COVID-19 Vaccine Education

This training was created by UCLA Health for Emerging Infectious Diseases (EID) Preparedness Clinical Epidemiology and Infection Prevention Center for Nursing Excellence and adapted for use at UCR.
Disclaimer

• COVID-19 vaccine is recommended by the U.S. Centers for Disease Control and Prevention and the California Department of Public Health for healthcare workers to protect our patients, students, faculty, staff, and families from COVID-19 and its associated complications, including death
• UCR’s objective is to ensure the safety of employees and patients
• Updated information/guidelines will be communicated to staff
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
  - Wear appropriate personal protective equipment (PPE)
- 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 healthcare workers at UCR
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 long-term risks, and rare adverse events
# Clinical Trial Demographic Data

<table>
<thead>
<tr>
<th></th>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
<th>Johnson &amp; Johnson</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td>43,448</td>
<td>30,351</td>
<td>43,783</td>
</tr>
<tr>
<td><strong>Racial / Ethnic</strong></td>
<td>28% Hispanic</td>
<td>21% Hispanic</td>
<td>45% Hispanic</td>
</tr>
<tr>
<td>Distribution</td>
<td>9% African</td>
<td>10% African</td>
<td>17% African</td>
</tr>
<tr>
<td></td>
<td>American</td>
<td>American/Black</td>
<td>American</td>
</tr>
<tr>
<td></td>
<td>4% Asian</td>
<td>5% Asian</td>
<td>3.5% Asian</td>
</tr>
<tr>
<td></td>
<td>0.5% Native</td>
<td>4% Other</td>
<td>8% Native</td>
</tr>
<tr>
<td></td>
<td>American</td>
<td>and multi-</td>
<td>American or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>racial</td>
<td>Alaska Native</td>
</tr>
<tr>
<td>Age</td>
<td>25% ages 65+</td>
<td>25% ages</td>
<td>34% ages 60+</td>
</tr>
<tr>
<td>Information</td>
<td></td>
<td>65+</td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Inactivated or Weakened Virus</th>
<th>Protein Based</th>
<th>Viral Vector</th>
<th>RNA and DNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Use a form of virus that been inactivated or weakened so it doesn’t cause disease but still generates an immune response</td>
<td>• Use harmless fragments of proteins or protein shells that mimic the virus to safely generate an immune response</td>
<td>• Use a virus that has been genetically engineered so that it can’t cause disease, but produces proteins to safely generate an immune response</td>
<td>• A cutting-edge approach that uses genetically engineered RNA or DNA to generate a protein that itself safely prompts an immune response</td>
</tr>
</tbody>
</table>
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:

  Health care workers and long-term care facility residents → People age 65 and older → Workers in essential and critical industries → People age 16-64 with underlying health conditions → General public (those not in groups listed)
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?

<table>
<thead>
<tr>
<th><strong>Pfizer Vaccine</strong></th>
<th><strong>Moderna Vaccine</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>2 doses, 21 days apart</td>
<td>2 doses, 28 days apart</td>
</tr>
<tr>
<td>One vial = 6 doses</td>
<td>One vial = 10 doses</td>
</tr>
<tr>
<td>Ultra low temp storage (-80C or -112F)</td>
<td>-20C or -4F storage</td>
</tr>
<tr>
<td>Vaccine shelf-life</td>
<td>Vaccine shelf-life</td>
</tr>
<tr>
<td>6 months @ -80C</td>
<td>7 days refrigerated</td>
</tr>
<tr>
<td>5 days refrigerated (not reconstituted)</td>
<td>2 hours room temp</td>
</tr>
<tr>
<td>6 hours room temp (reconstituted)</td>
<td>6 hours (once vial is first punctured)</td>
</tr>
</tbody>
</table>
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

• 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 not 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

- 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 personnel and trainees must participate in the SARS-CoV-2 Vaccination Program by consenting to or declining vaccination
  
  • Staff will provide consent for receiving vaccine at the required intervals or sign a vaccination declination statement
  
  • On-Site Vaccination: receives vaccine at UCR
  
  • Off-Site Vaccination: provides written documentation of the location vaccine was received i.e. private health care provider’s office, local pharmacy, etc.
  
  • Declination: formally declining the vaccine by completing and signing the Vaccine Declination Statement
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
  - If you are receiving a two dose vaccine at UCR Health, you will receive an email through MyChart after your first dose to schedule your second dose
- Cannot mix vaccinations or choose the vaccine that you want
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
Declining COVID-19 Vaccine

- The risks associated with declining the COVID-19 vaccine include:
  - 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 patients, 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 patients, 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
  • Eye protection
  • All appropriate PPE guidelines in clinical care areas
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 V-SAFE
References


References

Question 1

• 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
Question 2

• 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
Question 3

• 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
Question 4

• 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
Question 5

• 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
Question 6

• 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