**** **WHAT YOU NEED TO KNOW ABOUT THE MESSENGER**

 **RNA (mRNA) VACCINES - MODERNA & PFIZER**

**What does the Emergency Use Authorization Mean?**

Because COVID-19 is a public health emergency with the potential to affect national security and the health and security of people living in the U.S., the FDA can issue an emergency use authorization (EUA). The vaccines will not be approved for licensure until a larger number of vaccine recipients have been followed over a longer period of time (2 years or more).

The FDA gives an EUA only if experts determine that the study results show:

1. The vaccine may be effective in preventing, diagnosing, or treating the life-threatening conditions caused by coronavirus
2. The potential benefits of the vaccine outweigh the risks
3. There are no alternative treatments or prevention measures approved and available.

**Who can get the Vaccines?**

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| **mRNA vaccine** | **Who the FDA has said can get it** |
| Moderna COVID-19 vaccine | People who are 18 years or older |
| Pfizer-BioNTech COVID-19 vaccine | People who are 16 years or older |

**Who was in the vaccine studies?**

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| **Moderna*** Approximately 30,000 participants aged 18 years and older
* 100% US participants
* 47% females
* White (63%), Black/African American (10%), Hispanic/Latino (20%), Asian (5%), American Indian/Alaskan Native (1%) and Native Hawaiian/Pacific Islander (0.2%)
* 25% were >65 years of age; average age was 52
* 22% reported underlying health conditions (known as comorbidities). The top were**:**
	+ Diabetes (36%)
	+ Obesity (25%)
	+ Cardiac (heart) Disease (19%)
	+ Chronic Lung Disease (18%)
 | **Pfizer (Note: demographic data is not broken down by country)*** Approximately 43,000 participants aged 16 years and older
* USA (77%), Argentina (15%), Brazil (6%), and South Africa (2%)
* 49% females
* White (83%), Black or African American (9%), Asian (4%), Multiracial (2%), American Indian/Alaska Native (0.5%), and Native Hawaiian/Pacific Islander (0.2%)
* 28% Hispanic/Latino (across all racial groups)
* 21% were >65 years of age; average age was 50
* 20% reported other underlying health conditions. The top were:
	+ Obesity (35%)
	+ Diabetes (8%)
	+ Pulmonary (lung) disease (8%)
 |
| **Pulmonary (lung) disease****Obesity****Diabetes****Cardiac (heart) disease** |

**What does the mRNA vaccine data tell us?**

While there appears to be some protection after the 1st dose, **it is very important to receive** **two doses of the vaccine
 to get the most benefit** in preventing COVID-19 disease, hospitalization, and death.

This vaccine

requires **2 doses** to

get the most benefit

**We do not know if these vaccines prevent infection; in other words, we do
not know if a vaccinated person can still get the coronavirus AND if you can get the virus, even if you have no symptoms (asymptomatic), you CAN
 infect other people.**

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**Are the mRNA Vaccines Safe?**

**YES!** Independent experts who reviewed the safety data from both studies have concluded that the vaccines are safe.

* Researchers are still studying the long-term safety of these vaccines in the ongoing clinical trials.
* Most side effects happened within 7 days of vaccination and lasted for 1-3 days.

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| **ADVERSE EVENTS (SIDE EFFECTS)** |
| **Moderna** | **Pfizer** |
| **Common Side Effects:** less than 10 % of participants who received the vaccine experienced side effects (mostly mild or moderate) that lasted for 3 days or less. The most common side effects were injection site pain, fatigue, headache, achiness, and muscle pain.  | **Common Side effects:** less than 4% of participants reported fatigue or headache, generally lasting for a few days. |
| **Rare events:** Some participants (approximately 1% of those receiving the vaccine) had other health conditions during the studies that the FDA believes were **unrelated** to the vaccine.* Lymphadenopathy (swollen lymph nodes)
* Bell’s Palsy (condition that causes temporary weakness or paralysis of the muscles in the face)
 | **Rare events:** Some participants (less than 1% of participants), had other health conditions during the studies that the FDA believes were **unrelated** to the vaccine.* Lymphadenopathy
* Appendicitis
* Bell’s Palsy
 |
| There were no anaphylactic or severe hypersensitivity reactions that occurred close to the time of receiving the vaccine. | The vaccine may result in a hypersensitivity-related (**allergic reaction**) especially in individuals with existing allergic conditions. If you have a history of serious allergic reactions to any of the vaccine ingredients, you should not get the vaccine. If you have a history of serious allergic reactions to ANY vaccine(s), your doctor should do a full risk assessment. You should potentially defer and get a different vaccine. If you do decide to get vaccinated, you should be monitored for a half hour instead of 15 minutes. |

**What are the benefits of getting an mRNA COVID-19 vaccine?**

* Reduces the risk of confirmed COVID-19 disease, hospitalization, and death after receiving **2 doses** of the vaccine.
* The vaccines are effective across subgroups, including:
	+ racial and ethnic minorities
	+ people aged 65 years and older
	+ individuals with one or more of the following conditions: obesity, diabetes, hypertension, and chronic cardiopulmonary diseases.
* Efficacy was high among participants with comorbidities (pre-existing conditions).

**What we still don’t know:**

* We do not know if people who get mRNA vaccines will lose their immunity over time and will need to get revaccinated in the future.
* We need more data to determine if the mRNA vaccines can prevent coronavirus infection in addition to preventing disease.
* We need more data to determine whether a vaccinated person can transmit coronavirus to others.
* We do not know whether mRNA vaccines will have an impact on long-term effects of COVID-19 disease in individuals who are infected despite vaccination.
* We need more large observational studies to determine if mRNA vaccines can prevent death.
* We do not know yet if mRNA vaccines are safe for a few groups. If you belong to any of the groups below, you should speak with your provider to make a decision about getting an mRNA vaccine.
	+ Children younger than 16 years of age
	+ Pregnant and lactating individuals
	+ People with weaker immune systems

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