COVID-19 Vaccine Educational Brief
Kevin E Mackey MD, FAEMS
Sacramento Regional Fire
Essential Scientific Material is Included to Address Common Questions
SARS-CoV2 Virus Explained

- "SARS" = Severe Acute Respiratory Syndrome
- CoV = Coronavirus
- COVID 19 = COronaVIrus Disease - 19 (first identified in 2019)
- It is considered a "novel" virus, meaning there are no previous human diseases involving this virus’ exact genetic make up
- It IS considered to belong to the Coronavirus family, typically causing respiratory illness, along with virus that are less lethal (common cold) and more lethal (SARS, MERS)
**How Does COVID Infect Humans?**

- The COVID-19 virus preferentially binds to human cells expressing ACE2 receptors (highest cell count is in the respiratory system).
- Binds via the spike proteins found on the surface of the virus.
- Once bound to the cell, the virus undergoes a structural change allowing it to bind to the surface of the cell so it can enter the cell.
- Once inside, the viral genome is replicated using the host’s own cells to make new virus particles, which are then released from the cell.
Immunity
2nd Generation
The COVID-19 Vaccine
Two Leading Developers
HUMAN CORONAVIRUS FAMILY

- HCoV-OC43
- HCoV-229E
- HCoV-NL63
- HCoV-HKU1

- MERS-CoV
- SARS-CoV
- SARS-CoV-2

- 2012
- 2003
- 2019
EMERGENCY USE AUTHORIZATION
Why is an EUA necessary?

• Under normal, non-pandemic situations, most vaccine development happens in non-humans (ie: animals, in vitro testing)

• In emergency circumstances (ie: a pandemic), the FDA will allow tightly controlled, limited testing in healthy human volunteers in three phases
  • Phase 1: Limited small scale testing for safety in healthy human volunteers (generally 100 - 200)
  • Phase 2: Limited testing of varying doses, reconfirming safety profile (generally 1000 – 2000)
  • Phase 3: Tens of thousands of human volunteers accessing how well the vaccine works against the target (ie: COVID virus), with continued safety assessment
Pfizer Phase 3 Stats

**Trial Locations**

Approximately 150 clinical trial sites in 6 countries, including 39 U.S. states

**Trial Progress**

44,392 participants enrolled with 42,845 having received their second vaccination
Participants include 608 ages 16-17 and 266 ages 12-15

**Participant Diversity**

Approximately 42% of overall and 30% of U.S. participants have diverse backgrounds

<table>
<thead>
<tr>
<th>Participants</th>
<th>Overall Study</th>
<th>U.S. Only</th>
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</thead>
<tbody>
<tr>
<td>Asian</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Black</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Hispanic/Latina</td>
<td>26%</td>
<td>13%</td>
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<tr>
<td>Native American</td>
<td>1%</td>
<td>1%</td>
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<tr>
<td>Ages 56+</td>
<td>41%</td>
<td>46%</td>
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Pfizer Phase 3 Results

• Over 44,000 vaccinated volunteers
• 95% effective beginning 7 days after Dose 2
• 170 total COVID + cases observed in the 44,000
  • 162 in placebo group, 8 in immunized group after Dose 1
  • 3 in placebo group, 1 in immunized group after Dose 2
  • 10 cases of SEVERE COVID disease: 9 in placebo group, one in the vaccinated group
• Durability of immune protection under investigation
Modern Phase 3 Stats

• Over 25,650 fully vaccinated (both doses) volunteers
• 7000 over age 65
• 42% of enrollment in medically high risk populations (co-infection with HIV, HepB, HepC, diabetes)
• 28% minority vaccinated volunteers
• Durability of immune protection: recent study in NEJM shows excellent antibody protective ability 90 days after the second injection
Side by Side Comparison

**Pfizer**
- RNA-based vaccine
- Two injections, spaced 21 days apart
- 95% effective (Phase 3) at preventing SERIOUS disease after first injection
- Common side effects: injection site pain, self-limited fever, fatigue, headache, muscle or joint pain

**Moderna**
- RNA based vaccine
- Two injections, spaced 28 days apart
- 94% effective (Phase 3) at preventing SERIOUS disease after first injection
- Common side effects: Injection site redness, self-limited fevers (especially with second dose), headache, fatigue
How does the vaccine actually work?

Hint: Replication
Spike protein isolated/sequenced in lab

RNA Segment Inserted in lipid (fat) molecule

RNA segment replicated
- Viral mRNA encoding spike protein floating taken up into cell.

- The human cell’s own manufacturing plant (ribosomes) assemble the viral spike proteins.

- Non-infectious spike proteins remain in the cell until the cell dies naturally, at which time the spike proteins are released.

- If an immune response is already present to the viral spike proteins, the immune response will accelerate the release of the spike proteins.

***Note: the nucleus of the cell containing the DNA is not involved***
Viral spike proteins released from vaccinated cells are picked up by our own immune cells (called macrophages) which then process and “present” the spike proteins for the entire immune system to see and “learn”.

“Helper” T cells “memorize” what the spike protein looks like and programs itself to be able to “describe” the spike protein to the real army of the immune system, the mighty B cell.
Helper T cells, now equipped to activate other immune cells, engage with the antibody producing B cells

Activated B cells now seek out cells that are expressing the spike proteins and destroy them
Antibodies produced in and released by B cells now flow through the body looking for any cell containing the spike protein (like SARS-CoV 2 infected cells) and destroys them thereby stopping the spread of the infection to nearby cells.
**Myth:** The process of vaccine development was rushed and haphazard

**Fact:** Vaccine development was operated under an established program specifically designed to deal with this type of circumstance, called an Emergency Use Authorization, closely monitored for safety by the FDA.
Myth: COVID treatments have gotten much better, so a vaccine is unnecessary

Fact: We wish it were true. But it’s not. None of the “prophylactic” treatments have shown efficacy in preventing or treating COVID-19. Even steroids and the HHS-supplied treatments Remdesivir and the monoclonal antibodies have only decreased mortality by at most < 50%
**Myth:** The COVID vaccine was made from “aborted fetal tissue”

**Fact:** This is simply not true. Neither the Pfizer nor Moderna vaccines used any cell lines came from fetal tissue. The Catholic U.S. Bishops convention has issued a statement approving vaccination.
**Myth:** The COVID vaccine uses live virus

**Fact:** Both Pfizer & Moderna vaccines are mRNA, and do not use virus components. The mRNA vaccines can only code for one tiny cell part – the spike protein. They do not carry any other parts, or genetic/DNA material, from the COVID-19 virus.
**Myth:** There have not been any prior RNA vaccines used in humans

**Fact:** False. RNA vaccine technology has been used to treat gastric cancer in humans and hATTR, a rare debilitating human peripheral nerve disease.
**Myth:** RNA vaccines can implant material into the human genome or fundamentally change a human’s genetic structure

**Fact:** This is simply not true and frankly, biologically impossible. An RNA vaccine utilizes a cell’s innate processes to produce inert viral particles for the purpose of activating the human immune response. The cell that does this is ultimately destroyed by the immune system, which is the goal of ANY vaccine.
**Myth:** The COVID 19 Vaccine will stop you from contracting COVID-19

**Fact:** You can still contract COVID-19. HOWEVER the risk of serious disease and disease long-term sequelae is almost 100% neutralized, which is the goal of ANY vaccine.
**Myth:** Ill effects from the vaccine won’t be seen for months or years

**Fact:** 70 years of vaccines refute this. Under an EUA, 50% of all individuals vaccinated must have received all doses and 90 days must have passed to assess for side effects. For COVID-19, over 75000 have received both doses and NO serious side effects have occurred.
Myth: Can vaccination cause "false-positive" tests for COVID?

FACT: No. COVID vaccination will not affect PCR or Antigen tests for COVID. If you become symptomatic and test positive, this still means that you have contracted the disease.
Pregnancy and Lactation

• There is LIMITED data on the safety of the COVID vaccine in pregnant women. Pfizer and Moderna are currently evaluating safety in pregnant and lactating women

• 36 women became pregnant and were inadvertently exposed during the trials by Pfizer and Moderna. None had adverse effects to them or their fetus, at this point.

• ACOG has a position statement encouraging pregnant and lactating women to get the vaccine
Pregnancy and Lactation Considerations

• There is NO live virus in the vaccine
• The vehicle for the vaccine is destroyed quickly
• mRNA CAN NOT change the human genome
• Therefore, knowing this, women who are high risk (conditions such as asthma, COPD, diabetes, hepatitis) should be considered to receive the vaccine. However, this is a personal choice.
• Lactation is highly unlikely to affect the infant and considered safe
• This is a personal decision that should be made with your doctor.
NEXT STEPS

❖ Changes to PPE Use After Vaccination
❖ Vaccine Distribution
Will PPE Use Change After Vaccination?
PPE use shall continue until morale improves!

NOTHING changes. PLEASE continue to follow PPE guidance using eye protection, face masks, gloves, frequent hand sanitizing, cleaning procedures for equipment, and follow department specific and local policies. PROTECT YOURSELF, and PROTECT OTHERS!
How will vaccines be distributed?

SALK POLIO VACCINE PROVES SUCCESS; MILLIONS WILL BE IMMUNIZED SOON; CITY SCHOOLS BEGIN SHOTS APRIL 25

TRIAL DATA GIVEN

Efficacy of 80 to 90% Shown—Salk Sees Further Advance

Abstract of report, summary of data on tests, Page 22.

By WILLIAM L. LAURENCE
Special to The New York Times.
ANN ARBOR, Mich., April 12
—The world learned today that its hopes for finding an effective weapon against paralytic polio had been realized.
Operation Warp Speed

Operation Warp Speed Vaccine Distribution Process

Vaccines are made and filled/finished by the manufacturers

Pfizer

Pfizer transports Vaccine Drug Product to UPS and FedEx facilities for distribution

Pfizer Ancillary MegaKits delivered directly to UPS & FedEx for distribution to Administration Sites

Dry Ice Recharge Kits Delivered to Administration Sites for Pfizer Vaccine

McKesson Distributors

Moderna Vaccines and Ancillary Kits then stage at Distribution Centers before moving to the States and Jurisdictions

Leveraging Existing Networks, Processes and Partnerships

Hospitals
Large Clinics Outpatient
Pharmacies
Long Term Care Facilities
Doctor’s Offices
Indian Health Services
Public Health Clinics
Mobile Units
Homebound
Other Federal Entity Sites
Operation Warp Speed

- Partnership with Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD).

- Phased approach
  - Phase 1: focused, limited doses available, healthcare workforce and frontline workers
  - Phase 2: larger supplies available, expand to at risk populations first, as well as essential infrastructure, then general population
  - Phase 3: if pandemic persists, integration into routine vaccine programs and broadscale vaccine distribution
Limited Doses Available

- Constrained supply
- Highly targeted administration required to achieve coverage in priority populations

Volume doses available (per month)

- Tightly focus administration
- Administer vaccine in closed settings (places of work, other vaccination sites) specific to priority populations

Large Number of Doses Available

- Likely sufficient supply to meet demand
- Supply increases access
- Broad administration network required including surge capacity
- Expand beyond initial populations
- Administer through commercial and private sector partners (pharmacies, doctors offices, clinics)
- Administer through public health sites (mobile clinics, FQHCs, targeted communities)

Illustrative ramp-down, not based on CMS decisions or candidate projections

~660M cumulative doses available

Continued Vaccination, Shift to Routine Strategy

- Likely excess supply
- Broad administration network for increased access

- Open vaccination
- Administer through commercial and private partners
- Maintain PH sites where required
History Repeats

- In 1955, Salk introduced the 1st polio vaccine. The public was reluctant to try it.
- Elvis Presley received his publicly to encourage others.
- Rates of polio paralysis and death in the USA decreased from almost 20,000/year before the vaccine, to <100 afterwards.

> 300,000 Americans have died from COVID this year. How many lives might we save with vaccination?
References
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• Pfizer vaccine and trial results

• Moderna vaccine and trial results
• How the Pfizer and Moderna COVID vaccine work/durability

• Prior RNA vaccine use to treat disease
  • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7177048/
  • https://www.jci.org/articles/view/134915

• Vaccine distribution plan
• **Addressing COVID & Vaccine misinformation on the internet**
  
  
  • https://www.heritage.org/public-health/commentary/the-covid-vaccine-and-the-pro-life-movement
  
  
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• **Pregnancy and Lactation**
  
  