





### **COVID-19 Vaccine Education**

Emerging Infectious Diseases (EID) Preparedness Clinical Epidemiology and Infection Prevention Center for Nursing Excellence

### **Disclaimer**

- COVID-19 vaccine is recommended by the U.S. Centers for Disease
  Control and Prevention and the California Department of Public Health to
  protect our students, faculty, staff, and families from COVID-19 and its
  associated complications, including death
- The objective of this training is to ensure the safety of students
- Updated information/guidelines will be communicated to students

### What is the best response during a pandemic?

- Follow all CDC and the California Department of Public Health recommendations and guidance
  - Wear a mask and physically distance to reduce your chance of being exposed to the virus or spreading it to others
- Get a vaccine if one is available

### Why is a vaccine important during a pandemic?



A vaccine protects an individual...



When a community is vaccinated, everyone is protected, even those who can't be vaccinated due to underlying health conditions.

### **COVID-19 Training Purpose**

 The purpose of this training is to provide COVID-19 vaccine education for students at UCLA



### **COVID-19 Objectives**

At the end of this training, the learner will be able to:

- Describe how the body fights an infection
- Explain how the COVID-19 vaccines were created and how they work
- Describe safety measures in place for the COVID-19 vaccines
- Identify the process for receiving or declining the COVID-19 vaccine
- State safety precautions a person takes after getting the COVID-19 vaccine

### How does the body fight an infection?

### **Immune Response**

- Germs invade our bodies they attack and multiply causing an infection and illness
- The immune system protects the body against infection and illness by recognizing germs (bacteria, virus) and responding by creating proteins called antibodies
  - Antibodies fight infection, help a person recover, and prevent a person from becoming ill in the future



# How were the COVID-19 vaccines created?

### **Clinical Trials**

- Clinical trials test medical interventions
  - Drugs, vaccines, or procedures are tested in human volunteers to assess usefulness, efficacy, and safety
- Clinical trials for COVID-19 vaccines and treatments compare active medications with placebos
  - These trials, which included people at high risk for COVID-19, are specifically designed to identify any common side effects or other safety concerns
  - Clinical trials included people of all racial and ethnic backgrounds and the vaccine was found to be effective and safe for all participants
- Clinical trials in the United States have four phases

### Four Phases of Clinical Trials - FDA

#### Phase 1

Involves a smaller number of volunteers and looks for serious adverse events

### Phase 2

Focuses on efficacy and short-term adverse events

### Phase 3

Gathers information on dosage, efficacy, and safety in a large number of volunteers

### Phase 4

Medication is approved for distribution to study real-life reactions, effectiveness and longterm risks, and rare adverse events

### Clinical Trial Demographic Data

	Pfizer/BioNTech	Moderna	Johnson & Johnson
Participants	43,448	30,351	43,783
Racial / Ethnic Distribution	<ul><li>28% Hispanic</li><li>9% African American</li><li>4% Asian</li><li>0.5% Native American</li></ul>	<ul><li>21% Hispanic</li><li>10% African</li><li>American/Black</li><li>5% Asian</li><li>4% Other and multiracial</li></ul>	<ul><li>45% Hispanic</li><li>17% African American</li><li>3.5% Asian</li><li>8% Native American or Alaska Native</li><li>5.4% Multiracial</li></ul>
Age Information	<b>25</b> % ages 65+	<b>25</b> % ages 65+	<b>34%</b> ages 60+



### **Are COVID-19 Vaccines Safe? (CDC)**

- COVID-19 vaccines are being held to the same rigorous safety and effectiveness standards as all other types of vaccines in the U.S.
  - Many strict protections help ensure that COVID-19 vaccines are safe
  - Rigorous, multi-stage testing process, including large (phase III) trials involve tens of thousands of people
- Only COVID-19 vaccines that meet these standards are made available in the United States, by Food and Drug Administration (FDA) approval or emergency use authorization

### Vaccine Development: Vaccines Types

### Inactivated or Weakened Virus

 Use a form of virus that been inactivated or weakened so it doesn't cause disease but still generates an immune response

#### **Protein Based**

 Use harmless fragments of proteins or protein shells that mimic the virus to safely generate an immune response

#### Viral Vector

 Use a virus that has been genetically engineered so that it can't cause disease, but produces proteins to safely generate an immune response

### RNA and DNA

 A cutting-edge approach that uses genetically engineered RNA or DNA to generate a protein that itself safely prompts an immune response

### **COVID-19 Vaccine Development**

- Through Operation Warp Speed
  - A partnership between the Department of Health and Human Services (HHS) and Department of Defense (DOD)
    - To develop, make, and distribute millions of vaccine doses as quickly as possible
    - At the same time make sure vaccines are safe and that they work



### **COVID-19 Vaccine Emergency Use**

- Emergency Use Authorization (EUA)
  - This is a way for the FDA to make vaccines and treatments available to the public under emergency circumstances such as a pandemic, before those interventions have undergone the lengthy formal review process
  - FDA evaluates the options very quickly by using the evidence that is available and carefully balances any known or potential risks of the product with any known or potential benefits to the public of making them available during the emergency

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

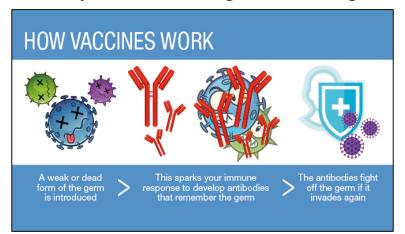
- LA County and the CDC have recommended a tiered approach to determine the order in which the vaccine will be distributed
- Vaccines are prioritized in the following way:



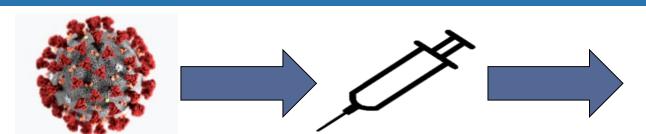
# How do the COVID-19 vaccines work?

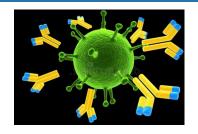
### **How Vaccines Work**

- Vaccines work by stimulating the immune system to make antibodies:
  - Helping our body develop immunity to a virus without getting an illness
  - Training the immune system to recognize and fight viruses or bacteria



### **How COVID-19 Vaccines Work**





COVID-19 vaccines give instructions for our cells to make a harmless piece of what is called the "spike protein" found on the surface of the virus that causes COVID-19.

COVID-19 vaccines are given in a muscle (i.e. upper arm). Once the instructions are inside the cells, the cells make the spike protein.

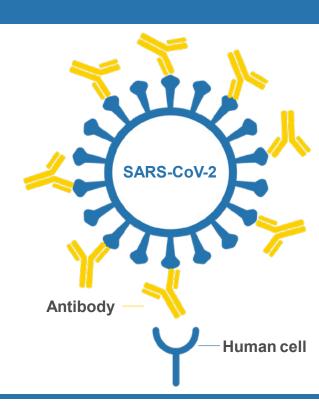
Our immune system recognizes that the protein doesn't belong there and builds an immune response by making antibodies. This is similar to what happens in a natural COVID-19 infection. At the end of the process, our bodies learn how to protect against future infection.

### **COVID-19 Vaccine Facts (CDC)**

- The vaccines cannot give someone COVID-19
- The vaccines do not use the live virus that causes COVID-19
- The vaccines do not affect or interact with our DNA in any way

### **How the COVID-19 Vaccines Work**

- The COVID-19 vaccine helps our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness
  - Teaches our immune systems how to recognize and fight the virus that causes COVID-19
  - Helps the immune system to produce antibodies that will remember how to fight that virus in the future and protects us from getting infected if the real virus enters our bodies



### **Types of COVID-19 Vaccines**

- There are currently two types of COVID-19 Vaccines approved under Emergency Use Authorization:
  - Messenger RNA (mRNA) Vaccines (Pfizer and Moderna)
  - Viral Vector Vaccine (Johnson & Johnson)
- The types of vaccines will be reviewed in detail

### What is an mRNA Vaccine

- Messenger Ribonucleic Acid (mRNA)
  - A new type of vaccine
  - Gives instructions for our cells to make a protein or piece of a protein to trigger an immune response to produce antibodies and protect from infection
  - mRNA vaccine does not alter or modify a person's genetic makeup (DNA)



### What is the difference – mRNA COVID-19 Vaccines?

### Pfizer Vaccine

- mRNA vaccine
- 2 doses, 21 days apart
- One vial = 6 doses
- Ultra low temp storage (-80C or -112F)
- Vaccine shelf-life
  - 6 months @ -80C
  - 5 days refrigerated (not reconstituted)
  - 6 hours room temp (reconstituted)

### Moderna Vaccine

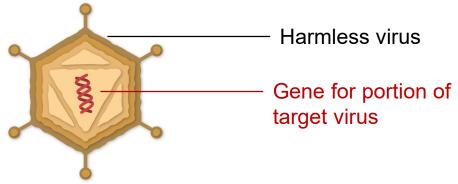
- mRNA vaccine
- 2 doses, 28 days apart
- One vial = 10 doses
- -20C or -4F storage
- Vaccine shelf-life
  - 30 days refrigerated
  - 2 hours room temp
  - 12 hours (once vial is first punctured)

### Study of mRNA Vaccines (CDC)

- Researchers have been studying and working with mRNA vaccines for decades in the study of flu, Zika, rabies, and cytomegalovirus (CMV)
- As soon as information about the virus that causes COVID-19 was available, scientists began designing the mRNA instructions for cells to build the unique spike protein into an mRNA vaccine
- mRNA vaccines can be developed in a lab with readily available materials, thus they can be developed faster than other traditional vaccines

### What is a Viral Vector Vaccine

- A harmless virus that cannot cause infection in humans is modified
- A gene for a portion of the target virus is inserted into the harmless virus to deliver instructions to the body's cells to make antibodies
- The body then makes antibodies for the target virus





### **Johnson & Johnson COVID-19 Vaccine**

- The Johnson & Johnson COVID-19 vaccine utilizes viral vector technology
- The gene for the SARS-CoV-2 spike protein is placed inside a harmless cold virus to instruct the body to make antibodies
- The genetic material for the SARS-CoV-2 virus spike protein used in the COVID-19 vaccine does not integrate into a person's DNA
- It is a 1-dose vaccine and can be stored at regular refrigeration temperatures

### **Study of Viral Vector Technology**

- Scientists began creating viral vectors in the 1790s
- Viral vectors are used for vaccines, gene therapy and cancer treatment
- There are viral vector vaccines for influenza, measles virus, VSV and adenovirus (the common cold)
- The Ebola vaccine is also a viral vector vaccine that has been used to respond to the recent Ebola outbreaks

### Contraindications to Receiving any COVID-19 Vaccine

- Contraindications (reasons <u>not</u> to get the vaccine)
  - Severe allergic reaction to any component of the vaccine
  - Life-threatening reaction to any previous vaccine
- If you have any of the above, you will be advised to decline, but you should check with your primary care provider
- If you have any current health conditions and have questions about whether you should receive the vaccine or not, please discuss the vaccine with your primary care provider

### Receiving COVID-19 Vaccine with Prior COVID-19 Infection

- There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again, called natural immunity
- Early evidence suggests natural immunity from COVID-19 may not last very long
  - Potentially 90 days from previous COVID19 infection



# What safety measures are in place for the COVID-19 vaccine?

### **Vaccine Safety Monitoring Measures**

### Vaccine Safety Monitoring

- There are many safety monitoring systems to watch for adverse events after a vaccine is authorized and approved for use
- This monitoring is critical to help ensure that the benefits continue to outweigh the risks for people who receive vaccines
- If an unexpected adverse event is seen, experts quickly study it further to assess whether it is a true safety concern
- Experts will then decide whether changes are needed in vaccine recommendations

### Vaccine Safety Monitoring Systems

safety continues with CDC + FDA safety monitoring

- CDC uses 3 systems to monitor vaccine safety:
  - Vaccine Adverse Event Reporting System (VAERS): an early warning system, managed by CDC and FDA, to monitor vaccine safety
    - Anyone can submit a report for any health problems that happen after vaccination i.e. healthcare staff, general public
  - Vaccine Safety Datalink (VSD): a collaboration between CDC and healthcare organizations that conduct vaccine safety monitoring
  - Clinical Immunization Safety Assessment (CISA): a CDC and several medical research centers partnership to conduct clinical research

### Vaccine Safety Monitoring (V-SAFE)

- Vaccine Safety Assessment
  - A smartphone-based text, text-to-web survey, and email-to-web survey active surveillance program for vaccine recipients
  - Uses contact information (phone numbers) at the registration process
  - Conducts health checks via text messages and email
    - · Daily for first week post-vaccination
    - Weekly thereafter for 6 weeks post-vaccination



# What you should know about receiving or declining the COVID-19 vaccine?

## **COVID-19 Vaccination Program**

- University of California SARS-CoV-2 Vaccination Program Policy
  - All UC students must participate in the <u>SARS-CoV-2 Vaccination Policy</u>
  - Vaccination: provides written documentation of the vaccine through the Ashe Patient Portal
    - **Exemption**: formally submitting a request for an allowable exemption (on medical, disability or religious grounds) or deferral (based on pregnancy)

## Receiving COVID-19 Vaccine

- Consent you will have the chance to read the FDA Fact Sheet for the vaccine and ask questions
  - Risks and benefits of the COVID-19 vaccine will be explained
- Number of doses and scheduling
  - Depending on the COVID-19 vaccine, it may be one dose or two doses
- Cannot mix vaccinations

## Receiving COVID-Vaccine – How long will it last?

- Additional research is needed to know the long-term protection of COVID-19 vaccine
- Clinical studies have so far followed patients for a few months after vaccination
  - Patients in the studies will eventually be followed for two years.
- Available data suggest that most people who recover from COVID-19 develop an immune response that provides at least some protection against reinfection for the length of time the study has been done

## **COVID-19 Vaccine Exemptions**

- The risks associated with <u>not receiving</u> the COVID-19 vaccine:
  - If I contract COVID-19, I can shed the virus for several days before any symptoms appear. During the time I shed the virus, I can transmit it to students, faculty, staff and family.
  - If I contract COVID-19, even if my symptoms are mild or non-existent, I can spread the disease to others. Symptoms that are mild or non-existent in me, can cause serious illness and death in others.
  - If I contract COVID-19, it could have life-threatening consequences for my health and the health of everyone with whom I have contact, including students, faculty, staff and family.

# What happens after I receive the COVID-19 vaccine?

## After Receiving the COVID-19 Vaccine

- Continue to follow all current CDC guidelines and precautions, including guidance on:
  - Hand hygiene
  - Physical distancing
  - Universal masking

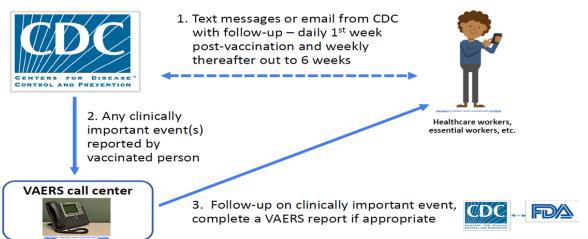
## **Expected Vaccine Reactions**

- COVID-19 vaccines may produce side effects after vaccination
- Side effects may include:
  - Pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, mild fever, nausea
- No significant safety concerns were identified in the clinical trials
- Side effects are unlikely to appear more than 8 weeks after vaccination
- For vaccines that require two doses, there may be more side effects after the second dose

## Follow-up (V-SAFE)

 Follow-up will be conducted with all people who receive the COVID-19 vaccine that sign up for <u>V-SAFE</u>

#### Vaccine safety assessment for essential workers (V-SAFE)





#### References

- Cohen, S. (2020, December 1). COVID-19 Vaccine Terminology Can Be Confusing Here's What You Need to Know. UCLA Health, https://connect.uclahealth.org/2020/12/01/covid-19-vaccine-terminology-can-be-confusing-heres-what-you-need-to-know/
- Coronavirus Disease (COVID-19): Vaccines (2020, October 28). Retrieved from https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines?adgroupsurvey=%7badgroupsurvey%7d&gclid=CjwKCAiA8Jf-BRB-
- Emergency Use Authorization (2020, December 8). Retrieved from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Ensuring the Safety if COVID-19 Vaccines in the United States (2020, October 14). Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html
- Fact Sheet: Explaining Operation Warp Speed (2020, November 30). Retrieved from https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html
- FACT: COVID-19 Vaccines Will Not Give You COVID-19 (2020, November 23). Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits/facts.html
- Frequently Asked Questions about COVID-19 Vaccination (2020, December 3). Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
- Hibberd, P. (2020, November). Patient Education: Adult Vaccines (Beyond the Basics). UpToDate, https://www.uptodate.com/contents/adult-vaccines-beyond-the basics?search=vaccine&topicRef=3884&source=related\_link



#### References

- Overview, History, and How the Safety Process Works (2020, September 9). Retrieved from https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html
- Shimabukuro, T. (2020 September 22). Enhanced Safety Monitoring for COVID-19 Vaccines in Early Phase Vaccination. CDC <a href="https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-03-Shimabukuro.pdf">https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-03-Shimabukuro.pdf</a>
- Understanding How COVIS-19 Vaccine Work (2020, November 2). Retrieved from <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Fabout-vaccines%2Fhow-they-work.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/how-they-work.html</a>
- Understanding mRNA COVID-10 Vaccines (2020, November 23). Retrieved from <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html</a>
- Vaccine Adverse Event Reporting System (VAERS) (2020, September 11). Retrieved from https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html



- How does the body fight an infection?
  - a) The body responds by creating antibodies
  - b) The body produces an antigen
  - c) The immune system does not respond
  - d) None of the above

- How does a vaccine work?
  - a) Changes a person's DNA
  - b) Increases the risk of infection
  - c) Helps body make antibodies to fight infection
  - d) None of the above

- What statement is true about the COVID-19 vaccine?
  - a) The vaccine cannot give someone COVID-19
  - b) The vaccine does not use the live COVID-19 virus
  - c) The vaccine does not affect or interact with DNA
  - d) All of the above are true

- What statement is false about the V-SAFE vaccine monitoring?
  - a) Uses a text, text-to-web survey, or email-to-web survey to enroll people in the active surveillance program
  - b) Uses contact information (phone numbers) at the registration process
  - c) Shares personal information
  - d) Conducts health checks via text messages and email

- What is the process of receiving a COVID-19 vaccine?
  - a) Person gives consent to receive the vaccine
  - b) Vaccine information including risk and benefits will be provided
  - c) Scheduling and timing of next dose of the same vaccine
  - d) All of the above

- What are the safety precautions a person takes after receiving the COVID-19 vaccine?
  - a) Continue to wear a mask
  - b) Physical distancing and hand hygiene
  - c) No safety precautions needed because the person will be immune to COVID-19
  - d) Continue to follow all CDC guidelines and precautions including hand hygiene, physical distancing, universal masking and eye protection