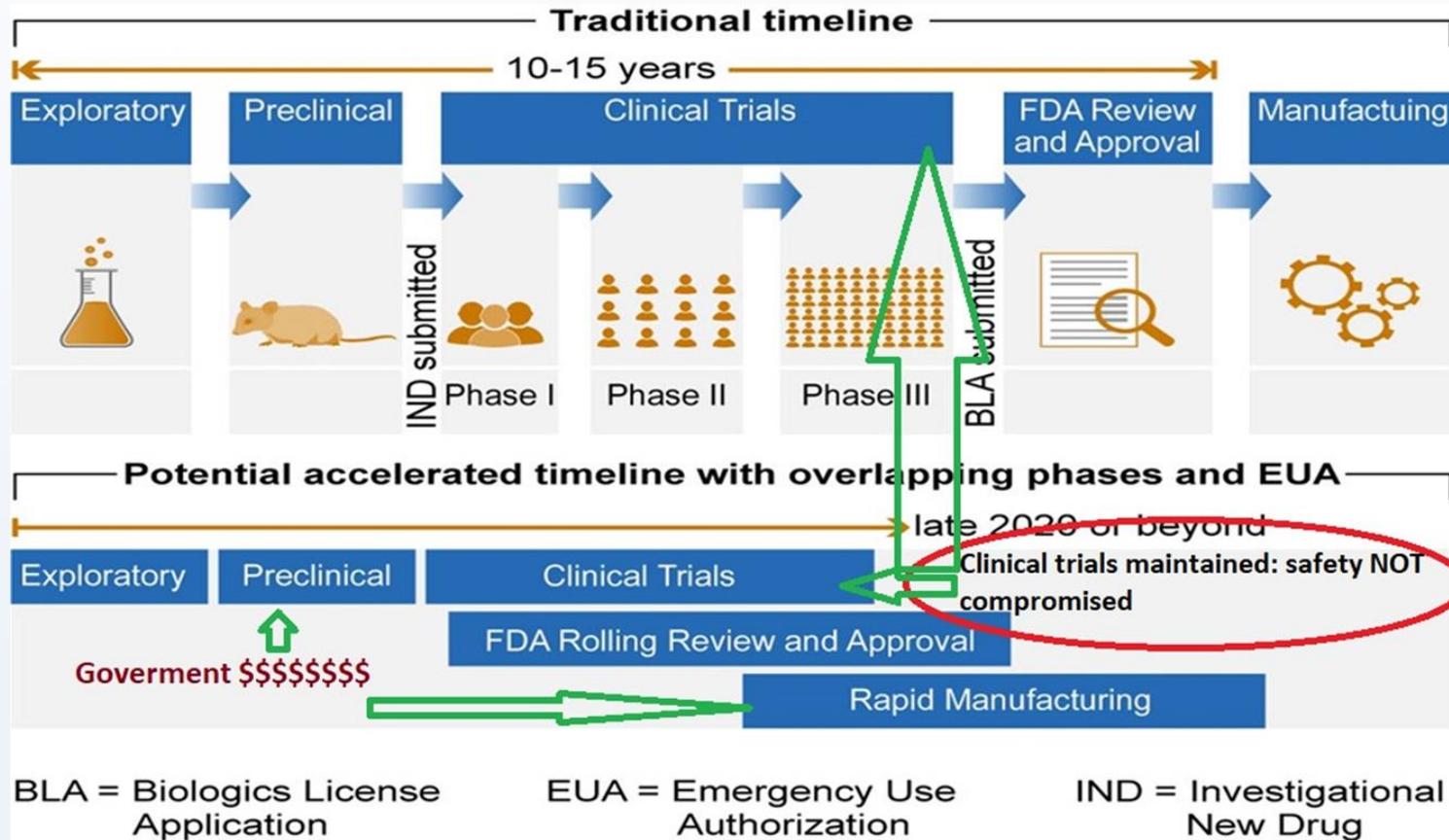
How Did the Vaccines Get Approved So Quickly?

- It comes down to when **production begins**.
 - Normally, production starts **after a pharmaceutical company completes the development stage**, which includes rigorous testing for safety and effectiveness, and a series of reviews and approvals by the FDA and the Advisory Committee on Immunization Practices (ACIP) amongst others.
 - In the case of COVID-19 vaccines, the federal government invested taxpayer dollars to encourage pharmaceutical companies **to start production before the development stage completed**.
 - The vaccines are **still going through the same rigorous testing for safety and effectiveness, review and approval process**.

How do I know it's safe?

- While the vaccines were developed quickly, **the pace did not compromise the safety**, nor did it compromise scientific integrity as any vaccine approved by the FDA had to adhere to the agency's strict research protocols.
- All vaccines are closely monitored for safety through mandated reporting and evaluation protocols.

Safety Not Compromised



Source: GAO analysis of GAO-20-215SP, FDA, HHS, and Pharmaceutical Research and Manufacturers of America (PhRMA) documentation. | GAO-20-583SP

How Long is the Immunity from the COVID-19 Vaccine effective for?

- Currently the exact information is unknown. We do not know how long protection will last following vaccination. **But further information will become public over time from ongoing clinical trials.** In comparison, immunity to two similar coronaviruses, SARS and MERS, lasted at least 3 years
- The data shows that it is **very likely that the immunity that you get from being vaccinated will last longer** than the immunity one may get after an infection
- The data shows a more robust immune response to the vaccination as compared to some low-level types of COVID infections (ie asymptomatic or mild infections)

Which Vaccine is Best?

- The first two being offered in the United States (Pfizer and Moderna) are very similar in efficacy (around 95% each).
- Both require two immunizations
 - Pfizer : shots 21 days apart
 - Moderna: 28 days apart
- The different vaccine products will NOT be interchangeable. The series of two doses must be completed with the same vaccine product. Second dose reminders for patients will be necessary.

If the vaccine is not 100% effective, can I still get COVID-19?

- **Short Answer: Yes, it is possible but not very likely**
- Longer Answer:
 - The current vaccines under FDA review appear to provide significant protection against COVID-19 but they do not offer 100% protection.
 - Preliminary data suggests the Pfizer and Moderna vaccines offer 95% protection against infection.

What happens if another COVID-19 vaccine is made available?

- It is very likely that there will be many vaccines that will be made available to the public in the coming months.
- McKenzie Health System will be closely reviewing their safety and effectiveness data and whether we will be able to offer additional vaccines to team members and our community.

What's in the Vaccine?

- There are currently multiple vaccine candidates in various stages of clinical trials.
- The first two vaccines anticipated to be available are not live, attenuated, or inactivated vaccines.
 - The vaccines contain the gene for a virus protein only.
 - **One cannot contract COVID-19 from the vaccine.**

What's in the Vaccine? (Ingredients)

- Each 0.3 mL dose of the **Pfizer-BioNTech COVID-19 Vaccine** contains 30 mcg of a nucleosidemodified messenger RNA (**modRNA**) **encoding the viral spike (S) glycoprotein of SARS-CoV-2**
- Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients:
- **lipids** (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide 0.09 mg 1,2-distearoyl-sn-glycero-3- phosphocholine and 0.2 mg cholesterol),
- 0.01 mg **potassium chloride**,
- 0.01 mg **monobasic potassium phosphate**
- 0.36 mg **sodium chloride**
- 0.07 mg **dibasic sodium phosphate dihydrate**
- 6 mg **sucrose**.
- The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg **sodium chloride** per dose.

How is the COVID-19 Vaccine Different Than Other Vaccines?

- They are essentially similar to other vaccines in the way that they trigger an immune response
- However, they differ because none of the US vaccines will be using the actual COVID19 virus (neither live nor killed), so there will be no chance of one getting COVID19 from the vaccine
- The actual vaccines will differ in how they trigger an immune response, and some may require 2 shots (a “primer” and a “booster” shot) while others may require only one

How Long After Injection Does it Start to Work?

Table 13. Primary Efficacy Endpoint –All-Available Efficacy Population

Efficacy Endpoint	BNT162b2	Placebo	Vaccine Efficacy % (95% CI)
	N ^a =21669 Cases n ^{1b} Surveillance Time ^c (n ^{2d})	N ^a =21686 Cases n ^{1b} Surveillance Time ^c (n ^{2d})	
First COVID-19 occurrence after Dose 1 – Dose 1	50 4.015 (21314)	275 3.982 (21258)	82.0 (75.6, 86.9) ^f
After Dose 1 to before Dose 2	39	82	52.4 (29.5, 68.4)
Dose 2 to 7 days after Dose 2	2	21	99.5 (61, 98.9)
≥7 Days after Dose 2	9	172	94.8 (89.8, 97.6)

^a N = number of participants in the specified group.

^b n¹ = Number of participants meeting the endpoint definition.

^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 or 14 days after Dose 2 to the end of the surveillance period depending on specified endpoint.

^d n² = Number of participants at risk for the endpoint.

^e Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

^f Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

Starts to work about 7 days after getting the vaccine

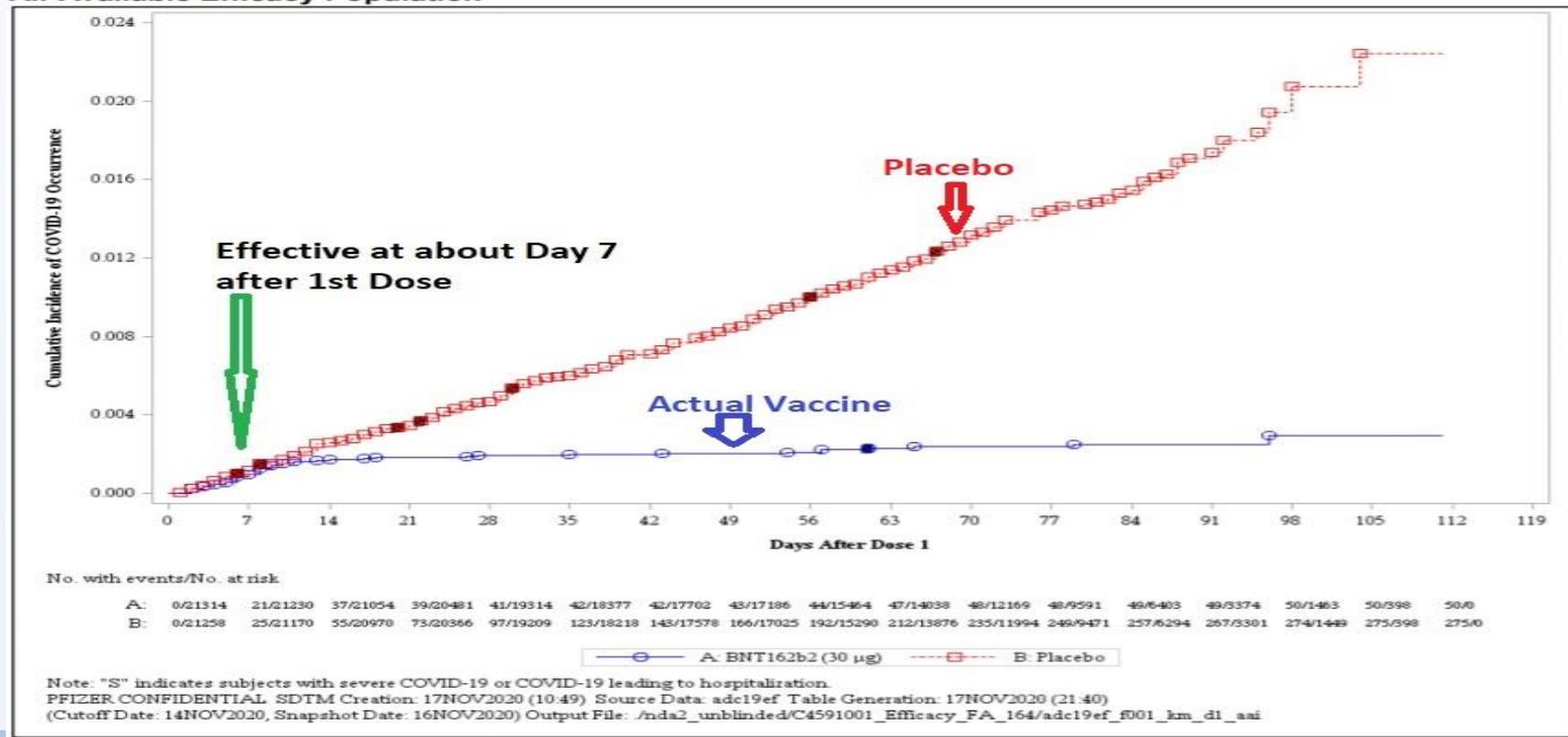
After the 1st dose and until the 2nd dose: 52.4% effective

However much more effective after 2nd dose

7 days after the 2nd dose: **94.8% effective**

Effectiveness After 1st Dose

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Dose 1 All-Available Efficacy Population



If I've Had COVID-19, Should I Still Get the Vaccine?

- **Short Answer: Yes, but not right away**
- Longer Answer:
 - Evidence suggests that if you were already diagnosed with COVID-19, you are believed to have developed specific antibodies in your blood which may provide some level of natural immune defense.
 - Research is still being done both domestically and globally to determine how long that immune response lasts.
- Experts believe that vaccine immunity may last longer than natural immunity after an infection.
- The suggestion currently is that those who had COVID19 **should probably still eventually get vaccinated**. However as long as supplies of vaccine are limited, you will likely not be prioritized for vaccination.

Do I Still Have to Wear a Mask?

Short Answer: YES

- Longer Answer:
- A safe and effective vaccine against COVID-19 will be a major breakthrough in preventing COVID-19 infections and needs to be used in combination with other prevention methods.
 - But vaccine alone won't end the pandemic right away.
- We will need to **continue** with the core COVID-19 safety precautions including limiting activities outside of the home, physical distancing and mask wearing for the foreseeable future as we learn more about how long vaccination protection lasts and as more people become protected through vaccination over time.

If a Person is Vaccinated Against COVID-19, Will They Still be able to Spread the Virus to Susceptible People?

- **Short Answer: Unknown Currently**
- Longer Answer:
- The clinical trial endpoints studied only at whether or not a person developed COVID19 and if the infection was severe or not.
- It did not study whether they were contagious or not.
- General Assumptions regarding the COVID19 vaccines:
 - If an individual is vaccinated and they are protected from all forms of infection (asymptomatic to severe), they will not transmit the virus to someone else.
 - However, it is expected that COVID19 vaccines may protect against severe infection, but not necessarily prevent mild or asymptomatic infection. If this is the case, a vaccinated person could still spread the virus if they are infected. This is why it is expected that even after a vaccine becomes available, people will need **to use masks and practice social distancing measures for some time**

Should I Talk to My Provider Before Getting the Vaccine?

- It's always a good idea to discuss healthcare maintenance issues with your provider regularly, including immunizations
- Your provider may be able to answer questions you may have about the vaccination

How are the Vaccines Being Prioritized?

- The priority groups follow the CDC recommendations for prioritization of distribution and administration of COVID-19 vaccines. According to the state, those phases are:
- **Phase 1A** : paid and unpaid persons serving in health care settings who have direct or indirect exposure to patients or infectious materials and are unable to work from home, as well as residents of long-term care facilities.
- **Phase 1B**: some workers in essential and critical industries, including workers with unique skill sets such as non-hospital or non-public health laboratories and mortuary services.
- **Phase 1C**: people at high risk for severe COVID-19 illness due to underlying medical conditions, and people 65 years and older.
- **Phase 2** is a mass vaccination campaign for all adults.

- It is important to note that vaccination in one phase may not be complete before vaccination in another phase begins. Vaccination in these phases will likely overlap.
- Vaccine distribution will roll out over a series of weeks, and current estimates are that by late Spring 2021 enough vaccine will be available for everyone who is recommended to receive it.

Will there be a cost?

No. The vaccine will be free to all who need it.

Will this Be a Government-Mandated Vaccine?

- According to statements released by the current and Incoming US President, no this will not be a Federal government-mandated vaccine
- The State of Michigan is not mandating the vaccine at this time either.

How about Side Effects?

- Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include:
- **injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy**
- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.
 - ****For those patients, may require pre-treatment with Benadryl or being monitored longer than the 15 minutes to ensure no severe allergic reaction occurs**
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine

Safe for Pregnant or Breastfeeding Women?

- **Short Answer: No Data; Should weigh Risk vs Benefit**
- Not studied in pregnant or breastfeeding women before the EUA issued (however currently being studied in pregnant and breastfeeding women in new trial)
- Not contraindicated, however this requires a discussion with your healthcare provider
 - COVID19 can cause severe illness in pregnant women, much higher than in non-pregnant women
 - If you are pregnant and work in an environment with significant high-risk exposures to COVID19, the benefits of getting the vaccine may outweigh the risks of not getting the vaccine and contracting COVID19
 - However, discuss this with your healthcare provider before deciding to do so

Safe for all ages?

- The Pfizer vaccine was granted Emergency Use Authorization for ages 16 and over.
- It was found to be safe and efficacious for those ages 16 and over.
 - There are current safety and efficacy studies in children as young as 12 years old.

Safe for People with Underlying Health Conditions?

- **Short Answer: Yes**
- Longer Answer:
 - People with underlying severe chronic conditions are encouraged to get the COVID19 vaccine because they are at highest risk of severe illness and death if they contract COVID. They are among the highest prioritized group slated to get the vaccine.
 - Note: those with immunocompromised immune systems or who are taking immunosuppressant medications may have less of an immune response to the vaccine

How About those who Developed Allergic Reactions in the United Kingdom?

- Currently, the Pfizer vaccine is not recommended for people who have had a history of SEVERE (anaphylactic) allergic reactions to any components of the shot
 - (“Severe” meaning serious enough to need to carry an Epi-Pen to reverse the allergic reaction).
- No patients in the clinical study developed anaphylactic reactions to the vaccine
 - Two individuals in the United Kingdom did develop allergic reactions which needed medication to reverse (Epinephrine), however they were known to have a history of allergies to the components of the vaccine

Are there Contraindications To Getting the Vaccine?

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known **history of a severe allergic reaction** (e.g., anaphylaxis) to **any component** of the Pfizer-BioNTech COVID-19 Vaccine

Should Someone With Confirmed/Suspected Active COVID19 get the Vaccine?

No, they should isolate until their isolation period is complete

Will the Vaccine Give Me COVID?

- No, the vaccine is not made with the actual COVID virus and will NOT give you COVID.
- However, it is possible to contract COVID while your body is starting to build up antibodies shortly after the vaccination, so it will be very important to continue practicing the usual safety precautions (PPE, distancing, hand-washing, etc)

Is There Any Risk to Those Around Me After Getting the Vaccine?

- No, there is no increased risk to anybody around you to get COVID after you get vaccinated.
- As a matter of fact, their risk of COVID may decrease after you get vaccinated, as you will have protection against COVID once your antibodies develop.

Summary

- Safety measures not skipped in development of vaccine; Gov't funded early production shaved many years off traditional vaccine development process
- Large phase 3 clinical trials of over 30,000 participants each
- Nearly 95% effective 7 days after 2nd dose, one of most effective vaccines ever produced
- Short and medium term (to 9 months) side effect profile is good, long term side effects expected to be none, however FDA will monitor for the usual 2 years before making that determination
- Will not cause COVID in vaccine recipient
- Duration of vaccine immunity not yet known due to this being a new vaccine and novel virus, expected to be longer than natural post-infection immunity
- FDA EUA for age 16 and older and for those with most chronic health conditions
- Pregnant/Breastfeeding: No data; discussion with healthcare provider regarding risks vs benefits
- If had COVID already, should eventually get vaccinated when supplies less limited

Summary (continued)

- Contraindicated only if history of severe reaction (anaphylaxis) to vaccine components
- Vaccine will likely make significant impact on community COVID cases by Summer 2021
- Must still wear mask, distance, handwashing, other safety measures until enough of community develops immunity
- Prioritization : MDHHS follows CDC prioritization recommendations: healthcare workers (direct/indirect patient care with risk to COVID exposures)and long-term care residents among first group 1A
- No cost for vaccine